Ascension

Centers for Medicare & Medicaid Services
Office of Strategic Operations and Regulatory Affairs
Division of Regulations Development
Attention: OMB Control Number 0938-1327
7500 Security Boulevard
Baltimore, MD 21244-1850

May 28, 2019

Submitted electronically via: www.regulations.gov

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

To Whom It May Concern:

Ascension Living appreciates the opportunity to submit comments in response to the Information Collection Request regarding revision with changes of a currently approved collection, *Programs of All-Inclusive Care for the Elderly (PACE) 2020 Audit Protocol (CMS-10630)*.[1]

Ascension Living is a mission-driven senior care and living provider deeply connected to our Catholic faith that cares for the physical, mental, spiritual and social well-being of all individuals we serve. Our Mission calls us to provide spiritually centered, holistic care to seniors, particularly those most in need. We offer a wide range of programs tailored to meet the unique needs of older adults. Regardless of each individual's stage in life, our goal is to provide seniors with opportunities designed to make their lives joyful, enriching and satisfying. With communities in 11 states and the District of Columbia, our ministries are continually developing and adopting new best practices in care that enhance the experiences of our residents, program participants and patients. We also deliver care through live-at-home programs and PACE.

Ascension Living 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. 9526 (Mar. 15, 2019).

Background

Beginning in audit year 2020, CMS proposes to increase the number of data collection tools from 18 to 31 documents, as outlined in the supporting statement. CMS states that the data collected with the data request tools included in this package is intended to allow CMS to conduct a comprehensive review of PACE organizations' compliance in accordance with specific federal regulatory requirements. Based on our review of the proposed changes to this information collection, we are concerned that some of the new and added data collections could prove extremely burdensome for our PACE programs, which seems at odds with the Administration's desire to reduce regulatory burden rather than increase it. While we focus the majority of our comments on the proposed changes to the PACE Audit Process and Data Request, we support additional input offered by the National PACE Association on this and other aspects of the proposed changes to the existing information collection.

Burden Estimate (Total Hours &Wages)

CMS estimates that each audit under the new protocol will require approximately 150 hours per person for each PACE organization (PO), or 600 hours total per PO. CMS further estimates that the cost for a single PO to undergo a CMS PACE audit will amount to $41,250. As a threshold matter, we are concerned that this is a significant underestimate of the time associated with preparing for, engaging in, and responding to an audit. Given our experiences to date with the audit process, we believe the hours involved – all of which represent a diversion of clinician and staff resources away from patient care – are likely to exceed what CMS has estimated by at least several hundred additional hours. In accordance with CMS's broader Patient Over Paperwork initiative, we strongly encourage CMS to work with the PACE industry to evaluate ways the audit process can be streamlined, to reduce clinician and staff burden and ensure resources are most appropriately invested in patient care.

PACE Audit Process and Data Request

As noted above, we have focused the majority of our review and comments on the proposed changes to CMS's PACE Audit Process and Data Request, which we believe includes the majority of proposed changes and will have the most significant impact on our PACE programs.

In the section entitled *Universe Preparation & Submission*, CMS proposes to provide medical record samples for the Clinical Appropriateness and Care Planning Element will be provided to the PO 1 hour prior to the start of the review of medical records. We are very concerned that this limited timeframe will not allow for sufficient review that ensures a timely and complete response. We encourage CMS to provide medical record samples with more sufficient opportunity for review and evaluate.

In the section entitled *Audit Elements: Service Delivery Requests, Appeals and Grievances (SDAG)*, CMS proposes that the SDAG sample set will include 5 approved appeals. We would ask that CMS expressly clarify what steps should be taken if the PO does not have 5 approved appeals to include in the SDAG sample set.

In the section entitled *Appeal Request (AR) Record Layout*, CMS proposes new required documentation of "Time Appeal Received" and "Time of Written Notification." While these columns technically apply only to expedited appeals, we are concerned that this requirement could create added burden in terms of

requiring new electronic medical records (EMRs) time stamp documentation across all appeals; even standard appeals would require new entries of "NA". This can be cumbersome, and potentially costly to roll out – both in terms of system changes and training resources, as all persons documenting the receipt of an appeal and the provision of written notification would be required to document the time line differently in different cases. We appreciate that the expedited appeals process is measured in terms of hours (*i.e.*, 72 hours, subject to specified limited permissible extensions), but believe the current audit process and data elements have provided auditors sufficient information to assess the timeliness of expedited appeals. These proposed additions would instead run counter to CMS's overarching priorities related to reducing unnecessary burden on providers and increasing efficiencies, without enhancing the quality of patient care. As such, we urge CMS to refrain from finalizing these additional columns.

In the section entitled *List of Personnel (LOP) Record Layout*, CMS proposes to require that in the "IDT Member" column, the PO must enter Y if the employee is a part of the PO's IDT. If a PO has multiple IDTs, the PO should enter Y if this individual is a member of any IDT. We would ask that CMS clarify how POs should treat a scenario in which the IDT member has designated someone who is appropriate to fill in for him or her. For example, if the supervising Registered Nurse (RN) steps in for the usual IDT RN, we would appreciate guidance on how to complete this column appropriately for purposes of audit compliance.

In the section entitled *List of Participant Medical Records (LOPMR) Record Layout*, CMS proposes to require that POs provide two separate data elements: "Specialist Ordered Medications" and "Specialist Recommended Medications". CMS also proposes to require POs to provide separate data elements regarding "Delivery of Specialist Ordered Medications" and "Delivery of Specialist Recommended Medications". We are concerned that this data element does not account for the fact that all PACE providers order medications – or that specialists typically do not order medications but will recommend medications but defer to and coordinate with a participant's PACE provider(s), who then ultimately puts in the order. Additionally, these data elements will create significant burden, as noted in greater detail by the National PACE Association. However, as we appreciate the intent of these data elements, we would recommend that CMS finalize only the proposed columns of "Specialist Recommended Medications" and "Delivery of Specialists Recommended Medications."

Also proposed in this section (*LOPMR Record Layout*), CMS proposes to add a data element entitled "Significant Weight Gain" and revise an existing data element entitled "Significant Weight Loss". These new and revised weight gain/weight loss fields in the proposed LOPMR would require POs to report weight gain or loss of two points in 24 hours or five pounds in seven days. To provide this information, a detailed review of progress notes in the medical record would be required. We are also concerned that these new and revised data elements will be very hard for POs to quantify as it is not usual practice to weigh participants on a daily basis, absent a necessitating condition or encounter.

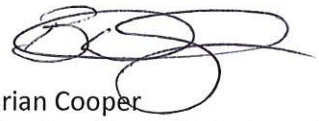
Finally, CMS proposes two additional new data elements in this section: "Low Blood Glucose Level" and "High Blood Glucose Level". We are concerned these proposed data elements are not the most appropriate measures of whether diabetes is being appropriately controlled. We instead recommend to CMS that a better measurement would be Hemoglobin A1C, which is the gold standard for diabetic control.

Conclusion

We sincerely appreciate your consideration of these comments and those offered by the National PACE Association. If you have any questions, or if there is any additional information we can provide, please do

not hesitate to contact me at 314-729-3500 or brian.cooper@ascension.org, or reach out to Mark Hayes, Senior Vice President for Federal Policy and Advocacy for Ascension, at 202-898-4683 or mark.hayes@ascension.org.

Sincerely,



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