June 1, 2022

Office of Information and Regulatory Affairs
Office of Management and Budget
Submitted electronically via: www.reginfo.gov/public/do/PRAMain

RE: CMS-10630 (OMB control number: 0938-1327)—The PACE Organization (PO) Monitoring and Audit Process in 42 CFR part 460

On behalf of the National PACE Association (NPA) and its 145 PACE organization (PO) members in 31 states serving over 60,000 Medicare and Medicaid beneficiaries, we appreciate the opportunity to respond to the Centers for Medicare & Medicaid Services' (CMS) second request for comment on the 2023 PACE Audit Protocol. In developing both this comment and the comment submitted to CMS in response to the 60-day notice concerning this collection of information, NPA consulted extensively with numerous of its PACE organization members, and the Audit and Compliance, and Regulations subcommittees of NPA's Quality and Public Policy committees. Our comment is based on a detailed review of the proposed 2023 audit protocol materials released in connection with the 30-day notice published in the Federal Register on May 10, 2022.

NPA would like to express its appreciation for CMS' review of the comments previously submitted on the audit materials in response to the 60-day notice published in the Federal Register on December 21, 2021. In particular, we appreciate CMS' favorable consideration of NPA's and others' comments resulting in the following:

- Reduction in the scope of the requirement for reports detailing 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 from all participants enrolled in a PO during the data collection period to a sample of 30 participants selected by CMS.
- Elimination of the Observation Participant List from the 2023 PACE audit materials.
- Removal of "Date of Initial Participant Contact" and "Date Individual Began Providing Care Independently" fields from the List of Personnel (LOP) Record Layout.
- Modification of the Contracted Entities and Providers (CEP) Record Layout to recognize practices as contracted entities, in addition to providers and facilities.
- Removal of the "Call Category" field from the On-Call (OC) Record Layout.
- Modification of the CoordinationofCare1P95 Impact Analysis to focus on residential facilities.
- CMS' commitment to providing updated record layout templates as soon as possible once the audit protocol has been approved by the Office of Management and Budget.

These modifications to the proposed 2023 PACE audit materials will substantially reduce the burden of the audit on POs in ways that we believe will not compromise CMS' ability to identify systemic compliance issues.

We have one additional request of CMS related to the report(s) 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 for 30 participants selected by CMS. Due to the additional demands placed upon POs resulting from the changes to the List of Participant Medical Records (LOPMR) data universe, the addition of the Contracted Entities and Providers data universe, and the new documentation requirement related to POs' compliance oversight programs, we ask CMS to consider providing additional time to POs to submit the monitoring and tracking report(s). Rather than requiring the report(s) within 20 business days of the audit engagement letter, would it be possible for POs to submit them 10 business days later, i.e., within 30 business days of the audit engagement letter, or at a time corresponding to submission of the SDAG and/or personnel sample cases? To a significant degree the same staff work on all these documentation and data submission requirements so extending the timeframe for submission of the monitoring and tracking report(s) would be extremely helpful.

Although CMS did not adopt NPA's recommendation to impose a sampling methodology for the impact analyses (IAs) involving 50% of participants or personnel, we appreciate CMS' explanation that the 50% threshold is, "an upper limit that is reduced depending on the nature of the issue of noncompliance and in consideration of the PO's enrollment size." We ask that CMS utilize this discretion to the greatest extent possible when IAs are required. Further, we would appreciate it if CMS would clarify that 50% of participants or personnel is an upper limit by modifying the language describing the scope of relevant impact analyses to indicate that their scope is limited to no more than 50% of the participants enrolled or newly enrolled, or no more than 50% of staff.

In further responding to the 30-day notice, NPA would like to reiterate our concerns regarding the List of Participant Medical Records (LOPMR) record layout as well as provide CMS with detailed comments that we hope will be helpful to CMS in finalizing its 2023 PACE audit materials.

LOPMR Record Layout. NPA remains concerned about the burden associated with completing the LOPMR and requests CMS consider opportunities to reduce the burden of the LOPMR if imposing a sampling strategy is not possible, e.g., by dropping LOPMR fields that CMS considers desirable but not essential to the audit protocol. As NPA expressed in its response to CMS' 60-day notice, NPA believes that the LOPMR requires POs, when undergoing audits, to extract data from participants' medical records that are not needed to be readily extractable for purposes of participant care and care coordination. Hence, when audited, POs must devote substantial clinical staff time and resources to extracting information from participants' medical records. We would appreciate CMS' further consideration of the necessity of non-essential fields in the LOPMR.

In addition, we received feedback from NPA's Palliative and End-of-Life Care Workgroup that Column X "Received Comfort Care" of the LOPMR may be interpreted inconsistently. More specifically, the concern is that respondents may answer "Y" only if ALL curative or maintenance care, including such medications, are withdrawn. Another example illustrating this concern would be if a participant

receiving comfort care were treated with an antibiotic for a UTI, leading the respondent to answer "N." Efforts to further clarify/simplify this question to minimize the potential for inconsistent interpretation across POs would be appreciated.

Detailed Comments. Referring to Appendix I, NPA offers specific comments on several of the impact analyses templates with the intention of assisting CMS in further clarifying specific questions and statements.

Lastly, understanding that the 2020 audit protocol was initially implemented at the onset of the COVID-19 public health emergency and, as a result, opportunities for training may have been limited, we hope that CMS will provide POs an opportunity(ies) for training and engagement with CMS staff on the 2023 audit protocol. Further, we encourage CMS to make such training available as soon as possible after the 2023 audit materials are finalized to inform fully POs' preparations for audits in 2023.

NPA and its members appreciate CMS' further consideration of NPA's comments on the 2023 PACE Audit materials and the recommendations offered above. If there is any need for additional information or dialogue, please reach out to me (shawnb@npaonline.org) or Mark Loggins (markl@npaonline.org), NPA's senior director of compliance. Thank you.

Sincerely,

Shawn M. Bloom
President and CEO

Specific comments on impact analyses templates:

Appeals1P651P661P681P73:

Column P: It is not clear to us why the PO would enter NA in columns Q-U if the answer to column P is No.

Column AH: Referring to §460.124, it is our understanding that Medicare participants have additional appeal rights under Medicare, Medicaid participants have additional appeal rights under Medicaid, and dual eligible participants have additional appeal rights under Medicare or Medicaid. Should the question ask about appeal rights under "Medicare or Medicaid?" because a participant would not be able to pursue an external appeal under both Medicare and Medicaid?

Column AI: See preceding comment on column AH.

Column AL: Referring to §460.124, it is our understanding that Medicare participants have additional appeal rights under Medicare, Medicaid participants have additional appeal rights under Medicaid, and dual eligible participants have additional appeal rights under Medicare or Medicaid. Should column AL ask for the date the appeal was forwarded to Medicare or Medicaid, but not Both?

Effectuation1P021P111P30:

Column P: Is it necessary to also include, "Enter NA if the service was not provided to the participant."?

Column AG: Since the scope of this impact analysis is limited to approved and partially denied appeals, is it necessary to include, "Enter NA if the service was denied."?

Grievances1P311P751P77:

Column V: Include MM/DD/YYYY.

MedErrors1P02:

Column L: Include MM/DD/YYYY.

Column T: Should this statement be modified to reference a medication error as opposed to "the failure to provide the item or service?"

Personnel:

Column J: Referring to "Enter NA in columns J and K if the employee did not have providing participant care independently during the audit review period," "have providing" should be "provide."

RequiredServices1P93:

Column V: Should the question reference individuals or entities not employed or contracted by the PACE organization (other than a caregiver)?

Column W: Should the question be modified as follows: When did the IDT determine that a service (including IADLs, ADLs, supervision and other services) provided through individuals or entities not employed or contracted with the PACE organization (other than a caregiver) was necessary?

Should the NA statement read: Enter NA if the participant only receives care and services through employees or contractors of the PACE organization or from a caregiver.

Column X: Should the question be modified as follows: If a service(s) was provided by an individual or entity not employed or contracted with the PACE organization (other than a caregiver), identify the individual or entity providing services to the participant.

Should a NA option be included in column X (see column W above)?

Column Y: See NA option for columns W and X above.

Column Z: Should a NA option be included in column Z (see columns W, X, Y above).

Restraints1P09:

Column G: If the answer to Column G is no, should the PO enter NA in columns H though Z, rather than H through Y?

Use of "Enter NA if physical and chemical restraints were not used." is inconsistent within the impact analysis template, e.g., used in columns K and L, but not column H, I, N, etc.

Column T: Providing an example of a response would be helpful.

Column U: Providing an example of a response would be helpful.

SDRIdentification1P76:

Column F: Should respondents be given the opportunity to "Enter NA if the participant is still enrolled."?

In the Instructions for columns G-K, it may be clearer if there is a reference to both the participant and participant's representative or caregiver, and to "service determination request" rather than just "request."

Column L: Should the possible responses also include "withdrawn" consistent with the SDR Record Layout?

SDRs1P601P61P85:

In Scope, reference to "service delivery determination requests" should be changed to "service determination requests."

Column Z: Should "Enter NA if the service determination request was denied." be changed to "… was fully denied." consistent with columns X and Y?

SrvcRestrict1P90:

Column M: It would be helpful to provide examples of potential responses.

WoundCare1P02:

Column G: Should it read, “If No, Enter NA in columns H through X.”?

Column H: Include MM/DD/YYYY.

Column R: Should “Enter NA if wound care was not provided” be added?

Column V: Should the question specifically reference wound care?