

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



Medicare Drug & Health Plan Contract Administration Group

March 5, 2024

CORRECTIVE ACTION PLAN

Contract ID: H2064

Parent Organization Name: Geisinger Health

Legal Entity Name: Geisinger Community Health Services

Ms. Teena Kubasti
Medicare Compliance Officer
100 North Academy Avenue
MC 78-01, Danville, PA 178227801

VIA EMAIL: tmkubasti@geisinger.edu

RE: Corrective Action Plan - Failure to Provide Medically Necessary Covered Services

Dear Teena Kubasti:

The Centers for Medicare & Medicaid Services (CMS) is requesting that Geisinger Health, which operates LIFE Geisinger under contract H2064, develop and implement a corrective action plan (CAP) to address your organization's failure to provide medically necessary covered services, specifically medications, to LIFE Geisinger participants.

Pursuant to 42 CFR § 460.98(a), a PACE Organization is 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. Further, 42 CFR § 460.70(b)(1)(iii) requires contractors of PACE Organizations to comply with the regulatory requirements (including § 460.98) with respect to service delivery, participant rights, and quality improvement activities. Finally, 42 CFR § 460.112(5) provides that each PACE participant has the right to be free from harm, including excessive medication.

On May 25, 2023, during CMS's review of LIFE Geisinger's first quarter quality data, we noted an increase in medication errors reported by your organization. In response, CMS requested supplementary information from LIFE Geisinger, including a root cause analysis of the increase

in medication errors reported. On June 21, 2023, CMS met with representatives of LIFE Geisinger, Geisinger Pharmacy, and the State Administering Agency for the Pennsylvania Office of Long-Term Living, to discuss the medication errors. During that call, CMS identified a lack of communication between your organization's larger and smaller contracted pharmacies and LIFE Geisinger's Mail-Order Medication System. This lack of communication was supported in the documentation CMS reviewed that was provided by LIFE Geisinger.

This communication issue resulted in your organization's failure to ensure your participants received medications and resulted in your participants experiencing significant delays in their receipt of needed medication. These delays included, but are not limited to the following:

- One participant not receiving prescribed memantine for more than 6 weeks;
- One participant not being administered doses of metoprolol for 28 days; and
- One participant not receiving metolazone for nearly 8 months, from October 2022 to May 2023, when the problem was finally identified.

CMS also discovered through its discussions with your organization that your organization's errors caused some of your participants to receive the incorrect dosage of their needed medication. These errors included, but are not limited to the following:

- Four participants being provided continuous/28-day cycle fills and bridge dosages of critical medications such as Dilantin, Lasix, warfarin, Lyrica, and tramadol-APAP, resulting in three of the four participants taking duplicate medications.
- One participant being provided short-acting insulin via an injection pen, which was a newly prescribed method that replaced the vial of insulin. The participant's wife incorrectly administered the insulin based on the instructions for long-acting, rather than the short-acting insulin, which resulted in the participant presenting to your clinic with hypoglycemia.

CMS has determined that your organization is out of compliance with PACE requirements because it failed to provide the medically necessary covered services to the participants. An inadequate process of tracking and monitoring of contracted pharmacy services, as well as an inadequate medication-reconciliation process to avoid duplications and omissions, pose potential harm to the health and safety of participants and risk negative impacts to the participants' overall wellbeing.

CMS requests that your organization implement a detailed CAP. The CAP should address the corrective actions LIFE Geisinger will take in response to the lack of communication with the contracted pharmacies, including how LIFE Geisinger will update their tracking and monitoring of contracted services to ensure participants receive the correct medication doses timely. Because of the complexity and sensitivity of this matter, CMS will review materials and intermediary implementation steps throughout the process. Further, our engagement throughout this process will provide CMS with the information we need to eventually close the CAP.

By April 5, 2024, please send a timeline to your CMS Account Manager for implementing each element of the CAP. CMS is issuing this compliance notice pursuant to 42 C.F.R. § 460.50(b), which requires CMS to afford an organization 30 days to develop and implement a corrective action plan to correct deficiencies before taking steps to terminate the organization's a PACE program agreement. CMS is not obligated to grant a greater than 30-day cure period, however, we acknowledge that an extended cure period may be appropriate, depending on the nature of the correction required. CMS advises that, for any part of its timeline scheduled to be completed in more than 30 days, your organization must provide a justification of the need for that additional time. 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 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 PACE program agreement termination.

If you have questions related to the compliance implications of this notice, please contact your CMS Account Manager, Lisa Ramsumair at Lisa.Ramsumair@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:

Lisa Ramsumair, CMS Regional Office Account Manager
Annemarie Anderson, CMS Division Director, Region 3
Theresa Wachter, CMS Baltimore