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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 http://www.regulations.gov

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

Dear Mr. Parham:

I am writing on behalf of PACE Southeast Michigan to respond to the Centers for Medicare & Medicaid Services' (CMS) request for comment on the PACE 2026 Audit Protocol published in the *Federal Register* on December 23, 2024. We share CMS' commitment to ensuring PACE participants' access to high quality care consistent with PACE regulatory requirements. With this being our primary focus every day, we appreciate the opportunity to provide feedback on the proposed audit protocol.

PACE Southeast Michigan has been caring for senior participants in southeast Michigan for over 30 years. We serve older adults in Wayne, Oakland, and Macomb Counties at our nine centers located in Clinton Township, Dearborn, Detroit (2), Eastpointe, Pontiac, Southfield, Sterling Heights, and Westland. The need for PACE in our community is vast. We currently have a census of participants over 2,000 participants. Our program is the largest, fastest-growing PACE program in Michigan and among the top ten largest in the nation. We are a non-profit organization jointly sponsored by Henry Ford Health System and Presbyterian Villages of Michigan.

As a member of the National PACE Association (NPA), we want to express our support for NPA's comments on the PACE 2026 Audit Protocol. We support NPA's comments, specifically as it relates to the significant burden imposed by the audit on PACE organizations (POs) overall and, most importantly, on POs' provider/clinical staff. The audit as currently implemented and as proposed for 2026 requires an excessive amount of time from providers who are then not available for participant care. We believe that NPA's recommendations accomplish the goal of reducing burden without compromising CMS' ability to assess compliance with key regulatory requirements. More specifically, we agree with NPA that:

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- CMS' approach to auditing the provider aspects of PO 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.
- The burden estimates of 780 hours, at approximately \$70/hour equating to \$54,600 provided by CMS for the PACE 2026 Audit Protocol, are too low and fall short of reflecting the time and resources required of POs being audited, especially for medium and large size programs. 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 organization's ability to provide care to the participants we serve.
- There is a scaled impact of the protocol related to program size; the burden of data collection/documentation requirements is very directly related to volume in this case driven by program census. This places an undue hardship on any program of substantial size or complexity.

Thank you for considering PACE Southeast Michigan's input and experience in assessing the impact of the PACE 2026 Audit Protocol on POs. We are hopeful that CMS will consider these and NPA's comments to revise the proposed protocol in ways that will reduce the burden experienced by POs when they are audited by CMS. If you have questions or need for follow-up, please do not hesitate to contact me at Tracey.Diroff@pacesemi.org. Sincerely,

Tracey Diroff

Director of Compliance

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