# Ascension

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

December 27, 2019

Submitted electronically via email: OIRA_submission@omb.eop.gov

**Re: Programs of All-Inclusive Care for the Elderly (PACE) 2020 Audit Protocol (CMS-10630; OMB control number: 0938-1327)**

To Whom It May Concern:

Via Christi Healthcare Outreach Program for Elders, Inc. (HOPE) appreciates the opportunity to submit comments in response to the proposed revision with change of a currently approved collection entitled *Programs of All-Inclusive Care for the Elderly (PACE) 2020 Audit Protocol*, as proposed by the Centers for Medicare & Medicaid Services (CMS).[1]

HOPE is a ministry of Ascension Living. As a subsidiary of Ascension, Ascension Living is committed to providing services, amenities, opportunities and support, so seniors can enjoy living healthier and happier, at every age and at every stage. We're the second-largest nonprofit system in the U.S. Our living choices include independent living, assisted living, memory care, short-term rehabilitative care, PACE, and long-term skilled nursing care. More than 10,000 adults live in our 54 senior living communities, which are located in 12 states, and Washington, D.C. Also, more than 5,500 associates are employed by Ascension Living – professional, compassionate individuals who believe in empowering people to age successfully.

Ascension is a faith-based healthcare organization dedicated to transformation through innovation across the continuum of care. As one of the leading non-profit and Catholic health systems in the U.S., Ascension is committed to delivering compassionate, personalized care to all, with special attention to persons living in poverty and those most vulnerable. In FY2019, Ascension provided $2 billion in care of persons living in poverty and other community benefit programs. Ascension includes approximately 150,000 associates and 40,000 aligned providers. The national health system operates more than 2,600 sites of care – including 150 hospitals and more than 50 senior living facilities – in 20 states and the District of Columbia, while providing a variety of services including clinical and network services, venture capital investing, investment management, biomedical engineering, facilities management, risk management, and contracting through Ascension's own group purchasing organization.

Via Christi HOPE is committed to achieving and maintaining the highest standards of quality care. The PACE population is one of particular importance to us, given Ascension's Mission to serve all persons, with special attention to those who are poor and vulnerable. We recognize our immense responsibility to and for these patients and continually work to ensure our interdisciplinary teams, staff, and caregivers have the resources and support necessary to deliver high quality care in our PACE programs.

[1] 84 Fed. Reg. 65396 (Nov. 27, 2019).

**Background**

As a general matter, we support and reiterate comments offered by the National PACE Association (NPA). In particular, we would strongly echo their appreciation for CMS's thorough review of the comments submitted by Via Christi HOPE, NPA, and our fellow Association members in response to the 60-day notice on the PACE 2020 Audit Protocol materials issued earlier this year (the "60-day notice"). It is evident that CMS reviewed those comments in detail and is now proposing modifications in response to many of the recommendations put forward. We believe these changes, particularly the modifications to the List of Participant Medical Records (LOPMR) record layout, modifications to the Grievance Request and Appeal Requests record layouts, and changes to the Impact Analyses (IAs), will meaningfully reduce burden for PACE providers.

While we support many of the revisions made between the initial proposal and the one at hand, we would offer the following input, in line with NPA's comments, and appreciate your consideration of same. We also support and reiterate the specific proposed modifications to the proposed PACE Audit Protocol as set forward by NPA in their comments (see pages 4 - 6).

**Burden Estimates**

We appreciate CMS's acknowledgement that burden estimates included in the 60-day notice were not fully reflective of the time and resources that would be required of PACE Organizations (POs) to complete the audit process. An NPA estimate found the burden was likely to be double the amount estimated by CMS — potentially requiring more than 1,200 hours of PO time. While the estimated total number of hours required has not changed between the 60-day notice and the current proposal, CMS notes that the changes proposed to the PACE 2020 Audit Protocol materials should substantially reduce the burden relative to what it would have been under the 60-day notice. Although we agree the demands on clinical staff should be moderated by changes laid out in the current proposal, we remain concerned that the burden estimate is low and excludes post-audit activities—including development and implementation of corrective action plans.

In addition, we remain concerned that the burden associated with completing the On-site Observation Participant List will be significant. This aspect of the Audit Protocol was not modified in the most recent notice and we encourage CMS to consider making changes to the List based on recommendations offered below. We also ask that CMS monitor POs' experience under the 2020 Audit Protocol to assess the reasonableness of these burden estimates.

With respect to CMS's cost estimate, we agree with NPA that the increase in the estimated cost per audit from $29,711 under the 2017 Audit Protocol to $149,915 under the proposed 2020 Audit Protocol may not be sustainable if the number and size of POs expands considerably in the future. We look forward to working with CMS to identify opportunities for future efficiencies.

**Recommendations to Further Improve the Proposed Information Collection**

*Comments in Response to CMS's Latest Proposed Modifications*

We are very appreciative of CMS's 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, we ask CMS to consider

further reducing the sample size by using a statistical sampling methodology. Use of statistically valid sample sizes would reduce burden for POs while ensuring that IA results are representative. We agree with NPA that the relatively smaller samples from larger programs would not compromise the ability of auditors to obtain a clear picture of compliance.

Additionally, in situations wherein a PO is required to undertake multiple IAs, we recommend that auditors be permitted to select the same or overlapping samples of participants or staff for participation. Absent this flexibility, we are concerned that POs could be required to perform medical record reviews on many more than the proposed 50% of their participants or staff.

We also recommend that CMS clarify its expectations for "Hospitalization/Emergency Room Reason," a new field (Column L) in the LOPMR record layout. We encourage CMS to confirm that the agency's expectation is that POs will use hospital or emergency room claims data as the basis for completing this field. More specifically, we urge CMS to confirm that 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 a primary or secondary diagnosis on the claim, the PO would enter "N". If this is not CMS's expectation, and POs are expected to review all hospital discharge notes, etc., we are concerned that this field will impose a significant burden on POs.

*Outstanding Concerns*

We also wish to reiterate several of the comments made by NPA and others in response to the 60-day notice that were not reflected or addressed in the current proposal. We remain hopeful that CMS will continue to take these comments into consideration as the 2020 Audit Protocol is implemented:

- **Scope of data included in the On-Site Observation Participant List**. We reiterate concerns that the scope of this list as currently proposed will create an unnecessarily excessive burden. While it is helpful that CMS proposes to allow POs more latitude with respect to how they report the required information to CMS, it will still prove burdensome for staff to transcribe data tracked in multiple formats into a document or documents that can be effectively used by auditors. To provide this information in a workable format for auditors, POs will need to transcribe manually data from numerous sources. And at present, the request encompasses virtually all PACE participants largely as a result of including all participants scheduled to receive home care. Thus, we encourage CMS to reconsider previous recommendations put forward that the agency limit in some manner the number of participants for which these data elements must be provided.

- **Appropriately Limit Required Root Cause Analyses (RCAs) and IAs**. We echo NPA's request that CMS limit when POs must undertake RCAs to include only those situations in which reasonable thresholds trigger such requirements. We understand that auditors currently require RCAs in virtually all situations when an instance of non-compliance has been observed in sample cases. We recommend that auditors be instructed to exercise reasonable discretion with respect to whether RCAs are required, such that a single or even a minimal number of issues of non-compliance need not automatically trigger an RCA.

  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 still require an IA. We agree with NPA that RCAs, taken together with dialogue between auditors and PO staff, can provide POs and their auditors considerable insight into the

scope of most issues. We strongly recommend that auditors be instructed to exercise more discretion or that CMS raise the threshold for requiring IAs.

- **Improve Access to Audit Review Opportunities for POs.** Consistent with comments provided in response to the 60-day notice, we recommend that CMS establish a process through which POs have access to the PACE Audit Consistency Team (PACT). This process would allow POs 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.

- **Allow certain staff to oversee audits involving Electronic Medical Records (EMRs).** In situations in which auditors access PACE participants' EMRs, either remotely or onsite, we recommend that CMS permit a PO staff member who is experienced with the EMR system to be present or be permitted to electronically facilitate access to necessary information. We believe this approach would decrease the number of documentation requests made of POs, which in turn require scanning and uploading of documentation in HPMS. We are hopeful this can reduce considerably the burden POs are experiencing as a result of documentation requests.

**Conclusion**

We sincerely appreciate your consideration of these comments. If you have any questions, or if there is any additional information we can provide, please do not hesitate to contact me at melissa.mcpherson@ascension.org or 316-946-5341, or reach out to Mark Hayes, Senior Vice President for Policy and Advocacy for Ascension, at 202-898-4683 or mark.hayes@ascension.org.

Sincerely,

Melissa C. McPherson

Melissa McPherson
Executive Director
Via Christi Healthcare Outreach Program for Elders, Inc. (HOPE)