November 21, 2022

William N. Parham, III
Director
Paperwork Reduction Staff
Office of Strategic Operations and Regulatory Affairs
Centers for Medicare and Medicaid Services
200 Independence Avenue, SW
Washington, DC 20201

Submitted via: Public Comment (reginfo.gov)

Re: Information Collection Request: Medicare and Medicaid; Programs for All-Inclusive Care for The Elderly (PACE) Contained in 42 CFR Part 460 (CMS-R-244) (ICR Reference Number: 202210-0938-012)

Dear Director Parham:

On behalf of the 148 operating Programs of All-Inclusive Care for the Elderly (PACE) organizations in 32 states – and numerous additional entities pursing PACE development and supportive of PACE – the National PACE Association (NPA) appreciates the opportunity to comment on the proposed revision of a currently approved PACE information collection.[1] The information collection delineates updated administrative burden and cost estimates anticipated of PACE organizations (POs) and other stakeholders to comply with PACE federal regulatory requirements.

PACE organizations (POs) serve among the most vulnerable of Medicare and Medicaid populations— medically complex older adults over age 55 who are State certified as requiring a nursing home level of care. The average PACE participant has nearly 6 medical conditions, many of which are chronic conditions that include diabetes, dementia, coronary artery disease and cerebrovascular disease. Over half of all PACE participants require assistance with various activities of daily living (ADL), including dressing, bathing, and transferring. PACE's objective is to safely maintain the independence of older individuals with medically complex needs or disabilities in their homes and communities for as long as possible. POs currently serve over 62,000 patients, known as participants, nationwide.

The Contract Year (CY) 2022 Policy and Technical Changes to the Medicare Advantage Program, Medicare Prescription Drug Benefit Program, Medicaid Program, Medicare Cost Plan Program, and PACE final rule (2021 PACE final rule)[2] required POs, by January 1, 2022, to update several policies and procedures (P&Ps). These include those related to service determination requests (SDRs); medical record documentation; training for

[1] 87 Fed. Reg. 64052 (October 21, 2022).
[2] 86 Fed. Reg. 5864 (January 19, 2021).

employed and contracted staff on revised requirements; and participant bill of rights and enrollment agreements, among other actions. NPA's comments on CMS' proposed burden estimates associated with PACE operational requirements, including significant revisions codified in the 2021 PACE final rule, follow.

- **460.32 Content and Terms of PACE Program Agreement: SAE (No Change) –** Based on feedback from our membership, 15 hours is an appropriate approximation of the time it takes a PO to work with CMS to update the program agreement upon approval of a service area expansion (SAE) application.

- **460.98(b)(5) Service Delivery: Policies and Procedures –** Based on feedback from our members, CMS' one-time burden estimate of 50 hours to implement the revised requirement (pursuant to the 2021 PACE final rule)[3] of POs to document, track, and monitor the provision of services across all care settings, regardless of whether services are formally incorporated into a participant's plan of care, is far too low. One PO indicates a more realistic time estimate as 450 hours.

  Specifically, the PO's estimate is based on it having updated 18 policies and procedures (P&Ps) to comply with the 2021 PACE final rule at an average time of 25 hours per P&P. Updating PACE P&Ps requires a thorough review by policy technical writers along with subject matter experts. This process ensures P&Ps are written clearly and concisely and are not simply a regurgitation of the regulations. All updated P&Ps are vetted through the PO's internal Policy Integration Committee.

- **460.112 Specific Participant Rights: Update Participant Rights –** The Participant Rights document is a critical document. It requires a thorough review and thoughtful edits to ensure participants are accurately informed of how the recent changes affect them. Based on informal feedback of NPA members, we believe a more appropriate time estimate to account for the time and effort to appropriately update the participant rights is 4 hours (versus the 2 hours approximated by CMS).

- **460.121 SDRs (New) –** CMS includes new burden estimates associated with written notification for SDR extensions; and creating and revising the SDR extension and denial notification template letters. Based on NPA feedback from select POs, while CMS' new one-time burden of 2 hours to create and revise the SDR extension and denial notification template may be appropriate for most POs, it fails to account for significant related SDR compliance considerations. Specifically, the limited burden estimate does not account for POs' review and education pertaining to the new SDR process, development of the new SDR protocol and staff education training materials, as well as initial and ongoing SDR training. One PO notes for example that, due to the intricacies of the updated SDR process, it is continuously educating staff via in-person and open forum training sessions, as well as through peer-to-peer (i.e., PO-to-PO) continuous learning.

  Another PO estimates the following hourly burden to comply with the revised SDR requirements, which took effect in January 1, 2022. The estimate accounts for Calendar Year (CY) 2021-2022 period SDR-related compliance for the PO with an aggregate census of nearly 800 participants:

[3] *Ibid.*

SDR-related Compliance Activity	CY 2021 Total Hours	CY 2022 Total Hours
Review and preparation of initial and ongoing education materials, resources (e.g., FAQs, case studies)	20	16
Staff training (initial and ongoing education)	56	100
Tracking, including follow-up with staff, and Electronic Health Record (EHR) note comparison		520
Compliance performance reporting, leadership discussions		6
Auditing records for compliance with SDR process		135
Total Hours	76	777

- **460.122(g) PO Appeals Process: Appeal Decision Notification –** CMS estimates the time burden to notify CMS and the State Administering Agency (SAA) of an adverse determination for an appeal to be approximate 5 minutes per notification. Based on feedback we received from NPA members, we estimate that 1 hour per notification is a more accurate approximation to ensure all information is communicated appropriately to CMS and the SAA, and to allot for any time related to further communication and follow-up.
- **460.210 Medical Records –** NPA's feedback on the estimated time associated with new requirements of POs related to medical records, including the revision of policies and procedures; maintenance of original documentation; and documenting records follows.
    - **Revision of Policies and Procedures:** As noted in comments above pertaining to PO compliance with SDR requirements, feedback from our members suggests that the time burden to update each P&P is approximately 25 hours. Considering this, coupled with the training requirements of the Compliance officer regarding such revisions, we suggest a more accurate estimate of 50 hours to revise select P&Ps.
    - **Keeping Original Documentation:** Based on NPA member feedback, it is not reasonable to estimate that PACE programs will only spend 10 hours annually to ensure all communication documentation for every participant enrolled is reviewed, validated, and maintained in the medical record. NPA feels strongly that 520 hours annually (or 10 hours per week) is a more reasonable estimate, especially when considering larger PO participant census.
    - **Documenting Recommendations:** CMS estimates the time burden to document recommendations for services from PO employees or contractors, including specialists, and the requirement of POs to document the reason a service is not approved or provided, to be 1 hour a week for a total of 52 hours annually. Considering the time it takes for the interdisciplinary team (IDT) to discuss the information and ensure all necessary information is captured for each

participant, we feel a more appropriate estimate is 250 hours annually, or approximately 1 hour per weekday.

Thank you in advance for considering our feedback. Should you have any questions or wish to discuss our comments further, please contact Katie Pahner, vice president, Regulatory Affairs, at katiep@npaonline.org or (703) 615-6473.

Sincerely,

R. Peter Fitzgerald
Executive Vice President, Policy and Strategy