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May 28, 2019

William N. Parham, III
Centers for Medicare and Medicaid Services (CMS)
Office of Strategic Operations and Regulatory Affairs
Division of Regulations Development
Attention: CMS–10630
Room C4-26-05
7500 Security Boulevard
Baltimore, MD 21244–1850

RE: CMS–10630 - Programs of All-Inclusive Care for the Elderly (PACE) 2020 Audit Protocol; Agency Information Collection Activities: Proposed Collection; Comment Request; published at Vol. 84, No. 51 Federal Register 9526-9527 on March 15, 2019.

Submitted electronically via http://www.regulations.gov

Dear Director Parham,

UnityPoint Health ("UPH") and Siouxland PACE appreciate this opportunity to provide comment on this proposed information collection related to the 2020 audit protocol for the Programs of All-Inclusive Care for the Elderly (PACE). UPH is one of the nation's most integrated healthcare systems. Through more than 32,000 employees and our relationships with more than 310 physician clinics, 39 hospitals in metropolitan and rural communities and 19 home health agencies throughout our 9 regions, UPH provides care throughout Iowa, central Illinois and southern Wisconsin. 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 208 Participants receiving PACE services from four northwest Iowa counties.

Siouxland PACE is member of the National PACE Association (NPA) and supports the comment letter submitted by NPA. In addition to that feedback, UPH and Siouxland PACE respectfully offer the following comments.

PROGRAMS OF ALL-INCLUSIVE CARE FOR THE ELDERLY (PACE) 2020 AUDIT PROTOCOL

Beginning in audit year 2020, the number of data collection tools is proposed to increase from 18 to the 31 documents:

- *A PACE Audit Process and Data Request,*
- *A Pre-audit issue summary document,*
- *A PACE supplemental questionnaire,*
- *One onsite participant sample collection document,*
- *One root cause analysis template (for use as-needed),*

- *25 Impact Analyses templates (for use as-needed), and*
- *One audit feedback questionnaire.*

Comment:

Documentation consolidation, not additions: While we are supportive of improvements to the audit process, we are concerned that this proposal does not "streamline the elements, clarify CMS expectations, refine our data-driven and participant outcomes-based audit approach, and improve transparency." Rather this approach appears to significantly increase PACE Organization administrative burden by substantially revising the audit process after only one full cycle (with annual updates), adding 13 new templates/documents (an increase of 42%) and generally increasing data universe requirements. This seems at odds with trends in the HHS 2018 Annual Report, which touted 25 deregulatory actions with a total present-value economic burden impact of $12.5 billion. In this 2020 protocol, it is unclear how stakeholders were involved in developing the proposal and whether some of the changes/templates should have been piloted before mandating their use. Overall, ***we would encourage CMS to consolidate rather than multiply the audit templates.***

Time and effort estimation: ***CMS continues to misjudge the total personnel and hours required for PACE Organization audit preparation, desk review and onsite audits, and follow-up.*** Below are some items requiring further consideration in this time and effort calculation.

- *Number of personnel*: The CMS estimate includes time and effort by four PACE Organization personnel – nurse manager, executive assistant, medical records and health information technician, and compliance officer. At our PACE Organization, time and effort is required by all management staff – executive director, two clinical managers, business manager, operations manager and transportation lead – as well as an informaticist and a QAPI analyst. While we do not expect CMS to specifically name each management position that would apply to all PACE Organizations, ***we do believe that the hours and salary estimates should be revised to reflect a larger organizational effort*** and that they currently underrepresent the overall wage level of those who contribute to this effort.
- *EMR access*: ***CMS requires PACE Organization staff familiar with our EMR to be available to each auditor during the onsite review and this time and effort does not appear to be reflected in the burden estimates.*** During our 2017 audit, there were not only 3 CMS auditors, but the CMS auditors were supplemented by state Medicaid agency personnel and contractors at CMS' request, which added 5 more personnel. In total there were 8 onsite auditors present at the CMS review that requested access to our EMR, requiring 8 PACE personnel with knowledge of our EMR to be available. It should also be noted that some of our records, such as personnel, are housed outside the EMR and may require other staff resources for auditor access.
- *Manual extraction*: ***Despite having an EMR, data collection for pre-audit as well as some of the follow-up requests involve a significant amount of manual extraction.*** While we would characterize our EMR (i.e. Epic) as fairly sophisticated, it is not necessarily tailored to CMS audits or HPMS reporting and the cost to customize those reports are prohibitive for a PACE Organization with a census just above 200. For example, while we house scanned versions of care plans and assessments in the EMR as attachments, they are not searchable. As a result, many data points (i.e. fields) required by this audit are not able to be electronically generated. For instance, significant weight gain/loss (defined as a 2% difference) must be manually reviewed and tracked.

- *Scope of records in impact analysis/root cause analysis*: The 2020 protocol requires that the Impact Analysis must identify participants subject to or impacted by the issues of non-compliance "generally from the beginning of the data collection period through the audit exit conference." This requires a review of 100% of participants for each requested analysis to be completed in 10 days. It is unclear how CMS developed a 40-hour-per-person work effort, given the number of impact analyses and root causes that have been requested and performed over the last audit cycle. ***We offer specific suggestions related to the 100% audit threshold in the "Timeframes for response and document production" narrative below.***

Timeframes for response and document production:

- *Data universe preparation and submission timeframes*: ***We 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 and that the 2020 protocol increases the fields in many of these data universes.
- *Desk review timeframes*: ***We would request a 5-day notice period for collection of review documents.*** Consistent with guidance dated February 22, 2019, 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. While we appreciate that the protocol is now 2 days, this timeframe is currently challenging, and the 2020 protocol increases the number of records to be reviewed.
- *Medical record review*: ***We would urge CMS to continue the 1-business-day timeframe.*** The 2020 protocol indicates that samples for the Clinical Appropriateness and Care Planning elements will be provided to the PACE Organization 1 hour prior to the start of the review of medical records. The one-hour timeframe does not enable PACE Organizations to manually capture comprehensive records that may be 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 PACE Organization understand when auditors do and do not have discretion to trigger a 100% record review.

Role of State Agency within CMS audit: PACE Organizations operate under a three-way agreement with CMS, the State Agency and themselves. The 2020 protocol is silent as to the expected role of the State Agency within the CMS audit process and the use of Core Audit Teams. Before the 2017 cycle, CMS and our State Agency performed the audit in tandem. During the 2017 cycle, State Agency personnel listened during the CMS desk review, had 5 personnel onsite and in attendance during select CMS meetings, but performed a "separate" audit with a report that was issued after the completion of CMS corrective action plans (6 months after auditors were onsite). State Agency personnel performed level of care reviews and participant interviews. In our case, the State Agency duplicated several of the CMS findings, which had since been resolved under the CMS corrective action plan; however, in some instances, the State Agency required additional actions. This process was confusing and elongated the audit unnecessarily. ***We would request that CMS clarify the role of the State Agency during the CMS audit process*** so that audit expectations are clear and preparation can be streamlined.

PACE audit survey: This survey is a new document and it is voluntary. Since we are uncertain how CMS currently gathered suggestions for the 2020 protocol, we view this as a standardized means to collect input into the process which is more transparent. That said, ***we believe that the audit survey should be mandatory so that CMS can monitor trends, have transparent results and be accountable for further revisions.*** As written, the current survey focus is on the audit team itself, and not necessarily the substance of the audit. We would urge CMS to consider the inclusion of more pointed questions on overall process efficiencies and/or improvements. For instance:

- Do you have any suggestions related to the reduction of audit burden or redundancies?
- Do you have suggestions related to additional audit efficiencies and/or improvements?
- Do you have suggestions for additional audit and/or compliance trainings?

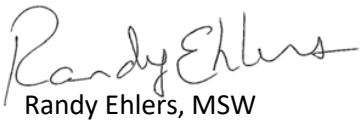
Other clarifications:

- *Under "5. Small Business" justification*, it states "*The collection of information will have a minimal impact on small businesses since applicants must possess an insurance license and be able to accept substantial financial risk. Generally, state statutory licensure requirements effectively preclude small business from being licensed to bear risk needed to serve Medicare enrollees*." Please note that PACE Organizations are not required to possess an insurance license. While PACE Organizations must provide evidence of arrangements to cover expenses, this is not equated to an insurance license. ***We do believe that most PACE Organizations would be considered small businesses and, as such, additional regulatory burdens should be weighted accordingly.***
- *Timeframe for CMS draft audit report*: Is it still the expectation that CMS will issue a draft report inclusive of condition classification and audit score to PACE Organizations approximately 60 calendar days after exit conference? ***We would urge CSM to consider putting in a defined timeframe and eliminate "approximately."*** To accommodate the extent of actual findings, CMS could consider relating the timeframe for issuance of the report to the receipt of Impact Analyses/Root Cause Analyses responses.

- *PACE Audit Consistency Team (PACT)* – With the development and use of Core Audit Teams, which are expected to result in more consistent and accurate PACE audits, it is unclear whether CMS intends to continue its use of the PACT. As envisioned, the PACT was to serve as the subject matter experts on PACE and audit policy and ensure consistency in classification of audit conditions across all audits. ***Will the PACT continue to exist? If the PACT is to continue, we would request that CMS clarify its composition, role relative to the Core Audit Teams and whether PACE Organizations would have an opportunity to participate in the process of classification of audit conditions.***
- *2020 PACE Supplemental Questions*: The questionnaire asks, "Does your organization have the ability to provide remote access to medical records? If so, please provide instructions for CMS to be granted access." This question references the "ability" of the PACE Organization. We are assuming that this would allow a PACE Organization that has an EMR with the capability to permit remote access to have a policy that would further restrict such remote access. Since our PACE Organization uses the same EMR as our parent organization and the EMR houses more than one million patient records, it has been challenging to restrict remote EMR access to our PACE participants. ***We seek clarification as to how to interpret this question and to better understand what specific information CMS would like remote access to.***
- *Universe Preparation and Submission*. Consistent with the February 22, 2019 memo, PACE Organizations have 3 attempts to submit data universes. Given the significant changes in the data fields, ***we would request clarification on whether CMS intends to apply this standard to the 2020 protocol.***

We are pleased to provide input on the proposed PACE 2020 audit protocol and its impact on our PACE Organization, PACE participants and their families, and the communities we serve. As CMS looks to further refine these protocols, we would be happy to participate in further dialogue to assure that future audits are appropriately targeted and do not become overly burdensome for CMS or PACE Organizations. To discuss our comments or for additional information on any of the addressed topics, please contact Cathy Simmons, Executive Director of Regulatory Affairs, at 319-361-2336 or cathy.simmons@unitypoint.org.

Sincerely,



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