

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

May 17, 2024

Ms. Amy Bretz
Executive Director
PACE Partners of Northeast Florida, Inc.
5450 Ramona Blvd
Jacksonville, FL 32205

Re: Notice of Imposition of Sanction to Suspend Enrollment of Programs of All-inclusive Care for the Elderly (PACE) participants into contract number: H7469

Dear Ms. Bretz:

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 PACE Partners of Northeast Florida, Inc. (PACE of NE Florida) that, effective May 18, 2024, CMS is suspending PACE of NE Florida's enrollment of new Medicare beneficiaries under contract number H7469.

CMS has concluded that PACE of NE Florida 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 deficiencies discovered during the 2021, 2022, and 2023 audits by CMS. In addition, in 2024, CMS determined that PACE of NE Florida failed to comply with requirements to have contracts with certain medical specialists. CMS has determined that the seriousness of these deficiencies requires the suspension of any new enrollments of Medicare beneficiaries into PACE of NE Florida.

The enrollment sanction will remain in effect until CMS is satisfied that PACE of NE Florida 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.

Background

PACE of NE Florida currently has 128 enrolled participants and offers a PACE program operating in the state of Florida (H7469). This organization began operations in 2020 and for the first three years of operations, CMS conducted trial period audits of the organization, as mandated by statute. During the 2021, 2022, and 2023 trial period audits, CMS identified substantial issues of non-compliance.

Since the first-year trial audit conducted in 2021, PACE of NE Florida has experienced significant issues maintaining staff with sufficient knowledge of PACE program requirements. During this first-year trial audit, CMS found that many key roles, such as a home health coordinator and transportation coordinator, had not been filled. By the following year, PACE of NE Florida experienced significant turnover at all levels, including the Interdisciplinary Team (IDT). PACE of NE Florida stated many of the issues with continued non-compliance were the result of staff turnover, difficulty filling positions, and insufficient training at all levels, including physician providers, IDT members, leadership, management, and support staff. Because of these deficiencies, PACE of NE Florida failed to provide effective oversight to ensure compliance with PACE requirements and to adequately oversee day to day operations.

In addition to staffing issues, PACE of NE Florida failed to develop and implement quality improvement programs and an operational compliance program. A quality improvement plan was eventually approved by PACE of NE Florida's Board of Directors during the second-year trial audit but was not yet operationalized by the time of the third-year trial audit. PACE of NE Florida's lack of an effective compliance program has compounded the impacts of its inability to build and maintain a staff with knowledge and expertise in the PACE program. During the first- and second-year trial audits, PACE of NE Florida leadership and staff admitted to and demonstrated a considerable lack of understanding of PACE regulatory requirements. The PACE organization is still working to form a team that is knowledgeable in the regulatory requirements of the program. The third-year trial audit revealed that the PACE organization's staff still needed to be trained to complete essential tasks. As a result, PACE of NE Florida continues to have substantial failures of the PACE program requirements.

Also, auditors found that participants were not receiving services from certain medical specialists because PACE of NE Florida did not have executed contracts with those specialists. Changes to the PACE regulations that took effect on January 1, 2024, require PACE organizations to have contracts with certain medical specialists. *See* 42 C.F.R. § 460.70(a)(1). As of March 13, 2024, PACE of NE Florida did not have executed contracts with 14 of those specialists.

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 ensure reasonable and timely access to specialists as indicated by participants' health condition and consistent with current clinical practice guidelines;
- Failure to document, track and monitor the provision of services across all care settings;
- Failure to oversee participants' use of medical specialists and/or inpatient care; and
- Failure to conduct assessments as required in response to each service determination request.

Given the nature of the deficiencies and the critical need for PACE of NE Florida 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.

Starting on January 1, 2024, contracts with medical specialists must be executed prior to enrollment of participants and must be maintained on an ongoing basis to ensure participants receive appropriate and timely access to all medically necessary care and services. PACE organizations must have contracts in place for 26 specific medical specialties including anesthesiology, gastroenterology, gynecology, internal medicine, neurosurgery, oncology, ophthalmology, dentistry, oral surgery, pulmonology, rheumatology, urology, and thoracic and vascular surgery.

The PACE organization is responsible for making all reasonable and timely attempts to contract with medical specialists. If at any time a PACE organization is unable to directly contract or maintain a contract with a specific specialty, the PACE organization must: (i) ensure care and services that would otherwise be provided to participants by a contracted specialist are provided and that the participant's needs are met through a different mechanism to include hospitalization; and (ii) promptly report the contracting issue to CMS and the State Administering Agency, including the attempts made to contract, the reason why the contract was not effectuated, and the PACE organization's plan to provide access to the necessary 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, and 460.106)

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 other team members, participants, and caregivers; and
- Documenting changes in a participant's condition in the participant's medical record consistent with policies established by the medical director.

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

Service Determination Process
(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. If the IDT expects to deny or partially deny a service determination request, the appropriate members of the IDT, as identified by the IDT, must conduct an in-person reassessment before making a final decision. The team members performing the reassessment must evaluate whether the requested service is necessary to meet the participant's medical, physical, emotional, and social needs.

Description of Non-Compliance

I. PACE of NE Florida failed substantially to comply with the conditions of the PACE program or the terms of its PACE program agreement.

PACE of NE Florida substantially failed to comply with the conditions of the PACE program or terms of its PACE program agreement due to four primary reasons: (1) PACE of NE Florida failed to ensure participants received necessary services from certain specialists; (2) PACE of NE Florida is not tracking and monitoring the provision of services; (3) PACE of NE Florida's primary care providers did not oversee participants' use of medical specialists and/or inpatient care; and (4) PACE of NE Florida's IDT did not conduct assessments as required in response to each service determination request.

1. PACE of NE Florida failed to ensure participants received necessary services from certain specialists.

PACE of NE Florida failed to provide participants with necessary services from specialists including dentistry, oral surgery, and neurology services. Auditors discovered that there were 20 participants with pending neurology consultations. In addition, there are currently 44 participants with pending dental appointments and 11 pending dental procedures. PACE of NE Florida did not have standing contracts with these specialists. Even though PACE of NE Florida lacked contracts to secure these services, PACE of NE Florida is still responsible for furnishing all services covered under the PACE benefit, which includes all Medicare-covered items and services, all Medicaid-covered items and services, and all other services determined necessary by the IDT to improve and maintain the participant's overall health status.

Additionally, auditors found that PACE of NE Florida did not have contracts in place for the following medical specialties: anesthesiology, gastroenterology, gynecology, internal medicine, neurosurgery, oncology, ophthalmology, dentistry, oral surgery, pulmonology, rheumatology, urology, and thoracic and vascular surgery. Auditors continued to track PACE of NE Florida's progress in securing contracts with specialists and to ensure participants are receiving the services from specialists if necessary. As of March 13, 2024, PACE of NE Florida still did not have contracts in place for the following medical specialties: anesthesiology, gastroenterology, gynecology, internal medicine, oncology, dentistry, oral surgery, pulmonology, rheumatology, urology, and thoracic and vascular surgery. Therefore, there is a substantial likelihood that participants may not receive necessary services due to not having contracts with certain specialists.

2. *PACE of NE Florida did not document, track, and monitor the provision of services across all care settings.*

PACE of NE Florida failed to effectively utilize its electronic medical records (EMR) system to track and ensure effectuation and provision of services. In the first- and second-year trial audits, the EMR was missing medical documentation such as provider consultation notes and diagnostic results. PACE of NE Florida's inexperience caused a breakdown in the timely acquisition of medical records from external providers for EMR entry. In some cases, there was no documentation to support whether physician-ordered services were completed. In the third-year trial audit, PACE of NE Florida staff failed to follow procedures for tracking the effectuation of care planned or IDT-approved services. PACE of NE Florida stated that its staff was not using the system correctly because they were not adequately trained. As a result, during all three trial period audits, PACE of NE Florida was not able to provide evidence that IDT-approved services were provided to participants.

3. *PACE of NE Florida is not following up on consultations with specialists.*

During all three trial period audits, PACE of NE Florida inconsistently monitored and tracked specialty consultations ordered by participants' primary care providers. The failure to oversee the participants' use of medical specialists and/or inpatient care was determined to be a direct consequence of PACE of NE Florida both (1) not having an effective process to ensure specialty consultation documentation was obtained and placed in the medical record and (2) not having a staff that understands PACE regulatory requirements. Across all three trial period audits, auditors found that PACE of NE Florida still needed to implement processes for PCP review of inpatient care. As a result, PACE of NE Florida failed to follow-up on specialists' recommendations for care.

4. *PACE of NE Florida failed to conduct assessments as required in response to each service determination request.*

During the first- and second-year trial audits, PACE of NE Florida disclosed issues involving a complete turnover of its IDT, difficulty filling positions, and an increased need to train and educate its staff on the process for conducting assessments in response to service determination requests. These issues remained unresolved during the third-year trial audit. Audit testing revealed that PACE of NE Florida did not have a fully trained staff or an effective process for ensuring that IDT assessments were completed. As a result, service requests were still being denied without an assessment to determine if the service was necessary.

II. *PACE of NE Florida failed to develop and successfully initiate a plan to correct the deficiencies or failed to continue implementation of the plan of correction.*

The first-year trial audit was conducted in May 2021. During this audit, CMS found that PACE of NE Florida failed to conduct assessments in response to each service determination request and failed to oversee participants' use of medical specialists and/or inpatient care. PACE of NE Florida was required to initiate and implement a corrective action plan to address the deficiencies. Consistent with the timeline outlined in the corrective action plan, CMS expected full correction of these issues by February 2022. However, these issues were discovered again

during the second-year trial audit conducted in August 2022. In addition, during the second-year trial audit, CMS found that PACE of NE Florida failed to document, track, and monitor the provision of services across all care settings. PACE of NE Florida had a complete turnover of its staff and admitted to not comprehending the relevant PACE requirements.

In response to PACE of NE Florida's failures, on February 8, 2023, CMS held a meeting with PACE of NE Florida to discuss the organization's plan to correct these issues of non-compliance. CMS informed PACE of NE Florida that it failed substantially to comply with the conditions of the PACE program or the terms of its PACE program agreement and stressed the importance of committing the time and resources to develop and build their compliance protocols around effectuating ordered services. CMS warned PACE of NE Florida that if the failures were not corrected, CMS might have to impose sanctions in order to protect PACE participants.

PACE of NE Florida was required to initiate and implement a corrective action plan to address the deficiencies. Consistent with the timeline outlined in the corrective action plan, CMS expected correction of the failures by May 2023. However, in November 2023, CMS conducted a third-year trial audit of PACE of NE Florida and found that PACE of NE Florida continues to have the same failures. Although PACE of NE Florida has attempted to implement a system to document, track, and monitor the provision of services, the staff continues to struggle with using the system and, as a result, is failing to provide approved services to PACE participants. In addition, PACE of NE Florida continues to fail to conduct assessments in response to service determination requests and to oversee participants use of medical specialists.

Violations of PACE Requirements

CMS determined that PACE of NE Florida violated the following PACE requirements:

1. PACE of NE Florida failed to ensure participants received necessary services from certain specialists. As a result, PACE of NE Florida 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; (2) ensure accessible and adequate services to meet the needs of its participants; and (3) ensure reasonable and timely access to specialists as indicated by participants' health condition and consistent with current clinical practice guidelines, in violation of 42 C.F.R. §§ 460.70(a), 460.98(a), 460.98(d)(2), and 460.112(c)(3). In addition, as of March 13, 2024, PACE of NE Florida failed to obtain adequate contract coverage in violation of 42 C.F.R. § 460.70(a)(1).
2. PACE of NE Florida 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)(5).
3. PACE of NE Florida failed to oversee participants' use of medical specialists and/or inpatient care. As a result, PACE of NE Florida failed to follow-up on specialists' recommendations for care, in violation of 42 C.F.R. § 460.102(c)(2).
4. PACE of NE Florida failed to conduct assessments as required in response to each service determination request. As a result, service requests were denied without an

assessment to determine if the service was necessary, in violation of 42 C.F.R. §§ 460.104(d)(2) and 460.121(h)(1).

Basis for Enrollment Sanction

Pursuant to 42 C.F.R. §§ 460.40(b) and 460.50(b)(1)(ii) and (2), 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, and the PACE organization failed to develop and successfully initiate a plan to correct the deficiencies or failed to continue implementation of the plan of correction. CMS has determined that PACE of NE Florida'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 PACE of NE Florida has corrected the causes of the violations which form the basis for the sanction and the violations are not likely to recur. PACE of NE Florida 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 PACE of NE Florida 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 June 1, 2024. If PACE of NE Florida needs additional time beyond fourteen (14) days to submit its CAP, please contact your enforcement lead.

Validation Audit

PACE of NE Florida 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

PACE of NE Florida may respond to this notice in accordance with the procedures specified in 42 C.F.R. §§ 460.56(a) and 422.756(a)(2). PACE of NE Florida has ten (10) calendar days from the date of receipt of this notice to provide a written rebuttal, or by May 28, 2024. Please note that CMS considers receipt as the day after the notice is sent by fax, email, or overnight mail, or in this case May 18, 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 May 18, 2024. Pursuant to 42 C.F.R. §§ 460.56(a) and 422.756(b), PACE of NE Florida 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 15 calendar days from the date CMS notified you of this determination, or by June 3, 2024¹. 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”).

PACE of NE Florida should complete the one-time OH CDMS registration process as soon as possible after receiving this Notice, even if PACE of NE Florida is unsure whether it will appeal CMS’s determination. After the registration process is complete, PACE of NE Florida 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.²

A copy of the hearing request should also be sent 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 e-mail address of the contact within PACE of NE Florida (or an attorney who has a letter of authorization to represent the organization) with whom CMS should communicate regarding the hearing request.

Please note that we are closely monitoring your organization, and PACE of NE Florida 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 PACE of NE

¹ 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.

² 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.

Florida 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 PACE of NE Florida cannot ensure the health and safety of its participants, CMS will consider action to immediately terminate your contract pursuant to 42 C.F.R. § 460.50(c).

If you have any questions about this notice, please call or e-mail 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
Mortez Williams, CMS/OPOLE
Annemarie Anderson, CMS/OPOLE
Karla Taylor, CMS/OPOLE
Sherri Gholston, CMS/OPOLE
Ann Dalton, Bureau Chief, Florida Agency for Health Care Administration
Austin Noll, Deputy Secretary, Florida Agency for Health Care Administration
Bunnie Calloway, Florida Agency for Health Care Administration
Kimberly Quinn, Florida Agency for Health Care Administration
Benjamin Fullington, Florida Agency for Health Care Administration