



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

Senior LIFE appreciates the opportunity to respond to the Centers for Medicare & Medicaid Services' (CMS) request for comment on the PACE 2020 Audit Protocol materials released in connection with the 30-day notice published in the Federal Register on November 27, 2019. Senior LIFE has experienced 9 PACE audits since the implementation of the 2017 PACE Audit Protocol. The following comments will be based on these audit experiences, as well as a review of the 2020 PACE Audit Protocol materials.

The Senior LIFE programs refer to six mutually exclusive health plans, including Pennsylvania PACE, Inc., Senior LIFE Washington, Inc., Senior LIFE York, Inc., Senior LIFE Greensburg, Inc., Senior LIFE Altoona, Inc., and Senior LIFE Lehigh Valley, Inc. These plans operate 12 PACE centers that serve 13 counties and over 2,100 frail and elderly participants throughout Pennsylvania.

Senior LIFE plans are members of the National PACE Association (NPA) and would like to express support for NPA's comments on the PACE 2020 Audit Protocol. Rather than repeating them here in detail, we refer you to NPA's comment dated December 19, 2019. Briefly, we are supportive of NPA's comments that:

- (1) recognize and express appreciation for CMS' careful consideration of NPA's and others' comments in response to the 60-day notice on the PACE 2020 Audit Protocol materials;
- (2) request that CMS further reduce the scope of required Impact Analyses (IAs), particularly for larger PACE organizations, such as many of the Senior LIFE programs, for which data on fewer

than 50% of participants or staff would give auditors a clear understanding of compliance issues;

(3) request that auditors select overlapping samples of participants or staff in instances when multiple IAs are required of PACE organizations;

(4) request that CMS reconsider its use of the On-Site Observation Participant List to identify participants for on-site observation and, minimally, limit the number of participants for whom data are required; and

(5) request that CMS implement the audit protocol such that (a) auditors will exercise reasonable discretion in requiring Root Cause Analyses and Impact Analyses rather than requiring them in virtually all instances of non-compliance observed in sample cases; and (b) steps will be taken to reduce, when possible, auditors' requests to upload documentation in HPMS.

Additionally, Senior LIFE offers the following comments for CMS consideration in addressing CMS's stated intent to streamline the elements, clarify CMS expectations, refine the data-driven and participant outcomes-based audit approach, and to improve transparency.

Burden Estimates:

Senior LIFE appreciates CMS' acknowledgement of burden on the PACE Organization. Some of the changes made from the March revisions will alleviate some of that burden, however, based on experiences with pre-audit, audit, and post-audit activities, Senior LIFE believes that the burden estimates for PACE Organizations continue to be substantially less than what will occur, while the burden estimates on CMS staff is over-estimated.

Audit administration: It is unreasonable to expect that CMS will have 6 staff at 80 hours each (480 hours) participating compared with 4 PACE staff at 40 hours each (160 hours). Senior LIFE experience has been for an average of 8-10 staff working greater than 8 hour days during the 2 weeks of auditing to satisfy the documentation request log requirements that have a 24 hour submission deadline. Auditors are typically on-site for greater than 8 hours per day. They typically leave 1-3 hours after the daily debrief, and the PACE organization is left with a documentation request log containing a significant amount of requests with a 24 hour submission deadline, which requires staff to stay even later.

Post-audit activities: It is unreasonable to expect that 6 CMS auditors will spend 90 hours each (540 hours) reviewing data entered and spreadsheets and specific documentation requested while estimating that it will take 4 PACE staff 40 hours each (160 hours) to complete 100% medical record reviews, corresponding data entry/validation on spreadsheets, and documentation submission. Even with reduction

of samples to 50%, Impact Analysis completion alone is going to require significantly greater than 40 hours each for 4 staff to complete a 100% manual medical record review of 6 months of material for over at a minimum of 100 participants within a 10 business day timeframe. When adding in the review of the draft audit report that is typically received months after audit exit, supporting documentation cited, and creating responses to the draft report, this burden is severely underestimated.

Sample Increases

The intent of increasing the samples for SDAG and provision of care samples is unclear in the audit protocol, and it would benefit both CMS and the PO in defining the intent of increased sample sizes.

SDAG: The majority of CMS's findings related to service delivery requests and appeals comes from denials. There is no shortage of SDAG conditions being cited, so the benefit of adding 5 additional service delivery request approvals and 5 appeal approvals is not clear. In an effort to streamline the elements, it would be beneficial for CMS to consider coordinating the service delivery request denials and the appeals being requested. This would streamline the documentation being requested while still providing the same number of service delivery request denials being reviewed. Otherwise, the targeted SDAG samples then becomes 50, since the service delivery request denial case notes, progress notes and assessments related to the underlying service delivery request denial is being requested with all appeal case files.

Provision of Care: The intent of increasing the Provision of Care samples to 30 is unclear and concerning, especially where the PACE Organization burden estimates remain half of what the CMS burden is estimated. Audit trends have shown an increase in data requests, Root Cause Analyses, and Impact Analyses since implementation of the audit protocol in 2017. Without established CMS guidelines that warrant these requests, this will continue to be subjectively left to the audit team.

Data Requests

The protocol does not outline the thresholds for documentation requests, Root Cause Analyses, or Impact Analyses. Much of the wording indicates "when warranted," "may be requested," or "when necessary," but these criteria are not defined. Providing thresholds for these requests would be a crucial step in CMS's stated intent to streamline the elements, clarify CMS expectations, refine the data driven and participant outcomes-based audit approach, and to improve transparency.

Documentation Requests: When the 2017 protocol was initiated, Senior LIFFE was informed by audit teams and experienced that documentation being used to support a condition of noncompliance was being requested to be uploaded to HPMS on the

Documentation Request Log. There was dialogue between auditors and Senior LIFE staff to minimize upload requests in the event documentation could not be located in the medical record or if other questions on policy or process existed. This practice has shifted in 2019, where documentation requests are being made without cause, and in some situations, Senior LIFE is completing and uploading parts of the medical record audit for the auditors. As a result upload requests have increased by about 150% from 2018 and about 200% from 2017, despite no significant changes in audit scores. Both CMS and PO burden would be decreased with more definition in types of documentation requested for upload.

Root Cause Analyses: Root Cause Analysis requests have been more predictable, where one potentially noncompliant case identified equates to a RCA request. To improve transparency, if this is CMS's intent, this should be clearly defined in the protocol.

Impact Analyses: Impact Analysis requests have been less consistent or predictable and appear to be left up to the subjective opinion of the audit team. As a result, Impact Analysis requests have increased substantially in 2019, and some IAs requesting significantly more information than what is on the previously used templates. To improve transparency, clarify CMS expectations, and reduce burden on CMS and the PO, the criteria used to determine the necessity of an Impact Analysis should be more clearly outlined in the audit protocol.

Condition Classification

The audit protocol does not define the definitions or criteria used for application of Immediate Corrective Action Required, Corrective Action Required, or Observation findings that result in the audit score. At present, this is not defined for the PO until the receipt of the Draft Audit Report, however Senior LIFE experience has been that the conditions are applied inconsistently and differently than the currently outlined definitions. Outlining the thresholds with concrete data and clearly defining these condition classifications would increase consistency and be an important step in streamlining the elements, clarifying CMS expectations, refining the data-driven and participant outcomes-based audit approach, and improving transparency.

PACE Organization Input

In the audit protocol, there is no opportunity for PACE Organizations to have any input in the audit until the issuance of the Draft Report. There is no discussion built into the protocol related to policy/procedure or why the organization acted in a certain manner in a certain situation. In the protocol, if auditors believe there may be noncompliance, they can request a Root Cause Analysis in which the PACE Organization must explain the nature of the problem and describe why the non-compliance occurred. There is no opportunity built into the audit process for discussions of PO policy or processes that may eliminate the need for data requests. Based on Root Cause Analysis responses, the audit team can subjectively request an Impact

Analysis, again, without the opportunity for the PACE Organization to have input. The PACE Audit Consistency Team meets with the audit team to discuss and classify conditions, again, without participation or opportunity for input from the PACE Organization. It is not until the Draft Report is issued that the PACE Organization has any opportunity for their input to be considered. This often occurs significantly later than the issuance of Immediate Corrective Action Required findings that necessitate a Corrective Action Plan within 3 business days. Senior LIFE has experienced the issuance of an ICAR finding that resulted in completion, submission, acceptance, and implementation of a CAP, only to have the finding later removed after Senior LIFE had the opportunity to respond via response to the Draft Audit Report. This lack of discussion or opportunity for PACE Organization input increases the burden on both CMS and the PACE Organization. It would behoove CMS to build in some dialogue and discussions into the audit protocol to reduce burden and streamline the audit process prior to the issuance of the Draft Audit Report.

Timeframes

All audit timeframes are very well defined for the PACE Organization, but there are no timelines outlined for CMS, other than engagement letter issuance. Some examples of Senior LIFE experiences that demonstrate the need for more clearly defined expectation on the CMS audit team include:

- Root Cause Analysis requests issued 10-45 days after the audit exit conference.
- ICAR notifications issued greater than 5 months after the exit conference, and in one instance over 2 months after notification that the PACT had met and determined there would be ICAR findings.
- Draft Audit Reports issued over 6 months after the exit conference.
- 2 audits that had exit conferences in March 2019 have not received Final Audit Reports as of the date of this letter, despite responses to the Draft Audit Reports being submitted 2-4 months ago.

As shown with the current audit protocol, the lack of defined timelines is leading to audits being extended for significantly longer than necessary, with little to no communication to the PO on the status of the audit. Clear timelines for both CMS and POs would streamline the elements, clarify CMS expectations, refine the data-driven and participant outcomes-based audit approach, and improve transparency.

We appreciate your consideration of our input. If you have any questions, please contact Michele Garrity at mgarrity@pace-cs.com and (814) 535-5433.

Sincerely,



Michele Garrity
Quality Analyst

