

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

December 22, 2021

Ms. Maureen Hewitt
President & CEO
Total Longterm Care, Inc.
d/b/a InnovAge Colorado PACE
8950 East Lowry Boulevard
Denver, CO 80230

Re: Notice of Imposition of Sanction to Suspend Enrollment of Programs of All-inclusive Care for the Elderly (PACE) participants into contract number: H0613

Dear Ms. Hewitt:

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(a) and 460.42(a), the Centers for Medicare & Medicaid Services (CMS) hereby notifies Total Longterm Care, Inc. d/b/a InnovAge Colorado PACE (InnovAge CO) that, effective December 23, 2021, CMS is suspending InnovAge CO's enrollment of new Medicare beneficiaries under its contract number H0613.

CMS has concluded that InnovAge CO failed substantially to provide its participants with medically necessary items and services that are covered PACE services, which adversely affected (or had the substantial likelihood of adversely affecting) its participants. This determination was made as a result of deficiencies discovered during a 2021 audit by CMS. Consequently, CMS has determined that the seriousness of these deficiencies requires the suspension of any new enrollments of Medicare beneficiaries into InnovAge CO.

The enrollment sanction will remain in effect until CMS is satisfied that InnovAge CO 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

From June 21 to July 8, 2021, CMS conducted a routine audit of InnovAge CO's operations. CMS's review raised concerns that InnovAge CO was not providing services in accordance with the PACE requirements. Following the audit, InnovAge CO provided CMS with impact analyses identifying additional participants that may have been impacted by the failures. In September of 2021, CMS validated the submitted impact analyses for accuracy by selecting additional cases to

review. Both the audit and impact analysis validation showed that InnovAge CO is substantially failing to provide to its participants medically necessary items and services that are covered PACE services and that those failures adversely affected (or have the substantial likelihood of adversely affecting) its participants. Violations of the PACE program requirements include:

- Failure to provide all Medicare and Medicaid covered services, as well as other services determined necessary by the interdisciplinary team (IDT) to improve and maintain the participant's overall health status;
- 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 its participants;
- Failure of the IDT to coordinate 24-hour care delivery and to remain alert to pertinent information from other team members, participants, and caregivers; and
- Failure of the InnovAge CO's primary care providers (PCP) to manage their participants' medical situations and oversee their participants' use of medical specialists.

Given the nature of the deficiencies and the critical need for InnovAge CO 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 provider 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)

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.

Description of Non-Compliance

During the 2021 audit, auditors found that InnovAge CO failed to provide medically necessary items and services to participants and that those failures adversely affected or had the substantial likelihood of adversely affecting participants. These failures occurred due to three primary

reasons: (1) InnovAge CO failed to schedule or delayed scheduling appointments for necessary services (in some cases, for urgently needed services); (2) InnovAge CO failed to adequately follow-up on pertinent information, including diagnoses and recommendations from specialists; and (3) InnovAge CO's clinical staff failed to inform the IDT of important medical information for the IDT to evaluate the participant's condition.

1. InnovAge CO failed to provide medically necessary services to its participants because it failed to schedule or delayed scheduling those services.

InnovAge CO's PCPs determined certain services were medically necessary and then ordered those services. InnovAge CO was then responsible for scheduling and providing those services to meet the needs of its participants. However, in a number of cases, InnovAge CO either failed to schedule the service or delayed scheduling the service and, as a result, services were not provided or were delayed. InnovAge CO admitted to having scheduling delays but was unable to provide auditors with documentation providing a clear rationale for these delays.

(Case Details Removed for Privacy Consideration)

2. InnovAge CO failed to provide medically necessary services to its participants because it did not follow-up on information, diagnoses, and recommendations from specialists.

In a number of cases, InnovAge CO failed to follow-up on information, diagnoses, and recommendations from specialists. As a result, InnovAge CO failed to manage the participant's medical condition in response to information provided by specialists and failed to provide care that meets the needs of its participants.

(Case Details Removed for Privacy Consideration)

3. InnovAge CO failed to provide medically necessary services to its participants because InnovAge CO clinical staff failed to share important medical information for the IDT to properly evaluate the participant's condition.

(Case Details Removed for Privacy Consideration)

Violations of PACE Requirements

CMS determined that InnovAge CO violated the following PACE requirements:

1. InnovAge CO failed to provide all Medicare and Medicaid covered services, as well as other services determined necessary by the IDT to improve and maintain participants' overall health status. This is in violation of sections 1894(b)(1) and 1934(b)(1) of the Act and 42 C.F.R. § 460.92.
2. InnovAge CO failed to provide care that meets the needs of each participant across all care settings, 24 hours a day, every day of the year. This is in violation of 42 C.F.R. § 460.98(a).

3. InnovAge CO failed to ensure accessible and adequate services to meet the needs of its participants. This is in violation of 42 C.F.R. § 460.98(d)(2).
4. InnovAge CO's IDT failed to coordinate 24-hour care delivery and failed to remain alert to pertinent input from other team members, participants, and caregivers. This is in violation of 42 C.F.R. § 460.102(d)(1) and (d)(2)(ii).
5. InnovAge CO's PCP failed to manage their participants' medical situations and oversee their participants' use of medical specialists. This is in violation of 42 C.F.R. § 460.102(c)(2).

Basis for Enrollment Sanction

Pursuant to 42 C.F.R. §§ 460.40(a) and 460.42(a), CMS may impose an enrollment suspension if CMS determines a PACE organization failed substantially to provide to a participant medically necessary items and services that are covered PACE services, if the failure adversely affected (or had the substantial likelihood of adversely affecting) the participant. CMS has determined that InnovAge CO'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 InnovAge CO has corrected the causes of the violations which form the basis for the sanction and the violations are not likely to recur. InnovAge CO 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 InnovAge CO 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 January 6, 2022. If InnovAge CO needs additional time beyond fourteen (14) days to submit its CAP, please contact your enforcement lead.

Validation Audit

InnovAge CO will be required to undergo a validation audit of all the operational areas 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 sanctions have been corrected and are not likely recur.

Opportunity to Respond to Notice

InnovAge CO may respond to this notice in accordance with the procedures specified in 42 C.F.R. §§ 460.56(a) and 422.756(a)(2). InnovAge CO has ten (10) calendar days from the date of

receipt of this notice to provide a written rebuttal, or by January 3, 2022¹. Please note that CMS considers receipt as the day after the notice is sent by fax, email, or overnight mail, or in this case December 23, 2021. If you choose to submit a rebuttal, please send it to the attention of Kevin Stansbury at the address noted below. Note that the sanctions imposed pursuant to this letter are not stayed pending a rebuttal submission.

Right to Request a Hearing

This determination is effective on December 23, 2021. Pursuant to 42 C.F.R. §§ 460.56(a) and 422.756(b), InnovAge CO 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 January 7, 2022. Please note, however, a request for a hearing will not delay the effective date of the sanction.

The request for hearing must be sent to CMS electronically, and may also be sent via hard copy to the CMS Hearing Officer at the following address:

CMS Office of Hearings
Attn: Benjamin R. Cohen, Director
7500 Security Boulevard
Baltimore, MD 21244-1850
Mail Stop: B1-01-31
Phone: (410) 786-3169
E-Mail: Benjamin.Cohen@cms.hhs.gov

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 email or the date it receives the fax or traceable mail document, whichever is earlier, as the date of receipt of the request. The request for a hearing must include the name, fax number, and e-mail address of the contact within InnovAge CO (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 InnovAge CO may also be subject to other applicable remedies available under law, including the imposition of additional

¹ The 10th 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.

sanctions or penalties as described in 42 C.F.R. Part 460, Subpart D. If InnovAge CO 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 InnovAge CO 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 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/DAPS
Caroline Zeman, CMS/CM/MOEG/DAPS
Laura Coleman, CMS/OPOLE
Michael Moore, CMS/OPOLE
Verna Hicks, CMS/OPOLE
Mary Jane Spuhler, CMS/OPOLE
Kim Bimstefer, Executive Director, Colorado Department of Health Care Policy and Financing (DHCPF)
Bonnie Silva, Office of Community Living Director, DHCPF
Colin Laughlin, Office of Community Living Deputy Director, DHCPF
Michele Craig, Complex and Supportive Services Section Manager, DHCPF
Bryan Fife, Department of Health Care Policy and Financing, Supportive Long Term Care Programs Unit Supervisor, DHCPF
Winter Roberts, PACE Compliance Specialist, DHCPF
Rachel Entrican, Legal Division Director, DHCPF
Elaine McManis, Division Director, Colorado Department of Public Health and Environment