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

The Centers for Medicare and Medicaid Services (CMS) received 12 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 May 10, 2022. We combined the public submissions into 21 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 Impact Analyses (IAs), and finally, those that pertain to burden.

General Comment:

Comment: Multiple commenters expressed appreciation for CMS' consideration of 60-day comments. These commenters commended CMS on making changes in response to comments, and specifically, noted that CMS had reduced burden with these changes.

Response: CMS appreciates this support.

Comment: Multiple commenters asked that CMS provide POs with training and opportunities to engage with CMS on the 2023 PACE audit materials as soon as possible after they are finalized.

Response: We are committed to providing training to the industry on the 2023 audit protocol once it has been finalized.

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

Audit Protocol - Initial Documentation and Data Submissions:

Comment: Multiple commenters expressed appreciation that CMS reduced the collection of tracking and monitoring reports related to services from all participants to 30 participants. However, these commenters noted that the same clinicians that are responsible for pulling the information in the List of Participant Medical Records (LOPMR) universe, are also responsible for putting together this tracking information. These commenters requested that the information for these 30 participants be due more than 20 business days from the date of the engagement letter. These commenters suggested that the information be due within 30 business days to give staff additional time to focus on pulling this information. One commenter recommended that CMS collect documentation describing PO processes, policies, and procedures for monitoring and tracking of all ordered, approved, and care planned services

across all care settings, rather than monitoring reports. This commenter asked that CMS limit the monitoring report sample to 10-15 participants chosen at random by auditors from the PO's participant list if CMS does not eliminate the monitoring report.

Response: In response to the 60-day comments, CMS limited the request from all participants to 30 participants for which the PO would submit all services across all care settings that were ordered, approved, or care planned during the data collection period. As we noted in our response to 60-day comments, we will then use that information, in conjunction with the universes, to determine the samples selected for audit. Because we will use these monitoring reports to assist with sample selection, we cannot allow for them to be due more than 20 business days following the audit engagement letter. In addition, given the regulatory requirement to track and monitor all services, we expect this information to be readily available and therefore would not anticipate that it would be a significant burden to staff to provide this information as requested by CMS. No changes will be made in response to these comments.

Comment: One commenter requested that CMS allow additional time to submit initial documentation and data submissions.

Response: We thank this commenter for the recommendation, however, we have already allowed as much time as possible for organizations to compile and submit this information, while still allowing CMS to analyze and prepare for audit fieldwork. While we cannot grant additional time for submission of initial documentation and data submissions, we would remind organizations that nothing prevents them from compiling and gathering data on a routine basis so it is ready for submission when CMS issues an engagement letter.

Audit Protocol - I. Service Determination Requests, Appeals and Grievances (SDAG)- General:

Comment: One commenter believes that the SDAG policy requirements are too burdensome, and asked for CMS to consider how to reduce burden related to repeat service determination requests. The commenter specifically referenced situations when participants with dementia continue to repeat requests for the same service, and despite no change in the participants' status, requiring an in-person assessment each time. The commenter stated that requiring in person assessments in these situations deprives other participants of time and attention and drives clinician burnout and turnover.

Response: This is a policy question and outside the scope of this audit protocol package.

Comment: One commenter requested that CMS exclude Part D medications from the SDAG review process if a PO already has a CMS approved formulary in place. This commenter believes that since CMS would have already reviewed and approved the PO formulary,

including step therapies and prior authorization requirements, the service determination request process for medication requests is an additional, unnecessary burden.

Response: This is a policy question and outside the scope of this audit protocol package. However, for purposes of audit, all requests that are processed as service determination requests, including those requests for medications, should be included within the universe.

Audit Protocol – Record Layouts

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

Comment: Multiple commenters asked that CMS further consider the LOPMR record layout and eliminate any columns that may not be necessary. They indicated this universe was burdensome to pull and they would appreciate any further reduction in fields.

Response: CMS reviewed the LOPMR universe again in response to commenters concerns. While CMS believes the information requested to be important, we have identified four fields we are removing from the final audit protocol package. We are removing the following fields: Direct SNF Admission (column R), Transplant (column W), Received Comfort Care (column X), and Date Comfort Care Began (column Y).

Comment: One commenter requested further clarification on the field "Received comfort care" (column X) and indicated there may still be confusion when people fill this out. This commenter requested CMS further clarify the intention of this field.

Response: We have removed this column from the record layout collection.

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

Comment: Multiple commenters asked that CMS clarify that 50 percent of participants or personnel is the upper limit for the impact analysis scope and suggested modifying the language describing the scope of relevant impact analyses to indicate that their scope is limited to no more than 50 percent of the participants enrolled or newly enrolled, or no more than 50 percent of personnel. Additionally, one commenter suggested using a statistically valid sample size to reduce impact analysis burden for POs with a large enrollment.

Response: We appreciate the comments on the scope of the IAs and the support for the changes made in the revised protocol. As we stated in response to 60-day comments, the 50 percent threshold established in our 2020 package 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. This scope is currently reflected in the instruction tabs of the IA templates. In consideration of the comments received for this package, we are changing the language in the IA templates from "up to 50%" to "no more than 50%".

Impact Analyses (IAs) - Specific:

Comment: For the Appeals1P651P661P681P73 IA, multiple commenters asked for clarification on Columns P, AH, AI, and AL. Specifically, for Column P, commenters were unclear as to why they would respond "NA" in columns Q-U if the answer to column P is "No". Commenters asked whether the question in this IA should reference appeal rights under "Medicare or Medicaid" and not "Medicare and Medicaid" because a participant would not be able to pursue an external appeal under both Medicare and Medicaid. Lastly, commenters asked whether column AL should ask for the date the appeal was forwarded to Medicare or Medicaid, but not both.

Response: We thank the commenters for their recommendations. We have modified column P to remove "NA" as a possible response. We also modified column AH; however we disagree with the comments that column AH should refer to "Medicare or Medicaid" appeal rights. Dual eligible participants have the right to appeal adverse decisions to Medicare or Medicaid and, as a result, POs are required to provide dual eligible participants with written information about their Medicare and Medicaid appeal options. Therefore, we will be revising column AH to say, "For denials, did the PO provide written notification to the participant/participant representative informing them of their appeal rights under Medicare, Medicaid, or both (if applicable)?" Finally, we agree with the commenters that columns AI and AL should say, "Medicare or Medicaid" and we have revised those questions accordingly.

Comment: For the Effectuation1P021P111P30 IA, multiple commenters asked for clarification on Columns P and AG. Specifically, commenters asked if it would be necessary to also include the instruction: "Enter NA if the service was not provided to the participant" in Column P. Commenters asked if it necessary to include, "Enter NA if the service was denied" in Column AG, since the scope of this impact analysis is limited to approved and partially denied appeals.

Response: We thank the commenters for their recommendations. Column P currently states, "Did the participant experience any negative outcomes between the date the service was approved and the date that the service was provided?" We believe that PACE organizations need to identify any negative outcomes that occurred as a result of delays in providing approved services or as a result of not providing approved services. As a result, we are not making any modifications to Column P at this time. We agree with the commenters that denied appeals are not evaluated in Columns Z through AG therefore we have modified Column AG to remove "Enter NA if the service was denied."

Comment: For the Grievances1P311P751P77 IA, multiple commenters suggested CMS include "MM/DD/YYYY" as the response format for Column V.

Response: We thank the commenters for their recommendation and have modified Column V to include "MM/DD/YYYY."

Comment: For the MedErrors1P02 IA, multiple commenters suggested CMS include "MM/DD/YYY" as the response format for Columns L and to clarify whether the response for Column T should be modified to reference a medication error as opposed to "the failure to provide the item or service".

Response: We thank the commenters for their recommendations. We have modified Column L to include "MM/DD/YYYY." We have also modified Column T to clarify that negative outcomes should be reported if they were the result of medication errors.

Comment: For the Personnel IA, multiple commenters noticed a typo in the Column J description "Enter NA in Columns J and K if the employee did not have providing participant care independently during the audit review period" and that "have providing" should be "provide."

Response: We thank the commenters for their recommendation and have modified Column J to say, "Enter NA in columns J through K if the employee did not provide participant care independently during the audit review period."

Comment: For the RequiredServices1P93 IA, multiple commenters recommended clarifying edits to, or had questions to the content of, Columns V, W, X, Y and Z. Specifically, commenters asked if the columns in question should specify that it is an individual other than a caregiver. Additionally, commenters requested clarification on when NA was allowed as an option.

Response: We thank the commenters for their recommendations and have modified columns V, W, X, Y and Z to clarify that these questions do not refer to services provided by employees or contractors of the PACE organization or by caregivers. We have also offered additional guidance on when NA is an allowed option.

Comment: For the Restraints1P09 IA, multiple commenters mentioned a possible error in the instructions for Column G. Commenters also requested a more consistent approach to the instructions in Columns H, I, K, L and N. Additionally, commenters requested examples to help clarify the information requested in Columns T and U.

Response: We thank the commenters for their recommendations. We disagree with the recommendations to revise the instructions for Column G. The instructions correctly identify that

"NA" may be entered in rows H through Y if the response in column G is "No." Column Z is an optional column therefore a response is not required. In order to improve the consistency of the instructions provided, we have modified Columns H, I, K, L, M, and N to say, "Enter NA if no restraints were utilized." We have also modified Columns T and U to provide examples.

Comment: For the SDRIdentification1P76 IA, multiple commenters suggested clarifying edits to Columns F and Columns G-K, and asked if "withdrawn" was a response option for Column L.

Response: We thank the commenters for their recommendations. Column F has been modified to add, "Enter NA if the participant is still enrolled." We also modified the instructions tab to include the term "caregiver." We did not include the term "service determination request" in the instructions because the purpose of the SDRIdentification1P76 IA is to identify requests that were not processed as service determination requests. We also modified Column L to allow for "withdrawn" as an option.

Comment: For the SDRs1P601P61P85 IA, multiple commenters noticed the scope language referenced "service delivery determination requests" and should be changed to "service determination requests." Additionally, those commenters suggested that Column Z should be changed from "Enter NA if the service determination request was denied" to "… was fully denied" consistent with Columns X and Y.

Response: We thank the commenters for their recommendations. We have modified the instructions tab to correct all references to service determination requests. We have also modified Column Z in the participant impact tab to say, "fully denied."

Comment: For the SrvcRestrict1P90 IA, multiple commenters requested that CMS provide examples of potential responses for Column M.

Response: We thank the commenters for their recommendation and have modified Column M to provide examples of possible responses.

Comment: For the WoundCare1P02 IA, multiple commenters recommended edits to Columns G, H, R, and V.

Response: We thank the commenters for their recommendations. We have modified Column G to say, "If No, enter NA in columns H through X." Column H has been modified to add, "MM/DD/YYYY." Column R has been modified to add, "Enter NA if wound care was not provided." Finally, Column V has been modified to clarify that negative outcomes should be reported if they were the result of a failure to order wound care, a failure to provide wound care as ordered by a PCP, because wound care was provided without an order, or a failure to communicate with a contracted provider.

Burden Estimate:

Comment: One commenter believes that CMS underestimated the burden of the PACE audit protocol, particularly for POs with medium and large enrollment sizes resulting from less audit experience with POs of these sizes during 2020 and 2021 audits. This commenter also expressed concern that CMS' approach to PACE audits was originally developed for insurer based plans rather than providers, and that PACE organizations are not equipped to provide detailed data reports from their electronic medical records databases in the same manner that Medicare Advantage Organizations (MAOs)/ Part D plans access data through their administrative databases. The commenter expressed particular concern with the burden of providing CMS with the PO's monitoring reports tracking all ordered, approved, and care planned services across all care settings.

Response: 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.

As we stated in response to the 60-day comments, 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.