



February 19, 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 Tungsten Health Holdings, LLC d/b/a Habitat Health 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 appreciate the opportunity to provide feedback on the proposed audit protocol.

Habitat Health was founded in 2023 to deliver fully integrated health and social care to older adults on Medicare or Medicaid who wish to remain living independently in their homes and communities. The company currently operates one PACE center in Sacramento, California with plans, if approved by CMS and the state administering agencies, to open additional sites throughout California and throughout the U.S. in 2026 and beyond. Habitat Health is supported by Kaiser Permanente, Town Hall Ventures, and New Enterprise Associates. Due the novel collaboration between Habitat Health and Kaiser Permanente, our company has been able to enroll and provide PACE benefits to an above average number of participants. Beginning in March, the Habitat Health census is projected to be 21 participants.

We share the CMS commitment to ensuring PACE participants' access to high quality care consistent with PACE regulatory requirements. Our company embraces audits as opportunities to learn and to improve on how we provide PACE to those who can benefit from it. *In furtherance of that attitude and goal, Habitat Health recently requested an early audit directly from our CMS Account Manager.* We share that information today to make it clear our comments today are intended to reduce PO burden without compromising CMS' ability to assess compliance with key regulatory requirements.

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. More specifically, we agree with NPA that:

- 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.
- In many POs, such as ours, the staff who provide the necessary information to CMS auditor regarding care are precisely those staff responsible for participant care. Increasing the burden on POs has a high potential to distract from providing the care to which is the foundation of the PACE program. Audit fatigue is real and can lead to staff resignations; balance must be struck between minimum information needed for oversight and undermining the purpose of PACE to provide care to participants.

Thank you for considering Habitat Health'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 directly at 515-333-8338 or adey@habitathealth.com.

Sincerely,

Anna Dey, J.D., LL.M.
Vice President, Compliance