

DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
7500 Security Boulevard
Baltimore, Maryland 21244-1850



MEDICARE PARTS C & D OVERSIGHT AND ENFORCEMENT GROUP

August 23, 2024

Ms. Jessica Petro
Vice President and Executive Director
PACE4DC, LLC
2211 Town Center Drive SE
Washington, DC 20020

Re: Notice of Imposition of Sanction to Suspend Enrollment of Programs of All-inclusive Care for the Elderly (PACE) participants into contract number: H9564

Dear Ms. Petro:

Pursuant to the authority of sections 1894(e)(6)(B) and 1934(e)(6)(B) of the Social Security Act (the Act) and 42 C.F.R. §§ 460.40(b) and 460.42(a), the Centers for Medicare & Medicaid Services (CMS) hereby notifies PACE4DC, LLC (PACE4DC) that, effective August 24, 2024, CMS is suspending PACE4DC's enrollment of new Medicare beneficiaries under contract number H9564.

CMS has concluded that PACE4DC failed substantially to comply with the conditions of the PACE program or the terms of its PACE program agreement. This determination was made as a result of PACE4DC failing to correct deficiencies discovered during its 2024 PACE initial comprehensive review (ICR).¹ CMS has determined that the seriousness of these deficiencies requires the suspension of any new enrollments of Medicare beneficiaries into PACE4DC.

The enrollment sanction will remain in effect until CMS is satisfied that PACE4DC has corrected the causes of the violations, and the violations are not likely to recur. This enrollment suspension will apply to the enrollment of all Medicare beneficiaries regardless of their Medicaid eligibility status.

¹ Sections 1894(e)(4)(A) and 1934(e)(4)(A) of the Act and implementing regulations at 42 C.F.R. §§ 460.190 and 460.192 mandate that CMS, in cooperation with the State Administering Agency (SAA), evaluate PACE organizations annually for the first 3 contract years during the PACE organization's trial period. Therefore, CMS conducts an ICR for all PACE organizations in the first year of the trial period. 2024 was the first year CMS conducted ICRs instead of full audits for first-year trial period audits.

Background

PACE4DC currently has 72 participants and offers a PACE program operating in the District of Columbia (H9564). PACE4DC began operations in 2023, and CMS conducted an ICR of the organization in January 2024 as mandated by statute. During the ICR, CMS identified substantial issues of non-compliance. Auditors found that PACE4DC did not provide all approved services and did not track, document, and monitor the provision of services across all care settings. PACE4DC had insufficient providers and staff to provide all the necessary services and failed to understand PACE program requirements.

On March 13, 2024, CMS provided notice to PACE4DC that PACE4DC would need to promptly correct the deficiencies identified in the ICR within 60 days. Additionally, PACE4DC was given notice that CMS had significant concerns with the non-compliance identified during the ICR and although CMS was not taking an enforcement action at that time, failure to correct these issues or identification of additional substantial non-compliance of PACE program requirements would result in another referral to determine if enforcement actions are warranted.

CMS, along with the State Administrating Agency (SAA), conducted monitoring activities for 60 days after the ICR which consisted of weekly technical support calls. During the monitoring activities, representatives from CMS and the SAA found that PACE4DC had failed to correct issues identified in the ICR. Additionally, PACE4DC disclosed to CMS on July 30, 2024, that PACE4DC still had not implemented several key compliance activities including self-monitoring audits and service/appointment trackers. As a result, PACE4DC continues to have substantial failures of the PACE program requirements.

Violations of the PACE program requirements include:

- Failure to provide care that meets the needs of each participant across all care settings, 24 hours a day, every day of the year;
- Failure to ensure accessible and adequate services to meet the needs of participants;
- Failure to document, track, and monitor the provision of services across all care settings;
- Failure to document the reason(s) for not approving or providing services recommended by employees or contractors, including specialists; and
- Failure to appropriately categorize and process service determination requests.

Given the nature of the deficiencies and the critical need for PACE4DC to correct these issues, CMS has determined that a suspension of enrollment is the appropriate enforcement action.

PACE Program Requirements

The PACE program provides comprehensive medical and social services to certain frail, elderly individuals, most of whom are dually eligible for Medicare and Medicaid benefits. PACE

programs are designed to provide a range of integrated preventative, acute care, and long-term care services to manage the often complex medical, functional, and social needs of the frail elderly. Health care services provided by PACE organizations are designed to meet the following objectives:

- Enhance the quality of life and autonomy for frail, older adults;
- Maximize dignity of, and respect for, older adults;
- Enable frail, older adults to live in the community as long as medically and socially feasible; and
- Preserve and support the older adult's family unit.

PACE Required Services

(Sections 1894(b)(1)(A), (B), and (D) and 1934(b)(1)(A), (B), and (D) of the Act; 42 C.F.R. §§ 460.70(a), 460.90(b), 460.92, and 460.98(a))

A PACE organization must provide all items and services that are covered or specified under the PACE statute and regulations, including all Medicare- and Medicaid-covered items and services, and other services determined necessary by the IDT to improve and maintain the participant's overall health status. Participants must have access to necessary covered items and services 24 hours per day, every day of the year. In implementing that requirement, a PACE organization must establish and implement a written plan to furnish care that meets the needs of each participant in all care settings.

While a participant is enrolled in the PACE organization, he or she must receive Medicare and Medicaid benefits solely through the PACE organization. If the PACE organization cannot provide those items and services directly, it must specify them and arrange for the delivery of those items and services through a contractor. A PACE organization must have a written contract with each outside organization, agency, or individual that furnishes administrative or care-related services not furnished directly by the PACE organization, except for emergency services.

Interdisciplinary Team, Plan of Care, Primary Care Provider, and Service Delivery

(Sections 1894(f)(2)(B)(iii) and 1934(f)(2)(B)(iii) of the Act; 42 C.F.R. §§ 460.98, 460.102, 460.104, 460.106, and 460.210(b)(4) and (5))

PACE organizations are required to establish an IDT, composed of members filling specific roles at each PACE center, to comprehensively assess and meet the individual needs of each participant. The IDT is responsible for conducting initial assessments and periodic reassessments of participants, developing and executing a plan of care, and coordinating 24-hour care delivery. The IDT must continuously monitor the participant's health and psychosocial status, as well as the effectiveness of the plan of care, through the provision of services, informal observation, input from participants or caregivers, and communications among members of the IDT and other providers in implementing the plan of care for a participant.

Each IDT member is responsible for the following:

- Regularly informing the IDT of the medical, functional, and psychosocial condition of each participant;

- Remaining alert to pertinent input from any individual with direct knowledge of or contact with the participant; and
- Documenting changes in a participant's condition in the participant's medical record consistent with policies established by the medical director.

The PACE organization must document, track, and monitor the provision of services across all care settings in order to ensure the IDT remains alert to the participant's medical, physical, emotional, and social needs regardless of whether services are formally incorporated into the participant's plan of care. In addition, the PACE organization must ensure that participants receive any services authorized or approved by the IDT in a manner that meets the participants' needs.

One of the required members of the IDT is the participant's primary care provider (PCP). PCPs are responsible for managing a participant's medical situations and overseeing a participant's use of medical specialists and inpatient care. In order for the PCP (and IDT) to accomplish this, the participant's medical record must include all recommendations for services made by employees or contractors of the PACE organization, including specialists. If a service recommended by an employee or contractor of the PACE organization, including a specialist, is not approved or provided, the medical record must include the reason(s) for not approving or providing that service.

In order for PACE organizations to ensure that services are accessible and adequate to meet the needs of participant, PACE organizations must be sufficiently managed, staffed, and equipped to provide the necessary care. Delays in receiving necessary services can result in adverse outcomes for participants.

Service Determination Requests (42 C.F.R. § 460.121)

Each PACE organization must have formal written procedures for identifying and processing service determination requests in accordance with the PACE requirements. A service determination request is a request to initiate a service, to modify an existing service (including to increase, reduce, eliminate, or otherwise change a service); or to continue coverage of a service that the PACE organization is recommending be discontinued or reduced. A participant, participant's designated representative, or participant's caregiver may make a service determination request.

Description of Non-Compliance

PACE4DC substantially failed to comply with the conditions of the PACE program or terms of its PACE program agreement due to three primary reasons: (1) PACE4DC failed to provide services that were adequate to meet the needs of its participants; (2) PACE4DC failed to provide services recommended by employees or contractors, including specialists, or failed to document a reason for not approving, or providing the services; and (3) PACE4DC failed to appropriately categorize and process service determination requests.

1. *PACE4DC failed to provide services that were adequate to meet the needs of participants.*

PACE4DC failed to provide services that were adequate to meet the needs of participants. In addition, PACE4DC failed to provide services that were approved by the IDT because it did not effectively document, track, and monitor the provision of services across all care settings. PACE4DC did not have adequate processes in place to track and ensure approved services were scheduled and provided. For example, during the ICR, auditors found that PACE4DC did not provide or schedule 19 services for one participant. After PACE4DC was given the opportunity to correct these issues, auditors found that there were still six services that had not been scheduled or provided for that same participant. Additional instances of PACE4DC failing to provide approved services were also identified during the 60-day correction period. In some cases, there was no documentation to support whether physician-ordered services were completed. As a result, participants did not receive services that were ordered, care-planned, or approved by the IDT.

2. *PACE4DC failed to provide services recommended by employees or contractors, including specialists, or failed to document a reason for not approving, or providing the services.*

PACE4DC did not ensure that all recommendations made by employees and/or contractors, including specialists, were received and documented in the participant medical records. Also, PACE4DC did not have an effective process to ensure its IDT either approved and provided recommended services or documented the rationale for not approving recommended services. As a result, contractor recommendations, including specialists were either never provided to the participants or discussed by the IDT to determine if they were necessary. This was found during the ICR as well as after the ICR during the 60-day correction period.

3. *PACE4DC failed appropriately categorize and process service determination requests.*

PACE4DC did not appropriately categorize and process service determination requests (SDRs) because it did not follow the SDR process. During the ICR and the 60-day correction period, auditors found several instances where services were requested and SDRs were not initiated. As a result, PACE4DC did not appropriately assess participant needs and provide necessary care and services.

Violations of PACE Requirements

CMS has determined that PACE4DC violated the following PACE requirements:

1. PACE4DC failed to ensure participants received necessary services. As a result, PACE4DC failed to (1) provide care that meets the needs of each participant across all care settings, 24 hours a day, every day of the year; and (2) ensure accessible and adequate services to meet the needs of its participants, in violation of 42 C.F.R. § 460.98(a) and (b).
2. PACE4DC failed to document, track, and monitor the provision of services across all care settings. As a result, IDT-approved services were not provided to participants, in violation of 42 C.F.R. § 460.98(b)(4).

3. PACE4DC failed to document services recommended by an employee or contractor of the PACE organization, including a specialist, and the reason(s) for not approving or providing a recommended service, if applicable. As a result, services were either never provided to the participants or discussed by the IDT to determine if they were necessary, in violation of 42 C.F.R. § 460.210(b)(4) and (5).
4. PACE4DC failed to categorize and process service determination requests. As a result, PACE4DC failed to initiate service determination requests, in violation of 42 C.F.R. § 460.121.

Basis for Enrollment Sanction

Pursuant to 42 C.F.R. §§ 460.40(b) and 460.50(b)(1)(ii), CMS may suspend enrollment into a PACE organization if CMS determines the organization substantially failed to comply with the conditions of the PACE program or the terms of its PACE program agreement. CMS has determined that PACE4DC's violations provide a sufficient basis for the imposition of sanctions as provided in 42 C.F.R. § 460.42(a).

Opportunity to Correct

Pursuant to 42 C.F.R. § 460.42(c), the enrollment suspension will remain in effect until CMS is satisfied that PACE4DC has corrected the causes of the violations which form the basis for the sanction and the violations are not likely to recur. PACE4DC is solely responsible for the development and implementation of its Corrective Action Plan (CAP), and for demonstrating to CMS that the underlying deficiencies have been corrected and are not likely to recur. CMS requests that PACE4DC submit a CAP to CMS that covers all violations which form the basis for the sanction within fourteen (14) calendar days from the date of receipt of this notice, or by September 7, 2024. If PACE4DC needs additional time beyond fourteen (14) days to submit its CAP, please contact your enforcement lead.

Validation Audit

PACE4DC will be required to undergo a validation audit of all the operational issues cited in this notice before the enrollment suspension will be lifted. Upon completion of the validation audit, CMS will determine whether the deficiencies that are the basis for the sanction have been corrected and are not likely recur.

Opportunity to Respond to Notice

PACE4DC may respond to this notice in accordance with the procedures specified in 42 C.F.R. §§ 460.56(a) and 422.756(a)(2). PACE4DC has ten (10) calendar days from the date of receipt of this notice to provide a written rebuttal, or by September 3, 2024. Please note that CMS considers the date of receipt to be the day after the notice is sent by fax, email, or overnight mail, or in this case August 24, 2024. If you choose to submit a rebuttal, please send it to the attention of Kevin Stansbury at the address noted below. Note that the sanction imposed pursuant to this letter are not stayed pending a rebuttal submission.

Right to Request a Hearing

This determination is effective on August 24, 2024. Pursuant to 42 C.F.R. §§ 460.56(a) and 422.756(b), PACE4DC may request a hearing before a CMS hearing officer in accordance with the procedures outlined in 42 C.F.R. Part 422, Subpart N. Pursuant to 42 C.F.R. § 422.662, your written request for a hearing must be received by CMS within fifteen (15) calendar days from the date CMS notified you of this determination, or by September 9, 2024.² Please note, however, a request for a hearing will not delay the effective date of the sanction.

The request for a hearing must be sent to CMS electronically to the CMS Office of Hearings (OH). OH utilizes an electronic filing and case management system, the Office of Hearings Case and Document Management System (“OH CDMS”).

PACE4DC should complete the one-time OH CDMS registration process as soon as possible after receiving this Notice, even if PACE4DC is unsure whether it will appeal CMS’s determination. After the registration process is complete, PACE4DC must then file its request for a hearing within the time frame set forth above.

Registration information (including how to add an outside representative/law firm to participate in the appeal), filing instructions and general information may be found on the OH webpage at <https://www.cms.gov/medicare/regulations-guidance/cms-hearing-officer/hearing-officer-electronic-filing>.

Follow the OH CDMS External Registration Manual for step-by-step instructions regarding registration and the OH CDMS Hearing Officer User Manual for appeal filing instructions.³

A copy of the hearing request should also be emailed to CMS at the following address:

Kevin Stansbury
Director, Division of Compliance Enforcement
Centers for Medicare & Medicaid Services
7500 Security Boulevard
Baltimore, MD 21244-1850
Mail Stop: C1-22-27
Email: Kevin.Stansbury@cms.hhs.gov

CMS will consider the date the Office of Hearings receives the request via the CDMS as the date of receipt of the request(s). The request for a hearing must include the name, fax number, and email address of the contact within PACE4DC (or an attorney who has a letter of authorization to represent the organization) with whom CMS should communicate regarding the hearing request.

² The 15th day falls on a weekend or holiday, therefore the date reflected in the notice is the next regular business day for you to submit your request.

³ If technical assistance is required, please contact the OH CDMS Help Desk at 1-833-783-8255 or by email at helpdesk_ohcdms@cms.hhs.gov. The hours of operation are Monday–Friday (excluding federal holidays) from 7:00 a.m. to 8:00 p.m. Eastern Time.

Please note that we are closely monitoring your organization, and PACE4DC may also be subject to other applicable remedies available under law, including the imposition of additional sanctions or penalties as described in 42 C.F.R. Part 460, Subpart D. If PACE4DC fails to correct the deficiencies cited in this notice, CMS may terminate the PACE program agreement pursuant to 42 C.F.R. § 460.50(b). In addition, if CMS determines that PACE4DC cannot ensure the health and safety of its participants, CMS will consider action to immediately terminate your PACE program agreement pursuant to 42 C.F.R. § 460.50(c).

If you have any questions about this notice, please call or email the enforcement contact provided in your email notification.

Sincerely,

/s/

John A. Scott
Director
Medicare Parts C and D Oversight and Enforcement Group

Enclosure:
Attachment A – Corrective Action Plan Template

cc: Kevin Stansbury, CMS/CM/MOEG/DCE
Kathleen Flannery, CMS/CM/MOEG/DPAO
Tamara McCloy, CMS/OPOLE
Annemarie Anderson, CMS/OPOLE
Kathy Covert, CMS/OPOLE