

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 22, 2019

Mr. Mark Irwin
Chief Executive Officer
Senior LIFE York, Inc.
401 Broad Street
Johnstown, PA 15906

Re: Notice of Imposition of Sanctions to Suspend Enrollment of PACE participants into contract number: H0819

Dear Mr. Irwin:

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 Senior LIFE York, Inc. (Senior LIFE York) that CMS has made a determination to suspend Senior LIFE York's ability to enroll new Medicare beneficiaries under its contract, number H0819, to provide services under the Programs of All-Inclusive Care for the Elderly (PACE) in Harrisburg and York, PA. Senior LIFE York must cease all enrollment activities by August 23, 2019.

CMS has concluded that Senior LIFE York 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 severe deficiencies uncovered during a February 2019 audit by CMS and a March 2019 audit by the State Administrating Agency of Pennsylvania, Pennsylvania Department of Human Services (PA-DHS). Consequently, CMS has determined that the level of deficiencies are so significant that it requires the suspension of any new enrollments for Medicare beneficiaries into Senior LIFE York.

The enrollment sanction will remain in effect until CMS is satisfied that Senior LIFE York has corrected the causes of the violations and the violations are not likely to recur. This enrollment suspension will apply to all potential participants who are Medicare-only or dual eligible beneficiaries.

Summary of Noncompliance

From February 19th through March 1st, 2019, CMS conducted a routine audit of Senior LIFE York operations. CMS' review raised concerns that Senior LIFE York was not providing

services in accordance with the PACE requirements. Given these initial concerns, CMS continued to request documentation from Senior LIFE York and analyzed this information to determine the full scope of the findings. Around the same time, the PA DHS received a complaint regarding the care of a Senior LIFE York participant, which prompted the State to conduct an unannounced focused audit in March. Both audits found that Senior LIFE York is not providing adequate and required services that meet the medical needs of its participants. Significant findings include:

- Denying PACE covered services that were necessary for the 24-hour care of participants.
- Failing to provide timely services or approved services to meet participant needs, which put participants at risk of serious harm.
- Senior LIFE York's interdisciplinary team failing to act on information or to remain alert to pertinent information to coordinate the care of participants, which, in some cases, may have resulted in hospitalization, risk of serious harm, and/or death.
- Failing to take caregivers' statements and information on the health of the participant into consideration when making decisions on service requests, which resulted in denials of long-term care services that were necessary to meet the needs of the participant.
- Failing to initiate service requests when a participant or the participant's designated representative expressed a need to initiate or continue a service.
- Repeatedly and substantially failing to document whether services have been received by participants or whether participants' health or conditions were assessed based on information in medical reports.

CMS found that these are substantial failures of PACE requirements that have resulted in failing to provide medically necessary PACE items and services, which adversely affected or had the substantial likelihood of adversely affecting PACE participants. Given the nature of the deficiencies and the critical need for Senior LIFE York 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, community-dwelling 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 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 organizations are entities that have a PACE program agreement with CMS and the State administering agency (SAA) to operate a PACE program. Individuals can participate in PACE if they meet certain eligibility requirements, including that they must:

- Be age 55 or older;
- Live in the service area of a PACE organization;
- Be determined by the SAA to need the level of care required under the state Medicaid plan for coverage of nursing facility services; and
- At the time of enrollment, be able to live safely in a community setting.

PACE Required Services

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

A PACE organization must provide all items and services that are covered and specified under the PACE statute and regulations. Participants must have access to those 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 24 hours a day.

If the PACE provider cannot provide those items and services, 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. A PACE organization must provide services to participants through a comprehensive, multidisciplinary health and social services delivery system that integrates both acute and long-term care services. For most participants, the comprehensive service package enables them to receive care at home rather than in a nursing home. However, long-term skilled nursing facility placement is included in the PACE benefit package. Therefore, if skilled nursing facility care is necessary to meet the healthcare needs of the participant, it must be provided by the PACE organization or its designated contractor.

Interdisciplinary Team, Plan of Care, and Service Delivery

(Sections 1894(f)(2)(B)(iii) and 1934(f)(2)(B) of the Social Security Act; 42 C.F.R. §§ 460.92, 460.98, 460.102, 460.104, 460.106)

PACE organizations are required to establish an interdisciplinary team, composed of various health care professionals, at each PACE center to comprehensively assess and meet the individual needs of each participant. In addition to ensuring access to the full range of PACE required services, 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 when implementing the plan of care for a participant.

To facilitate this process, 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 of a participant's condition in the participant's medical record consistent with policies established by the medical director.

For any services authorized or approved by the IDT, the PACE organization must ensure participants receive those services in a manner that meets the participants' needs. Furthermore, PACE centers must be sufficiently managed, staffed and equipped to ensure that services are accessible and adequate to meet the needs of participants.

Medical Records

(42 C.F.R. §§ 460.102(d)(2)(iii), 460.104(f), 460.200, 460.210(a) and (b); Chapters 12 and 8 of the Programs of All-Inclusive Care for the Elderly (PACE) Manual, (IOM Pub.100-11))

PACE organizations must maintain a single, comprehensive medical record for each participant, in accordance with accepted professional standards and furnish them upon request to CMS and state auditors for inspection. The medical record must be complete, accurate, readily accessible, systematically organized, available to staff and maintained and housed at the PACE center where the participant receives services. Medical records must contain certain documentation, including the following: documentation of all services furnished by PACE employees at the PACE center; interdisciplinary team assessments, reassessments, plans of care, treatment and progress notes; laboratory reports and other medical test results; medication records; hospital discharge summaries; reports of contact with informal support; physician orders; and advance directives, if applicable.

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 PACE services, if the failure adversely affected (or had the substantial likelihood of adversely affecting) the participant.

CMS has determined that Senior LIFE York's violations provide a sufficient basis for the imposition of sanctions as provided in 42 C.F.R. § 460.42(a).

Violations of PACE Requirements

CMS and PA DHS uncovered numerous violations of PACE requirements, ultimately resulting in failure to provide medically necessary PACE items and services that adversely affected or had the substantial likelihood of adversely affecting its participants. These violations include:

- 1. Failure to provide necessary PACE services, either through the PACE organization or through its contractor, and to provide access to those services 24-hours per day, every day of the year. This is in violation of sections 1894(b)(1)(A),(B), and (D) and 1934(b)(1)(A),(B), and (D) of the Social Security Act and 42 C.F.R. §§ 460.70(a) and §460.98(a).**

CMS auditors found a number of cases where Senior LIFE York was denying services and using the presence or availability of a caregiver as a basis for denying those services.

(Case Details Removed for Privacy Consideration)

The PACE statute and regulations are clear that it is the PACE organization that must provide the PACE services and must provide access to those services 24-hours per day, every day of the year. If the PACE organization cannot provide those services directly it must contract with an entity to provide those services.

- 2. Failure to provide services to participants through a comprehensive, multidisciplinary health and social services delivery system which integrates acute and long-term care services, by denying long-term care services (skilled nursing home and homecare) despite information and assessments indicating the participants were in need of those services. This is in violation of Sections 1894(b)(1)(C) and 1934(b)(1)(C) of the Social Security Act and 42 C.F.R. §§ 460.92 and 460.106(c)(2).**

In the same cases cited above, Senior LIFE York denied long-term care services (skilled nursing facility placement and homecare services), despite Senior LIFE York's records documenting that caregivers were either: (1) Overwhelmed by the participants' care requirements (*Case Details Removed for Privacy Consideration*); (2) Unable to take care of the participants; or (3) Concerned for the participants' safety (*Case Details Removed for Privacy Consideration*).

In addition to those statements from caregivers, Senior LIFE York's assessments and case notes state the participants were either: (1) In need of "24 hour" care; (2) Unable to be left alone or should not be left alone; (3) An elopement risk; (4) Dependent on a caregiver for all activities of daily living (medication, food, fluids, self-care); or (5) Diagnosed with severe cognitive impairment or dementia.

In all of the cases, Senior LIFE York's denials of service requests do not address the statements from the participants' caregivers or specific medical concerns listed in the assessments and case notes. In addition, Senior LIFE York did not provide alternative options to support the caregivers' concerns or the needs of the participant.

It is the role of the IDT to continuously monitor the participant's health and the effectiveness of the plan of care by using information from a range of sources, including input from caregivers, to make healthcare decisions and implement the participant's plan of care. Although the plan of care often enables participants to receive care at home rather than in a skilled nursing facility, the participant's needs may change over the course of the participant's enrollment. Here, Senior LIFE York's records indicate the participants were in need of 24-hour care and the PACE organization did not ensure that the participants received that level of care. *(Case Details Removed for Privacy Consideration)*

3. Failure by the IDT to properly coordinate 24-hour care delivery for participants and 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 (2).

(Case Details Removed for Privacy Consideration)

Senior LIFE York also provided CMS auditors with numerous other instances where Senior LIFE York either had no documentation or the available documentation did not show that the participants were assessed or received follow-up for reported health concerns.

4. Failure to furnish services and ensure accessible and adequate services to meet the needs of its participants. This is in violation of 42 C.F.R. § 460.98.

CMS auditors found a number of cases where either Senior LIFE York failed to ensure participants received timely services to meet their needs or to ensure participants received approved services.

(Case Details Removed for Privacy Consideration)

CMS auditors found an additional eight cases where participants did not receive, or there was no documentation that they received, approved services. Services included weekly glucose monitoring, an electrocardiogram lab, blood pressure monitoring, a neurology consult, and blood-thinning medication monitoring. In addition, Senior LIFE York provided auditors with numerous other instances where it did not have documentation that approved services were provided to participants.

5. Failure to conduct an in-person reassessment when the participant (or his or her designated representative) believed he/she needed to initiate or continue a particular service. This is in violation of 42 C.F.R. § 460.104(d)(2).

(Case Details Removed for Privacy Consideration)

6. Failure to maintain medical records that were complete, accurate and available to all staff. This is in violation of 42 C.F.R. §§ 460.102(d)(2)(iii), 460.104(f), and 460.210.

Auditors found eight cases where there was a lack of documentation in the medical record for IDT approved services or treatments provided by contracted individuals. In addition, there were

numerous instances identified by Senior LIFE York where Senior LIFE York stated it did not have documentation either that participants received services or that follow-up occurred on participants' health issues.

Senior LIFE York received a civil money penalty in 2017 for failing to document the administration of approved medications for 24 participants. Senior LIFE York was not able to tell CMS if the medications were ever provided to the participants. In that case, CMS stated that the lack of documentation limits the IDT and other clinical staff from properly assessing and reassessing participants, delivering coordinated care, and adjusting care plans. In CMS' most recent audit, auditors found many cases where Senior LIFE York was not able to demonstrate that participants ever received approved services.

The nature and scope of the above violations supports the suspension of Senior LIFE York's ability to enroll new Medicare beneficiaries into its PACE program.

Opportunity to Correct

Pursuant to 42 C.F.R. § 460.42(c), the enrollment suspension will remain in effect until CMS is satisfied that Senior LIFE York has corrected the causes of the violations which form the basis for the sanction and the violations are not likely to recur. Senior LIFE York 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 Senior LIFE York submit a CAP to CMS that covers all violations which form the basis for the sanction within seven (7) calendar days from the date of receipt of this notice, or by August 30, 2019. If Senior LIFE York needs additional time beyond seven (7) days to submit its CAP, please contact your enforcement lead.

Validation Audit

Senior LIFE York 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 make a determination about whether the deficiencies that are the basis for the sanctions have been corrected and are not likely recur.

Opportunity to Respond to Notice

Senior LIFE York may respond to this notice in accordance with the procedures specified in 42 C.F.R. § 422.756(a)(2). Senior LIFE York has ten (10) calendar days from the date of receipt of this notice to provide a written rebuttal, or by September 3, 2019.¹ Please note that CMS considers receipt as the day after the notice is sent by fax, email, or overnight mail, or in this case August 23, 2019. 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.

¹ The 10th day fell on a weekend or holiday, therefore the date reflected in the notice is the next regular business day for you to submit your request.

Right to Request a Hearing

This determination is effective on August 23, 2019. Senior LIFE York 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 September 9, 2019.² 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 the CMS Hearing Officer at the following address:

Benjamin Cohen
CMS Hearing Officer
Office of Hearings
ATTN: HEARING REQUEST
Centers for Medicare and Medicaid Services
2520 Lord Baltimore Drive
Suite L
Mail Stop LB-01-22
Baltimore, MD 20244-2670
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
MAIL STOP: C1-23-17
Baltimore, MD 21244
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 Senior LIFE York (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 Senior LIFE York 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 Senior LIFE York fails to correct the deficiencies cited in this notice, CMS or the PA DHS may terminate the PACE program agreement pursuant to 42 C.F.R. § 460.50(b). In addition, if CMS or PA DHS

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

determines that Senior LIFE York cannot ensure the health and safety of its participants, CMS or PA DHS will consider taking 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
Acting Director
Medicare Parts C and D Oversight and Enforcement Group

Enclosure:
Attachment A – Corrective Action Plan Template

cc: Kevin Stansbury, CMS/CM/MOEG/DCE
Tamara McCloy, CMS/CMHPO/Region III
Annemarie Anderson, CMS/CMHPO/Region III
Judy Gushue, CMS/CMHPO/Region III
Kevin Hancock, Deputy Secretary, Office of Long-Term Living, PA DHS
Randy Nolen, Director, Bureau of Coordinated and Integrated Services, PA DHS
Jonathan Bowman, Director, Division of Integrated Care Programs, PA DHS