

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



Medicare Drug & Health Plan Contract Administration Group

May 29, 2024

CORRECTIVE ACTION PLAN REQUEST

Contract IDs: H0819
H2992
H3925
H5902

Mark Irwin
CEO – Senior Official for Contracting
Senior LIFE
401 Broad Street
Johnstown, PA 15905

VIA EMAIL: Mirwin@pace-cs.com

Subject: Failure to Properly Administer and Document Medications Across All Care Settings

Dear Mark Irwin:

The Centers for Medicare & Medicaid Services (CMS) is issuing this Request for a Corrective Action Plan (CAP) to Senior LIFE, which operates the contracts listed above, regarding your organization's failure to ensure the proper administration and documentation of medications provided to PACE participants across multiple contracts.

In December 2022, CMS issued a notice of non-compliance (NONC) to PACE contract H0819 for a similar issue. In 2023, CMS found errors in three additional contracts operated by your organization that were similar to those documented in our 2022 NONC. Due to your organization's failure to address the issues identified in the 2022 NONC, repeated non-compliance, increase in the proportion of participants impacted by this failure across multiple contracts, the types of medications that were administered incorrectly, and the lack of sufficient documentation regarding the medications provided to participants, CMS is escalating its compliance action against Senior Life and issuing this request for a CAP.

Your organization is out of compliance with the following regulations:

- 42 C.F.R. § 460.70(b)(1)(iii) requires contractors working for PACE organizations to comply with PACE regulation requirements related to service delivery, participant rights, and quality improvement activities.
- 42 C.F.R. § 460.71(a)(4) explains that PACE organizations must designate a staff member to oversee these activities for employees and work with the PACE contractor liaison to ensure compliance by contracted staff.
- 42 C.F.R. § 460.98(a) states that PACE organizations are responsible for providing care that meets the needs of each participant across all care settings, 24 hours per day, every day of the year, and must establish and implement a written plan to ensure that care is appropriately furnished.
- 42 C.F.R. § 460.98(b)(5) requires PACE organization to document, track, and monitor the provision of services across all care settings in order to ensure the interdisciplinary team remains alert to the participant's medical, physical, emotional, and social needs.
- 42 C.F.R. § 460.106(c)(2) requires that the team must continuously monitor the participant's health and psychosocial status, as well as the effectiveness of the plan of care, including through the provision of services.
- 42 C.F.R. § 460.112(a)(5) provides that each participant has the right to be free from harm, including excessive medication.

During our review of the first quarter 2023 quality data associated with H5902, CMS noted one egregious medication error involving a participant residing in your organization's contracted Assisted Living Facility (ALF). This participant received 104 doses of kayexalate, an anti-hyperkalemia medication, when only two doses of the medication had been prescribed. Upon further investigation and review of the requested root cause analysis, your organization identified several failures that contributed to the medication error. Notably, the clinical coordinator in the ALF wrongly transcribed the medication. In addition, your contracted pharmacy provider failed to alert your organization regarding the excessive dispensing of kayexalate, a dispensing level that did not correlate with the provider's order. Finally, your root cause analysis found that your organization did not have a real-time medication reconciliation process that would have helped your organization to identify such discrepancies in the participant's medical record.

On July 7, 2023, your organization reported to CMS that it had discovered a significant increase in medication errors in six of your organization's contracted Skilled Nursing Facilities (SNFs) and ALFs that provide services to participants. Your organization indicated that your preliminary investigation of the issue identified that a recent transition in ownership of the six SNF and ALF facilities, which was effective July 1, 2023, may have contributed to the significant increase in medication errors. As part of the ownership transition, a new Electronic Medical Record (EMR) system was instituted in the SNFs and ALFs. Further, your organization reported that it was not aware of the effective date of the new EMR system and did not have access to the system until July 10, 2023. Lastly, your organization noted that facilities' pharmacy provider changed,

effective July 1, 2023, and that also contributed to participants not having access to their medications.

CMS requested your organization focus on medication errors related to protected drug classes, including anti-depressants, anti-psychotics, anti-convulsants, anti-retrovirals, immunosuppressants, anti-neoplastics, anti-coagulants, insulin, oral anti-hyperglycemics, and opioids. CMS asked your organization to include any adverse impacts on participants from your organization's failure to administer these medications. In addition, CMS reviewed documents submitted by your organization, and this review revealed that your contracted facilities lacked proper documentation of medication administration and your organization failed to establish an effective medication transcription process with your facilities to ensure accurate administration of ordered medications.

Your organization also reported that it discovered that 2,718 medication errors occurred between July 1 and July 21, 2023, impacting 237 participants. CMS reviewed documents submitted by your organization and found that, of the 2,718 identified medication errors, 339 were associated with medications in protected drug classes, and 32 errors involved a failure to administer opioid medications. One-hundred twenty-nine (129) of the 371 errors associated with protected class drugs were missing documentation of medication administration and 28 of the errors within the protected classes were due to participants lacking access to the ordered medications as of July 1, 2023. CMS noted that the remaining 242 protected drug class errors involved multiple failures, including incorrect dispensing of medication doses.

You informed CMS that your organization initiated routine calls with the facility administrators, conducted on-site visits, and negotiated a reinstatement of the previous pharmacy provider to improve the delivery of medications to your participants to improve your quality improvement process.

Due to the errors and failures described above, your organization failed to provide participants with adequate medical care. Inadequate medical care resulted in participant harm because your organization's participants did not receive their medication or received the wrong dose, including receiving excessive amounts of medication not in accordance with the providers' orders. Your organization's failure to track and monitor your contracted providers and their services, as well as your failure to monitor the provision of services to ensure participants' health needs are met across all care settings contributed to your organization's failure to provide adequate care to participants residing in your contracted facilities.

CMS requests that your organization develop and implement a detailed CAP. The CAP should address the corrective actions you will take in response to the medication errors to adopt and implement effective oversight requirements, per 42 C.F.R. § 460.63. This includes providing

details that describe how you will oversee these processes in your contracted facilities, as well as how you will implement an adequate process for monitoring participants' health, psychosocial status, and effectiveness of the plan of care through the provision of services, as described in 42 C.F.R. § 460.106(c)(2). In addition, the CAP should describe actions you will take to ensure you are compliant with § 460.71(a)(4). Because of the complexity and sensitivity of this matter, CMS will review materials and intermediary implementation steps throughout the CAP process. Further, your organization's engagement with CMS throughout this process is necessary for CMS to determine whether your organization has successfully remediated these known failures and has received sufficient information from your organization in order to close the CAP.

CMS is issuing this compliance notice pursuant to 42 C.F.R. § 460.50(b)(2), which requires CMS to afford an organization 30 days to develop and successfully initiate a CAP to correct deficiencies. Therefore, by July 1, 2024, please send a timeline to your CMS Account Managers, which should include a timeline for implementing each element of the CAP. CMS expects that the correction timeline will be no longer than necessary and will reflect an appropriate level of urgency in resolving this matter.

CMS considers your organization's efforts in self-reporting information concerning the non-compliant activity as a mitigating factor in determining the severity of this notice. However, prior to this self-disclosure, CMS had repeatedly raised concerns regarding medication management in your contracted facilities on prior quarterly calls as was noted from the participant residing in the ALF who received 104 doses of kayexalate.

If your organization fails to correct these deficiencies, CMS has the authority to impose sanctions, penalties and other enforcement actions as described in 42 C.F.R. Part 460 Subpart D. Should your organization fail to develop, implement, or complete its CAP, CMS may consider the imposition of intermediate sanctions (e.g., suspension of marketing and enrollment activities), civil money penalties, or termination of your organization's PACE program agreements.

If you have any questions related to the compliance implications of this notice, please contact your CMS Account Managers: Kathryn Covert at: (215) 861-4762, or kathryn.covert@cms.hhs.gov and Sarah Kamangu at: (215) 861-4321, or sarah.kamangu@cms.hhs.gov.

Sincerely,

A handwritten signature in black ink that reads "Heather Rudo". The signature is written in a cursive style with a long horizontal line extending to the right.

Heather Rudo, Deputy Director

Division of Surveillance, Compliance, & Marketing
Medicare Drug & Health Plan Contract Administration Group

CC via email:

Annemarie Anderson, CMS Division Director, Region 3

Kathryn Covert, CMS Philadelphia

Sarah Kamangu, CMS Philadelphia

Theresa Wachter, CMS Baltimore