NATIONAL PACE ASSOCIATION
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February 20, 2025

William N. Parham, III
Director, Division of Information Collections and Regulatory Impacts
Office of Strategic Operations and Regulatory Affairs
Centers for Medicare and Medicaid Services
Attention: CMS-10630 (OMB Identifier: 0938-1327)
Room C4-26-05
7500 Security Boulevard
Baltimore, Maryland 21244-1850

Submitted electronically via Regulations.gov (Docket ID:CMS-2024-0361)

RE: The PACE Organization (PO) Monitoring and Audit Process (CMS-10630)

Dear Mr. Parham:

On behalf of the 179 operating Programs of All-Inclusive Care for the Elderly (PACE) organizations in 33 states and the District of Columbia – and numerous additional entities pursuing PACE development and supportive of PACE – the National PACE Association (NPA) appreciates the opportunity to comment on the 2026 PACE Audit Protocol, including the 60-day notice published in the *Federal Register* regarding the collection of information,[1] as well as the corresponding Paperwork Reduction Act (PRA) materials posted on the Centers for Medicare and Medicaid Services' (CMS) website.[2]

PACE organizations (POs) serve among the most vulnerable and expensive of Medicare and Medicaid populations – medically complex older adults over age 55 who are State certified as requiring a nursing home level of care. The objective of PACE is to maintain older adults' independence in their homes and communities for as long as possible. Fully integrated POs provide program patients, known as participants, with all necessary medical, behavioral, and long-term care services and supports (LTSS) to maintain or improve participants' health. POs currently serve over 80,000 participants nationwide.

NPA's comments offered in response to the 2026 PACE Audit Protocol were developed with the extensive involvement of our membership. The PACE Audit and Compliance

[1] https://www.federalregister.gov/documents/2024/12/23/2024-30620/agency-information-collection-activities-proposed-collection-comment-request
[2] https://www.cms.gov/regulations-and-guidance/legislation/paperworkreductionactof1995/pra-listing-items/cms-10630

Subcommittee of the NPA Compliance Committee, made up entirely of PO representatives, reviewed the 2026 PACE Audit Protocol to provide input for this comment letter. NPA's comments reflect a thorough understanding of both the statutory and regulatory underpinnings of PACE, and the operational experiences of POs.

In submitting this comment, NPA reaffirms its ongoing commitment to ensuring that PACE participants have access to all the benefits they are entitled to through PACE enrollment and that their care upholds the program's high standards. We greatly appreciate CMS' continuous monitoring efforts and the recognition of practices that require correction, as well as the significant resources CMS dedicates to these important activities.

Overall Comments

NPA appreciates CMS' timely update of the PACE Audit Protocol and the broader goals underlying this work, namely: to implement the new regulatory provisions that were effective in June 2024, and to incorporate the lessons learned from CMS' audit experiences in 2023 and 2024. As CMS notes, key changes to the 2026 PACE Audit Protocol include: modifying element data requests and compliance standards to align with the new regulatory requirements; introducing case file cover sheets and new impact analysis (IA) templates; providing templates with instructions for responding to requests for additional information and for submitting corrective action plans (CAPs); removing burdensome collections and updating the PACE Audit Protocol and corresponding documents to provide further clarification

Further, NPA appreciates CMS' consideration and incorporation of PACE stakeholder feedback, including feedback offered as part of the CMS PACE Workgroup that convened last fall. Feedback provided through the CMS PACE Workgroup, along with the broader NPA comments that follow, align with CMS' aim to improve transparency and enhance audit outcomes data through the development and application of streamlined audit elements and processes. We look forward to ongoing transparency and continued opportunities for POs to share their feedback on audit experiences, ensuring that this information is used to further evolve and refine the audit process with minimal burden for both POs and CMS.

As detailed in our full comments on the 2026 PACE Audit Protocol (Section I), and consistent with NPA's comments on the 2020 and 2023 PACE Audit Protocol packages, NPA continues to have substantial concerns about CMS' retrofitted application of an audit process for PACE that was developed for Medicare Advantage Organizations (MAOs) and Part D Prescription Drug Plans. As such, CMS' estimate of the burden incurred to POs during the audit process fails to account for the extremely data intensive aspects of the audit that extend well beyond PACE's "plan-like" features to its core as a provider. Though CMS' efforts to streamline the audit process are commendable, we strongly recommend that CMS review and update its burden estimates for POs to account for the factors outlined in Section I below.

NPA's detailed comments follow and are organized according to:

- Section I: Supporting Statement A: Burden Estimates
- Section II: 2026 PACE Audit Protocol Instrument (Attachment I)
- Section III: Templates
- Section IV: Other Attachments
- Section V: Additional Considerations

Section I. Supporting Statement A: Burden Estimates

Pursuant to Supporting Statement A of the PRA package (as outlined in Section 12), CMS indicates that, beginning in audit year 2026, the number of data collection instruments will increase from 24 to 34 proposed documents. However, as detailed below, CMS does not anticipate that the 10 additional documents, or the other changes introduced in the 2026 PACE Audit Protocol, will equate to a meaningful increase in PO burden. Rather, CMS indicates that the burden reducing revisions to the 2026 PACE Audit Protocol are more impactful and better align with CMS' original estimates.

Specifically, the new data collection instruments in the 2026 PACE Audit Protocol include the addition of: 7 total IA templates (3 of which are the result of splitting existing I templates, while the other 4 documents were created to align with new regulations); and 3 new documents that include instructions for supporting documentation submitted as part of the audit process to evaluate potential non-compliance and develop CAPs, as required (namely, a Cover Sheet for Element Case Files; a Request for Additional Information (RAI) Template; and CAP Template).

In addition to the new data collection instruments in the 2026 PACE Audit Protocol, CMS omitted in the 2026 PACE Audit Protocol two collection requirements from the 2023 PACE Audit Protocol; namely, eliminating requirements for monitoring reports for the provision of services and CAP implementation submissions. CMS states, and NPA agrees, that the former information collections "necessitated considerable PO resources to complete and delayed closing the audit, thus extending the time commitment for POs."

Based on the 2026 PACE Audit Protocol, reflective of the addition and modification to the data collection instruments and other revisions, CMS anticipates that approximately 40 POs will undergo a PACE audit annually (either trial year or routine audit), with the total burden per PO equaling 780 hours (or 31,200 total hours across all POs annually, at a total cost of $2,184,000). The total burden estimate of 780 hours per audited PO is predicated on CMS' assumption that a total of 4 personnel from each PO will work simultaneously for each audit. CMS provides the following breakdown of the hours per person per PO are disaggregated according to the PACE audit lifecycle:

- Pre-audit Activities – CMS estimates an average of 25 hours per person prior to the audit start to assemble the data and review the information for completeness. Activities conducted prior to the audit start include those pertaining to data universes; PACE supplemental questions; the pre-audit issue summary; and submission of requisite documentation (e.g., Quality Assurance and Performance Improvement (QAPI) plans, Participant Advisory Committee (PAC) minutes, and current organization charts).

- Administration of Audit – CMS estimates an average of 80 hours per person for the actual administration of the audit.

- Review and Provide Requested Documentation – CMS estimates 40 hours per person to review and respond to the documentation requests, IAs (as applicable) and the draft audit report.

- Submit and Implement CAPs – CMS estimates 50 hours per person to submit and implement corrective action plans.

For 2026, CMS has updated the PACE audit protocol, adopting a similar approach to the 2023 updates. This includes addressing the PACE regulatory changes introduced in 2024. While NPA appreciates CMS' commitment to a more focused, data-driven, and outcomes-based audit approach, emphasizing high-risk areas that pose the greatest potential for participant harm, we believe that CMS's approach to auditing the provider aspects of POs' operations is predicated on the assumption that POs can easily extract large volumes of information from participant medical records. However, since clinical documentation is typically narrative in nature, this data is not easily retrievable. Consequently, the significant data demands built into the 2023 audit and the proposed 2026 audit must largely be met through manual reviews of PACE participants' medical records. While POs' data systems are improving, electronic medical records (EMRs) are mainly designed to capture clinical data needed for documenting and coordinating assessments and treatments. The extensive data requests during the audit process place a significant burden on clinical staff, diverting them from their primary role of providing participant care to manually reviewing medical records. We are unaware of any other instance where such detailed information is required on a per-enrollee basis to monitor MAOs or other Medicare or Medicaid provider types.

POs should not be expected to retrieve data from their EMR systems in the same way that MAO/Part D plans access their administrative databases. While EMRs are designed to provide immediate and continuous access to patient health records to enhance care, they are not built to generate comprehensive data reports covering all the information documented in the system. There is a key distinction between the data entered into the EMR for access by healthcare providers and the data that can be extracted for audit purposes.

NPA's estimates of burden, based on input from many POs, are substantially higher than these figures. In large part, this is due to requirements for information that often is only accessible by undertaking in-depth medical record reviews involving significant numbers of providers. It is extremely important that CMS continue to take steps to reduce the burden on the audit process which, as proposed, is excessive and will harm our PACE organization's ability to provide care to the participants we serve.

NPA Burden Estimate Recommendations

NPA appreciates CMS' acknowledgement in Supporting Statement A that CMS underestimated the time required for certain new data collections in the 2023 PACE Audit Protocol. We furthermore appreciate CMS' use of updated burden assumptions to more accurately account for the total burden of conducting audits using the 2026 PACE Audit Protocol. Based on CMS' updated projections, the estimated cost to conduct 40 audits using the 2026 PACE Audit Protocol is $2,184,000, down slightly from CMS' previous estimate based on use of 2023 PACE Audit Protocol of $2,340,000.

A key assumption underlying CMS' burden estimates relates to the number and types of PACE staff required for an audit. As noted on page 5 of Supporting Statement A, these include: 1) Medical and Health Services Managers; 2) Executive Secretaries and Executive Administrative Assistants; 3) Medical Records Specialists and 4) Compliance Officers. However, in addition to these roles, POs have consistently reported to NPA that they must also involve their program and medical directors, numerous IDT members/direct care staff for medical record reviews, PACE center managers to assist with participant observation activities, quality managers/staff to provide information on quality improvement efforts and compliance oversight, network or contract services managers, and human resources staff. The involvement of many more than just four staff members is often essential across all four phases of the PACE audit lifecycle. NPA recommends that the burden estimates account for the significant number of PACE staff involved in all aspects of audit activities, beyond the four personnel CMS identified for its burden estimates.

CMS has stated that it continues to collect feedback and data from POs, which enables more accurate estimates of the costs associated with a PACE audit for organizations. We understand that a key source of data and feedback used to inform the burden estimates for the PACE audit comes from the CMS PACE Audit Survey, which POs are invited to complete after receiving the final audit report. The survey includes specific questions aimed at estimating the total number of hours PACE staff spent on various activities throughout the audit process, including pre-audit, audit, and post-audit tasks.

Based on member feedback from POs audited under the 2023 PACE Audit Protocol, many members reported being unaware of or not receiving the survey to participate. NPA

encourages CMS to assess the response rate of the PACE Audit Survey to determine whether the survey process should be reevaluated to better capture the data it seeks, particularly to ensure that enough data is gathered to support accurate calculation of burden estimates. Additionally, we recommend that CMS consider adding questions to the survey that would help identify the specific PACE staff involved in audit activities throughout the entire PACE audit lifecycle.

Additionally, IAs take a considerable amount of time to complete considering 50 percent of a PO's census is typically reviewed. One suggestion that may alleviate some of the burden on POs would be for CMS auditors to initially select fewer participants to review as part of the IA. However, if results of the initial analysis indicate there is or may be a potential systemic issue of noncompliance, additional participants may be selected for review. If the initial analysis does not identify instances of noncompliance, then no further participants would need to be reviewed, and CMS auditors could base their findings on the samples reviewed during field work.

Finally, NPA respectfully seeks further clarification regarding the proposed burden reduction estimate associated with CAP implementation submission. POs are still required to develop, submit, and implement corrective actions within 60 days of CAP acceptance. Additional clarification is sought regarding the specific PO responsibilities that have been eliminated related to developing, submitting, and implementing corrective actions, and how this reduces PO burden.

Section II: 2026 PACE Audit Protocol (Attachment I)

NPA offers the following recommendations to reduce burden and enhance the quality, utility, and clarity of the proposed information collection, the 2026 PACE Audit Protocol.

- **Audit Purpose and Scope –** In reviewing the Audit Purpose and Scope portion of the Audit Protocol Instrument, it is unclear why the Initial Comprehensive Review (ICR) process is not addressed in this section (e.g., how the ICR impacts POs' ability to submit a service area expansion (SAE) application). We recommend that CMS formalize and clarify the ICR process and provide POs with process documents.

- **Initial Documentation and Data Submissions –** NPA supports CMS' removal of the monitoring reports, which necessitated considerable PO resources and time to complete, often delaying the closing of the audit. We offer the following technical recommendations to improve the clarity of the instrument:

- Appendix: In the first paragraph, second sentence, we recommend changing "place" to "placed." In the first paragraph, third sentence, we recommend amending the text to read "...alternative formats such 'as' Microsoft..."

- Table 7: In the second to last bullet, we recommend changing "types" to "type."

- **Audit Element Review: SDAG –** Referring to page 10, section 3.3.2.4 of the 2026 PACE Audit Protocol, the question asks, "If the IDT extended the service determination request processing timeframe, did the IDT provide notice of the extension to the participant or designated representative in writing no later than 24 hours after the IDT decided to extend the timeframe?" As outlined at 42 CFR 460.121(i)(2), when the interdisciplinary team extends the timeframe, it must notify the participant or their designated representative either orally or in writing. NPA recommends that CMS modify the question to reflect the current PACE regulations, which allow for notification of an extension through either oral or written communication. Additionally, we recommend updating Table 1: Service Determination Requests (SDR) Record Layout, row J, in Appendix A to include the option of notifying the participant and/or designated representative of the extension either orally or in writing.

  To clarify the Service Determination Requests, Appeals, and Grievances (SDAG) audit element, NPA recommends CMS reorganize the compliance standards similar to the way the documentation section is organized, to evaluate each element separately under the umbrella of SDAG. Further, the audit element does not appear to account for delays in the provision of items or services due to supply or labor shortages that are beyond the PO's control. As such, on p. 10, at section 3.4.2, NPA recommends that CMS modify the question to read: "Did the PO arrange and/or schedule the delivery of approved services within the required timeframe, or document any reason for delay and interim measures taken to address the participant's needs?"

- **Audit Element Review: Provision of Services –** NPA supports CMS' changes to this audit element, including reducing the number of medical records subject to review (from 30 to 25); identifying participants for observation by working with the PO to determine if participants are available for observation, then notifying the PO of the participants selected *prior* to their observation; and removing the participant observation area from the medical records review section. The changes align with CMS' broader effort to enhance audit outcomes data through the development and application of streamlined audit elements and processes.

- **Audit Element Review: Personnel Records –** NPA supports CMS' inclusion of additional criteria to guide auditors' evaluation of POs' compliance with personnel

medical clearance requirements. We appreciate CMS' efforts to provide further clarity around the application of these standards, as well as the opportunity for POs to demonstrate compliance with a particular requirement through the Request for Additional Information (RAI) process.

Section III: Templates

NPA offers the following recommendations to reduce burden and enhance the quality, utility, and clarity of the proposed PACE Audit Protocol templates.

- **Case File Cover Sheet Template –** Throughout the document, in the "Information Requested by CMS" column, the language does not appear to align with the instructions. For example, the second item on the SDR Cover Sheet reads, "Documentation identifying when the request was brought to the IDT (not applicable for immediate approvals)." NPA recommends aligning the language in the template to reflect the language in the instructions to improve the clarity of the template. For example, NPA recommends changing the language from "(not applicable for immediate approvals)" to "(does not apply for immediate approvals)," or vice-versa.

- **RAI Template –** NPA acknowledges and appreciates that this new template will serve as invaluable resource for PACE organizations, providing clear and structured guidance on how to effectively respond to requests for information during an audit. It will help to simplify the process of addressing potential non-compliance issues by ensuring that all necessary details are submitted in a consistent and organized manner. This proactive approach will not only support transparency but also streamline communication between the organization and CMS auditors, helping to resolve concerns efficiently.

- **CAP Template –** The proposed update of the CAP template no longer includes a question concerning timeframes or milestones. Further, the example in the CAP template contains minimal information. NPA recommends that CMS clarify the expectation for CAP development and submission. NPA also recommends that CMS clarify that the example CAP content and language is sufficient for submission and acceptance.

  Additionally, the question in column H asks how the CAP will be integrated into the *compliance program;* however, the example provided in column H states, "Results will be collected, aggregated, and analyzed and maintained in ongoing quality review. Results will be reported in monthly quality meetings and quarterly calls with BOD." To clarify the proposed template, NPA recommends modifying the language to provide an example related to compliance and compliance requirements rather than quality.

Section IV: Other Attachments

NPA offers the following recommendations to reduce burden and enhance the quality, utility, and clarity of information in the following PACE Audit Protocol attachments.

- **Attachment II: PACE Supplemental Questions –** The instructions tab, second bullet states, "PACE organizations *may* also upload grievance and service determination request policies pertaining to the questions in the PACE Supplemental Questions tab" [NPA emphasis added]. Based on this language, POs are not *required* to upload their grievance and SDR policies & procedures (P&Ps), and there are no questions related to grievances or SDRs in the PACE Supplemental Questions tab. NPA recommends clearly delineating what CMS requires POs to complete and/or upload, versus what can be completed and/or uploaded at the PO's discretion.

- **Attachment III: Pre-Audit Issue Summary –** The instructions on the Pre-Audit Issue Summary, second bullet, last sentence state, "The audit review period for this audit is, September 3, 2023, through March 3, 2026." It appears that one date was updated, but the other was inadvertently missed, so the example provides an audit review period of years rather than the 6 month look back period. NPA recommends changing "September 3, 2023" to "September 3, 2025."

- **Attachment IV: Audit Survey –** As mentioned earlier, NPA strongly encourages CMS to evaluate the response rate of the PACE Audit Survey to determine if the survey process needs to be reassessed to more effectively capture the necessary data, ensuring sufficient information is collected to support accurate burden estimates. We also recommend that CMS consider including questions in the survey that would help identify the specific PACE staff involved in audit activities throughout the entire audit lifecycle.

- **Attachment V: CAP Process –** In Supporting Statement A, CMS states that it eliminated two collection requirements, including the requirement for CAP implementation submission. However, CAP acceptance and implementation is still included in Attachment V: Corrective Action Plan Process. It is not clear what the process is once CAPs have been accepted by CMS. Further, there does not appear to be guidance or instructions related to oversight during the CAP monitoring phase (e.g., PO responsibility for providing CMS with information on CAP progress; how/who will determine the CAPs have been fully implemented and effective; and how/who will release CAPs and close out the audit). NPA respectfully requests clarification on the specific PO responsibilities related to developing, submitting, and implementing corrective actions, in addition to PO requirements, during the monitoring phase and prior to CAP release.

Section V: Additional Considerations

NPA offers the following additional feedback for CMS' consideration.

- **Audit Scoring Methodology** – NPA respectfully seeks clarification regarding CMS' audit scoring methodology. It is unclear how CMS calculates a PO's final audit score. NPA recommends that CMS stipulate the points assigned to each condition akin to the way points are stated in CMS' "Routine Program Audit Process Overview" applicable to Medicare Advantage organizations (MAOs).[3]

- **Threshold for Issuing Condition** – CMS' threshold for issuing a condition, and the condition level, are not clear. Some POs report that they are issued a condition in instances when one sample is deemed noncompliant related to a specific condition (i.e., a "one-off issue" or anomaly). NPA respectfully requests further transparency related to CMS' threshold for issuing an observation, Corrective Action Requested (CAR), or Immediate Corrective Action Requested (ICAR) (e.g., a given (xx) number of samples that have the same issue of noncompliance equals a CAR; or a condition is cited if a *systemic* issue of noncompliance is identified; and an observation is issued when the issue of noncompliance is not systemic but is a one-off issue or anomaly).

- **Other (Wound Care RCA/IA Template)** – In the wound care RCA/IA template, Participant Impact tab, column I, the final statement indicates that the IA will be returned for correction if each medication error is not listed in a new row. However, this IA is not related to medication errors but, rather, wound care. NPA recommends that "medication error" be changed to "wound care error."

In closing, we appreciate your consideration of NPA's comments. For questions or additional information, please reach out to Mia Phifer, senior vice president, Quality and Compliance, at miap@npaonline.org.

Sincerely,

Shawn M. Bloom
President and CEO

[3] https://www.cms.gov/files/document/program-audit-process-overview.pdf-0