



CENTER FOR MEDICARE

February 22, 2023

Corrective Action Plan

Contract ID: S7694

Parent Organization Name: Rite Aid Corporation

Legal Entity Name: ELIXIR INSURANCE COMPANY

Dan O'Donnell
Medicare Compliance Officer
7835 Freedom Avenue NW
North Canton, OH 44720

VIA EMAIL: dodonnell@elixirsolutions.com

RE: FAILURE TO COMPLY WITH PART D DRUG MANAGEMENT PROGRAM ACCESS LIMITATION REQUIREMENTS

Dear Dan O'Donnell:

The Centers for Medicare & Medicaid Services (CMS) is issuing a request for ELIXIR INSURANCE COMPANY, which operates Medicare Part D Contract ID S7694, to develop and implement a Corrective Action Plan (CAP) to address the organization's failure to comply with the Part D drug management program (DMP) access limitation requirements.

CMS regulations in 42 CFR § 423.153(f) outline the requirements that Part D sponsors must follow regarding DMPs. As detailed in 42 CFR § 423.153(f)(4), a sponsor may not limit the access of an at-risk beneficiary to coverage for frequently abused drugs under 42 CFR § 423.153(f)(3), unless the sponsor has done all of the following:

- (A) Conducted case management as required by paragraph (f)(2) of this section and updated it, if necessary.
- (B) Except in the case of a pharmacy limitation imposed pursuant to paragraph (f)(3)(ii)(B) of this section, obtained the agreement of at least one prescriber of frequently abused drugs for the beneficiary that the specific limitation is appropriate.
- (C) Provided the notices to the beneficiary in compliance with paragraphs (f)(5) and (6) of this section.

Additionally, as required in 42 CFR § 423.153(f)(15)(ii)(D), a Part D sponsor must provide information to CMS as soon as possible but no later than seven days from the date of the initial notice or second notice that the sponsor provided to a beneficiary, or as soon as possible but no later than seven days from a

termination date, as applicable, about a beneficiary-specific opioid claim edit or a limitation on access to coverage for frequently abused drugs. The HPMS memorandum, “2021 Part D Drug Management Program Guidance” (dated December 23, 2020), instructs Part D sponsors to disclose the information to CMS by entering this information into the Medicare Advantage Prescription Drug (MARx) system.

CMS is issuing this compliance notice to your organization because CMS identified a case where an at-risk beneficiary had a DMP limitation that your organization had not entered in the MARx system, in violation of 42 CFR § 423.153(f)(15)(ii)(D), both when your organization initially implemented the DMP limitation (October 2020) and when it decided to extend the limitation for an additional year (September 2021). This at-risk beneficiary was then able to use the low-income subsidy (LIS) special enrollment period, in violation of 42 CFR § 423.38(c)(4), to change plans on October 1, 2021. The beneficiary returned to your plan on January 1, 2022, at which point you resumed the prior DMP limitation on this beneficiary without doing proper case management as required at 42 CFR § 423.153(f)(4).

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 expects your organization to develop and successfully complete a CAP designed to bring it into compliance with the Part D DMP access limitation 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.

In the future, please ensure that your organization properly follows all regulatory requirements prior to limiting the access of an at-risk beneficiary to coverage for frequently abused drugs. For questions regarding DMP requirements, please contact the CMS mailbox at PartD_OM@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 copy your account manager.

Sincerely,



Amy Larrick Chavez-Valdez, Director

Medicare Drug Benefit and C&D Data Group

CC via email:

MARK HOLLY, CMS

Linda Anders, CMS

Arienne Spaccarelli, CMS

Christine Hill, CMS

PartD_OM@cms.hhs.gov