Responses to Comments Received
Federal Register Notice on (CMS-10630)
PACE Audit Protocol

CMS received 14 public submissions, which included 265 distinct comments on the August 5, 2016 (CMS 10630) The PACE Organization Monitoring and Audit Process proposed information collection. We then combined the 265 comments into 103 unique comments and provided responses in the document below. Comments are separated by element or record layout. Additionally, some general comments received are addressed in the first part of this document.

GENERAL COMMENTS

Comment 1: Several commenters supported our distinction between Medicare Advantage (MA) and PACE as two distinct programs in our supporting statement. These commenters offered further justification as to why the programs are different, including the fact that PACE is a direct care model as well as a payer. One commenter requested clarification on whether any audit protocols other than the PACE audit protocol would be used to assess a PACE Organization's (PO's) compliance with regulations. This commenter specifically referenced the Part D Coverage Determinations, Appeals and Grievances (CDAG) protocol used in Part D audits.

Response 1: We appreciate the feedback from these commenters. Due to the different requirements in PACE, PACE programs have always undergone different audits than MA and Part D organizations. However, we had previously included the PACE audit protocols in the MA and Part D audit PRA package. For 2017 we decided that we should pull those PACE protocols out of the MA and Part D audit package, and create a standalone PACE audit PRA package that only included the documents relevant to PACE audits and included a burden estimate specific to PACE audits. At this time, POs (POs) will only undergo audits using the protocol in this PRA package.

CMS Action 1: 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 2: Multiple commenters supported the idea of focusing on outcomes during the PACE audit rather than administrative requirements. Some of these commenters supported CMS's use of a data driven approach as a good way to measure outcomes, and supported our revised protocols as achieving that goal. A few commenters specifically supported CMS no longer requesting numerous documents and policies and procedures prior to conducting the audit. However, a few commenters thought that the proposed audit protocol was still too administrative and should instead focus on quality metrics to determine if a PO was providing high level care to participants. These commenters suggested our audits focus on review of medical records and observations of participants. One commenter requested assurance that the audit process would be person-centered. Another commenter urged CMS to focus more on the provider based nature of the PACE program, rather than the operational effectiveness of the insurer side. This commenter suggested that the PACE audit protocol was more focused on compliance with federal requirements than whether the PO delivered high quality care.

Response 2: We appreciate both the support and outstanding concerns of these commenters relating to the structure of our audits. This protocol significantly modified our audit structure to be an outcomes based model of auditing. We have significantly reduced the administrative

burden on POs by eliminating over 80 distinct policies and procedures that POs used to be required to produce. Instead, our audit is now focused on the participant experience within the PO and whether those participants are receiving the access to care required by federal regulations. We determined the best way to conduct these person centered audits would be to request real data on participants, in areas relating to access to services and care such as service requests, appeals and participant medical records. We then take that participant level data and examine whether the participant received medically necessary services and care. Additionally, our audit continues to place a heavy emphasis on both participant medical records and participant observations. We believe that by using real participant data and by conducting a review of medical records and observations we will be able to appropriately assess whether a PO is both meeting federal requirements, as well as providing appropriate, high quality care.

CMS Action 2: 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 3: One commenter requested clarification on whether we will audit at the Parent Organization level or the contract level.

Response 3: For PACE we audit at the contract level.

CMS Action 3: No change was made to the protocol in response to this comment. No change was made to the burden estimate as a result of this comment.

Comment 4: One commenter recommended we consider the PACE Innovations Act and how it may impact audits.

Response 4: We appreciate this commenter's request. We continually review any new guidance or regulations issued by the agency and modify our audit protocols as necessary once the new guidance is implemented. In addition to modifying our external protocols, we also modify our internal methods of evaluation. At this time no modifications are needed in response to the PACE Innovations Act.

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

Comment 5: One commenter supported our recommendation to limit the audit review period to one year of time.

Response 5: We appreciate this comment and agree that one year provides enough data for auditors to do a comprehensive and thorough review of a PO's compliance with regulations.

CMS Action 5: No change was made to the protocol in response to this comment. No change was made to the burden estimate as a result of this comment.

Comment 6: One commenter requested clarification on whether CMS would be visiting only one PACE center during an onsite audit, or possibly more than one center or Alternative Care Setting (ACS).

Response 6: CMS may visit more than one center or ACS during an onsite audit. How many sites are visited may depend on multiple factors including geographical spacing, participant complaints and any other factors deemed relevant by the auditors. The same audit protocol will be utilized by auditors no matter how many physical sites are visited.

CMS Action 6: No change was made to the protocol in response to this comment. No change was made to the burden estimate as a result of this comment.

Comment 7: Several commenters, while appreciative of the detailed compliance standards that were included in the PACE protocol, expressed concerns that a lack of interpretive guidance within the compliance standards would lead to inconsistent audits.

Response 7: While CMS appreciates the concerns raised by these commenters, we want to assure commenters that CMS takes consistency in audits very seriously. As such, we have revised every single audit document that is currently used in audits. This includes not only a new external audit protocol, but also new internal methods of evaluation, auditor tools, and finally a new PACE Audit Consistency Team (PACT). All of these tools will be used by all auditors to ensure consistent application of CMS regulations and manual guidance. Additionally, we encourage POs to have open communications with auditors during the audit. We strive to be as transparent as possible in our audits, and consider the audit an opportunity to provide clarification or guidance on regulatory requirements. If POs have concerns with the interpretation of a requirement, they should address this with their audit team. Lastly, POs will have a formal opportunity to dispute any audit findings if they disagree with CMS interpretation.

CMS Action 7: 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 8: Multiple commenters raised concerns regarding the universes of data that we proposed collecting in the PACE audit protocol. Some commenters said that we requested too much data, and questioned whether the data requested was really needed and whether it would actually drive improvements. A few commenters suggested that different POs, depending on their size, would have a difficult time pulling the information.

Response 8: We appreciate the concerns raised by these commenters. We consider the amount of data we are requesting reasonable compared to what has been previously requested during audit. We greatly reduced the amount of documents requested during audits, eliminating the need for POs to send in numerous policies and procedures prior to auditors going onsite. We believe most of the data requested in these universes is information that is already collected by the PO. Additionally, these universes will not change throughout the year, allowing POs to maintain this data in this format prior to an audit being conducted. However, after receiving these comments, we reviewed all of the universes again and eliminated some fields that we thought were either too burdensome or that were unnecessary. Those specific fields will be discussed below when each element or specific record layout is discussed.

CMS Action 8: We reviewed and revised the universes of data that are collected for audit.

Comment 9: A few commenters suggested that due to the changes in the universes we are requesting that we delay this new audit process until 2018. These commenters suggested that if we don't delay the new process until 2018, we should at least ensure that we will not penalize a PO for not providing accurate universes in 2017. One commenter suggested that if we collected this much data the PO would need additional time to compile the data.

Response 9: We thank these commenters for their suggestion, but we feel that it is important to make improvements to the audit process immediately. Therefore we will continue implementing this new outcomes based auditing strategy with an implementation date of January 2017. In

order to do this, we will need to collect these universes of data from a PO. PACE organizations are expected to provide data to CMS for audits as requested, however, we recognize that it may take some time to build systems and track this data, so CMS will be reasonable when accepting the data. We also believe that because much of the information we are requesting is already collected by the PO, 30 calendar days is enough time for POs to pull and submit the requested information. We are deleting some of the text in this section that discusses the three attempts to submit a universe. Instead we are simplifying the language to only say that POs must submit data as requested.

CMS Action 9: We modified the language surrounding submitting universes to clarify that POs must submit the data as requested, but it no longer references a maximum of three attempts.

Comment 10: A few commenters suggested that our collection of universes was duplicative of other reporting requirements or quarterly reporting that POs already have to comply with. They encouraged us to not request similar data more than once as it would be burdensome to the PO.

Response 10: We agree with commenters that we should avoid requesting duplicative information whenever possible. We believe the information collected during audits is not duplicative of other collections. Information submitted quarterly or during Level I and Level II reporting is aggregate data. The information we are requesting on audit is participant specific. This level of personal information is necessary for an audit to be conducted, while not necessarily needed for quarterly reporting or calls.

CMS Action 10: 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 11: One commenter mentioned that the universes had some questions that contained drop down options. This commenter stated that the drop downs were similar but not exact to already used HPMS terms. The commenter suggested we modify the terms to be consistent.

Response 11: We have reviewed the fields to determine if changes were possible, however, most of the fields that aren't a specific response field (e.g., yes/no, dates, etc.) are free text fields which allow the PO to populate answers as they wish. If a PO wishes to use the terms currently used in HPMS reporting in these free text fields, they are welcome to do so.

CMS Action 11: 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 12: One commenter suggested that instead of collecting full universes, we collect only data for a sample of participants.

Response 12: While we appreciate this commenter's suggestion, we cannot only ask for data on a sample of participants. In order to do a comprehensive audit, we need all data requested. We will be targeting our samples in 2017, which means we need a full universe of information in order to appropriately select participants to review. Additionally, we will be running some tests at a universe level, such as the timeliness of service delivery requests, appeals and grievances. In order to appropriately run this test, we must have a full universe of all requests.

CMS Action 12: 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 13: Several commenters requested clarification on our sampling methodology. A few of these commenters asked for us to release our sampling methodology, including what we mean by "significant or clinically significant" samples. Another commenter suggested that we increase the number of samples for larger organizations, or if we would increase our sample size if we discovered issues at the PO. One commenter stated that using a targeted sampling methodology is unfair to organizations, and suggested we use random sampling to assess the true compliance of the organization. Lastly, one commenter requested information on when samples would be provided to the PO prior to the review.

Response 13: We have tried to be transparent regarding our sampling methodology in the PACE audit protocol, by specifically informing POs of the number and types of samples we will pull (i.e., how many denials, approvals, etc) as well as some of the clinical or operational triggers that we may use when sampling (i.e., hospitalizations in the medical record, or sampling a variety of personnel). We cannot release more information as auditors need some flexibility in determining which samples are relevant for a particular audit. We also do not believe that targeting samples is unfair to POs. It is important to pull samples that will be as clinically significant or useful as possible, especially since we have a relatively small sample set. For purposes of audit, the term "clinically significant" or "significant" means that we are looking for samples that seem to warrant review based on the triggers identified in the protocol (e.g., a hospitalization). The purpose of our audit is to determine a POs compliance with our regulations as well as to ensure the safety of PACE participants. This does not necessarily mean that we will be targeting for non-compliance. Additionally, if a sample involves an issue of non-compliance, the audit team will still need to review additional information to determine how to classify that non-compliance, which could be either a CAR, ICAR or an observation (worth zero points) depending on what the auditors discover. Auditors will not be expanding the sample size when issues are noted, but may request the PO to conduct an analysis to determine the scope or impact of the issue. As for when we will be releasing the samples to the PO, all samples will be sent 1 business day prior to the review of that element starting. This means that for the onsite portion of the audit, the samples will be sent 1 business day before auditors begin their onsite review, or it may mean that samples are given 1 business day prior to conducting a remote review of medical records or other samples. We added a new section into the protocol which discusses when samples will be given to the PO.

CMS Action 13: Added a new section titled "Selecting Samples" into the PACE audit protocol.

Comment 14: A few commenters requested clarification on the scoring methodology. One commenter requested clarification on how the scores would be used by CMS and whether they would be released to the industry. Another commenter requested clarification on how we intend to score POs, and specifically the use of ICARs, CARs, and Observations. Lastly, one commenter stated that they appreciated the revised scoring by combining the enhanced Level 1 and Level 2 reporting.

Response 14: We appreciate this opportunity to clarify our scoring methodology for PACE audits. In our 2017 audit protocol, we proposed scoring POs during audits. In order to achieve these scores we would classify conditions of non-compliance as either an observation, Corrective Action Required (CAR) or Immediate Corrective Action Required (ICAR). Generally,

a condition will be classified as an observation when it is not systemic (i.e., it is a one-off instance of non-compliance). Observations would not be worth any points and would not count against the PO in scoring. CARs are conditions that are systemic in nature but do not impact access to services or care. ICARs are those conditions that are systemic, impact access to care and need to be immediately corrected. CARs would receive 1 point and ICARs would receive 2 points. This classification would be done at the cross-regional PACT and applied consistently throughout audits. Once the conditions are classified, all conditions would be added up to achieve an initial score. For example, if the PO received 5 CARs and 3 ICARs in an audit, the initial score would be 11 points (5 CARs at 1 point each and 3 ICARs at 2 points each). Then that initial score would be divided by the number of elements reviewed (i.e., 5 elements) to achieve the PO's overall score. In the example above, 11 would be divided by 5 and the PO's overall score would be 2.2. We do intend to release these scores to the industry in our annual audit report which will discuss individual scores so that POs, advocates and States can assess how different organizations compare. As for the comment regarding Level I and II reporting, we are unsure what this commenter meant by this comment, but will clarify that audit scores are not tied to Level I or II reporting and should not be compared.

CMS Action 14: 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 15: A few commenters requested clarification on the draft audit report process. One commenter asked when a PO could expect to receive the draft audit report following the audit. Several commenters requested clarification on the dispute process following the draft audit report. These commenters encouraged CMS to have any disputes heard by an impartial third party.

Response 15: We appreciate these commenters' questions regarding the draft audit report process. While we intend to release the draft audit reports within 30 calendar days following the onsite portion of the audit, we cannot guarantee that this will always be the case. Because of the feedback we have received regarding consistency in audits, we are implementing multiple new processes designed to ensure that every PACE audit is handled consistently. Included in these new processes is the PACE Audit Consistency Team (PACT) which will weigh in on every condition from every audit prior to issuing the draft audit report. This process, while beneficial to ensuring consistency, may extend the time it takes for auditors to issue reports following the audit. Additionally, auditors will be requesting Impact Analysis templates to be completed when noting conditions of non-compliance, and POs will have 10 business days to submit those templates following the onsite portion of the review. These templates must be received before the PACT can appropriately classify conditions. Once the draft report has been issued, the PO will have 10 business days to respond to the report and dispute any findings. A PO may use this process to provide written disputes or evidence in response to conditions, or offer suggestions on rewording statements concerning the findings, such as the cause and effect report language. As for the request that disputes to the draft report be handled by an impartial third party, that comment is beyond the scope of this collection, but we will take the suggestion under consideration. If disputes do occur, the audit team that was onsite must be involved in the dispute process as they have the most personal knowledge of the conditions cited. While these auditors will be the responders to any comments received, they will have the PACT available to them for any assistance with how to re-word, re-classify or discard any conditions cited in the draft report.

CMS Action 15: 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 16: A few commenters provided overall support for the process improvements made by CMS in this protocol. Specifically, commenters supported not only the revised audit process, but also the other attempts at being transparent, such as releasing an annual audit report, using improved tools, and utilizing a PACE Audit Consistency Team (PACT).

Response 16: We appreciate the support from these commenters. We believe the process improvements we are proposing will help ensure that PACE participants are appropriately protected, while also ensuring that POs are treated consistently and fairly during CMS audits. We are committed to conducting our audits as transparently as possible, including encouraging POs to engage auditors during the audit and during the dispute process, as well as releasing an annual audit report. We also believe by instituting a PACT for PACE we will be taking an important step to making sure that we consistently apply and classify audit conditions across the nation.

CMS Action 16: 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 17: Several commenters requested specific clarification regarding the role of State Administering Agencies (SAAs). One commenter encouraged us to issue guidance to SAAs since state practices greatly differ. Another commenter requested that CMS clarify that the SAA would still have their own authority to audit or monitor a PO as the State determines necessary. Specifically, the commenter requested confirmation that the SAA could audit elements not covered by CMS, including requesting additional documentation, policies and procedures, or expanding the universes if needed. This commenter mentioned that a State needs the ability to monitor state specific requirements and initiatives as needed.

Response 17: We thank these commenters for their questions regarding SAAs. As part of the three-way agreement, CMS and the SAAs share oversight responsibility for ensuring POs compliance with pertinent regulations. This oversight can differ from State to State, with some States choosing to join CMS onsite for audits, and other States conducting their own audits at different times of the year. While CMS intends to share our audit strategy and tools with the SAAs, we recognize a state's need for their ability to conduct oversight as their state sees fit. This oversight may include conducting an audit other than the CMS audit, or it may include auditing elements or requirements that are outside the scope of the CMS audit. While CMS intends to be consistent with the elements we audit, the State has the authority to expand the scope of our audit as they determine necessary. For example, if the SAA joins CMS onsite during our audit, and determines that they need to review additional elements, such as enrollment or disenrollment, the SAA has the authority to do so. Additionally the SAA will have the authority to audit or monitor any State specific requirements that the PO is required to adhere to. We are not making changes to the CMS protocol, as our protocol does not dictate or limit the SAA's authority in any way.

CMS Action 17: 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 18: One commenter also requested that CMS and the SAA coordinate findings so that the stricter standard would apply. Specifically, this commenter requested that we ensure

one agency doesn't "pass" a requirement that the other agency would fail. Similarly, this commenter requested that we clarify that just because an element passed in one audit, does not mean that it will pass future audits if regulations or guidance is changed.

Response 18: We appreciate this commenters concerns on maintaining consistency with findings and ensuring the stricter standard applies during audit. CMS, in an effort to audit POs consistently, will be applying federal regulations when onsite to determine compliance. That being said, if a State has a stricter standard that the PO must adhere too, the State can and should monitor that PO for compliance with that standard. If a PO meets the federal standard, but does not meet the stricter State standard, that finding can be reported by the SAA as an issue of non-compliance, even if it does not get cited as a finding by CMS auditors. Also, when regulations or guidance change, POs are expected to implement the new guidance in accordance with any implementation timeframes.

CMS Action 18: 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 19: One commenter asked how SAAs would report audit findings to POs. This commenter suggested that SAAs be allowed to post their own findings into HPMS through uploading a word or excel document, but stressed that reporting should be optional and should not determine whether a SAA takes an enforcement action on their own.

Response 19: We appreciate these suggestions and agree with this commenter. We intend to allow any SAAs that are onsite during our audit to upload a separate word document to the CMS audit report that will contain any additional elements reviewed by the SAA or any State specific requirements that the PO failed to meet. This reporting is entirely optional, and a SAA can choose not to upload any findings, or not to conduct an additional review outside of the CMS elements. If the SAA goes onsite at a different time than CMS, or conducts a review outside of the timeframe of our audit, the SAA would continue to report on those findings in the same way they do now. Additionally, an SAA being onsite with CMS, or reporting findings through HPMS will in no way determine whether or not an SAA may take an enforcement action on their own.

CMS Action 19: 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 20: One commenter asked how the Star Ratings and PACE audits correlate. This same commenter asked that we make sure that results from audits and Star Ratings would be similar, so that a PO with a low audit score wouldn't have a high star rating.

Response 20: POs are not part of the Star Ratings program, so there is no correlation between our audits and Star Ratings.

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

Comment 21: One commenter requested that we clarify what the PACE Questions document was that the PACE Audit Process and Data Request referred to. This commenter did not see that document in the package.

Response 21: We apologize for the confusion. We have changed the reference in the PACE protocol to refer to the correct attachment name in the package. The name of the document is PACE_SupplementalQuestions.

CMS Action 21: Changed the protocol to refer to the correct attachment name.

Comment 22: Multiple commenters requested clarification on the reporting of disclosed and self-identified issues. A few commenters requested clarification on what should be included in this reporting. Some commenters stated that this reporting could discourage POs from reporting self-identified issues since if they are not fully corrected they could be cited a finding. Another commenter wanted clarification on what "corrected" meant and what period of time would impact the reporting of these issues.

Response 22: CMS appreciates the points raised by these commenters and agrees that changes should be made to the request for disclosed and self-identified issues. CMS has always recognized the importance of a robust internal monitoring system in order for an organization to ensure ongoing compliance with CMS regulations. Even though POs are not currently required to have a formal robust monitoring program, POs are required to stay in compliance with CMS regulations, and as such, they often identify areas of non-compliance on their own. It is important that a PO can quickly identify and correct issues of non-compliance before a PACE audit is conducted. It is also important for POs 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 POs 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. In other words, if the condition was severe enough to warrant classification as an ICAR, but the PO promptly identified, disclosed and corrected the issue, CMS would downgrade the ICAR to a CAR. This modified approach will also ensure CMS appropriately recognizes organizations that are transparent with CMS when discovering issues of non-compliance. Additionally, while POs will be required to discuss what corrective action was taken in Attachment III, we have removed the language from the protocol that discusses how to classify issues as either corrected or uncorrected. For purposes of Attachment III, a PO will be required to identify their remediation (correction) efforts, which could entail a variety of activities depending on the issue identified. Full correction would mean that if there was a system issue, the system was fully fixed so that the issue no longer occurred. If the issue identified impacted participants, correction would be considered complete once all impacted participants were made whole. However, for purposes of Attachment III, POs will be asked to provide the status of correction, including if the corrective action is ongoing. Lastly, we want all disclosed issues that were disclosed to CMS prior to the PO receiving the audit engagement letter that might affect the one year review period for the universes. We are changing the instructions for submitting disclosed issues in the audit protocol to reflect this new guidance. We are also updating Attachment III to reflect these changes.

CMS Action 22: We modified the disclosed and self-identified issues section of the protocol to reflect this new guidance. We also updated Attachment III to reflect these changes.

Comment 23: Several commenters had questions relating to the attachment for reporting of disclosed and self-identified issues (Attachment III_Pre-AuditIssueSummary). Two commenters

questioned why CMS would need the name of the individual to whom an issue was reported (i.e., CMS or PO). Two other commenters questioned why CMS would need to know all actions taken to address individual participants, as that could be onerous on the PO to submit.

Response 23: We appreciate the opportunity to provide clarification on how to populate Attachment III. CMS has asked for the name of the individual at CMS that the PO reported the issue of non-compliance to. This would not be the name of an individual at the PO, but only the CMS employee that the disclosed issue was reported to. This would likely be the PO's account manager. We need that name in order to verify that the disclosure actually occurred. As for reporting the corrective action take to remedy individual participants, Attachment III is looking for an explanation of that corrective action, not an individual accounting. Therefore, if 10 participants were adversely impacted by the issue, and the remedy was to mail corrected materials to those individuals, an overall explanation as well as the date the remedy was completed (i.e., when mailings were finished) would be all that was needed.

CMS Action 23: 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 24: One commenter requested clarification on whether CMS would collect issues disclosed to the SAA or only issues disclosed to CMS. This commenter also asked if the SAA would be able to review the disclosed issues.

Response 24: While we certainly encourage POs to disclose issues to both CMS and the SAA, for purposes of the CMS audit the only disclosures we are requesting would be issues disclosed to CMS. As we partner with SAA in the monitoring and oversight of POs, any disclosures received by CMS will be shared with the SAA.

CMS Action 24: 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 25: One commenter requested clarification on when CMS may cite a condition of non-compliance based on an issue that was disclosed. This commenter pointed out that if an issue had not been corrected they would recommend that CMS change the "may" to "will" and cite a condition of non-compliance.

Response 25: The language referenced by the commenter has been deleted in the protocol revisions issued by CMS. Auditors will collect and analyze disclosed issues that impact the universe and determine how to cite conditions as appropriate, and what classification should be used.

CMS Action 25: In response to other comments received, this language was deleted from the protocol.

Comment 26: One commenter requested that CMS validate all self-identified issues that were corrected. This commenter stated that ensuring appropriate correction is important and should be done onsite.

Response 26: We are no longer requesting self-identified issues to be reported to CMS prior to us going onsite. We are only requesting issues that were previously disclosed to CMS to be reported to us. However, for those issues that were corrected, we will attempt to verify correction when onsite whenever possible.

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: One commenter requested that the timeframe to submit this report be extended from 5 business days to 10 business days in order to allow the PO appropriate time to QA the report.

Response 27: We appreciate this suggestion, however we believe that 5 business days is sufficient when considering the new changes to this section. The only issues we are requesting from PO's would be issues that were previously disclosed to CMS (prior to the PO receiving the engagement letter or audit start notice). This list should be readily available and it should not require much effort for the PO to submit to CMS.

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.

Burden Estimate:

Comment 28: Multiple commenters stated that we underestimated the burden for POs that undergo a CMS audit. Several commenters suggested that because of the increased amount of data we are requesting, that we should allow for more upfront costs that will be required for a PO to build the logs and systems to capture this data. One of these commenters requested that we add a one-time burden of $42,500 per PO. Other commenters suggested that the hours CMS projected for the entire audit were underestimated. Some commenters thought that the burden should, at a minimum, be the same as what CMS projected the government burden was (i.e., 220 hours). One commenter offered specific feedback on increasing the pre-audit time allotment from 40 hours to 80 hours.

Response 28: We appreciate the feedback from commenters on our burden estimate. We agree that we underestimated the burden on POs and are making adjustments to reflect specific comments received. We agree that although the information we requested from POs is information most organizations already collect, there will probably be a one-time burden for POs to create systems to capture, track and submit the data in the format we are requesting. We considered each universe, the information we were requesting, and determined what we believe is an appropriate hourly burden on tracking and capturing the information in that universe. The specific hours per universe have been added into the revised burden estimate. We believe that it will take approximately 630 hours for a PO to build new systems, at $61 dollars an hour, which will equal a one-time burden of $38,430 for each of the 119 POs. We also believe that the hours involved in both the pre-audit and post-audit estimates are underestimated. We therefore modified the pre-audit hours from 40 hours to 80 hours in response to comments. We also made adjustments to the overall hours a PO spends for a CMS audit. The breakdown of those hours are discussed more specifically in comments below, but the overall hours for a PO to undergo a CMS audit was adjusted from 180 to 240 hours. When taking into account the one-time burden of $38,430 for each PO and the increased hours for POs during the actual audit, the total cost of the collection went from $790,560 to $5,627,250. This total is for the industry as a whole and not per PO.

CMS Action 28: We adjusted the burden estimate to include a one-time burden for all POs, and to reflect more pre-audit hours spent by the PO in preparation for audit and adjusted the overall hours for a PO to undergo an audit. We also adjusted the total collection estimate for POs to account for this new hourly estimate.

Comment 29: One commenter requested that we also account for more hours post audit. This commenter suggested that a PO would need more than 20 hours to respond to the draft report, and suggested we increase this estimate to 40 hours. Additionally, this commenter thought that 80 hours for corrective action and audit close out activities was underestimated and suggested we increase that time to account for implementing corrective action plans following the CAP process.

Response 29: We agree with this commenter that we should increase the time allowed for the draft audit report response to more accurately reflect a POs time in drafting that response. Therefore we are changing our estimate from 20 hours to 40 hours. However, we disagree with the commenter that we should allow for implementing the CAPs as a part of our burden estimate. Although we allow for some close out activities as a part of the audit, such as building and submitting a CAP. The actual process improvements or implementing the CAP are not a part of our burden estimate.

CMS Action 29: We changed the draft response burden to account for more hours to prepare disputes and responses to audit conditions or deficiencies.

Comment 30: One commenter requested that our burden estimates be adjusted based on size of the PO.

Response 30: While we appreciate this suggestion, we cannot modify our burden to account for individual POs. Instead, we have attempted to create an average burden that would account for both small and large organizations. While this burden may not reflect the true costs of every PO, we feel it would accurately reflect the majority of POs.

CMS Action 30: 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 31: One commenter requested that we consider implementation costs to be $1,200, annual maintenance costs of the proposal to be $72,775 and audit preparation of logs to be $10,800.

Response 31: We appreciate this commenter's feedback. We took into account the time required to gather and submit this information when creating our burden. We added a one-time burden of $38,430 for collecting and tracking this data which we believe accounts for the costs raised by this commenter. However, we also recognize that all POs are different and that this burden may not accurately reflect every POs experience. We tried to adjust the burden to represent a fair average for what expenses and time a PO may incur.

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: One commenter stated that the hours a PO spent during the actual audit used to be 28 hours and asked why CMS had increased the amount of hours to 40. This commenter also asked for confirmation that the audit would happen all onsite.

Response 32: As mentioned previously, we had to derive an average amount of hours spent by a PO during an audit, even though that may not be accurate for every PO. Some POs choose to have staff involved in all stages of the audit, which could mean a PO has staff involved in the full 40 hour week. We therefore estimated this burden at 40 hours to account for those organizations. Some organizations may spend less staff time on audit during this onsite week. Additionally, some of the CMS review may be conducted prior to arriving onsite (such as remote review of medical records) but we believe that any PO staff utilized for that effort would have a minimal burden in time or money.

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 clarification on how we arrived at the estimation that there would be 72 audits in 2017. This commenter asked if that number was based on the current regulations at 42 CFR 460.190 and 460.192, and wanted to confirm that should the new regulation be finalized the number would decrease.

Response 33: We calculated this number based on current regulation requirements in 42 CFR 460.190 and 460.192 which stipulates how often a PO must be audited by CMS. The estimated 72 audits is a combination of ongoing and trial period audits. The proposed regulation that would potentially limit the number of audits each year is not yet final.

CMS Action 33: 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.

Onsite Element:

Comment 34: A few commenters raised concerns regarding the onsite element in the new proposed protocol. These commenters were concerned that CMS was severely limiting the scope of the onsite review. These commenters noted several areas or elements that were in the CMS audit prior to this revision, including dietary services (e.g., checking food temperatures, food storage, kitchen inspections, emergency food supplies), physical environment/ infection control standards (e.g., water temperatures, Life Safety Code, disposal of waste, etc.), transportation (e.g., checking maintenance logs, verifying emergency equipment is on board, verifying no smoking signs, etc.). Some of these commenters pointed out that not all states have licensures, and without CMS to do this onsite review, these commenters weren't sure anyone would review these items. These commenters wanted to know how CMS would ensure these onsite requirements were met without doing a thorough onsite review.

Response 34: We appreciate the concerns raised by these commenters regarding the scope of our proposed onsite element. When we began making revisions to the CMS audit protocols, we focused first on creating an outcomes based auditing process that we believe, once implemented, will ensure that participants are safe as well as receiving medically necessary care and medications. We are also making efforts to be as transparent as possible in our auditing approach, and in doing so, we have eliminated any items that we feel are either not outcomes based or are not clearly defined in regulations or manual guidance. We determined that some of the onsite requirements that we had formally included in our audits fell into one of the two categories mentioned above. Additionally, in the three way agreement CMS holds with

the SAA, it clearly states that auditing of the Life Safety Code is the responsibility of the State. That being said, although CMS does not intend to include some of these former elements into our proposed revisions for the onsite element, that does not mean that POs are not required to adhere to any regulations or manual guidance that we are not specifically auditing. It also doesn't prohibit SAAs, even ones without a specific licensure, from auditing any areas they deem relevant.

CMS Action 34: No changes were made to the protocol in response to these comments. No changes were made to the burden estimates as a result of these comments.

Comment 35: One commenter requested clarification on what sort of review would be done on emergency equipment at the PO. This commenter specifically asked whether CMS would just check whether or not the emergency equipment was there (Yes or No) or whether CMS would also check whether equipment and drugs were not expired and functioning.

Response 35: We intend to verify that the emergency equipment specified in CMS regulations or manual guidance is available onsite. This will include ensuring the physical presence of the equipment as well as some basic functionality (i.e., emergency drugs are not expired).

CMS Action 35: No changes were made to the protocol in response to these comments. No changes were made to the burden estimates as a result of these comments.

Comment 36: One commenter was concerned with CMS's removal of specific elements or parts of previous elements, specifically contracts, governing body, observations of a participant's shower/bath, observations of IDT meetings, and interviews with participants and/or staff.

Response 36: When redesigning the audit protocol, we tried to focus on those elements that were most specific to the participant experience and access to care/services. We determined that some of the elements previously reviewed through audits (such as governing body or contracts) were not outcomes based and mainly focused on written policies and procedures. These elements can easily be reviewed through ongoing monitoring of a PO, either by CMS or the SAA. As for observations, we want to focus our efforts on clinical observations whenever possible. However, we still intend to observe an IDT meeting as a part of the clinical appropriateness and care planning/onsite elements. Additionally, we still intend to conduct interviews of staff and participants as necessary in order to verify any audit documentation discovered during medical records or service/appeal requests. While we added an IDT observation into the list of observations that may be conducted as part of the onsite element, we did not specify conducting specific interviews. We believe that auditors need some flexibility in determining which interviews need to be conducted based on what they observe at the PO.

CMS Action 36: We modified the onsite element in order to specify that CMS may conduct an observation of the IDT.

Comment 37: One commenter raised concerns that CMS was proposing to reduce the frequency of audits, while also proposing to reduce the scope of the onsite element. This commenter was concerned that if these two proposals went forward it would potentially negatively impact participants.

Response 37: While we appreciate the concerns raised by this commenter, the frequency of audits is outside the scope of this PRA package. That is a part of a proposed rule that is not

finalized. While we are reducing the scope of the onsite element, we have increased the focus on participant experience and ensuring that they are receiving appropriate services and medications, and that the PO is adhering to our requirements for providing that care. We believe the new protocol will drive improvements in the care provided to PACE participants.

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

On-Call Logs:

Comment 38: Two commenters requested clarification on what CMS would use the on-call logs for as the protocol was unclear. These commenters also stated that this information is currently captured through different mechanisms by different POs.

Response 38: We will be using the on-call logs to help us appropriately target participants for review. Although the information specific to the call is located in the medical record, we will need a universe of calls in order for us to know what participant to select. We will then verify the call details and responses when reviewing the medical record or service delivery request records. This on-call log is also an important universe for ensuring that participants have access to care at all hours.

CMS Action 38: We clarified in the protocol that the on-call log would be utilized for targeting participants in clinical appropriateness and the SDAG element.

Comment 39: Two commenters stated they felt requesting the on-call Log is duplicative and unnecessary as call information is maintained in the medical record and can therefore be reviewed during the medical record review.

Response 39: While we agree that verifying the PO's actions through the medical record is important, we do not request this call data as a part of the participant medical record universe. In order to know which medical records to review, we need a universe of calls prior to going onsite. Therefore we are keeping this as a separate universe.

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.

Comment 40: One commenter asked if we intended to match participants with the Medical Records and pointed out that we did not include participant ID in the on-call log table.

Response 40: We appreciate this commenter's point. We do intend to match participants with the on-call log and we have added a column into the on-call record layout for participant ID.

CMS Action 40: We added a participant ID column into the record layout for on-call logs.

Comment 41: One commenter questioned why we needed to capture seconds when requesting the time a call was received.

Response 41: We have changed all time requests within the record layouts to no longer request seconds in the fields. The record layout now asks for time to be enter with hours and minutes but not seconds.

CMS Action 41: We have made revisions to all record layouts to no longer include seconds in the time fields.

Comment 42: One commenter stated that the date field would need to be specifically programmed by the PO in order to capture that information.

Response 42: We agree that some fields, including the date field in the on-call universe, will need to be customized or specifically programmed in order to capture the data the way we requested it. However, we feel we have appropriately captured the customization of these fields in the burden estimate we constructed in the supporting statement.

CMS Action 42: 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 43: Two commenters requested clarification on why we needed to ask for the "response to call" in the record layout as this information is contained in the medical record.

Response 43: As we stated above, this information is useful to know for each call in order to appropriately select participants for review. This information will also be verified through the medical record during the sample selection and audit.

CMS Action 43: 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 44: Two commenters requested clarification on why we were requesting "PO Follow Up" and "Date of PO Follow Up" as this information is also included in the medical record.

Response 44: We agree with commenters that we do not need these two fields in order to sample participants. This information can be ascertained during the medical record review while CMS reviews participant samples. We have therefore removed these two fields from the universe.

CMS Action 44: Removed “PO Follow up” and “Date of PO Follow up” from the on-call record layout.

Quality Assessment:

Comment 45: Two commenters wanted clarification on what a quality initiative was, and how CMS defined it.

Response 45: We appreciate these commenter’s request for clarification. A quality initiative is a set of data used to measure and identify areas of good or problematic performance within a PACE organization. We have added this definition into the PACE audit protocol for POs to use.

CMS Action 45: We defined quality initiatives in the PACE audit protocol.

Comment 46: One commenter mentioned that several of these fields would need to be customized by the PO in order to populate them.

Response 46: We agree that POs will have to customize some fields to meet CMS expectations. We feel we have appropriately captured the cost of populating these universes in our revised burden estimate.

CMS Action 46: 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 47: One commenter requested that we change our quality assessment language to quality improvement to match the proposed regulation.

Response 47: The use of “quality improvement” is a change that has been proposed in the new regulation put forward by CMS. This regulation is not finalized and therefore no changes can be made to this audit protocol based on these proposals at this time.

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

Comment 48: One commenter asked if we needed separate fields for "corrective action required" and "corrective action implemented". This commenter suggested having these two fields was redundant.

Response 48: A PO may identify that corrective action is needed, but not have the time or resources to implement it immediately. Therefore we believe that keeping both of these two columns is necessary.

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

Comment 49: Two commenters requested clarification on the date corrective action was implemented. These commenters asked if multiple dates would be needed if multiple actions were taken within one quality initiative.

Response 49: We appreciate the opportunity to provide clarification on this field. We have modified this field from Date of Corrective Action Implementation to Start Date of Corrective Action Implementation. POs should populated this field with the date corrective action began, regardless of whether there were multiple actions taken in performing correction.

CMS Action 49: We modified the Date of Corrective Action Implementation to the Start Date of Corrective Action Implementation.

Personnel:

Comment 50: Two commenters requested clarification on what criteria CMS expects to include in the personnel background checks. One commenter mentioned that some SAAs require police background checks to be conducted.

Response 50: While we publish our external protocol, we do not share our internal methods of evaluation. For information on what CMS expects for background checks, please refer to 42 CFR 460.68 and the PACE Manual, Chapter 2, Section 50.1. For purposes of the audit, CMS will verify that the PO has satisfied federal requirements. SAAs will be responsible for ensuring that State specific requirements are met.

CMS Action 50: 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 51: Two commenters requested clarification on what criteria CMS expects to be included in OSHA trainings.

Response 51: While we publish our external protocol, we do not share our internal methods of evaluation. For information on what CMS expects for OSHA training, please refer to the PACE Manual Chapter 9, Section 20.4. For purposes of the audit, CMS will verify that the PO has satisfied these federal requirements for training.

CMS Action 51: 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 52: One commenter requested clarification on how often a PO was expected to conduct competency evaluations.

Response 52: While we publish our external protocol, we do not share our internal methods of evaluation. For information on what CMS expects for competency evaluations, including how often they should be conducted, please refer to 42 CFR 460.66, 460.71 and the PACE Manual Chapter 9, Section 10.3. For purposes of the audit, CMS will verify that the PO has satisfied these federal requirements for competency evaluations.

CMS Action 52: 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 53: One commenter stated that they felt most of the fields requested in the List of Personnel record layouts were reasonable, even though some would require some customization in order to implement them.

Response 53: We recognize that some of the fields we are requesting will require a PO to customize their systems, but we feel we have appropriately captured the burden of that customization in our new burden estimate.

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

Comment 54: One commenter requested that we add "volunteer" as an option for “Type of Employment”.

Response 54: While we appreciate this suggestion, “volunteer” is already a type of employment in this category, therefore no revisions will be made.

CMS Action 54: No changes were made to the protocol in response to this comment. No changes were made to the burden estimates as a result of this comment.

Comment 55: One commenter requested that we change the name of one field from "Direct Participant Contact" to "Immunizations/ Medical Clearance". This commenter mentioned that some states require all staff to be medically cleared, not just those with direct participant contact.

Response 55: We based the name of this column off of federal requirements therefore we are keeping the column name “Direct Participant Contact”. We cannot modify our record layouts to account for different state interpretations.

CMS Action 55: No changes were made to the protocol in response to this comment. No changes were made to the burden estimates as a result of this comment.

Comment 56: One commenter requested we add a column to inquire about emergency training.

Response 56: We appreciate this commenter’s suggestion and we agree that testing to ensure a PO provides appropriate emergency training is an important part of the personnel record review. However, we will ascertain this during the review of the personnel records and will not ask for this information upfront.

CMS Action 56: 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 57: One commenter argued that the burden of populating this personnel universe was enormous as it would require the PO to review every personnel record individually when populating this universe.

Response 57: We have reviewed the personnel record layout again and we agree that some of the fields we asked for do not need to be requested upfront. We are therefore eliminating four fields from the personnel universe. These fields include: “Background Check”, “Excluded Provider List”, “Competency Evaluations”, and “OSHA training”. Instead of requesting this information up front, we will sample personnel records and review this information in the record. However, if we see an issue in one of these areas we will ask for an Impact Analysis (IA) to be done to see the scope of the issue. We are therefore creating an IA template for personnel.

CMS Action 57: We removed the following fields from the personnel record layout: “Background Check”, “Excluded Provider List”, “Competency Evaluations”, and “OSHA training”. We also created an Impact Analysis template for personnel related conditions.

Comment 58: A few commenters requested that we add a compliance standard that specifically assesses whether the PO is conducting training related to infection control standards.

Response 58: We are limiting our review in personnel to trainings that are specifically referenced in either regulations or manual guidance. Therefore we are not going to add in an infection control training. However, we believe that through other elements, including clinical appropriateness and quality assessment, we will be able to adequately assess whether a PO is appropriately implementing an infection control plan.

CMS Action 58: 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 and Care Planning:

Comment 59: A few commenters asked for clarification on when an assessment should not be conducted "in person" as the regulation requires all assessments to be in person. This commenter suggested we remove the "when applicable" from the bullet in clinical appropriateness under Review Sample Case Documentation.

Response 59: We agree with the commenter that this phrase is not necessary and have removed the phrase “when applicable” from the bullet.

CMS Action 59: We modified the bullet under Review Sample Case Documentation to remove “when applicable” from the phrase “documentation that assessments were done in-person.”

Comment 60: A few commenters requested we clarify two of our care plan compliance standards by removing "if appropriate" from compliance standards 3.5.4 and 3.5.5. These care planning compliance standards referred to the explanation of the care plan being given to a participant and also the participant having a role in care planning decisions, which these commenters argued was always appropriate. These commenters also requested clarification on how CMS would define "having a role" and requested confirmation that having a signature is not enough.

Response 60: We agree with these commenters and have removed the phrase “if appropriate” from both of these compliance standards. As for how CMS would define “having a role”, while we publish our external protocol, we do not share our internal methods of evaluation. For purposes of audit, CMS will ask the PO to provide evidence that shows that the participant had a role in care planning decisions.

CMS Action 60: We removed “if appropriate” from compliance standards 3.5.4 and 3.5.5.

Comment 61: A few commenters stated that the amount of information we are requesting in the List of Participants was too burdensome. These commenters argued that POs are often small without advanced systems, and that asking for this much information upfront would be difficult for a PO to provide. One commenter suggested that in addition to requesting more data, we were also requesting a larger roster. This commenter stated that we had previously only requested information on a portion of participants, and not the full PACE roster. One commenter wanted clarification on whether we were requesting the entire census of participants or only those newly enrolled.

Response 61: We appreciate the concerns raised by these commenters. We considered the burden on POs when putting forward audit protocols, and believe that the amount of information requested was reasonable considering the reduction in documentation that we requested in prior years. Most of the information contained in the record layouts is either information that has been previously collected in audit, or information that should be readily assessable to the PO when populating a universe. However, we have reviewed the record layouts again for fields that are not imperative to conducting our audit. We have removed some fields from the record layout when we thought the burden outweighed the benefit. Additionally, we want to clarify that we are requesting the full roster of PACE participants. We do not need the medical records for all of these participants, only a listing of the information described in Table 5. This approach, requesting a full census of participants, is consistent with how we have conducted audits in the past. We also believe that by publishing our record layouts in advance of an audit, it will help a PO to prepare and be ready to submit this data, as they could utilize our universes as a way to track data on participants if they chose to. The deleted fields are discussed in more detail below.

CMS Action 61: We eliminated some of the fields in the record layout where we deemed the burden outweighed the benefit. The fields deleted include: “Most recent date of hospitalization”, “Most recent date of emergency room visit”, “Number of falls reported as a Level I event”, “List of Infections”, “Ambulation” and “Quality Analysis”.

Comment 62: A few commenters noted that specific fields in the List of Participants record layout were reasonable for CMS to ask for information on. One commenter noted that some of these fields would need to be customized in order to meet CMS intent but did not raise a concern about including them.

Response 62: We appreciate the support on these fields and agree that most of the fields in the record layout are reasonable to request of the PO. We are not going to specifically address fields deemed “reasonable” and are focusing the remainder of comments on fields that commenters either addressed concerns or where commenters requested clarification.

CMS Action 62: 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 63: One commenter requested clarification that how a PO populates the field "Reason for Disenrollment" is left to the PO's discretion.

Response 63: This field is a free text field and can be populated with any reason the PO feels is appropriate so long as that entry is less than 100 characters.

CMS Action 63: No changes were made to the protocol in response to this comment. No changes were made to the burden estimate in response to this comment.

Comment 64: Two commenters requested clarification on a few fields, specifically: "Number of Hospital Admissions/Observations" and the "Number of Emergency Room Visits" fields. Specifically that this information used to be requested as a "yes/no" field in prior audits, and that this change would require PO's to customize how they track this data.

Response 64: Although in past audits we requested this field to be entered with a “Yes/No” answer, we are now requesting a number to be entered. We feel knowing how many hospitalizations is important for understanding a participant’s medical history. We recognize that this change will require the PO to customize how they track and record this information.

CMS Action 64: 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 65: Two commenters requested confirmation that "Most Recent Date of Hospitalization" and "Most Recent Date of Emergency Room Visit" is a new field and would require customization from POs.

Response 65: In reviewing the record layout, we determined that these fields were not necessary and have deleted them from the revised record layout.

CMS Action 65: We deleted these two fields from the revised record layout.

Comment 66: Two commenters requested clarification on the "Number of SNF/NF admissions" and that this information used to be requested as a "Yes/No" field. These commenters also requested clarification on how to populate the field. Specifically, whether POs should separate medical admissions from admissions that were based on a service request.

Response 66: We appreciate the opportunity to provide clarification on this field. We do want a number of admissions as we feel this information is important for understanding a participant’s medical history. We are also clarifying the field to indicate that this field should capture all

admissions, for any cause, regardless of whether the admission was based on medical need or as a result of a request for services.

CMS Action 66: We clarified this field to include language that all admissions should be counted, even those that happened as a result of a service delivery request.

Comment 67: Two commenters requested clarification on the field "Current Center Attendance", specifically how CMS would define "partial" when requesting whether the participant attended the center for a full or partial day.

Response 67: In an effort to limit confusion for this field, we are modifying our request to the number of days a participant attends the center, and we are no longer asking for whether those days are full or partial.

CMS Action 67: We modified this field to ask for how many days a week the participant attends the center and not whether those days are partial or full.

Comment 68: Two commenters remarked that CMS should not request the fields "Number of Falls Reported as a Level I Event" and "Number of Falls Reported as a Level II Event." These commenters argued that these two fields are duplicative of information already requested by CMS. These commenters mentioned that POs have to report these events and go over them on quarterly calls with CMS.

Response 68: While we appreciate the concerns raised by these commenters, we do not believe that requesting this information is duplicative. While POs are required to report Level I and Level II events to CMS, that reporting is done through aggregate data and not at a participant specific level. For audits, we need participant specific information in order to understand the participant's medical history. However, when reviewing the record layouts, we determined that requesting falls reported as a Level II were sufficient, and we are no longer requesting falls reported as a Level I event.

CMS Action 68: We deleted the column requesting falls reported as Level I events.

Comment 69: Two commenters requested clarification on the field "Currently Recovering from a Fall Reported as either a Level I or Level II event". Specifically, these commenters wanted to know CMS's definition of "recovering".

Response 69: As mentioned above, we are no longer requesting information on falls related to Level I events, only those falls related to Level II events. Generally, CMS would consider a participant to be "recovering" if they are continuing to receive any treatment related to the fall (e.g., physically therapy, pain medication, or the participant still resides in a SNF due to a fall). We do not believe we should define "recovering" in the record layout as the definition may change slightly depending on the PO.

CMS Action 69: We removed the reference to Level I falls.

Comment 70: Two commenters requested clarification on the "Number of Infections" field. Specifically, that this field would require customization from POs in order to populate it. Also commenters requested a definition of "infections".

Response 70: We agree with commenters that this field will require the PO to customize how they track and record data, however, we believe that knowing how many infections a participant

has faced in a one year period is important to understanding the participant's medical history and how POs handle infection control. We are not defining infection control in the record layout as the definition could vary slightly among organizations. For purposes of audit, a PO should populate this field based on how they define infections within their infection control plan. We are including this guidance in the record layout field.

CMS Action 70: We modified the record layout field to instruct POs to populate this field based on how they define infections in their infection control plan.

Comment 71: Two commenters stated that the field "List of Infections" was burdensome for the PO to populate.

Response 71: We are removing this field from the record layouts in response to these comments.

CMS Action 71: We have removed the column "List of Infections" from the record layouts.

Comment 72: Two commenters stated that the field "Number of Pressure Ulcers" was duplicative of reporting requirements and therefore CMS did not need to request this information again.

Response 72: As we stated in our response to the Level I and Level II reporting requirements, we do not believe this request is duplicative as this record layout is focused on participant specific information and Level I and Level II reporting is done at an aggregate level. Additionally, Level II reporting only requests pressure ulcers staged III or IV. We are requesting pressure ulcers staged II or higher. However, we are modifying this field to simplify our request, and changing the field from requesting the number of pressure ulcers, to a "Yes/No" field of whether the participant had a pressure ulcer during the audit review period.

CMS Action 72: We modified the field name from "Number of Pressure Ulcers" to "Pressure Ulcers" and changed the field description of this field to make it a "yes/no" field.

Comment 73: Two commenters requested clarification on the field "Ambulation", specifically how CMS would define this field.

Response 73: We have removed this field in an effort to reduce the burden on POs in populating this record layout.

CMS Action 73: The field "Ambulation" has been removed from the record layout.

Comment 74: Two commenters requested clarification on the field "Significant Weight Loss" and how CMS would define that term. These commenters asked if the following examples were considered significant (5% in 30 days; 7.5% in 90 days, or 10% in 180 days), and also asked CMS to distinguish unplanned/ unanticipated versus planned/anticipated weight loss.

Response 74: We do not believe that we should define "significant weight loss" in the record layout as that definition could change slightly in different POs. We believe the examples presented by the commenters could meet what we would consider significant weight loss, depending on the participant and their health status. We do want to clarify that we are only requesting unplanned or unanticipated weight loss, and we have clarified that in the record layout.

CMS Action 74: We have modified this field in the record layout to reflect that we are only asking for significant unanticipated weight loss.

Comment 75: Two commenters argued that the "Skilled Therapy" field was cumbersome the way it was written with a description of the type of therapy involved.

Response 75: We agree with commenters that this field was cumbersome and requested more information than we needed. We have therefore changed this field from requesting a description of the therapy to only requiring the PO to input “Yes or No” as to whether the participant ever received skilled therapy during the audit review period.

CMS Action 75: We modified the “skilled therapy” column to be a “Yes/No” answer.

Comment 76: Two commenters requested clarification on what CMS considers a "Functional Decline" for purposes of populating that field.

Response 76: We believe that the PO is in the best position to define whether the participant has had a functional decline. This information has been requested on past audits and should be defined by the PO as it would have done so in the past. We are therefore not making any adjustments to the record layout for this field.

CMS Action 76: 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 77: Two commenters requested clarification on how CMS would define "Oxygen Use" for purposes of populating this field.

Response 77: We appreciate the opportunity to clarify this field. We are clarifying in the record layout that we only expect a “Yes” to be entered when the participant regularly uses oxygen as a part of their care plan (not as a result of an acute event).

CMS Action 77: We modified this field to clarify our expectations for what constitutes “oxygen use”.

Comment 78: Two commenters requested clarification on how CMS defines "Impaired Vision" for purposes of populating this field.

Response 78: We are clarifying this field to define “impaired vision” as when a participant is blind or he/she has visions that is severely impaired without corrective lenses.

CMS Action 78: We modified this field to include a description of what we considered “impaired vision”.

Comment 79: Two commenters requested clarification on how CMS defines "Impaired Hearing" for purposes of populating this field.

Response 79: We are clarifying this field to define “impaired hearing” as when a participant is deaf or his/her hearing is severely impaired without an assistive hearing device.

CMS Action 79: We modified this field to include a description of what we considered “impaired hearing”.

Comment 80: Two commenters requested clarification on the intent of the field "Quality Analysis" as the field seemed vague and not clearly defined.

Response 80: We are removing this field from the record layout to prevent confusion.

CMS Action 80: We removed “Quality Analysis” from the record layout.

Service Delivery Requests, Appeals and Grievances (SDAG):

Comment 81: A few commenters requested clarification on why CMS was requesting information on both approved and denied service delivery requests. These commenters thought this was an administrative burden without offering a benefit.

Response 81: We disagree with these commenters. While we understand the importance of testing denied service requests, there is also a benefit to testing approved requests. First, regardless of whether the request is approved or denied, the PO must process that request within a specific timeframe, so those requests will also be run through the timeliness test. Second, once a request is approved, the PACE organization should provide the service as expeditiously as the participant’s health condition requires, and we may choose to review some samples to ensure services are being provided in a manner that meets that requirement.

CMS Action 81: 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 82: One commenter requested that instead of using the templates (record layouts) we created for audit we use information already gathered from CMS through Level I or Level II reporting.

Response 82: While we appreciate this commenter’s suggestion, we cannot use the information in Level I and Level II reporting because it is not participant specific. We need to have participant specific information in order to conduct a comprehensive audit that focuses on participant care and the participant experience.

CMS Action 82: 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 83: A few commenters noted that specific fields in the Service Delivery Requests, Appeals and Grievances record layouts (Tables 1-3) were reasonable for CMS to ask for during an audit. One commenter noted that some of these fields would need to be customized in order to meet CMS intent.

Response 83: We appreciate these commenters and agree that most of the requested information is reasonable, even though some will require customization from the PO. We will only be discussing those specific fields where commenters raised concerns or questions regarding the data we were requesting.

CMS Action 83: 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 84: A few commenters raised concerns regarding CMS's request for "time" as it relates to service delivery requests and appeals. Specifically fields requesting the time of decision, time of notification, and time request was received. These commenters stated that time should not be requested as that level of specificity is not required in order for CMS to do

their review. Additionally these commenters said that if CMS requested time, they should not request this time to include seconds, only hours and minutes.

Response 84: We appreciate the concerns raised by these commenters and have closely reviewed our requests for time within the different record layouts. We agree that we do not need to request time for service delivery requests in order to assess timeliness of the decisions. Therefore we have removed all of the “time” fields from the service delivery request universe. However, in order to appropriately assess timeliness of expedited appeal requests we do need to ascertain the time of receipt and notification, so we are keeping the “time” fields in the appeals universe, although we have noted that POs do not need to populate the time for non-expedited appeals. Lastly, we agree with commenters that we do not need to request time in seconds for any of the time fields.

CMS Action 84: We have removed the “time” fields from the service delivery requests universe and modified the time fields in the other universes to remove the seconds from them.

Comment 85: Two commenters noted that there was one use of "beneficiary" instead of "participant" under the Review Sample Case Documentation. These commenters also requested "decision letter" be changed to "resolution letter" in this section. Lastly, these commenters requested that "time" be removed from the grievance documentation list.

Response 85: We appreciate these commenters pointing these items out, and have made the changes mentioned above in the protocol.

CMS Action 85: We changed the term “beneficiary” to “participant”, changed “decision letter” to “resolution letter” and removed “time stamp” from the documentation list.

Service Delivery Requests (Table 1):

Comment 86: A few commenters requested clarification on when a request is deemed "received" by the IDT for purposes of starting the service request.

Response 86: For purposes of audit, POs should input the date they deemed the request received in the “Date Service Delivery Request Received” field. Additionally, we are adding a new question to the PACE Supplemental Questions document requesting information on when the PO deems the request “received” and the portion of internal policy or procedure that addresses the PO’s receipt of the service request.

CMS Action 86: We have added a question to the PACE Supplemental Questions document relating to when a service delivery request is deemed received.

Comment 87: One commenter requested clarification on the field "Category of Requests" and wanted to verify that this field was free text and could be populated as the PO sees fits.

Response 87: This field is free text and can be populated as the PO wants as long as the category is within the 50 character field limit.

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

Comment 88: Two commenters requested clarification on the fields "Date(s) Assessment(s) Performed", “Discipline(s) Performing Assessment(s)”, and “Assessment(s) In Person”.

Specifically these commenters argued that the population of these fields were cumbersome, and requested clarification on what would happen if a PO entered NA in these fields, and whether they would automatically be cited for non-compliance.

Response 88: Although we understand that providing this information may require the PO to track and record data differently, we feel this information is important to have for every participant. When populating these fields, POs should enter NA if there were no assessments performed for that particular service delivery request. CMS encourages PO to begin programming their system or creating records that house this information prior to an audit, so it will be less of a burden when an audit occurs. CMS will be reasonable and work with POs during the initial transition to the new protocol and record layouts.

CMS Action 88: 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 89: Two commenters stated that the field "Request Disposition" only had approved and denied as options, even though the compliance standard in SDAG referred to partial denials as well.

Response 89: We agree with commenters and modified the “Request Disposition” field to include “partially denied” as a third option.

CMS Action 89: We added “Partially Denied” as an option for request disposition.

Comment 90: Two commenters requested clarification on why CMS was requesting the date and time of the decision for the service delivery request as there is no requirement in the regulation regarding decision making.

Response 90: We agree with commenters that we do not need to request this information as we are not performing a timeliness assessment on the decision date, only on the notification date. We are therefore removing these fields.

CMS Action 90: We have removed the “Date of Decision” and “Time of Decision” fields.

Comment 91: One commenter requested clarification on whether the PO could populate the field "Date of written notification" with the date the written notification was printed.

Response 91: When requesting the date of the written notification we are requesting when the notification was provided to the participant or caregiver. A PO may populate this field with the print date if that date is also when the PO mails or delivers the letter.

CMS Action 91: 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 92: Two commenters requested clarification on the “Quality Analysis” field within the service delivery request layout.

Response 92: We have reviewed this field and do not believe it is necessary to collect for each participant. We are therefore removing this field from the record layout.

CMS Action 92: We removed the field “Quality Analysis” from the record layout.

Appeal Requests (Table 2):

Comment 93: Two commenters raised concerns regarding CMS's request for an appeals universe. These commenters argued that POs already report appeals data through Level I reporting and therefore this universe is duplicative. Additionally, these commenters pointed out that most POs already have appeals logs and therefore would need to make modifications to capture the data as requested by CMS.

Response 93: While we appreciate the concerns raised by these commenters, the information reported to CMS through Level I and Level II reporting is aggregate data and not participant specific. We need participant specific universes for purposes of audit. We are also standardizing universes, and we understand in doing so that some POs will need to modify or change the way they currently collect appeals information, however, we feel that we have appropriately captured those changes in our burden estimates.

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

Comment 94: Two commenters stated that the field "Reviewer" is not necessary as the reviewer must be a credentialed impartial third party.

Response 94: We agree with commenters that this field is unnecessary. We will verify the appropriate reviewer during the sample review.

CMS Action 94: We removed the field “Reviewer” from the record layout.

Comment 95: Two commenters stated that the field "Request Disposition" only had approved and denied as options, even though the compliance standard in SDAG referred to partial denials as well.

Response 95: We agree with commenters and modified the “Request Disposition” field to include “partially denied” as a third option.

CMS Action 95: We added “Partially Denied” as an option for request disposition.

Comment 96: Two commenters requested clarification on why CMS was requesting the date and time of the decision for the appeal request.

Response 96: We agree with commenters that we do not need to request this information as we are not performing a timeliness assessment on the decision date and time, only on the notification date and time. We are therefore removing these fields.

CMS Action 96: We have removed the “Date of Decision” and “Time of Decision” fields.

Comment 97: Two commenters requested that "Time of Oral Notification" include an option of NA for non-expedited appeals.

Response 97: We agree with commenters and have added the option for NA to be populated when the appeal is not an expedited appeal.

CMS Action 97: We added an option to provide NA if the appeal was not an expedited appeal.

Comment 98: Two commenters argued that the field "Time of Written Notification" is an unreasonable request, and that it is nearly impossible for a PO to provide that information.

Response 98: While we understand these commenters' concerns, POs are responsible for ensuring that they follow federal regulations, and that they can show federal auditors that they adhere to these regulations. POs are required to provide written notification within 72 hours of receiving the expedited appeal request, and they are also responsible for assuring federal auditors that they have satisfied this timeframe.

CMS Action 98: 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 99: Two commenters requested clarification on the field "Quality Analysis". These commenters suggested the field was vague. They also asked what this information might be used for.

Response 99: We appreciate the opportunity to provide clarification on this field. POs are required to analyze appeal information. This field is asking for whether the particular appeal in question was used or analyzed in the PO's quality program. We have clarified the field to add the word "particular" to clarify this intent.

CMS Action 99: We clarified the field "Quality Analysis" to indicate that we are referring to the particular participant's appeal.

Grievances (Table 3):

Comment 100: A few commenters stated that POs already keep logs of this grievance information and that CMS universes would mean changing the way they capture or track data. Additionally commenters raised concerns that this universe is duplicative to the reporting POs already do in Level I reporting.

Response 100: While we appreciate the concerns raised by these commenters, we do not believe this information is duplicative of information already requested by CMS. Level I and Level II reporting is aggregate data and not participant specific. We need participant specific information in order to efficiently audit. We understand that asking for the universes in a standardized format may require PO's to change how they track and record data, but we believe we have covered the costs of these changes in our estimated burden.

CMS Action 100: 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 101: One commenter requested clarification that the "category of request" field could be customized by the PO.

Response 101: This field is a free text field and can be populated as needed by the PO so long as it stays within the 50 character field limit.

CMS Action 101: 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 102: Two commenters stated that for the field "Date of Decision" that this field would require POs to create resolution timeframes and update policies and procedures.

Response 102: POs are already required to develop grievance timeframes and policies and procedures. In order to assess timeliness of grievances, we will request the policies and procedures that POs already have in place.

CMS Action 102: 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 103: Two commenters requested clarification on the field "Quality Analysis" as they saw this field as vague.

Response 103: We appreciate the opportunity to provide clarification on this field. We are requesting a Yes or No on whether that particular grievance was analyzed or used in the quality assessment program by the PO. We have modified the field to include the word “particular” into the description.

CMS Action 103: We added the word “particular” into the field description for “Quality Assessment”.