🌀 On Lok Senior Health Services

May 28, 2019

Centers for Medicare & Medicaid Services
Office of Strategic Operations and Regulatory Affairs
Division of Regulations Development
Attention: CMS-10630 (OMB control number: 0938-1327)
http://www.regulations.gov

RE: CMS-10630—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 published in the Federal Register on March 15, 2019. We share CMS' 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, related burden estimates, and supporting documentation.

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 1,600 PACE participants, who reside in three counties, the vast majority of whom are dually eligible for Medicare and Medicaid. On Lok Lifeways participants are 82 years of age on average, with 46% over the age of 85. Our average participant has 21 medical diagnoses and 61% have a diagnosis of Alzheimer's disease or related dementia.

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 support for the comments submitted by NPA on the PACE 2020 audit protocol. We support NPA's recommendations for changes to the protocol which would significantly reduce the burden imposed by the audit on PACE organizations overall and, most importantly, on PACE organizations' provider/clinical staff. The audit as currently implemented and as proposed for 2020 requires an excessive amount of time from providers who are then not available for participant care. Impact analyses can be requested of PACE organizations for weeks following the on-site portion of the audit so that demands on providers extend well beyond the two-week audit fieldwork period. We believe that NPA's recommendations accomplish the goal of reducing burden without compromising CMS' ability to assess compliance with key regulatory requirements. We endorse the comments submitted by NPA and, in particular, want to underscore On Lok's support for the following comments and recommendations:

- The burden estimates of 600 hours and $41,250 provided by CMS for the PACE 2020 audit protocol are too low and fall short of reflecting the time and resources required of PACE organizations being audited, especially for medium and large size programs. NPA's estimates of burden, based on input from many PACE organizations, are more than double 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 take steps to reduce the burden of the audit process which, as proposed, is excessive and will harm our PACE organization's ability to provide care to the participants we serve.

- It is possible to effectively and comprehensively audit PACE organizations using a less burdensome protocol more consistent with those developed for other types of providers. At a minimum, the proposed PACE 2020 audit protocol should be modified to reduce burden in numerous ways consistent with recommendations offered by NPA in its comment. These recommendations include: 1) reducing the number of requests for information that can be met only by undertaking exhaustive medical record reviews; 2) clarifying expectations of PACE organizations with respect to service delivery requests and grievances; 3) raising thresholds for requiring PACE organizations to undertake root cause analyses (RCAs) and impact analyses (IAs); and, very importantly, 4) using a sampling methodology that allows PACE organizations to initially undertake IAs for a sample, e.g., of participants, with 100% samples being required only in much more limited situations. We refer you to NPA's comment for more detail.

As a larger PACE organization with seven On Lok PACE centers serving close to 1,600 participants, we would also appreciate CMS' consideration with the following comments and recommendations:

- **Burden Estimate:** Based on our most recent experience with the PACE audit in 2018, we approximate that the staff burden is approximately five times the documented hours for a larger PACE organization. The current estimate for staff burden does not take into account information technology (IT) staff or interdisciplinary team (IDT) member involvement in the data universe preparation (including medical records review and validation), desk review, and on-site audit. It also does not take into account the difficulty in coordinating IDT staff availability across the PACE centers during the desk review and on-site audit components. Additionally, the process to scan and upload numerous documents into the CMS Health Plan Management System (HPMS) audit module was a significant burden, which will likely increase with the proposal to expand the sample sizes for the various data universes.

- **Data Universes and Sample Selections:** During the 2018 PACE audit of On Lok, we found that the collection of data universes for all PACE centers was an increased burden on staff workload. Additionally, we found that it was difficult to coordinate staff availability across the PACE centers without a defined daily schedule for both the desk review and on-site audit. We would appreciate CMS' consideration in reducing the data collection and sampling to a proportion of PACE centers and/or interdisciplinary teams

for larger PACE organizations. Prior to the release of the PACE 2017 audit protocol, CMS adopted this approach, selecting several of the PACE centers (i.e., two to three PACE centers) to conduct the on-site audit, data collection, and documentation review. By applying this approach to the PACE 2020 audit protocol, we believe this will reduce the staff burden for larger PACE organizations operating multiple PACE centers.

- **Documentation for Medical Record Samples for Clinical Appropriateness and Care Planning:** As a larger PACE organization, we believe that changing the timeframe for providing medical records samples to the PACE organization from one business day to one hour prior to the start of the review is not feasible considering participant records will be selected from multiple PACE centers. Additionally, we also believe that the coordination between the medical record samples selection and the on-site observation participant list will increase the staff burden especially if the observation list is different from the medical record samples.

- **On-site Observation Participant List:** We support NPA's recommendation regarding the on-site observation participant list. We also recommend that the participant-related data universe templates, especially the list of participants available for observation during the on-site portion, be modified to add a column to identify the PACE center. We believe that this will facilitate the identification of the PACE center for the participant specific observations during the on-site audit component when choosing the samples.

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 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 questions, please do not hesitate to contact me at ekunz@onlok.org or (415) 292-8722.

Sincerely,

Eileen Kunz
Chief of Government Affairs and Compliance

cc: Grace Li, Chief Executive Officer, On Lok
Jonathan Chau, Director of Regulatory Affairs and Compliance, On Lok