

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



CENTER FOR MEDICARE

January 03, 2025

Warning Letter

Contract ID: H7813

Parent Organization Name: CDS Monarch, Inc.

Legal Entity Name: ICIRCLE SERVICES OF THE FINGER LAKES, INC.

Diane Frederico
Medicare Compliance Officer
860 Hard Rd
Webster, NY 14580

VIA EMAIL: diane.frederico@icirclecny.org

RE: FAILURE TO SUBMIT CY 2025 TRANSITION POLICY BY DEADLINE

Dear Diane Frederico:

The Centers for Medicare & Medicaid Services (CMS) is issuing this warning letter to ICIRCLE SERVICES OF THE FINGER LAKES, INC. (H7813) for its failure to meet the June 3, 2024 deadline for the submission of a formulary transition policy, transition policy attestations, and description of the processes that have been adopted to make a transition process available to your beneficiaries for contract year (CY) 2025. We are issuing a warning letter because CMS issued a notice of non-compliance to your organization for its failure to comply with this same submission requirement during the CY 2024 bid cycle.

Consistent with 42 C.F.R. § 423.120(b)(3), a Part D sponsor must provide for an appropriate transition process for enrollees prescribed Part D drugs that are not on its Part D plan's formulary (including Part D drugs that are on a sponsor's formulary but require prior authorization or step therapy under a plan's utilization management rules). The specific requirements for the transition process are found at the above cited regulation. Since the transition process is required as part of a formulary, and formulary information is to be included as part of a bid submission, [1] each Part D sponsor must submit a description of its transition policy for the upcoming contract year to CMS by the bid deadline of the first Monday in June, which is codified at 42 C.F.R. § 423.265. For CY 2025, the first Monday in June was June 3, 2024

On June 4, 2024, CMS informed your organization that you did not submit your transition policy by the June 3rd deadline.

CMS afforded your organization an additional opportunity to submit a policy prior to approval of the formulary. While you may have taken advantage of that opportunity, the initial missed deadline placed your organization out of compliance with Part D program requirements.

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 exclusively on information that we obtained from sources other than the sponsor's own self-disclosure.

If you have questions regarding your Transition Policy Submission, please contact the Part D Transition mailbox at PartDTransition@cms.hhs.gov. If you have questions related to the compliance implications of this notice, please contact Christine Hill at Christine.Hill@cms.hhs.gov and send a copy to your account manager.

Sincerely,

A handwritten signature in black ink, appearing to read "Linda Anders".

Linda Anders, Division Director
Division of Benefit Purchasing and Monitoring
Medicare Drug Benefit and C&D Data Group

CC via email:

Jessica Quesada, CMS
Arianne Spaccarelli, CMS
Brian Martin, CMS
Christine Hill, CMS

[1] As discussed in the preamble of Final Rule CMS-4068-F, "information that would accompany the bid submission would, at a minimum, include...the plan's formulary." See p.4294 at <https://www.govinfo.gov/content/pkg/FR-2005-01-28/pdf/05-1321.pdf>.