

December 27, 2019

Office of Management and Budget
Office of Information and Regulatory Affairs
Attention: CMS Desk Officer
Email: OIRA_submission@omb.eop.gov

RE: CMS-10630 (OMB control number: 0938-1327)—Programs of All-Inclusive Care for the Elderly (PACE) 2020 Audit Protocol

On Lok Senior Health Services (On Lok) is pleased to submit comments on the Centers for Medicare and Medicaid Services' (CMS) PACE 2020 audit protocol materials released in connection with the 30-day notice published in the Federal Register on November 27, 2019. We share CMS' commitment to ensuring PACE participants' access to high quality care consistent with the PACE regulatory requirements. With this being our primary focus, we appreciate the opportunity to provide input on the proposed PACE audit protocol.

On Lok was founded over 45 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 in collaboration with interested organizations, federal and state policymakers, and national foundation. The success of the replication resulted 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 Lifeways, serves almost 1,650 PACE participants, who reside in three counties, the vast majority 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 appreciate CMS' thorough review of the comments and recommendations on the PACE 2020 audit protocol submitted by On Lok, NPA, and other stakeholders in May 2019. We want to express our support for the comments submitted by NPA on December 19, 2019 in response to the 30-day notice on the PACE 2020 audit protocol materials. We believe that NPA's recommendations accomplish the goal of reducing burden without compromising CMS' ability to assess compliance with the PACE regulatory requirements. We endorse the comments submitted by NPA and, in particular, want to underscore On Lok's support with our additional comments in the following areas:

- **Root Cause Analyses (RCAs) and Impact Analyses (IAs):** On Lok appreciates the modifications that CMS made to many of the impact analyses that will limit their scope

to 50 percent of participants enrolled or staff employed during the audit review period who are not included in the provision of services or personnel sample selections. As a larger PACE organization with seven On Lok PACE centers serving close to 1,650 participants, we request that CMS consider further reducing the sample size by requiring smaller proportions of participants to be included in their impact analyses through use of a statistical sampling methodology. We believe the use of statistically valid sample sizes would reduce burden among larger PACE organizations while assuring CMS that the impact analyses results are representative.

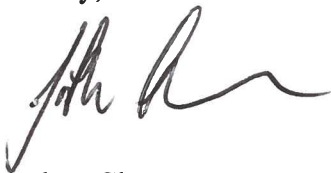
In situations when a PACE organization will be required to complete multiple impact analyses, On Lok requests that the auditors select the same or largely overlapping samples of participants or staff for these impact analyses. By not selecting the same or largely overlapping samples, there is a potential that On Lok may be required to complete medical record reviews on more than 50 percent (and up to 100 percent) of our participants and staff.

Finally, we urge CMS to limit the requirements for PACE organizations to complete root cause analyses and impact analyses to situations where reasonable thresholds trigger such requirements rather than every instance of non-compliance that has been observed in sample cases.

- **On-site Observation Participant List:** Although greater flexibility is being provided to PACE organizations on how to report the requested information for the on-site observation participant list, On Lok is extremely concerned that the use of the list as proposed is a burdensome means of identifying five participants for the on-site observation. We also believe that it will be burdensome to transcribe data tracked in multiple formats into a single document that can be used effectively by auditors. We request that CMS reconsider its use of the on-site observation participant list to identify participants for the on-site observation and limit the number of participants for which these data elements must be provided. As a larger PACE organization with multiple centers, we also ask that CMS reduce the on-site observation participant list to only the PACE centers where the auditors will be on-site.
- **Electronic Health Record (EHR) System Access and Documentation Requests:** When the auditors require access to the PACE participants' electronic health records for documentation review, we ask that an On Lok staff member, who is experienced with the EHR system, be present with the auditors on-site. In prior PACE audits of On Lok, auditors have found it helpful and preferred to have an On Lok staff member available to assist and guide them to the elements of the EHR of interest. By continuing this process, we believe that the number of documentation requests that must be scanned and uploaded into CMS' Health Plan Management System (HPMS) audit module will be reduced substantially.

We thank you for considering On Lok's input and experience in assessing the impact of the PACE 2020 audit protocol on PACE organizations. We are hopeful that CMS will consider these and NPA's comments in ways that will further reduce the burden experienced by PACE organizations when they are audited by CMS. If you have any questions, please do not hesitate to contact Eileen Kunz, Chief of Government Affairs and Compliance, at ekunz@onlok.org or (415) 292-8722, or me at jchau@onlok.org or (415) 292-8852.

Sincerely,



Jonathan Chau
Director of Regulatory Affairs and Compliance

cc: Grace Li, Chief Executive Officer, On Lok
Eileen Kunz, Chief of Government Affairs and Compliance, On Lok

