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Office of Strategic Operations and Regulatory Affairs

Centers for Medicare and Medicaid Services

Attention: CMS-10630 (OMB Identifier: 0938-1327; ICR Reference Number: 202507-0938-006)

Room C4-26-05

7500 Security Boulevard

Baltimore, Maryland 21244-1850

Submitted electronically via <https://www.reginfo.gov/public/do/PRAMain>

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

On behalf of the 186 operating Programs of All-Inclusive Care for the Elderly (PACE) organizations in 33 states and the District of Columbia—and many other organizations engaged in PACE development and supportive of PACE—the National PACE Association (NPA) appreciates the opportunity to respond to the Centers for Medicare & Medicaid Services' (CMS) second request for comment on the 2026 PACE Audit Protocol (protocol), including the 30-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 CMS website.²

PACE organizations (POs) serve some of the most vulnerable and costly Medicare and Medicaid populations—medically complex older adults aged 55 and above who are State-certified as needing a nursing home level of care. The core objective of PACE is to help these older adults maintain their independence in their homes and communities for as long as possible. Fully integrated POs provide participants with comprehensive medical, behavioral, and long-term care services and supports (LTSS)

¹ CMS, CMS-10630 The PACE Organization (PO) Monitoring and Audit Process, *90 Fed. Reg. No. 132*, July 14, 2025, <https://www.federalregister.gov/documents/2025/07/14/2025-13055/agency-information-collection-activities-submission-for-omb-review-comment-request>.

² CMS, "CMS-10630: The PACE Organization (PO) Monitoring and Audit Process in Part 460 of 42 CFR," July 14, 2025, <https://www.cms.gov/Regulations-and-Guidance/Legislation/PaperworkReductionActof1995/PRA-Listing-Items/CMS-10630>.

designed to maintain or improve their health. Currently, POs serve over 85,000 participants nationwide.

The comments NPA provided in response to the 2026 PACE Audit Protocol were developed with extensive input from our membership. Specifically, the PACE Audit and Compliance Subcommittee of the NPA Compliance Committee—comprising exclusively PO representatives—carefully reviewed the protocol to inform this comment letter. Our feedback reflects a deep understanding of the statutory and regulatory foundations of PACE, as well as the real-world operational experience of POs.

By submitting these comments, NPA reaffirms its commitment to ensuring that PACE participants receive all the benefits they are entitled to through enrollment, and that the care provided meets the program’s rigorous standards. We continue to appreciate CMS’ ongoing oversight efforts, the identification of areas requiring improvement, and the substantial resources CMS dedicates to these vital activities.

These points were fully incorporated in our prior 60-day comment letter and are reiterated here to emphasize their importance. We would like to take this opportunity to underscore NPA’s appreciation for CMS’ timely update of the PACE Audit Protocol and the important goals driving this effort. We commend CMS for implementing the new regulatory provisions effective June 2024 and for incorporating lessons learned from the 2023 and 2024 audit cycles. Key updates to the 2026 Audit Protocol—including aligning data requests with new requirements, introducing case file cover sheets and impact analysis (IA) templates, providing clearer response instructions, and reducing burdensome documentation requirements—such as eliminating the submission of *Monitoring Reports* detailing the PO’s tracking of all services ordered, approved, or care planned during the data collection period—demonstrate CMS’ commitment to improving the audit process.

Furthermore, we appreciate CMS’ thoughtful incorporation of stakeholder feedback from the CMS PACE Workgroup that convened in 2024, and other sources, promoting greater transparency and more efficient audit procedures. We look forward to ongoing collaboration and opportunities to provide feedback to ensure the audit process continues to evolve with minimal burden on both POs and CMS.

NPA would also like to express appreciation for CMS’ thoughtful review of the comments submitted in response to the 60-day notice published in the *Federal*

Register on December 23, 2024.³ In particular, we commend CMS for its consideration of feedback from NPA and other stakeholders, which resulted in several meaningful revisions to the proposed audit protocol, including:

- Revision to Service Determination Request (SDR) compliance standard 3.3.2.4, clarifying that when the interdisciplinary team (IDT) extends the timeframe, it must notify the participant or their designated representative either orally or in writing.
- Inclusion of new templates, such as the Request for Additional Information (RAI), Corrective Action Plan (CAP), and Case File Cover Sheets.
- Modification of the SDR Record Layout, Row J, to include oral communication.
- Clarifications to *Attachment II, PACE Supplemental Questions*, which include instructions to help define expectations more clearly.

These modifications to the proposed 2026 PACE Audit Protocol will enhance clarity and reduce the administrative burden on POs, while maintaining CMS' ability to identify systemic compliance issues.

Reaffirmation and Restatement of Previously Submitted Recommendations

NPA respectfully reiterates several comments previously submitted in response to the 60-day notice of comment that have not been addressed in the revised protocol. We maintain that these considerations are essential to ensuring a balanced and effective audit process and earnestly urge CMS to give them further consideration.

Initial Comprehensive Review (ICR)

We appreciate CMS' responsiveness to stakeholder feedback on the ICR and its clarification that the ICR follows the same audit procedures and compliance standards as the PACE Audit Protocol, except that CMS may not require submission of all data collection elements specified in *Attachment I, PACE Audit Protocol*.

While the ICR is an important tool for early engagement and audit readiness, NPA recommends that CMS formalize and clearly define the process in the audit protocol. Member feedback indicates that some POs remain unprepared for subsequent audits because key components—such as Root Cause Analyses (RCAs), IAs, and CAPs—are not reviewed or practiced during the ICR. Incorporating structured training on the RCA-IA-

³ CMS, CMS-10630 The PACE Organization (PO) Monitoring and Audit Process, 89 Fed. Reg. No. 246, December 23, 2024, <https://www.federalregister.gov/documents/2024/12/23/2024-30620/agency-information-collection-activities-proposed-collection-comment-request>.

CAP process would improve POs' understanding of compliance expectations, strengthen audit preparedness, and support long-term program success.

We also note concerns regarding ICR timing. Under §§ 1894(e)(4) and 1934(e)(4) of the Social Security Act and 42 CFR §§ 460.190 and 460.192, CMS must, with the State Administering Agency (SAA), audit POs annually during their first three contract years. However, ICR timing varies widely, occurring as early as four months or as late as twelve months after program initiation. This variability can:

- Delay Service Area Expansion (SAE) applications, slowing program growth and limiting access to PACE.
- Compress timelines so severely that adequate data collection and participant engagement are not possible, potentially requiring proportional sampling adjustments to maintain fairness and efficiency.

We recommend that CMS:

- Establish clear ICR timing expectations to ensure consistency and alignment with program development milestones.
- Integrate RCA-IA-CAP process training into the ICR to ensure POs are prepared for future audits and fully understand compliance requirements.

These refinements would enhance the ICR's educational value, reduce administrative burden, and advance the shared CMS-PO goal of protecting participants, safeguarding program integrity, and supporting sustainable growth.

PACE Audit Survey

We appreciate CMS' ongoing efforts to gather feedback through the PACE Audit Survey and the opportunity it provides POs to share their experiences and recommendations following an audit. We also recognize the value of comprehensive survey data in informing burden estimates and improving the audit process.

However, we respectfully reiterate our recommendation that CMS evaluate the survey response rate and reassess the process to ensure it effectively captures the information needed to meet its stated objective of obtaining actionable feedback.

Although *Attachment IV, Audit Survey*, states that POs will receive a weblink to the survey after the final audit report is issued, feedback from NPA members indicates that some POs are unaware of its release or unable to locate the link. Consequently, valuable input may go uncollected, limiting CMS' ability to identify opportunities for

improving the audit process and to accurately evaluate the time and resource demands placed on POs during audits.

To strengthen the utility of the survey and improve the accuracy of burden assessments, we recommend that CMS:

- Evaluate survey response rates to identify participation trends and barriers to completion.
- Ensure the survey link is clearly visible and accessible, potentially through a separate follow-up communication or reminder.
- Include targeted questions identifying the specific roles and departments involved in audit preparation and execution.
- Clarify how survey results are used to guide improvements to the audit process, which may encourage greater participation.

These enhancements would improve survey participation, provide CMS with more comprehensive and representative feedback, and ensure the collection of real-world data on audit-related burden. In turn, this data could better inform burden estimates and guide refinements to the PACE audit process, ultimately advancing the shared goal of a transparent, efficient, and participant-focused oversight system.

RCAs/IAs

We appreciate CMS' recognition of the burden associated with completing RCAs and IAs and its efforts to limit requests based on the nature of noncompliance and participant risk. However, we respectfully recommend that CMS reassess its current methodology for determining the magnitude of a potential noncompliance issue.

Given that the audit process already includes comprehensive record and file review, auditors are well-positioned to identify systemic noncompliance. PO staff time may be more effectively directed toward developing and implementing CAPs—which require CMS approval and include ongoing monitoring and auditing to ensure effectiveness and full remediation—rather than producing separate IAs. Requiring IAs often diverts resources from CAP development and implementation, where many meaningful improvements to care and operations occur. To reduce redundancy while preserving CMS' ability to monitor participant impact, we recommend:

- Adopting a tiered sampling approach: Begin with a smaller, statistically valid sample to assess the scope of noncompliance, expanding only if initial findings indicate a broader issue.

- Integrating participant remediation tracking into the CAP: Allow POs to include participant impact and remediation categories directly within CAP documentation, streamlining processes and reducing administrative burden.
- Leveraging CAPs to identify impacted participants: Require POs to flag and document participant-level remediation actions within their CAP, with CMS reserving the option to request additional detail or expanded review as needed.

These changes would lessen unnecessary burden on POs while maintaining CMS' ability to determine the root cause, assess the magnitude of noncompliance, and ensure timely participant remediation.

Burden Estimate

We appreciate CMS' efforts to revise the burden estimate for the 2026 PACE Audit Protocol and acknowledge the removal of certain data collection elements, such as monitoring reports and CAP implementation documentation in the Health Plan Management System (HPMS). However, we reiterate concerns regarding both the overall burden estimate and its underlying assumptions.

While CMS notes that HPMS-related CAP implementation and monitoring submissions are excluded from the estimate, POs remain federally required to correct noncompliance identified through audits. The core activities—developing, implementing, and monitoring corrective actions—remain unchanged, and the associated administrative burden persists, even without HPMS submission.

Further, NPA member feedback indicates that the estimated 780 hours does not reflect the actual time and resources required. PACE audits demand extensive data collection, manual review of narrative electronic medical records (EMRs), and cross-department coordination. Unlike Medicare Advantage (MA) or Part D plans, POs often lack structured data extraction capabilities, necessitating labor-intensive manual abstraction that draws staff away from direct participant care.

We recommend CMS:

- Reassess the burden estimate to capture the full scope of audit-related activities, including internal corrective action planning and manual data abstraction.
- Clarify which activities are included and excluded from the estimate, especially those tied to CAP development and implementation.
- Engage with POs to collect real-world data on time and resource use during audits. This should include strengthening the PACE Audit Survey process, as

noted in our earlier recommendations, by improving the survey's visibility, ensuring timely distribution, and enhancing accessibility of the survey link so that all POs can provide feedback.

These actions would help ensure the burden estimate is transparent, realistic, and aligned with POs' operational realities while enhancing CMS' ability to collect meaningful data to inform future audit refinements. In conclusion, NPA appreciates CMS' continued consideration of our comments on the 2026 PACE Audit Protocol materials and the recommendations outlined above.

For questions or additional information, please reach out to Mia Phifer, senior vice president, Quality and Compliance, at miap@npaonline.org.

Sincerely,

A handwritten signature in black ink, appearing to read "S.M. Bloom".

Shawn M. Bloom
President and CEO