Centers for Medicare and Medicaid Services Response to Public Comments Receivedfor CMS-10630

The Centers for Medicare and Medicaid Services (CMS) received 52 public submissions from Program of All-Inclusive Care for the Elderly (PACE) organizations (POs) and an association on The PACE Organization (PO) Monitoring and Audit Process in 42 CFR Part 460 (CMS-10630) proposed information collection issued December 21, 2021. We combined the public submissions into 38 unique comments and provided responses in the document below. Comments are categorized first by those that are general in nature, next, those that pertain to the audit protocol and other attachments, then, those that pertain to Root Cause Analyses (RCAs) and Impact Analyses (IAs), and finally, those that pertain to burden.

General Comment:

Comment: One commenter asked that CMS allow enough time for POs to make updates to their systems to adjust to the new audit protocol before implementing it for audits and commented that proposed changes to the audit protocol would take a year or more to implement through IT changes and training.

Response: CMS understands the importance of allowing sufficient time to implement changes. We will continue to work toward the goal of finalizing this collection to afford POs the maximum amount of time possible to update their systems and processes, while still allowing CMS to conduct the audits that are statutorily required.

Attachment I- PACE Audit Process and Data Request (Audit Protocol) Comments

Audit Protocol – General:

Comment: Multiple commenters expressed concern regarding CMS' removal of audit process information from the audit protocol. Specifically, one commenter was concerned about CMS' intent with responding to draft audit report comments and scoring since the audit process is no longer included in the audit protocol. Another commenter was concerned that the audit protocol no longer mentioned immediate corrective action required (ICAR) mitigation for pre-audit issue summary (PAIS) disclosures and sought clarification on CMS' intentions for the PAIS and condition classification.

Response: The purpose of the audit protocol is to provide information on CMS' data and documentation collection for PACE audits. We streamlined the PACE audit protocol by removing information that does not impact data collection or application of the compliance standards. However, we will continue to provide audit process related information separately and remain committed to transparency in our audit process.

Audit Protocol - Initial Documentation and Data Submissions:

Comment: Multiple commenters expressed concern over the additional burden of the proposed monitoring reports that detail the PO's monitoring and tracking of all services across all care settings that were ordered, approved, or care planned during the data collection period. Commenters stated that generating the report as proposed would be burdensome because of the volume of services that would need to be provided and because it would require a high degree of manual data collection from different sources. Commenters suggested eliminating the monitoring reports and alternative ways CMS could gather the information they need to assess compliance. This included requiring POs to provide their policies and procedures for monitoring and tracking of services followed by in-depth review of the cases evaluated during the provision of services and service determination requests, appeals, and grievances (SDAG) element reviews, or collecting a monitoring report for only 10-15 randomly selected participants rather than all participants. Additionally, commenters asked for clarification on what level of services CMS expects to be included in the monitoring reports.

Response: CMS considered these concerns and will not require monitoring reports for all participants. Instead, we will limit the request to 30 participants that CMS will select from enrollment data already collected by CMS, and for which the PO would submit all services across all care settings that were ordered, approved, or care planned during the data collection period. The PO will receive the list of 30 participants at the time the audit engagement letter is issued. The PO will then submit the monitoring of services for those individuals as part of the initial documentation and data submissions for the audit within 20 business days following issuance of the engagement letter. We will then use that information, in conjunction with the universes, to determine the samples selected for audit. We have updated the audit protocol to reflect this change.

Comment: Multiple commenters asked CMS to clarify its intent for the Compliance and Quality Improvement element request for documentation of all self-evaluations and audits conducted in the PO's compliance oversight program, which we proposed collecting up front as part of Initial Documentation and Data Submissions monitoring reports. More specifically, the commenters asked to confirm that there is no expectation inherent in this documentation request that POs must submit the results of routine auditing and monitoring activities for Part D required under 42 CFR 423.504(b)(4)(vi)(F) or that CMS requires POs to undertake routine monitoring and auditing for their operations as a whole.

Response: Section 460.63 requires that POs must investigate potential compliance problems as identified in the course of self-evaluations and audits. While we are removing this from the paperwork reduction act (PRA) package, during review of the Compliance and Quality Improvement element review, POs may choose to show self-evaluations and audits as

evidence of their efforts in developing an effective compliance oversight program. POs may also choose to show their monitoring and auditing of their Part D program in order to help demonstrate their compliance program oversight efforts.

Audit Protocol - Audit Element Review Comments

Provision of Services Element:

Comment: For the Provision of Services element sample case documentation, multiple commenters requested clarification on why CMS would request "Documentation of recommendations for care or services by IDT team members, participants, caregivers, PO employees, contractors, specialists, and designated representatives", because the commenters expected that participants, caregivers, and designated representatives would make a service determination request rather than a recommendation.

Response: We agree with the commenter and have updated the Provision of Services element sample case documentation request to "Documentation of recommendations or requests for care or services by IDT members, participants, caregivers, PO employees, contractors, specialists, and designated representatives".

Compliance and Quality Improvement Element:

Comment: Multiple commenters asked CMS to clarify what types of documentation CMS would collect for the Compliance and Quality Improvement element documentation demonstrating the measures developed as part of the PO's compliance oversight program to prevent, detect, and correct noncompliance with regulatory requirements and fraud, waste, and abuse. Commenters asked that CMS keep this request broad so that a variety of materials would be accepted to meet the documentation request.

Response: We appreciate the opportunity to clarify our expectations and understand that POs may have a wide range of materials in response to this documentation request. CMS will accept documentation of any kind and in any format that POs have available to demonstrate the measures they have developed as part of their compliance oversight program.

Audit Protocol – Record Layouts

Record Layouts – General:

Comment: Multiple commenters asked that CMS provide updated record layout templates at least three months before CMS intends to implement the new audit protocol.

Response: We will provide updated record layout templates as soon as possible once the audit protocol has been approved by the Office of Management and Budget (OMB) through the PRA process.

Record Layouts - Table 1 - Service Determination Requests (SDR):

Comment: One commenter recommended the removal of the fields: "Date of the first assessment completed in response to the service determination request" (column M), "Date of the last assessment completed in response to the service determination request" (column N), and "How many assessments were completed in response to the service determination request?" (column O). The commenter suggested that these fields add unnecessary burden since the data would already be captured in the current audit protocol SDR record layout field "Date(s) assessment(s) performed", which would include all assessment dates in one field. The commenter also noted there is no regulatory requirement to complete an assessment except for any denied or partially denied service determination request.

Response: While CMS agrees that the proposed audit protocol increases the number of data fields related to service determination request assessments, we do not believe this is a significant burden increase. The data is already being requested in the current audit protocol, we are merely separating that data into different columns in this version. Additionally, as one commenter pointed out, assessments are no longer required for approvals, which will limit how often the PO may need to populate data into these columns. No changes were made to the audit protocol in response to these comments.

Comment: Multiple commenters requested clarification on whether POs should enter "N" for the field "Immediate Approval" (column R), if the service determination request was approved in full by the entire interdisciplinary team (IDT). They suggested that it would be clearer to require "N" if a member of the IDT was not able to approve the service determination request in full at the time the request is made, as the preceding column provides information on the request disposition.

Response: CMS agrees with commenters that the description for "Immediate Approval" does not need to repeat dispositions that were included in the prior column. We modified the description of "Immediate Approval" to read "Enter N if a member of the IDT was not able to approve the service determination request in full at the time the request was made."

Record Layouts - Table 2 - Appeals Requests (AR):

Comment: Multiple commenters requested clarification on whether, for the field "Third-party reviewer or committee credentials" (column M), POs may enter IDT members employed by other POs as third-party reviewers, and if yes, when an individual IDT member (as opposed to

multiple IDT members) is the third-party reviewer, should POs provide the individual-specific credentials or should this individual be identified as "Another PO's IDT"?

Response: We appreciate the opportunity to provide clarification. As specified in the "Third-party reviewer or committee credentials" description, POs may indicate that the third-party committee is another PO's IDT. This response should be entered when the committee consists of another PO's full IDT representing every required IDT discipline. When the third-party reviewer is a single IDT member or consists of multiple members, but not the full IDT from another PO, this field should be populated with the individual-specific credentials only (e.g., primary care physician or PCP). We updated the "Third-party reviewer or committee credentials" description with this clarification.

Record Layouts - Table 3 - Grievance (GR):

Comment: One commenter requested that CMS align the grievance record layout with quarterly grievance reporting requirements to reduce burden.

Response: CMS has already aligned the grievance record layout data fields with quarterly reporting requirements where possible and no further modifications are applicable.

Record Layouts - Table 4 - List of Personnel (LOP):

Comment: Multiple commenters asked CMS not to replace the field for "Direct Participant Contact" in the current protocol with the proposed "Date of Initial Participant Contact" (column E) and "Date Individual Began Providing Care Independently" (column F) fields, because populating these fields would be time consuming. The commenters noted that, if a Personnel related IA is required, the PO would have to provide "Date of Initial Participant Contact" and "Date Individual Began Providing Care Independently", so CMS has a method for looking into this further if non-compliance is identified.

Response: CMS agrees with the commenters and will maintain the "Direct Participant Contact" field and remove the proposed new fields "Date of Initial Participant Contact" (column E) and "Date Individual Began Providing Care Independently" (column F).

Record Layouts - Table 5 - List of Participant Medical Records (LOPMR):

Comment: Multiple commenters recommended that POs report LOPMR data for a random sampling of participants enrolled during the data collection period with a "statistically valid sample" size, instead of reporting data for all enrolled participants. This would significantly decrease burden.

Response: The data CMS requests in the LOPMR record layout is used to ensure we can select an appropriate sample for the Provision of Services review rather than conducting a full review of all participants, thus limiting burden. No changes were made to the audit protocol in response to this comment.

Comment: Multiple commenters recommended removing "Change in Living Situation" (column L), because information requested for this field would not be available in the participant medical record and care need changes related to a change in living situation could be identified through other fields.

Response: In response to comments, we have revised the "Change in Living Situation" field description to clarify that we are asking whether the participant's living situation changed significantly, for example, if the participant went from the community or home to a facility, such as an Assisted Living Facility, or if the participant went from living with family to living alone.

Comment: Multiple commenters asked CMS to clarify how CMS defines "medication overdose" for "Hospitalization/Emergency Room Reason" (column P). Commenters also requested that CMS include ICD-10 codes in column P to ensure POs uniformly reported this information.

Response: This field is intended to capture intentional and unintentional drug overdoses resulting in an Emergency Room (ER) visit and/or a hospital admission, regardless of cause. While we are not requiring ICD-10 codes in the field description, POs may create a list of ICD-10 codes to assist with compiling this information.

Comment: Multiple commenters requested that CMS reconsider "Diagnoses" (column T), and how POs may submit that information that would reduce burden. These commenters indicated that typing the individual diagnoses into the field would take too long.

Response: Diagnosis information should be readily available to POs. CMS already limits the "Diagnoses" field to collecting only 20 diagnoses out of many possible diagnoses. We encourage POs to create and operationalize their own internal tools to assist them with compiling this information. POs are further encouraged to maintain this information in a readily accessible form to be prepared for audits.

Comment: Multiple commenters requested that CMS remove "CHF Exacerbation" (column U) and "COPD Exacerbation" (column V), as they believe that they are overly burdensome and the information could be gleaned from other data already submitted (for example, under "Diagnoses" (column T) and columns on hospitalizations and ER visits).

Response: We disagree with commenters that the information in "CHF Exacerbation" and "COPD Exacerbation" can be identified through other fields, and therefore we are not eliminating those fields. These fields allow us to maintain the proposed sample size rather than increase it, which reduces burden.

Comment: Multiple commenters requested clarification of the term "comfort care" for "Received Comfort Care" (column X) and recommended that this field focus exclusively on end-of-life care as defined by the PO with the name of the field changed to reference "end-of-life care" instead of "comfort care".

Response: We have modified the field description to offer further clarification on our intention. During audits we have seen a wide interpretation of what the terms "comfort care" and/or "palliative care" mean to different POs. For purposes of the audit protocol, POs should enter "Y" for this field when a participant is receiving comfort care that is considered end-of-life care and they are therefore no longer receiving curative or maintenance care for one or more of their health conditions. POs should enter "N" for this field when a participant is receiving comfort care in addition to other services meant to treat a condition or maintain health and no services were stopped or eliminated as a result of the comfort care, or when the participant is not receiving any form of comfort care. We maintained the field name of "Received Comfort Care", but have updated the description to include this clarification.

Comment: Multiple commenters recommended that we remove "Date Comfort Care Began" (column Y) and "Date Comfort Care Ended" (formerly column Z). They asked CMS to focus on end-of-life care for comfort care and expressed that including this data in the LOPMR universe would be burdensome.

Response: CMS has removed "Date Comfort Care Ended" and revised "Date Comfort Care Began" to allow for multiple start dates. Additionally, as mentioned in the previous comment response, the comfort care fields will focus on when comfort care is provided as end-of-life care in place of the participant receiving curative or maintenance care.

Comment: Multiple commenters asked CMS to modify the "Current Center Attendance" (formerly column AC, now column AB) field description to report PACE center attendance in terms of days per week rather than days per month, as that format is more consistent with PO tracking of center days.

Response: We appreciate the comment. The suggested modification will not allow the PO to account for weekly variations in participant center attendance during a given month, including those participants who attend the PACE center less than once every week. No changes to the audit protocol were made in response to this comment.

Record Layouts - Table 6 - On-Call (OC):

Comment: Multiple commenters suggested that CMS remove "Call Category" (column H), because they considered the information CMS intends to collect in this field to be covered by the "Call Description/ Reason for Call" field.

Response: CMS agrees with the commenters and has removed the "Call Category" field from the OC record layout.

Record Layouts - Table 7 - Contracted Entities and Providers (CEP):

Comment: Multiple commenters requested clarification whether CMS' intent with the CEP record layout is to obtain information on the PO's contracted entities, both individual providers and group practices in which multiple providers practice. Additionally, some commenters requested that CMS change the CEP record layout field name of "Provider/Facility Name" (column A) to "Provider/Practice/Facility Name" and allow for POs to provide the practice name if that is the contracted entity. Similarly, commenters suggested the field "Specialty or Facility Types" (formerly column C, now column B) should allow for multiple specialty types to accommodate a multi-specialty group practice.

Response: The intent of the CEP record layout is to collect contracted entity information for both individual or single practice providers and group practices with multiple providers. CMS agrees with the commenters on their recommendations for the fields. We updated the "Provider/Facility Name" (column A) to "Provider, Practice, Facility Name" to allow POs to provide the practice name if that is the contracted entity, removed the field "Practice Name", as it is no longer applicable, and modified the field "Specialty or Facility Types" to accommodate a multi-specialty group practice.

Comment: Multiple commenters requested clarification regarding what CMS means by "any limitations" in the description for the field "Limitations/Restrictions" (formerly column G, now column F), which could encompass a wide scope of factors.

Response: CMS has revised the "Limitations/Restrictions" description to clarify our expectations for this field and narrow its scope. POs would enter "Y" when the contracted entity or provider implemented or imposed any blanket restrictions or limitations on services that impacted participants at any point during the data review period. Examples of a limitation include, but are not limited to: the provider had a cap or quota on the number of PACE participants it could serve, or the provider did not accept new PACE participants as patients for a period of time during the data collection period.

Comment: One commenter wanted to eliminate the CEP record layout and recommended

that POs instead provide a list of the PO's provider network.

Response: We appreciate the comment and recommendation; however, the CEP record layout requests data that may not be included in a PO's provider network lists, and based on what we have learned on audit, this information is necessary for CMS' review. No changes were made to the protocol in response to this comment.

Root Cause Analyses (RCAs) and Impact Analyses (IAs) - General:

Comment: Multiple commenters recommend a sampling approach for IAs which takes into account the PO's census in determining the scope of the IAs. While they appreciated CMS' decision in 2020 to reduce the scope of numerous IAs from 100 percent to 50 percent of participants and personnel, they remain concerned about the burden of completing IAs, particularly for POs with medium and large enrollment sizes. One commenter suggested that 30 percent of the PO census would be a more reasonable threshold. The commenters expressed that if the results of an IA identify a widespread or systemic issue of significant concern, auditors could then ask the PO to expand its focus to a larger scope of records and a more comprehensive review could be saved for the PO's corrective action plan. Additionally, commenters want the participant samples chosen for the IAs to overlap to the greatest extent possible to limit the total number of records to be reviewed.

Response: We appreciate the comments and recognition of the significant reduction in scope for IAs beginning in 2020. IAs continue to be an effective mechanism to determine the cause and magnitude of an issue, and based on our experience, we believe the current threshold of up to 50 percent is appropriate. As we stated for our 2020 package, the 50 percent threshold represents an upper limit that is reduced depending on the nature of the issue of noncompliance and in consideration of the PO's enrollment size. Further, these analyses are not routinely requested as part of all audits, and are only requested when a PO is non-compliant with regulatory requirements. Lastly, when selecting the participant samples for the IAs, CMS will continue to select participants based on factors that allow us to determine compliance with program requirements, with overlapping samples across IAs whenever possible, as we have been doing since the approval of the 2020 audit protocol.

Comment: Multiple commenters suggested other ways that CMS could reduce the burden of IAs. Commenters suggested that CMS have more dialogue with POs during audits to avoid potentially unnecessary IAs through discussion and a thorough understanding of the identified issue. Additionally, commenters suggested that thresholds for IAs related to medical record documentation should consider the comprehensiveness of POs' documentation requirements and the threshold for an IA should be adjusted accordingly so that minor omissions without consequences for participant care do not lead to IAs consuming significant PO staff time.

Response: The current framework of audit fieldwork provides POs with multiple opportunities to demonstrate compliance and ensure that CMS and the PO have a thorough understanding of potential issues, before IAs are determined necessary. This is accomplished through various modalities including discussions between the PO and CMS about potential issues, joint review of electronic medical records via webinar when requested, and documentation requests for additional information. CMS carefully considers all information received from the PO prior to deciding whether to request an IA, and starting in 2020, we have eliminated multiple IA templates where the non-compliance was less likely to result in participant harm.

Comment: One commenter asked that CMS raise its threshold for requesting RCAs.

Response: RCAs are critical to understanding the cause and potential impact of non-compliance identified during an audit and they provide the PO additional opportunities to submit documentation that may address or mitigate the non-compliance. CMS will continue requesting RCAs based on the specifics of each issue and the information provided by the PO.

Impact Analyses (IAs) - Specific:

Comment: Multiple commenters would like further clarification of CMS' expectations of POs in completing the CoordinationofCare1P95 IA, in particular for participants receiving care in acute settings. They noted that in acute settings (e.g., a hospital), the IDT is limited in their authority to direct or approve the care provided. Commenters recommended modifying this IA to focus on whether the IDT ensured that care provided in the acute setting was consistent with the participant's care plan and the participant's wishes/goals for care.

Response: We thank the commenters for their recommendation and have modified column H of the IA to remove the focus from acute care and to be specific to long-term and short-term residential facilities, as noted in the facility definition provided on the Instructions tab of the IA.

Comment: For the RequiredServices1P93 IA, multiple commenters would like columns I and J to be changed to yes/no questions and suggested that the information requested in columns L, M, O, P and Q could be limited to situations in which the PO did not provide the services in full if a participant's caregiver expressed unwillingness or the IDT determined caregivers were unsafe. Some commenters also asked CMS to clarify if the PO would need to complete columns K through T if responses in columns I and J are "No". Commenters also requested that CMS clarify its intent with this IA.

Response: When needed, we will use this IA to assess whether POs are providing required services appropriately and not inappropriately utilizing individuals that are not an employee

or a contractor to provide required care. We have reviewed and modified the RequiredServices1P93 IA, and have added the option of "NA" for columns that do not apply when the PO is providing all care and services through their own employees or contractors. As for columns I and J, we do not believe a yes/no response is appropriate, as the information in those columns is necessary to understand what services caregivers may have been providing.

Comment: For the SpecialistRecommendations1P14 IA, most commenters asked for clarification on CMS' expectations regarding "all services recommended or ordered by the specialist, ER provider, or hospital provider" in column J. Specifically, they asked whether column J would include recommendations made by ER or hospital providers included in discharge summaries for ER visits and hospitalizations.

Response: We appreciate the opportunity to clarify the types or sources of documentation POs should consider when completing column J. At a minimum, the PO should identify all services (including items and/or drugs) included in any specialist consult notes, any ER or hospital discharge summaries and any other documentation the PO may have received from the hospital or ER. Additionally, we are changing the title for this IA to "SpecialistRecommendations1P94".

Comment: For the SpecialistRecommendations1P14 IA, multiple commenters noted that the use of "NA" appeared inconsistent, e.g., in column L, and asked whether "NA" should also be an option consistent with instructions for column K and others?

Response: We thank the commenters for their recommendation and have updated SpecialistRecommendations1P14 IA to include an "NA" response for column L if it does not apply to the record.

Comment: Multiple commenters noted that some of the columns in SpecialistRecommendations1P14 seemed to be related to the provision of services, and not remaining alert to information from specialists. Specifically, commenters noted columns N, O, and P, and recommended those columns be deleted.

Response: We disagree with commenters that these columns should be removed. These columns are meant to assess whether a specialist recommended service was actually ordered and/or provided to the participant, which is vital in understanding the participant's care and access to services.

Attachment IV - Observation Participant List Comments:

Comment: Multiple commenters requested that CMS eliminate Attachment IV, the

Observation Participant List. Commenters suggested that the participant information included in the LOPMR record layout and sample cases would be adequate for CMS to select five participants for the Provision of Services observations, as CMS has done for the past couple audit years. As an alternative, multiple commenters suggested allowing POs to provide a list of participants assigned to an IDT at a specific center who receive wound care, medication administration, home care and/or a specialized diet during the week of the participant observation review, rather than complete the full data request proposed in Attachment IV.

Response: CMS agrees with commenters and has eliminated Attachment IV from the audit protocol. In doing so, we have also reordered the audit survey as the new Attachment IV, and the Corrective Action Plan Process as the new Attachment V.

Attachment VI - Corrective Action Plan Process Comments:

Comment: Multiple commenters expressed appreciation for the information provided in Attachment VI, the Corrective Action Plan (CAP) Process, particularly for how it explains the role of the Account Manager during the CAP process.

Response: Thank you for this comment.

Burden Estimate:

Comment: Multiple commenters expressed that CMS audit data requirements are extensive, burdensome, and the amount of documentation requested demonstrates the intent to identify all possible non-compliance and human error, rather than creating focused audit samples to identify significant and recurring system failures. One commenter indicated that audits have shifted since 2017 and have started asking for more documentation, including at times, full participant medical records.

Response: We appreciate the commenters' concerns. The audit protocol was developed to assess compliance with statutory and regulatory requirements and ensure that enrollees receive the benefits they are entitled to under the PACE program. Since 2017, we have made numerous and significant changes to the documentation requests in response to comments, and with each protocol update, we have sought to strike a balance between ensuring participants are receiving appropriate and timely care and services, while not overwhelming POs with intensive data requests over the course of the audit. The current audit protocol has helped CMS improve the PACE program by identifying non-compliance and ensuring POs understand the actions that are needed to correct deficiencies. This includes identification of significant concerns with ensuring access to services, and inadequate processes and infrastructure. CMS will continue to request any and all documentation that is necessary to investigate and document potential non-compliance, including full participant medical records

when needed. We will also continue to identify opportunities to streamline the audit process while still ensuring CMS' ability to effectively monitor POs for compliance with regulatory requirements.

Comment: Multiple commenters suggested that POs should not be expected to retrieve data from their electronic medical record systems in the same manner CMS expects Medicare Advantage Organizations (MAOs)/ Part D plans to access their administrative databases, because electronic medical records (EMRs) are not designed to produce data reports representing all the information documented in the EMR. The commenters expressed that CMS' audit process creates excessive burden, because the narrative nature of EMRs require POs to perform manual reviews of audit data requests and diverts staff from participant care.

Response: POs have unique responsibilities as both an insurer for purposes of implementing the Medicare program and a direct care provider that is responsible for ensuring the health and safety of the participants enrolled in their programs. We understand that some POs do not have systems that are capable of efficiently tracking the provision of care and services for participants or compiling audit relevant information, which may hinder a PO's ability to respond to oversight requests. However, because PACE is a direct care provider, it is even more critical that POs have the ability to maintain information on requested and approved services to ensure services are being provided to participants. When a PO is unable to easily understand or track the services a participant should be receiving, we have found on audit that they are unable to effectively manage a participant's condition and ensure the participant is receiving the care they need. Therefore, we strongly encourage POs to develop and maintain an appropriate infrastructure to ensure the needs of participants are met in accordance with program requirements.

Comment: The majority of commenters who commented on the burden estimates indicated CMS underestimated almost every aspect of the PACE audit, including the number and types of staff involved in each phase of the audit, and particularly for medium and large enrollment POs. Their concerns for burden included the amount of time and resources involved in the pre-audit work, the amount of time and resources that were involved in the audit fieldwork phase, compiling and submitting RCAs and IAs, and responding to draft audit reports. Commenters did concur with the burden estimate for corrective action and close out activities. Furthermore, commenters recommended that CMS carefully consider how it integrates lessons learned from audit experiences during the 2020 and 2021 PACE audit years and COVID-19 public health emergency (PHE) so that the audit protocol takes into account burden for medium and large enrollment POs, as they believed the 2020 and 2021 audit years were not representative of POs with medium to large enrollments.

Response: We appreciate the opportunity to respond to these comments. The burden estimates for this package are based on our audit experience of small, medium and large enrollment POs

over the last two years, as well as survey feedback from audited POs on the average amount of time it has taken POs to complete certain audit-related requests and the staff that were involved in completing them. These lessons learned are reflected in the proposed changes. Additionally, changes proposed for the updated audit protocol, including those specified in this document, will further reduce PO burden while still ensuring CMS' ability to effectively monitor POs for compliance with regulatory requirements. For example, we have streamlined data fields, clarified instructions related to the collection tools for analysis of potential non-compliance, and developed a more efficient CAP process. Furthermore, CMS will use other data or information collected before or during the fieldwork stage of the audit for the participant observation review, and we are eliminating our request for Attachment IV (Observation Participant List) from this collection. With these updates, we believe the current burden estimates are accurate. We continue to be committed to trying to streamline the process when feasible in order to reduce burden and we will continue to use our survey at the end of audits to assess burden for POs in future PRA packages.

Comment: Multiple commenters states that the burden estimate of a total of 100 hours, or a 20 hour increase, for the pre-audit period is substantially underestimated because of the increase of information required of POs, particularly: reports logging the provision of all services ordered, approved, or care planned for the six-month data collection period, additional fields in the LOPMR record layout; the new CEP record layout, and new documentation and report requirements related to the PO's compliance oversight program.

Response: We have made a number of changes in response to comments that will significantly reduce PO burden during the pre-audit period including eliminating Attachment IV and reducing the monitoring report to just 30 participants. We have also clarified that we will accept documentation related to the PO's compliance oversight program in any format to demonstrate they are meeting the requirements established in 2019 at 42 CFR 460.63. As a result, we believe the original estimates for pre-audit activities now more accurately reflect the burden associated with a PACE audit.