December 19, 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

On behalf of the National PACE Association (NPA) and its 113 PACE organization members in 28 states, we are submitting comments on the Program of All-Inclusive Care for the Elderly (PACE) 2020 Audit Protocol. In developing both this comment and the comment submitted to the Centers for Medicare & Medicaid Services (CMS) in response to the 60-day notice concerning this collection of information, NPA has consulted extensively with numerous of its PACE organization (PO) members, and the audit and compliance, and regulation subcommittees of NPA's Quality and Public Policy committees. Our comment is based on a detailed review of the PACE 2020 Audit Protocol materials released in connection with the 30-day notice published in the Federal Register on November 27, 2019.

Before offering our comments below, we would like to recognize and express our sincere appreciation for CMS' thorough review of the comments previously submitted by NPA and its members in response to the 60-day notice on the PACE 2020 Audit Protocol materials. Based on the differences between the materials released in connection with the 30- and 60-day notices, it is clear to us that CMS staff reviewed these comments in detail; and modifications in response to many of them are evident in the latest release. Most notable are the following changes that we believe will significantly reduce the burden to POs of the audit protocol without compromising CMS' ability to review POs' regulatory compliance:

- Numerous changes to the Impact Analyses (IAs) including elimination of nine IAs compared to the materials released in connection with the 60-day notice, a significant reduction in the numbers of participants and staff included in the scope of many of the IAs, modifications to questions for many of the IAs that should reduce the intensity of medical record review; and
- Substantial modifications to the List of Participant Medical Records (LOPMR) record layout.

In addition, we would like to acknowledge CMS' modifications to the Grievance Requests and Appeal Requests record layouts which now synchronize responses for data elements in these record layouts with PACE Quality Monitoring reporting requirements.

We do have several remaining observations and comments on the materials released with the 30-day notice. These are organized into the following sections: Burden Estimates, Recommendations to Further Improve the Proposed Information Collection, and Detailed Comments intended to assist CMS in finalizing the materials.

Burden Estimates

We appreciate CMS' acknowledgement that burden estimates included in the 60-day notice materials did not reflect the time required of POs to complete the audit process. Although the estimated total number of hours of effort required of audited POs did not change from the 60- to 30-day materials and remains 600, as CMS points out, the changes to the PACE 2020 Audit Protocol materials should substantially reduce the burden relative to what it would have been under the 60-day materials. These changes include a decrease in the number of IAs from 25 to 16 and revisions to many of those remaining as outlined above, and changes to the LOPMR record layout. Whether these changes will reduce the burden by half of NPA's estimate of 1,210 hours is yet to be determined; particularly since POs report having to utilize many more than four staff, including clinical staff, during the audit process.

In addition, we remain concerned about the burden associated with the On-site Observation Participant List which was not modified in the 30-day release; and we are hopeful that CMS will consider changes to the list based on additional comments offered below.

We ask that CMS monitor POs' experience under the 2020 Audit Protocol to assess the reasonableness of its burden estimates. Assuming POs will respond to the voluntary PACE Audit Survey, changes to the PACE Audit Survey released with the 30-day notice should assist CMS in this effort.

Referring to CMS' estimate of the burden of the PACE audit on CMS staff and contracted auditors, we do not question CMS' estimates. However, the increase in the estimated cost per audit from $29,711 under the 2017 audit protocol to $149,915 under the 2020 audit protocol may not be sustainable if the number and size of POs expands considerably in the future. Although the total cost can be moderated to some degree by the discretion CMS now has in determining the number of PACE audits that are required for established POs no longer in the trial period, a five-fold increase in CMS' cost per audit is concerning. While we appreciate that some of the additional costs to CMS are a result of the modifications made in response to NPA's and others' comments that led CMS to expand the number of participant medical records sampled for the audit, we nonetheless feel compelled to raise this issue and look forward to working with CMS to identify opportunities for future efficiencies.

Recommendations to Further Improve the Proposed Information Collection

- Comments in Response to Changes in the November 27 (30-day) Materials

    - NPA is appreciative of CMS' modifications to many of the IAs that will limit their scope to 50% of participants enrolled or staff employed during the audit review period who are not included in the provision of services or personnel sample selections, respectively. However, it remains the case that staff of larger POs may still be in the position of having to review many hundreds or even in excess of a thousand records. We ask CMS to consider further reducing the sample size for larger POs by requiring smaller proportions of participants to be included in their IAs through use of a statistical sampling methodology. Use of valid sample sizes would reduce burden among larger POs yet assure CMS that IA results are representative. Smaller samples among larger programs would not compromise auditors' ability to obtain a clear picture of compliance.

- To the greatest extent possible without compromising auditors' ability to identify issues of non-compliance, in situations when a PO is required to undertake multiple IAs, we ask that auditors select the same or largely overlapping samples of participants or staff for these IAs. If this is not the case, it is possible that POs will be required to perform medical record reviews on many more than 50%, perhaps even 100%, of their participants or staff.

- NPA requests CMS' clarification of its expectations for "Hospitalization/Emergency Room Reason," a new field (Column L) in the LOPMR record layout. We want to confirm that CMS' expectation is that POs will use hospital/ER claims data as the basis for completing this field. More specifically, a PO would enter Y if hypoglycemia, hyperglycemia or decreased oxygen saturation is listed as a primary or secondary diagnosis on the claim. If one of these conditions is not listed as primary or secondary diagnosis on the claim, the PO would enter N. If this is not CMS' expectation and POs are expected to review all hospital discharge notes, etc., this field will impose a significant burden.

- <u>NPA Concerns Not Addressed in the November 27 (30-day) Materials</u>

  We would like to reiterate several of the comments that we made in response to the 60-day notice that were not reflected or addressed in the latest materials. In some instances, they may not have been reflected in the materials because they are not directly related to data collection instruments. We are hopeful, however, that they will be taken into consideration in CMS' implementation of the audit protocol. In another comment related to the On-Site Observation Participant List data collection instrument, we ask that further consideration is given to our continued concerns:

  - No changes were made to the scope of data included in the On-Site Observation Participant List as a result of NPA's comments in response to the 60-day notice. We continue to be extremely concerned that use of the List as currently conceived is an excessively burdensome means of identifying five participants for on-site observation. While it is helpful that CMS allows POs more latitude with respect to how they report the required information to CMS, it remains the case that it will be burdensome to transcribe data tracked in multiple formats into a single or even several documents that can be effectively used by auditors. To provide this information in a consolidated format of use to auditors, invariably POs will need to manually transcribe data from numerous sources. Thus, we request that CMS reconsider our previous request to limit the number of participants for which these data elements must be provided, e.g., to those attending a specific PACE center or a sample of the PO's enrollment rather than its entire census. At present, the request encompasses virtually all PACE participants largely as a result of including all participants scheduled to receive home care.

  - We ask that CMS limit requirements for POs to undertake RCAs and IAs to situations in which reasonable thresholds trigger such requirements. To our understanding it is currently POs' experience that auditors require RCAs in virtually all situations when an instance of non-compliance has been observed in sample cases. We request that auditors exercise reasonable discretion with respect to requiring RCAs such that a single or even a minimal number of issues of non-compliance not automatically trigger an RCA, even more so in light of the increase in the number of Service Delivery Requests, Appeals and Grievances

(SDAG) and Provision of Services sample cases to be drawn from their respective universes.

Similarly, when the number and seriousness of instances of non-compliance are low, if an RCA suggests that the means by which the issue should be addressed are well understood, auditors should not proceed to request an IA. Although the burden of many of the IAs has been reduced significantly compared to what it would have been under the 60-day notice, it is still the case that RCAs alone, together with dialogue between auditors and PO staff, can provide POs and their auditors considerable insight into the scope of the issue. We strongly recommend that auditors exercise more discretion and/or raise the threshold for requiring IAs.

- Consistent with our comments on the materials released in connection with the 60-day notice, we ask that CMS identify a process by which POs have access to the PACE Audit Consistency Team (PACT) to express concerns regarding a request for an IA if they feel such request is not warranted and the audit lead is unable to respond to the PO's concerns. This request stems from our understanding that the PACT determines the need for IAs. Such contacts would not be routine but should be possible. We ask that CMS provide instructions for such a process.

- In situations in which auditors access PACE participants' electronic medical records (EMRs), either remotely or onsite, we ask that a staff member of the PO who is experienced with the EMR system be present. In case of remote access, the PO staff member should be available via teleconference and able to view the EMR along with the auditor. In this way, the staff member would be available to guide the auditor(s) to the elements of the EMR of interest. As a result, we hope the number of documentation requests made of POs for which they must scan and upload documentation in HPMS would be reduced substantially.

  In situations when an Audit Team member asks PO staff to upload medical record documentation because he/she cannot locate it in the medical record, it would be much more efficient from the PO's perspective for the Audit Team member to ask PO staff to direct him/her to the appropriate place in the record. If the Audit Team member then wants a copy of this documentation, it could be uploaded to HPMS. We are hopeful this would reduce considerably the burden POs are experiencing as a result of requests to upload documentation to HPMS.

Detailed Comments

- On pp. 7-8 of Supporting Statement A, in Section 12.4 Information Collection Instruments and Instruction/Guidance Documents, references to "Clinical Appropriateness and Care Planning Impact Analysis Template" should be changed to "Provision of Services Impact Analysis Template."
- Referring to PACE Audit Process and Data Request document (Attachment I):
  - References to "Quality Assessment and Performance Improvement" and "QAPI" should be changed to "Quality Improvement" and "QI" consistent with PACE Final Rule dated June 3, 2019, e.g., on pp. 6 and 17.

    - Referring to Columns N and AB of the LOPMR record layout (p. 30 and p. 33), "Currently in SNF/NF" and "Current Center Attendance," how should these fields be completed for participants who disenrolled during the data collection period?
    - Referring to Column K of the Personnel record layout (p. 28), please provide instructions on how to complete this field if an individual fills two separate roles on the IDT.
- Referring to PACE Supplemental Questions (Attachment II), in Instructions, need to drop "also" from 2nd bullet.
- Referring to Pre-Audit Issue Summary (Attachment III), in Column E, it reads: "Was the non-compliance disclosed to the CMS account manager prior to the date of the Audit Engagement Letter **prior to the date of the Audit Engagement Letter**?" Repetition should be deleted.
- Referring to On-site Observation Participant List (Attachment IV),
    - In instructions, "Participants who are scheduled to have medications administer**ed** by any employee or contracted employee in the PACE center or participant's home on the week of onsite audit;"
    - In Column K, "Which days will wound care **be** performed?"
    - In Column N, "Enter NA if the participant does not receive **home** care from PO staff."
- Referring to WoundCare1P02,
    - The WoundCare1P02 template is inconsistent with the information in PACE 2020 PRA Crosswalk Based on 60 Day Comments. The crosswalk indicates that the scope of the IA is limited to 50% of the participants enrolled during the audit review period who were not included in the provision of services sample selection. The scope of WoundCare1P02 in the template is, "All participants enrolled during the audit review period." The template should be corrected consistent with the crosswalk.
- Referring to Appeals1P651P661P681P73
    - In Column G, should this read, "If the answer to this question is No the PO may enter NA in fields **H-0**"?
- Referring to HomeCare1P02,
    - In Column G, c. needs to be corrected to read, "Approved **as** part of an appeal;"
- Referring to Assessment1P491P501P82,
    - In Instructions, reference to "Annual/Semiannual Assessments" should be "Semiannual Assessments"
    - Column F, "Did the participant experience a change in their health or psychosocial status during the audit review period that?" – sentence needs to be completed
    - Should Column AD be clarified to indicate this information may be completed for all IAs?
- Referring to EmergencyCare1P07,
    - In Column N, format for "Time of assessment" is needed
    - In Column P, "before to going to" needs to be changed to "before going to"
- Referring to Effectuation1PO21P111P30,
    - In Column M, should this read, "What evidence/documentation does the PO have that demonstrates the service was **provided**?"
- Referring to SrvcRestrict1P90,
    - In Column J, should "recommendation" be "determination"?
    - In Column L, should this read, "Describe why the limitation was applied."?

- Referring to Grievances1P311P751P77,
    - In Instructions, Discussing grievances with participants, in 2nd bullet, change "annually" to "annual."
    - In Column Q, "Is their documentation…" should be changed to "Is **there** documentation…"
    - In Column W, "Is their documentation…" should be changed to "Is **there** documentation…"
    - In Column X, "Is their documentation…" should be changed to "Is **there** documentation…"
    - In Column X, should "if the participant was not disenrolled" be "if the participant **was** disenrolled"?
- Referring to Personnel,
    - In Column F, it would be helpful to add "Enter NA if employee was not terminated during audit review period."
    - In Columns, G, H and I, what specifically is being asked, e.g., for Column H, Direct Participant Contact, should the PO respond Yes or No?
    - In Column T, it should read, "…determined to be free of communicable **diseases** prior to engaging in direct participant contact?"
- Referring to SDRIdentification1P76,
    - In Column F, it should read, "**If** No, please …"
    - In Column G, it should read, "Enter **the** date the participant…"
    - In Column H, it should read, "Is **there** documentation…"
- Referring to SDRs1P601P611P85,
    - In Columns S, T and U, it should read, "Enter NA **if** the service delivery request was denied."
- Referring to PACE Audit Survey,
    - In Audit Activities, "Clinical Appropriateness and Care Planning" should be "Provision of Services"
    - In Audit Activities, should "Onsite" be deleted?
    - In Audit Activities, Question 7a, it should be "How **many** staff members…"

Thank you for the opportunity to respond to the 30-day request for comments on the 2020 PACE Audit Protocol materials. If you have questions or need for additional information, please contact Chris van Reenen, NPA's vice president for regulatory affairs at chrisvr@npaonline.org.

Sincerely,

Shawn M. Bloom
President and CEO