



May 24, 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

I am writing on behalf of Element Care to respond to the Centers for Medicare & Medicaid Services' (CMS) request for comment on the 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 every day, we appreciate the opportunity to provide feedback on the proposed audit protocol, related burden estimates and supporting documentation.

Founded in 1995, Element Care is the 6th largest non-profit PACE Organization in the nation. PACE at Element Care operates independently, without a parent organization such as a health system or federally qualified health center. Element Care serves over a thousand participants in over 50 cities/town across Essex and Middlesex Counties. Element Care has seven PACE Centers within the service area and the corporate headquarters are located in Lynn, Massachusetts. The median age of our participants is 73 years old; 33% are between ages 65-74, 62% are female and 38% are male; 42% of our participants live alone in the community, and 37% are ethnic minorities.

Our 2018 CMS PACE Audit score was 2.20 and resulted in zero (0) observations, one (1) corrective action required (CAR), five (5) immediate corrective action required (ICAR) without any sanctions. We received 1 CAR and 4 ICAR's under the Service Delivery Requests, Appeals and Grievances (SDAG) audit element; and 1 ICAR under the Clinical Appropriateness and Care Planning (CACP) audit element.

As a member of the National PACE Association (NPA), 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 onsite 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. More specifically, we agree with NPA that:

- 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.

Element Care agrees with NPA's comments and feel the 2020 protocol burden impact would be significant. While we recognize that the audit process is data-driven, we urge you to consider the tremendous amount of time it takes a large organization like Element Care to compile the data universes. During our 2018 audit, access to our electronic medical records was granted but we were still required to submit information through the documentation request log by deadline. In addition, the increased number of Root Cause Analyses (RCA) and Impact Analyses (IA) is worrisome.

Thank you for considering Element Care'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 or need for follow-up, please do not hesitate to contact me by telephone at 781-715-6661 or by email at kturnquist@elementcare.org.

Sincerely,

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