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April 01, 2022

**Corrective Action Plan**

Contract ID: S7694

Parent Organization Name: Rite Aid Corporation

Legal Entity Name: ELIXIR INSURANCE COMPANY

Dan ODonnell  
Medicare Compliance Officer  
2181 East Aurora Road  
Suite 201  
Twinsburg, OH 44087

VIA EMAIL: dodonnell@elixirsolutions.com

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

Dear Dan ODonnell:

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) coverage limitation requirements.

CMS regulations at 42 CFR § 423.153(f) outline the requirements that Part D sponsors must follow regarding DMPs. As outlined in 42 CFR § 423.153(f)(2)(i)(B), part of the case management process under this program requires the sponsor to elicit information as to whether a beneficiary is an exempted beneficiary for the purposes of the DMP. Section 423.100 defines an "exempted beneficiary" (with respect to a DMP) as an enrollee who--

- 1) Has elected to receive hospice care or is receiving palliative or end-of-life care;
- 2) Is a resident of a long-term care facility, of a facility described in section 1905(d) of the Act, or of another facility for which frequently abused drugs are dispensed for residents through a contract with a single pharmacy;
- 3) Is being treated for active cancer-related pain or
- 4) Has sickle cell disease. [1]

An exempted beneficiary is excluded from the definitions of "potential at-risk beneficiary" and "at-risk beneficiary." Therefore, a Part D sponsor may not place such beneficiaries in its DMP, nor can a sponsor implement any limitation on their access to coverage for frequently abused drugs under its DMP.

Additionally, a sponsor must remove an exempted beneficiary from a DMP as soon as it reliably learns that the beneficiary is exempt. [2] If an affected exempted beneficiary is a low income subsidy eligible individual (as defined at 42 CFR § 423.772), an active DMP coverage limitation in CMS's Medicare Advantage Prescription Drug (MARx) system would inappropriately restrict that beneficiary's access to special enrollment periods that such beneficiary would be entitled to per 42 CFR § 423.38(c)(4)(i).

CMS is issuing this compliance notice to your organization because CMS identified 3 cases with exempted beneficiary exceptions reported in the Overutilization Monitoring System (OMS) as of 11/28/2021. The corresponding cases files in MARx have active coverage limitations as of 1/14/2022, which is in violation of DMP coverage limitation exceptions related to exempted beneficiaries. Your organization also had 25 other cases identified in 2021 that have since been resolved.

Consistent with CMS's authority under 42 C.F.R. § 423.509(c), 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 case management and coverage limitation requirements. CMS requests that your organization provide documentation that it either never implemented or appropriately terminated the coverage limitation(s) in its point-of-sales (POS) system, including paid opioid claims following the termination of the POS edit for the following Verification Response Form (VRF) case numbers:

- S7694\_0007
- S7694\_0031
- S7694\_0065

CMS would also like to request that your organization provide the following case files for review of your case management process:

- S7694\_0001
- S7694\_0030
- S7694\_0068

Please reach out to the CMS mailbox at [PartD\\_OM@cms.hhs.gov](mailto:PartD_OM@cms.hhs.gov) within 2 weeks of receipt of this letter to coordinate the secure transmission of these files.

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 excludes exempted beneficiaries from any potential DMP coverage limitations. For questions regarding DMP requirements, please contact the CMS mailbox at [PartD\\_OM@cms.hhs.gov](mailto: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](mailto: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 HARTMAN, CMS

Linda Anders, CMS

Michael Neuman, CMS

Christine Hill, CMS

[PartD\\_OM@cms.hhs.gov](mailto:PartD_OM@cms.hhs.gov)

[1] Sickle Cell disease was added to the definition as of January 1, 2022.

[2] For further information, please refer to the HPMS Memo entitled “2021 Part D Drug Management Program Guidance” (dated December 23, 2020).