



May 12, 2025

Honorable Robert F. Kennedy Jr.
Secretary
U.S. Department of Health and Human
200 Independence Ave SW
Washington, DC 2001

Honorable Russell T. Vought
Director
Office of Management and Budget
725 17th Street NW
Washington, DC 202503

Honorable Mehmet Oz, M.D.
Administrator
Centers for Medicare & Medicaid Services
7500 Security Boulevard
Baltimore, MD 21244-1850

Submitted electronically via Regulations.gov

RE: Request for Information: Deregulation (FR Doc. 2025-06316)

Dear Secretary Kennedy, Administrator Oz and Director Vought:

On behalf of the 185 operating Programs of All-Inclusive Care for the Elderly (PACE) organizations in 33 states and the District of Columbia - and numerous additional entities pursuing PACE development and supportive of PACE - the National PACE Association (NPA) appreciates the opportunity to comment on the Office of Management and Budget's (OMB) request for information (RFI) soliciting ideas for deregulation across the country.¹

As the need for long-term services and supports (LTSS) continues to rise, NPA is advancing policy solutions that reduce administrative burden, lower costs, and expand access to high-quality care in the home and community. Home and community-based service (HCBS) providers play a critical role in supporting older adults and individuals with disabilities, yet individuals who depend on these services often face significant administrative and enrollment barriers hindering their access to PACE. NPA's recommendations focus on improving CMS' PACE application and enrollment procedures, addressing affordability challenges, and ensuring that individuals can access the full range of LTSS they need to live safely and independently. Reducing unnecessary red tape will help PACE organizations (POs) devote more time to care delivery and less to paperwork. By modernizing access pathways and

¹ OMB, "Request for Information: Deregulation," April 11, 2025, <https://www.federalregister.gov/documents/2025/04/11/2025-06316/request-for-information-deregulation>; and <https://www.regulations.gov/document/OMB-2025-0003-0001>.

aligning regulatory requirements, we can strengthen the HCBS infrastructure and improve outcomes for millions who depend on it.

POs serve among the most vulnerable and expensive 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 objective of PACE is to maintain older adults’ independence in their homes and communities for as long as possible. Fully integrated POs provide patients, known as participants, with all necessary medical, behavioral, and LTSS to maintain or improve participants’ health. POs currently serve over 83,000 participants nationwide.

Identified as an evidence-based care model by the Department of Health and Human Services (HHS),² POs achieve high quality outcomes for their participants as well as for Medicare and Medicaid. The PACE model of care was highlighted as a consistently “high performer” in an analysis of integrated care models published by HHS. That study also found “that full-benefit dual eligible beneficiaries in PACE are significantly less likely to be hospitalized, to visit the ED, or be institutionalized,” in comparison to the control group.³

The hallmark of the PACE model is the interdisciplinary team (IDT) comprised of primary care providers, nurses, social workers, physical and occupational therapists, recreational therapists or activity coordinators, dietitians, PACE center managers, home care coordinators, drivers and personal care aides or their representatives. These individuals comprehensively assess participants’ care needs and develop and implement comprehensive, fully integrated care plans providing many services directly in the PACE center and participants’ homes. Additional services needed are provided through POs’ contracts with other providers.

Due to the extensive health care needs of PACE participants, POs interact with participants and their family caregivers on a regular and frequent basis, often daily. In addition to providing medical care, POs and their staff provide extensive LTSS, including adult day center services, in-home services, dementia care, palliative, end-of-life (EOL) care and much more. PO staff are frequently in participants’ homes and involved in all aspects of their care due to the intensity of participants’ needs.

The comments offered in response to OMB’s RFI were developed with the extensive involvement of NPA’s membership. They reflect a thorough understanding of both the statutory and regulatory underpinnings of PACE and the operational experiences of POs.

² HHS, “Aging and Disability Evidence-Based Programs and Practices,” Last modified on January 31, 2018, <https://acl.gov/programs/strengthening-aging-and-disability-networks/aging-and-disability-evidence-based-programs>.

³ Zhanlian Feng et al., “Comparing Outcomes for Dual Eligible Beneficiaries in Integrated Care: Final Report.” HHS, <https://aspe.hhs.gov/reports/comparing-outcomes-dual-eligibles>.

Recommendations to Mitigate Excessive Regulatory Burden in PACE

NPA respectfully offers the following recommendations to reduce unnecessary and excessively burdensome federal PACE regulations, where the cost to comply with the regulation exceeds the benefit and, in several areas noted below, impedes Medicare and Medicaid beneficiaries' access to care.

Mitigate Barriers to CMS PACE Application Process that Impede PACE Access, Enrollment	<p>To ensure more PACE-eligible individuals have geographic access to PACE, especially in rural communities, we recommend CMS remove administrative barriers in the provider and participant PACE application process. These unnecessary and, in some cases, duplicative requirements delay PACE center openings, imposing an undue financial burden on POs and, importantly, delay participants' access to PACE services. Specifically, NPA recommends that CMS:</p> <p><i>PACE Participant Enrollment Barriers</i></p> <ul style="list-style-type: none">• Eliminate the current regulatory limitation of participant enrollment on the first day of the month to allow for mid-month enrollment (42 CFR §460.158). Doing so would help to ensure that qualifying individuals do not unnecessarily experience gaps in their care or in accessing PACE. If for any reason an enrollment application is delayed, and the individual misses the cut off to begin receiving PACE services on the first of the month, they must wait another full month. This can lead to a deterioration in their health or require them to find a different long-term care option. Simply put, it ought to be as easy to enroll in PACE as it is for an individual to enter a nursing home, if it is their choice to do so. <p><i>Barriers to Expanding Geographic Access to PACE</i></p> <ul style="list-style-type: none">• Streamline CMS' review of applications for new PACE programs and service area expansions (SAEs). Generally, it takes between 18-24 months to
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initiate a new PACE program⁴, with a medium cost to programs of approximately \$5.83 million (amount adjusted for inflation between 2003 and 2022).⁵ The extensive time and cost it currently takes to start up a PACE program or expand an existing program unnecessarily delays or prevents beneficiaries from accessing PACE. Specifically, NPA recommends that CMS:

- **Remove unnecessarily stringent application criteria for established POs in good standing.** This streamlining could include: (a) permitting established POs to add a new PACE center in an *existing* service area through a public notice process, foregoing the current SAE application requirement (42 CFR §§ 460.10, 460.12); and (b) allowing POs to have multiple applications under concurrent CMS review, such that the PO with an application under review is not precluded from submitting another application. Our understanding is that the latter is a limitation effectuated via CMS sub-regulatory guidance.
- **Increase the frequency at which CMS accepts applications for new and expanding POs from quarterly to monthly.** This change requires no statutory or regulatory change since the limitation was effectuated via CMS sub-guidance.⁶

⁴ Colin Higgins and Tom Stitt, "PACE Growth Post COVID-19." Health Dimensions Group, August 24, 2023, <https://healthdimensionsgroup.com/insights/blog/pace-growth-post-covid-19/#:~:text=PACE%20PHILOSOPHY%20AND%20NEW%202023%20PROGRAMS&text=The%20number%20of%20new%20PACE,by%20time%20frame%20of%20opening.&text=Not%20including%20the%20first%20half,new%20programs%20has%20remained%20stable>.

⁵ Bipartisan Policy Center, "Improving Access to and Enrollment in Programs of All Inclusive Care for the Elderly (PACE)." October 2022, https://bipartisanpolicy.org/download/?file=/wp-content/uploads/2022/10/BPC_PACE_Report_Final.pdf.

⁶ CMS, "2025 PACE Application Quarterly and Waiver Request Submission Dates." <https://www.cms.gov/files/document/2025-pace-application-quarterly-and-waiver-request-submission-dates.pdf>.

	<ul style="list-style-type: none"> ○ Clarify in the CMS Readiness Review Tool,⁷ used by State Administering Agencies (SAAs) to review non-operational PO applicants, that states may accept attestations from the PO that staff will be employed by the time the PACE center becomes operational. This is an administrative action that CMS could take, without necessitating rulemaking or a preceding statutory change, to effectuate, and one that would go a long way toward extending geographic access to PACE. ● Remove the anti-competitive and outdated federal regulatory limitation at 42 CFR § 460.24 that limits the total number of PACE programs that can be operational. This arbitrary and outdated regulatory limitation serves to further exacerbate beneficiaries’ barriers to accessing PACE, not to mention puts POs on an uneven playing field with Medicare Advantage (MA) plans, the latter of which are not subject to such anti-competitive requirements.
<p>Expand Access to Integrated Care Options, Including PACE, through CMS Innovation Center Models</p>	<p>There are more than 12 million older adults needing LTSS in our nation, including an estimated 2 million low-income older adults with complex care needs who could benefit from PACE enrollment. To provide improved access for these populations to the integrated, coordinated, comprehensive and person-centered care provided by fully risk-bearing PACE organizations, NPA respectfully requests that the CMS Innovation Center initiate PACE-specific model tests pursuant to the authority codified in the PACE Innovation Act (PIA) of 2015.</p> <p>NPA welcomes the opportunity to discuss opportunities with CMS to leverage section 1115A statutory authority to expand access to PACE. Suggested models include those</p>

⁷ CMS, “State Readiness Review Tool,” <https://www.cms.gov/Medicare/Health-Plans/PACE/Downloads/Statereadinessreviewtool1103.pdf>.

	that would: (a) address Part D affordability in PACE by allowing Medicare-only PACE participants the option to enroll in lower-cost marketplace Part D plans; (b) expand access to PACE in rural areas, as well as to additional high-need, high-cost individuals; and (c) facilitate access to HCBS, including PACE, through Medicaid presumptive financial eligibility.
Alleviate Burden Associated with New Federal Requirements	In the Contract Year (CY) 2025 MA, Part D and PACE Final Rule, CMS codified significant new federal regulatory requirements of POs that took effect January 1, 2025. ⁸ These provisions include new service delivery and care coordination timeframes in which the onus is placed not only on the PO but also the contracted long-term care provider or hospital to do its part for the PO to be deemed compliant (42 CFR §§ 460.98 and 460.102). CMS estimated that, in total, POs would incur a cost of \$2.1 million in CY 2025 to implement the PACE provisions in the final rule.
PACE Marketing Restrictions	NPA requests the elimination of the regulatory stipulation at 42 CFR § 460.82, underscored in CMS' PACE Marketing Guidelines (updated in 2018), that precludes POs' ability to begin marketing to prospective participants until the PO is operational. NPA also recommends the elimination of 42 CFR § 460.82(e)(5) that limits POs ability to engage in direct marketing. These regulatory prohibitions are overly stringent considering CMS' rigorous and thorough approval of all PO marketing materials to ensure compliance with federal regulations and prevent deceptive or misleading practices.
Targeted Telehealth Flexibilities	POs provide comprehensive, person-centered care for older adults with chronic conditions in the PACE center and in participant's homes. Telehealth is an important tool available to health care providers, including POs, to ensure uninterrupted access to essential services, especially for individuals living in rural communities. However, current

⁸ CMS, "Medicare Program; Changes to the Medicare Advantage and the Medicare Prescription Drug Benefit Program for Contract Year 2024-Remaining Provisions and Contract Year 2025 Policy and Technical Changes to the Medicare Advantage Program, Medicare Prescription Drug Benefit Program, Medicare Cost Plan Program, and Programs of All-Inclusive Care for the Elderly (PACE)," 89 Fed. Reg. No. 79, April 23, 2024, <https://www.federalregister.gov/documents/2024/04/23/2024-07105/medicare-program-changes-to-the-medicare-advantage-and-the-medicare-prescription-drug-benefit>.

	<p>federal regulations (42 CFR § 460.104) significantly limit POs' ability to leverage telehealth to conduct participant assessments.</p> <p>While in-person participant assessments are an integral part of the care model and drive the delivery and coordination of comprehensive care and services to PACE participants, there may be select circumstances under which, when medically necessary and with participant consent, conducting a remote assessment may be in the participant's best interest (e.g., when a participant is sick and wishes not to come into the PACE center for an unscheduled assessment). We recommend CMS provide enforcement discretion to POs in limited circumstances and with appropriate documentation and participant consent.</p>
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In closing, we appreciate your consideration of NPA's comments. For questions or additional information, please do not hesitate to reach out to me at katiep@npaonline.org.

Sincerely,



Katie Pahner
Vice President, Regulatory Affairs