

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

April 29, 2026

Ms. Celine Regalia
Executive Director
Collabria Care
414 S. Jefferson St.
Napa, CA 94559

Re: Notice of Imposition of Civil Money Penalty of Programs of All-Inclusive Care for the Elderly (PACE) contract number: H2085

Dear Ms. Regalia:

Pursuant to 42 C.F.R. §§ 460.40(b), 460.46(a)(4), and 460.50(b)(1)(ii) and 45 C.F.R. § 102.3, the Centers for Medicare & Medicaid Services (CMS) is providing notice to Collabria Care, that CMS has made a determination to impose a civil money penalty (CMP) in the amount of **\$48,833** for PACE contract number H2085.

CMS has concluded that Collabria Care failed substantially to comply with the conditions of the PACE program or the terms of its PACE program agreement.

Summary of Noncompliance

CMS conducted an audit of Collabria Care's operations from August 25, 2025 through September 8, 2025, in order to assess its overall compliance with federal PACE regulations at 42 C.F.R. Part 460. In a final audit report issued on December 12, 2025, CMS reported that Collabria Care failed to comply with PACE regulations related to PACE services and record maintenance in violation of 42 C.F.R. Part 460, Subparts F and L, respectively. Auditors found that Collabria Care did not provide all approved services; did not track, document, and monitor the provision of services across all care settings; did not ensure recommendations were reviewed, acted upon, and documented by the interdisciplinary team (IDT) within required timeframes; and did not arrange and/or schedule the delivery of medications and other IDT-approved services within required timeframes. As a result, CMS is imposing a CMP for Collabria Care's failures.

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 certain covered items and services directly, it must specify those items and services and arrange for their delivery through contracts that meet applicable regulatory requirements. 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 each participant's health and psychosocial status, as well as the effectiveness of the plan of care. Monitoring occurs through service provision, informal observation, input from participants or caregivers, and communication among IDT members and other providers in implementing the plan of care.

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 within the required timeframes. 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 within the required timeframes.

The PACE organization must arrange and schedule the dispensing of medications as expeditiously as the participant's condition requires, but no later than 24 hours after a primary care provider orders the medication. The PACE organization must arrange or schedule the delivery of IDT approved services, other than medications, as expeditiously as the participant's health condition requires, but no later than 7 calendar days after the date the IDT or member of the IDT first approves the service, except services that are considered routine or preventative under 42 C.F.R. § 460.98(c)(3).

In order for PACE organizations to ensure that services are accessible and adequate to meet the needs of participants, 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.

Violations of PACE Program Requirements

CMS determined that Collabria Care substantially failed to comply with the conditions of the PACE program or terms of its PACE program agreement due to three primary reasons:

1. *Collabria Care 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.*

Auditors found that Collabria Care did not have adequate processes in place to track and ensure approved services were scheduled and provided. For example:

- In seven instances, Collabria Care did not provide specialist consults that were determined to be necessary;
- In seven instances, Collabria Care did not complete lab work as ordered;

- In two instances, Collabria Care did not provide durable medical equipment (DME) as ordered;
- In one instance, Collabria Care did not provide imaging as ordered;
- In one instance, Collabria Care did not provide a medical device as ordered; and
- In one instance, Collabria Care did not provide a clinical screening as ordered.

As a result, Collabria Care 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) document, track, and monitor the provision of services across all care settings. Collabria Care's failure to comply with service delivery requirements violates 42 C.F.R. § 460.98(a) and (b).

2. Collabria Care failed to provide services recommended by an employee or contractor of the PACE organization, including specialists, or failed to document the reason(s) for not approving, or providing a recommended service, if applicable within the required timeframes.

Collabria Care lacked an effective process to ensure recommendations from employees or contractors, including specialists, were reviewed and acted on by the IDT within required timeframes. Additionally, Collabria Care did not have an effective process to ensure the IDT's review of recommendations was appropriately documented, including the reason for not approving or authorizing recommendations.

In eight instances, service recommendations were either never provided to the participants or discussed by the IDT to determine if they were necessary. The identified noncompliance involved recommendations from hospitals' discharge reports and specialist physicians. As a result, services were either never provided to the participants or discussed by the IDT to determine if they were necessary. Collabria Care's failure to comply with consideration of recommended services and medical record requirements violates 42 C.F.R. §§ 460.102(d)(1)(iv) and 460.210(b)(4) and (5).

3. Collabria Care failed to arrange and/or schedule the delivery of medications and/or other IDT approved services within the required timeframes.

Collabria Care lacked an effective process to ensure all ordered and approved services were scheduled or arranged within required timeframes. In 21 instances, medications and/or IDT approved services were never arranged and/or scheduled within the required timeframes, despite the organization's obligation to ensure timely access to approved services for its participants.

The noncompliance involved multiple services: specialist consultations, laboratory tests, DME, imaging studies, occupational therapy, and weekly skin checks. As a result, services were not provided as expeditiously as the participants' conditions required. Collabria Care's failure to comply with timeframes for arranging and providing services requirements violates 42 C.F.R. § 460.98(c).

Basis for Civil Money Penalty

Pursuant to 42 C.F.R. §§ 460.40(b), 460.46(a)(4), and 460.50(b)(1)(ii), CMS may impose a CMP 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 Collabria Care's violations provide a sufficient basis for the imposition of a CMP as provided in 42 C.F.R. §§ 460.40(b), 460.46(a)(4), and 460.50(b)(1)(ii).

Corrective Action Steps

Collabria Care will be subject to additional monitoring to ensure deficiencies identified during the audit have been corrected. CMS will provide Collabria Care with additional instructions regarding the required monitoring in a separate communication.

Please note that failure to correct the deficiencies, or any other failure to comply with PACE program requirements may subject Collabria Care to additional remedies available under law, including the imposition of intermediate sanctions, civil money penalties, or termination of the PACE program agreement as described in 42 C.F.R. Part 460, Subpart D.

Right to Request a Hearing

Collabria Care may request a hearing to appeal CMS's determination in accordance with the procedures outlined in 42 C.F.R. Parts 422 and 423, Subpart T. Collabria Care must send a request for a hearing to the Departmental Appeals Board (DAB) office listed below by June 29, 2026.¹ The request for hearing must identify the specific issues and the findings of fact or conclusions of law with which Collabria Care disagrees. Collabria Care must also specify the basis for each contention that the finding or conclusion of law is incorrect.

The request should be filed through the DAB E-File System (<https://dab.efile.hhs.gov>) unless the party is not able to file the documents electronically. If a party is unable to use DAB E-File, it must send appeal-related documents to the Civil Remedies Division using a postal or commercial delivery service at the following address:

Civil Remedies Division
Department of Health and Human Services
Departmental Appeals Board
Medicare Appeals Council, MS 6132
330 Independence Ave., S.W.
Cohen Building Room G-644
Washington, D.C. 20201

Please see https://dab.efile.hhs.gov/appeals/to_crd_instructions for additional guidance on filing the appeal.

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

¹ Pursuant to 42 C.F.R. §§ 422.1020(a)(2) and 423.1020(a)(2), the plan sponsor must file an appeal within 60 calendar days of receiving the CMP notice.

Kevin Stansbury
Director
Division of Compliance Enforcement
Centers for Medicare & Medicaid Services
Email: kevin.stansbury@cms.hhs.gov

If Collabria Care does not request an appeal in the manner and timeframe described above, the initial determination by CMS to impose a CMP will become final and due on June 30, 2026. Collabria Care may choose to have the penalty deducted from its monthly payment or transfer the funds electronically. To notify CMS of your intent to make payment and for instructions on how to make payment, please email the enforcement contact provided in the email notification.

Impact of CMP

Further failures by Collabria Care to provide its enrollees with Medicare benefits in accordance with CMS requirements may result in CMS imposing additional remedies available under law, including contract termination, intermediate sanctions, penalties, or other enforcement actions as described in 42 C.F.R. Part 460, Subpart D.

If Collabria Care has any questions about this notice, please call or email the enforcement contact provided in the email notification.

Sincerely,

/s/

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

cc: Kevin Stansbury, CMS/CM/MOEG/DCE
Kathleen Flannery, CMS/CM/MOEG/DPAO
Tamara McCloy, CMS/OPOLE
Annemarie Anderson, CMS/OPOLE
Ayanna Busby-Jackson, CMS/OPOLE
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