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PACE

February 21, 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 Monitoring and Audit Process (CMS-10630)

Dear Mr. Parham:

On behalf of On Lok Senior Health Services (On Lok), I am writing 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 the same commitment to ensuring PACE participants' access to high-quality care consistent with PACE regulatory requirements. With this being our primary focus, we appreciate the opportunity to provide feedback on the proposed audit protocol and related burden estimates.

On Lok was founded over 50 years ago to assist frail, older adults in the Chinatown-North Beach neighborhoods of San Francisco, California, remain in their own homes with community services. Through a series of federal demonstration projects, On Lok created the national prototype for the Program of All-Inclusive Care for the Elderly (PACE) and has operated PACE since 1983. On Lok led the national replication of the model successfully in establishing PACE as a permanent part of the Medicare program and option for state Medicaid programs in the Balanced Budget Act (BBA). Today, On Lok's PACE program, On Lok PACE, serves over 2,000 PACE participants, who reside in three counties, the vast majority of whom are dually eligible for Medicare and Medicaid.

On Lok is a founding member of the National PACE Association (NPA) and has played a leadership role in advancing the PACE model of care for the benefit of frail, older adults since its inception. We want to express our strong support for the comments submitted by NPA on the PACE 2026 Audit Protocol as it relates to the significant burden imposed by the audit on the overall PACE organization. The current and proposed audit protocols require an excessive amount of time from providers reducing availability 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. In particular, we want to underscore the following points:

- **Data Collection and Reporting:** CMS' approach to auditing the provider aspects of the

PACE organization's operations is predicated on the assumption that the organization 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 to generate comprehensive reports. Consequently, the significant data demands built into the 2023 and proposed 2026 audit protocols must largely be met through manual reviews of PACE participants' medical records. 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.

- **Burden Estimates:** The burden estimates of 780 hours are too low and fall short of reflecting the time and resources required during an audit. For a large PACE organization with over 2,000 participants at seven PACE centers, On Lok's estimates of burden throughout the PACE audit lifecycle 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 clinical and administrative staff, including interdisciplinary team members. 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.
- **Sample Selections:** It is possible to audit PACE organizations using a less burdensome protocol effectively and comprehensively that is more consistent with those developed for other types of providers. Based on our 2018 and 2024 PACE audit experience, the amount of time required for these audits have been highly significant for On Lok. We would appreciate CMS' consideration in reducing the data collection and sampling to a proportion of PACE centers or interdisciplinary teams for larger PACE organizations. In addition, we believe raising thresholds for requiring PACE organizations to undertake root cause analyses (RCAs) and impact analyses (IAs) would be appropriate. We also agree with NPA and suggest using a sampling methodology that allows PACE organizations to initially undertake IAs for fewer participants (e.g., a smaller sample of participants) and increase the sampling of participants if the initial analysis indicate there may be a potential systemic issue of non-compliance.

Thank you for considering On Lok's input and experience in assessing the impact of the PACE 2026 Audit Protocol on PACE organizations. 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 PACE organizations when they are audited by CMS. If you have any questions, please do not hesitate to contact me at jchau@onlok.org or (415) 292-8852.

Sincerely,

Jonathan Chau

Jonathan Chau
Director of Regulatory Affairs and Compliance

cc: Grace Li, Chief Executive Officer, On Lok
Nicole Torres, Chief Operating Officer, On Lok
Mark Mayeda, Compliance Officer, On Lok