



# UnityPoint Health

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December 26, 2019

Office of Management and Budget  
Office of Information and Regulatory Affairs  
Attention: CMS Desk Officer

RE: CMS–10630– Programs of All-Inclusive Care for the Elderly (PACE) 2020 Audit Protocol;  
published in Vol. 84, No. 229 Federal Register 65396-65397 on November 27, 2019.

*Submitted electronically via [OIRA\\_submission@omb.eop.gov](mailto:OIRA_submission@omb.eop.gov)*

Dear CMS Desk Officer:

UnityPoint Health (UPH) and Siouxland PACE are pleased to provide comments in response to the Centers for Medicare & Medicaid Services' (CMS) proposed Programs of All-Inclusive Care for the Elderly (PACE) 2020 Audit Protocol. Siouxland PACE started in 2008 with assistance from a CMS Rural PACE Development grant. Since 2011, Siouxland PACE has been under the ownership of UnityPoint Health – St. Luke's, a UPH senior affiliate in northwest Iowa. Currently, there are 221 Participants receiving PACE services from four northwest Iowa counties.

We submitted comments on CMS-10630 dated May 28, 2019 and appreciate CMS' time and effort in considering and incorporating portions of that feedback. As proposed, the administrative burden of the audit process was significantly increased in many areas. This Protocol has taken steps to reduce some of that burden. We respectfully offer the following comments to further improve and streamline the 2020 Audit Protocol.

## **SUPPORT OF NATIONAL PACE ASSOCIATION COMMENTS**

**Siouxland PACE is a member of the National PACE Association (NPA). We support the comments dated December 19, 2019 submitted by NPA** and are committed to participating with the NPA to further strengthen services and supports for the PACE population. To summarize, we support NPA's comments advocating for:

- (1) Further reduction in the scope of required Impact Analyses (IAs), particularly for larger PACE organizations (POs) for which data on fewer than 50% of participants or staff would give auditors a clear understanding of compliance issues;
  
- (3) Selection of overlapping samples of participants or staff by auditors in instances when multiple IAs are required of POs;

(4) Reconsideration of the proposed 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) Implementation of the audit protocol such that (a) auditors will exercise reasonable discretion in requiring Root Cause Analyses and IAs 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.

### TIME AND EFFORT ESTIMATIONS

Despite revisions, **we believe that CMS continues to misjudge the total personnel and hours required for PACE Organization audit preparation, desk review and onsite audits, and follow-up.** For Siouxland PACE, audits include more than four personnel and data collection effort, including manual extractions, have been underestimated. We would refer you to our May 28, 2019 letter for further detail.

### TIMEFRAMES FOR RESPONSE AND DOCUMENT PRODUCTION

We continue to be extremely concerned with expedited timeframes for response and document production with the Audit Protocol.

- Data universe preparation and submission timeframes: We would urge CMS to continue the 30-day response period. Timeframes have been reduced by 10 days, or one-third of the current timeframe, for most data universes, including Service Delivery Request (SDR), Appeals Request (AR), Grievance Request (GR), List of Personnel (LOP), List of Participant Medical Records (LOPMR), On-Call (OC) universe, Quality Assurance and Performance Improvement (QAPI) plans, Patient Advisory Committee (PAC) minutes and detailed PACE organizational chart. This condensed 20-day timeframe fails to recognize that the universe preparation and submission process is largely a manual process.
- Desk review timeframes: We would request a 5-day notice period for collection of review documents. While we appreciate that CMS is proposing to allow 2 business days (up from 1) to provide selected samples for SDAG and/or Personnel prior to review, our challenge is that not all data elements are searchable within the EMR, so our staff must prepare for this review by scanning and putting some documentation into PDFs. By permitting extended time to gather the documents, it enables the desk review to be more efficient and avoids having to continue this process during the onsite audit.
- Medical record review: We would urge CMS to continue the 1-business-day timeframe, instead of the proposed 1 hour prior to the start of the review of medical records. Although CMS has clarified that the PO is not expected to upload any medical record documentation within the 1-hour timeframe, POs are required to allow CMS immediate access to the medical records for each sample within that time. This timeframe may be problematic for POs that need to manually

capture comprehensive records maintained outside the EMR.

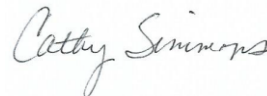
- Post-audit timelines: The 2020 protocol requires review of 100% of participants for each requested impact analysis to be completed in 10 days. We do not believe that one record omission should not necessarily result in a review of all records within a data universe. This burden is compounded when multiple analyses are requested, which makes the 10-day timeframe difficult at best. Instead of a 100% audit triggered in each impact analysis, we would suggest a sampling methodology, whereby another 5, 10 or 20 records are examined. If further noncompliance is found, then that could trigger either another sampling or 100% review at that point. When a 100% review is required, we would also request that CMS set the timeframe for completion in consideration of the totality of analyses being requested. When multiple requests are made, their sheer volume along with normal operations and compliance duties often requires time and effort outside regular work hours. Any timeframe flexibility (when participant welfare is not jeopardized) should be considered by CMS and would be greatly appreciated. We would also urge that these standards for review be clarified so that POs understand when auditors do and do not have discretion to trigger a 100% record review.

On behalf of our PACE Participants, Siouxland PACE and UnityPoint Health appreciate the opportunity to provide comments to the proposed information collection request. To discuss our comments or for additional information on any of the addressed topics, please contact Cathy Simmons, Government and External Affairs at [cathy.simmons@unitypoint.org](mailto:cathy.simmons@unitypoint.org) or 319-361-2336.

Sincerely,



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