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



MEDICARE PARTS C AND D OVERSIGHT AND ENFORCEMENT GROUP

October 13, 2023

Mr. Art Carlos Chief Executive Officer Clear Spring Health Insurance Company 250 South Northwest Highway Park Ridge, IL 60068

Re: Notice of Termination and Intermediate Sanctions (Suspension of Enrollment and Marketing) for Prescription Drug Plan Contract Number: S6946

Dear Mr. Carlos:

The Centers for Medicare & Medicaid Services (CMS) hereby notifies you of its decision to terminate (effective 11:59:59 P.M. Eastern Standard Time (EST) December 31, 2024) Clear Spring Health Insurance Company (Clear Spring) Prescription Drug Plan (PDP) contract S6946 pursuant to Sections 1860D-12(b)(3)(B) and 1857(c)(2) of the Social Security Act (the Act), and 42 C.F.R. § 423.509(a)(4)(x).

In addition to the termination and in accordance with 42 C.F.R. § 423.756(a) and (d), CMS is also providing notice to Clear Spring that CMS has made a determination to impose intermediate sanctions on PDP contract number S6946. The intermediate sanctions will consist of the suspension of enrollment of Medicare beneficiaries into Clear Spring's contract (42 C.F.R. § 423.750(a)(1)), and the suspension of all marketing activities to Medicare beneficiaries (42 C.F.R. § 423.750(a)(3)). The intermediate sanctions will be effective 15 calendar days from the date of receipt of this notice, or October 29, 2023. CMS will provide Clear Spring with detailed instructions regarding the enrollment and marketing suspension in a separate communication.

The basis for this action is that CMS has determined that Clear Spring has substantially failed to carry out its contract with CMS by failing to achieve a Part D summary Star Rating of at least three stars in three consecutive Star Rating periods for contract S6946.

Summary of Noncompliance

S6946 is a PDP contract that has been in operation since January 1, 2020. Medicare regulations at 42 C.F.R. § 423.505(b)(26) require PDP contracts to maintain a Part D summary plan rating score of at least three stars. S6946 has had three consecutive years of low Part D summary Star Ratings as of the 2024 Star Ratings released in October 2023, in violation of 42 C.F.R.

423.509(a)(4)(x) and 423.505(b)(26) and Art. II.D.3 of the Prescription Drug Plan Contract. Therefore, Clear Spring has failed substantially to carry out the terms of its contract and CMS has made the determination to impose intermediate sanctions and to terminate contract S6946 at the end of 2024.

Part D Star Rating Requirements

Since 2007, CMS has developed and published annual performance ratings for stand-alone Medicare prescription drug plan (PDP) contracts. The ratings are based on measures that address a range of drug plan performance categories, including access to prescription medications, and communication with members. The scores in each performance category are based on data reported by PDP sponsors, member satisfaction, and monitoring conducted by CMS and its contractors. PDP contracts receive a score for each performance measure, as well as an overall rating. This score is called a Star Rating.¹

The performance measures used to calculate a contract's Part D summary Star Rating reflect a PDP's contract performance across multiple Medicare program requirements. A contracting organization's administrative and management arrangements necessarily have a direct impact on its performance of a similarly broad range of program requirements.² Therefore, CMS considers a low Part D summary Star Rating to be evidence that the PDP has insufficient administrative and management arrangements as a Part D plan sponsor.

Based on that determination, CMS established the Medicare requirement that all contracts maintain a Part D summary plan rating score of at least three stars. *See* 42 C.F.R. § 423.505(b)(26). In addition, CMS may terminate a PDP contract if it achieves a Part D summary plan rating of less than three stars for three consecutive contract years (*see* 42 C.F.R. § 423.509(a)(4)(x)).

Violations Related to Part D Summary Star Ratings

CMS has determined that Clear Spring's contract S6946 failed to comply with Part D Star Ratings requirements by failing to achieve a Part D summary Star Rating of at least three stars for three consecutive years in violation of 42 C.F.R. §§ 423.505(b)(26) and 423.509(a)(4)(x). Specifically, the three consecutive annual Part D Star Ratings for contract S6946 are as follows:

- 2022 Part D Summary Star Rating of 2
- 2023 Part D Summary Star Rating of 1.5
- 2024 Part D Summary Star Rating of 1.5

¹ See 42 C.F.R. §§ 423.180-86 for details on the calculation of Star Rating measures.

² Medicare regulations at 42 C.F.R. § 423.504(b)(4)(ii) require PDP organizations to have administrative and management arrangements satisfactory to CMS, including personnel and systems sufficient for the organization to market and administer benefit plans and conduct utilization management and quality assurance activities consistent with Medicare requirements.

Clear Spring was informed of its Part D summary Star Ratings for 2022, 2023, and 2024 on October 6, 2021, October 4, 2022, and October 13, 2023, respectively.³

Basis for Termination and Intermediate Sanctions

Pursuant to 42 C.F.R. § 423.509(a)(4)(x), CMS may terminate a Part D sponsor's contract if it "achieves a Part D summary plan rating of less than 3 stars for 3 consecutive contract years."⁴ CMS has determined that Clear Spring's contract S6946 substantially failed to comply with the Part D Star Ratings requirements by failing to achieve a Part D summary Star Rating of at least three stars for three consecutive years. This is in violation of 42 C.F.R. §§ 423.509(a)(4)(x) and 423.505(b)(26), and Art. II.D.3 of the Prescription Drug Plan Contract.

Pursuant to 42 C.F.R. § 423.752(b), if CMS makes a determination that could lead to a contract termination under § 423.509(a), CMS may impose intermediate sanctions at § 423.750(a)(1) and (3). Also, pursuant to 42 C.F.R. § 423.756(d), CMS may terminate a contract in addition to imposing sanctions described at § 423.750. Therefore, since CMS has determined that Clear Spring's contract S6946 has substantially failed to comply with the Part D Star Ratings requirements at § 423.509(a)(4)(x), CMS is imposing intermediate sanctions specified at § 423.750(a)(1) and (3) in addition to terminating contract S6946.

Procedural Requirements for Termination and Intermediate Sanction

Pursuant to 42 C.F.R. § 423.756(c)(3), the sanction will remain in effect until CMS is satisfied that Clear Spring has corrected the causes of the violations which form the basis for the sanction and the violations are not likely to recur. In addition, pursuant to 42 C.F.R. 423.509(c)(1)(i), before providing a notice of intent to terminate the contract, CMS provides the Part D plan sponsor with notice specifying the Part D plan sponsor's deficiencies and a reasonable opportunity of at least 30 calendar days to develop and implement a corrective action plan to correct the deficiencies.

Clear Spring has been on notice of the need to improve its Part D summary Star Ratings performance since the issuance of the 2022 Star Ratings on October 6, 2021. Each year CMS provides PDPs with two preview periods before Star Ratings become public (see 42 C.F.R. § 423.186(h)(2)). During the preview periods, Clear Spring had the opportunity to review preliminary calculations and seek corrections to the underlying data and calculations before the Star Ratings become public. In addition, Clear Spring received a corrective action notice on February 25, 2022, for its 2022 Star Ratings and on February 24, 2023, for its 2023 Star Ratings. The corrective action notices informed Clear Spring of its Star Rating, informed Clear Spring that it should take steps to improve its operations for the areas that resulted in a low Star Rating,

³ Part D summary Star Ratings data for 2022, 2023, and 2024 is publicly available at https://www.cms.gov/medicare/health-drug-plans/part-c-d-performance-data by navigating to "2022 Star Ratings Data Table", "2023 Star Ratings Data Table", and "2024 Star Ratings Data Table."

⁴ Pursuant to 42 CFR § 423.4, the definition of "Part D sponsor" includes "a PDP sponsor, MA organization offering a MA-PD plan, a PACE organization offering a PACE plan including qualifying prescription drug coverage, and a cost plan offering qualified prescription drug coverage."

and put Clear Spring on notice that its contract will be eligible for termination if it achieves a Part D Summary Star Rating of below three stars for three (3) consecutive years.

Therefore, pursuant to 42 C.F.R. § 423.509(c), Clear Spring has had notice of its insufficient Part D summary Star Ratings and a reasonable opportunity to correct this deficiency by improving its Star Rating performance, which it failed to do.

Opportunity to Respond to Intermediate Sanction Notice

Pursuant to 42 C.F.R. § 423.756(a)(2), Clear Spring has (10) calendar days from the date of receipt of this notice to provide a written rebuttal to the intermediate sanction determination, or by October 24, 2023. Please note that CMS considers receipt as the day after the notice is sent by fax, e-mail, or overnight mail, which in this case would be October 14, 2023. If you choose to submit a rebuttal, please send it to the attention of Kevin Stansbury at the address noted below. Note that the intermediate sanctions imposed pursuant to this letter are not stayed pending a rebuttal submission. 42 C.F.R. § 423.756(a), (b)(3).

Right to Request Hearings for Termination and Intermediate Sanctions

Clear Spring may request a hearing before a CMS hearing officer in accordance with the procedures outlined in 42 C.F.R. § 423.650-668. If Clear Spring wishes to appeal both the contract termination determination and intermediate sanction determination, Clear Spring **must send separate written requests for a hearing for each determination** according to the procedures in 42 C.F.R. 423 Subpart N.

Pursuant to 42 C.F.R. § 423.651(b) and § 423.756(b), a written request(s) for a hearing must be received by CMS within fifteen (15) calendar days after receipt of this notice, or in this case by October 30, 2023. If Clear Spring is appealing the intermediate sanction determination, a request for a hearing will not delay the date specified by CMS when the intermediate sanctions become effective. See 42 C.F.R. § 423.756(b)(3).

The request for a hearing must be sent to CMS electronically to the CMS Office of Hearings (OH). OH utilizes an electronic filing and case management system, the Office of Hearings Case and Document Management System ("OH CDMS").

Clear Spring should complete the one-time OH CDMS registration process as soon as possible after receiving this Notice, even if Clear Spring is unsure whether it will appeal its determination. After the registration process is complete, Clear Spring must then file its request for a hearing within the time frame set forth above.

Registration information (including how to add an outside representative/law firm to participate in the appeal), filing instructions and general information may be found on the OH webpage at https://www.cms.gov/regulations-guidance/cms-hearing-officer/electronic-filing. Follow the OH CDMS External Registration Manual for step-by-step instructions regarding registration and

the OH CDMS Hearing Officer User Manual for appeal filing instructions.⁶

A copy of the hearing request(s) should also be emailed to CMS at the following address:

Kevin Stansbury Director, Division of Compliance Enforcement Centers for Medicare & Medicaid Services 7500 Security Boulevard Baltimore, MD 21244 Mail Stop: C1-22-06 Email: <u>kevin.stansbury@cms.hhs.gov</u>

CMS will consider the date the Office of Hearings receives the request via the CDMS as the date of receipt of the request(s). The request(s) for a hearing must include the name, fax number, and e-mail address of the contact within Clear Spring (or an attorney who has a letter of authorization to represent the organization) with whom CMS should communicate regarding the hearing request(s).

If Clear Spring has any questions about this notice, please call or email the enforcement contact provided in the email notification.

Sincerely,

/s/

John A. Scott Director Medicare Parts C and D Oversight and Enforcement Group

cc:	Kevin Stansbury, CMS/MOEG/DCE Vanessa Duran, CMS/MDBG
	Mark Newsom, CMS/MDBG
	Linda Anders, CMS/MDBG
	Arianne Spaccarelli, CMS/MDBG
	Kathryn Coleman, CMS/MCAG
	Julie Uebersax, CMS/MCAG
	Elizabeth Goldstein, CMS/MDBG
	Megan Mason, CMS/OPOLE
	Raymond Swisher, CMS/OPOLE
	Adams Solola, CMS/OPOLE
	Avalon Gordon, CMS/OPOLE

⁶ If technical assistance is required, please contact the OH CDMS Help Desk at 1-833-783-8255 or by email at <u>helpdesk_ohcdms@cms.hhs.gov</u>. The hours of operation are Monday–Friday (excluding federal holidays) from 7:00 a.m. to 8:00 p.m. Eastern Time.