

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



CENTER FOR MEDICARE

January 18, 2024

Corrective Action Plan

Contract ID: H4286

Parent Organization Name: Leon Health Holdings, LLC

Legal Entity Name: LEON HEALTH, INC.

Milagros Yzquierdo
Medicare Compliance Officer
8600 NW 41 Street
Miami, FL 33166

VIA EMAIL: milagros.yzquierdo@leonhealth.com

RE: Failure to Comply with CMS CY 2024 Bid Instructions

Dear Milagros Yzquierdo:

The Centers for Medicare & Medicaid Services (CMS) is issuing a request for LEON HEALTH, INC., which operates Medicare Part D Contract ID H4286, to develop and implement a corrective action plan (CAP) to address the organization's failure to comply with contract year (CY) 2024 Part D bid submission requirements. We are issuing this request based on your organization's receipt of a warning letter for failure to comply with similar bid submission requirements for CY 2023, as well as multiple compliance failures for CY 2024, as outlined below.

Part D program regulations at 42 C.F.R. § 423.265(c) state that each potential Part D sponsor must submit bids (and supplemental information specified by CMS) that reflect the features (e.g., premium amount, cost sharing) and projected cost estimates of each benefit package it expects to offer. For CY 2024, sponsors provided their bid information through three different submissions: a proposed formulary, a Bid Pricing Tool (BPT), and a Plan Benefit Package (PBP) submitted together by the statutory June 5, 2023 deadline. In general, the PBP describes the structure of a proposed benefit package (e.g., co-pay amounts, deductibles) while the BPT describes the underlying basis used to calculate the price of the benefit package. The information in all three of these submissions must combine to reflect a consistent benefit package. Additionally, pursuant to 42 C.F.R. § 423.505(k)(4), the sponsor's CEO or CFO must submit a certification (referred to as the "benefit certification") that the information provided in each bid is accurate, complete, and truthful.

Organizations are responsible for ensuring that complete and accurate CY 2024 bids were submitted by the June 5, 2023 deadline, and for following CMS bidding procedures. Yet, the Part D portion of H4286's initial bid failed to constitute a complete and accurate bid submission. These deficiencies were

revealed by the following:

The sponsor incorrectly answered the question indicating for which tiers the deductible will not apply.

The sponsor incorrectly submitted its PBP, listing that Tier 1 has Part D and excluded drugs on it. It needed to be updated to have Tier 1 as only including Part D drugs. The sponsor stated that this issue did not affect the BPT, but it had a separate issue that required an update to the BPT.

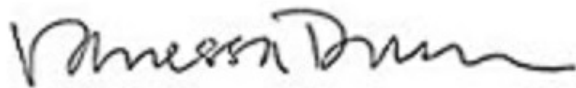
The need for CMS to work with H4286 to correct its CY 2024 bid indicates that it failed to comply with Part D regulatory requirements and follow CMS bid instructions.

Consistent with CMS's authority under 42 C.F.R. § 423.505(n)(3)(iii), we request that your organization take corrective action to come into compliance. CMS will rely on H4286's CY 2025 bid submission to determine whether the corrective action plan has been successfully implemented. CMS will consider the CAP closed once the Division of Formulary and Benefit Operations has determined that H4286's CY 2025 bid submission demonstrates that it has effectively resolved the issues described above.

Please be aware that this letter will be included in the record of your organization's past Medicare contract performance, which CMS will consider as part of our review of any application for new or expanded Medicare contracts your organization may submit. CMS deems this instance of non-compliance a Part D issue. CMS notes that we are issuing this compliance notice based on information that we obtained from the sponsor's own self-disclosure.

For questions regarding your bid submission, please contact the Part D Benefits mailbox at PartDBenefits@cms.hhs.gov. If you have any questions about the compliance implications of this notice, please contact Christine Hill at Christine.Hill@cms.hhs.gov and copy your account manager.

Sincerely,



Vanessa Duran, Acting Director
Medicare Drug Benefit and C & D Data Group
Center for Medicare

CC via email:

LAURA COLLINS, CMS

Linda Anders, CMS
Arianne Spaccarelli, CMS
Christine Hill, CMS

