DEPARTMENT OF HEALTH & HUMAN SERVICES



Centers for Medicare & Medicaid Services Office of Hearings 7500 Security Boulevard Mail Stop: N2-19-25 Baltimore, MD 21244

July 28, 2022

Via Electronic Delivery

Thomas R. Barker, Esquire Foley Hoag, LLP 1717 K Street NW Washington, DC 20006

Arianne Spaccarelli MAPD Appeals Team 7500 Security Boulevard Baltimore, MD 21244

RE: Hearing Officer Decision

Hearing Officer Docket Number: H-22-00015

Medicare Advantage/Prescription Drug Plan Contract Denial

Reliance HMO, Inc., Contract Number: H4306

Dear Mr. Barker and Ms. Spaccarelli:

A copy of the Hearing Officer's decision for the above-referenced appeal is attached.

The Hearing Officer's decision may be appealed to the Administrator of the Centers for Medicare & Medicaid Services. The parties may request review by the Administrator within 15 calendar days of receiving this decision. *See* 42 C.F.R. § 422.692; 42 C.F.R. § 423.666. Requests for review should be sent via email to Jacqueline R. Vaughn, Director, Office of the Attorney Advisor, at Jacqueline.Vaughn@cms.hhs.gov, with a copy to Arlene O. Gassmann, Paralegal Specialist, at Arlene.Gassmann@cms.hhs.gov.

Sincerely,

Office of Hearings

DEPARTMENT OF HEALTH AND HUMAN SERVICES CENTERS FOR MEDICARE & MEDICAID SERVICES

| Reliance HMO, Inc. | * | Denial of Application to Offer |
|------------------------|---|---------------------------------------|
| Contract No. H4306, | * | Medicare Advantage/Medicare |
| | * | Advantage-Prescription Drug |
| Appellant | * | Plan |
| | * | |
| v. | * | Contract Year 2023 |
| | * | |
| Centers for Medicare & | * | |
| Medicaid Services, | * | Hearing Officer Docket No. |
| , | * | H-22-00015 |
| Respondent | * | |
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ORDER GRANTING MOTION FOR SUMMARY JUDGMENT

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I. <u>FILINGS</u>

This Order is being issued in response to the following:

- (a) Reliance HMO, Inc.'s ("Reliance" or "Applicant") Hearing Request filed on June 1, 2022;
- (b) Reliance's Motion for Summary Judgment ("Reliance MSJ") filed on June 22, 2022:
- (c) Reliance's Hearing Brief and Exhibits filed on June 22, 2022;
- (d) Centers for Medicare & Medicaid Services' ("CMS") Brief in Reply to Reliance's Hearing Brief (including a Motion for Summary Judgment) ("CMS Brief") filed on June 29, 2022; and
- (e) Reliance's Reply Brief filed on July 6, 2022.

II. <u>JURISDICTION</u>

This appeal is provided pursuant to 42 C.F.R. §§ 422.660 and 423.650. The CMS Hearing Officer designated to hear this case is the undersigned, Benjamin R. Cohen.

III. <u>ISSUE</u>

Whether CMS' denial of Reliance's initial application for a Medicare Advantage/Medicare Advantage-Prescription Drug contract (H4306) (hereinafter "MA-PD") based on the failure of Reliance to comply with the terms of a current or previous year's contract in accordance with 42 C.F.R. §§ 422.502(b) (2021) and 423.502(b)(1) (2021) was proper.

IV. <u>DECISION SUMMARY</u>

The Hearing Officer grants CMS' Motion for Summary Judgment. The Hearing Officer's authority is limited to deciding if CMS' determination was consistent with regulatory requirements. See 42 C.F.R. §§ 422.660 and 423.650. Reliance's application was subject to the past performance regulations at 42 C.F.R. §§ 422.502(b) and 423.503(b). The regulations were published on January 19, 2021, and effective on March 22, 2021, well before the 2023 application review cycle which ran from February 2022 through May 2022. It is undisputed that Reliance failed to maintain fiscal soundness based on its 2020 audited financial statement, which was submitted in January 2022, and the State of Michigan did not release Reliance from its Order of Supervision until May 20, 2022. Reliance's fiscal problems were ongoing through the 12-month past performance review period. The Hearing Officer finds that CMS applied and followed the controlling regulations which were in effect. Accordingly, the Hearing Officer upholds CMS' denial of Reliance's applications.

Moreover, the Hearing Officer notes that Reliance did not provide a compelling factual argument that CMS' decision to deny the applications was impermissibly retroactive or fundamentally unfair in terms of fair notice, reliance, and settled expectations.

V. LEGAL BACKGROUND

A. Application Process

Any entity seeking to contract as an MA organization must fully complete all parts of a certified application in the form and manner required by CMS. See 42 C.F.R. §§ 422.501(c) and 422.503(b)(1); 42 C.F.R. §§ 423.502(c) and 423.504(b). Specifically, CMS requires that an application be submitted through the Health Plan Management System ("HPMS") and in accordance with instructions and guidelines that CMS may issue. Among other requirements, an applicant must provide "[d]ocumentation of appropriate State licensure or State certification that the entity is able to offer health insurance or health benefits coverage that meets State-specified standards applicable to MA plans" as required under 42 C.F.R. § 422.501(c)(i). See also 42 C.F.R. § 423.502(c)(1).

Under current regulations and procedures, after receiving an application, CMS reviews the application to determine whether the applicant meets all the necessary requirements. (42 C.F.R. §§ 422.502(c)(2)(i) and 423.503(a)(2)). When evaluating applications, CMS bases its decision to approve or deny each application solely on information appropriately submitted by the applicant through HPMS as part of the application itself and relevant past performance history associated with the applicant (42 C.F.R. § 422.502(a)(1), (b)(1); 42 C.F.R. § 423.503(a)(1), (b)(1)). In general, CMS uses information from an applicant's current or prior contract under 42 C.F.R. §§ 422.502(b) and 423.503(b).

Following its review, CMS notifies an applicant of any deficiencies by sending a Deficiency Notice. This is an applicant's first opportunity to amend its application.

If an applicant fails to cure its deficiencies, CMS will issue a Notice of Intent to Deny ("NOID"). 42 C.F.R. §§ 422.502(c)(2)(i) and 423.503(c)(2)(i). The NOID affords an applicant a second opportunity to cure its application. *See* 42 C.F.R. §§ 422.502(c)(2)(ii) and 423.503(c)(2)(ii). After a NOID is issued, an applicant has a final ten-day period to cure any deficiencies in order to meet CMS' requirements; otherwise, CMS will deny the application. 42 C.F.R. §§ 422.502(c)(2)(ii)-(iii) and 423.503(c)(2)(ii)-(iii).

The formal NOID process is outlined at 42 C.F.R. § 422.502(c)(2)(i)-(iii), which states:

(i) If CMS finds that the applicant does not appear to be able to meet the requirements for an MA organization or Specialized MA Plan for Special Needs Individuals, CMS gives the applicant notice of intent to deny the application for an MA contract or for a Specialized MA Plan for Special Needs Individuals a summary of the basis for this preliminary finding.

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¹ See 42 C.F.R. § 423.503(c)(2)(i)-(iii) for parallel cite for Part D.

- (ii) Within 10 days from the intent to deny, the applicant must respond in writing to the issues or other matters that were the basis for CMS' preliminary finding and must revise its application to remedy any defects CMS identified.
- (iii) If CMS does not receive a revised application within 10 days from the date of the notice, or if after timely submission of a revised application, CMS still finds that the applicant does not appear qualified or has not provided CMS enough information to allow CMS to evaluate the application, CMS will deny the application.

If, after review, CMS denies the application, written notice of the determination and the basis for the determination is given to the applicant. 42 C.F.R. §§ 422.502(c)(3) and 423.503(c)(3).

If CMS denies an MA application, the applicant is entitled to a hearing before a CMS Hearing Officer. 42 C.F.R. §§ 422.502(c)(3)(iii) and 423.503(c)(3)(iii). The applicant has the burden of proving by a preponderance of the evidence that CMS' determination was inconsistent with the requirements of 42 C.F.R. §§ 422.501 and 423.502 (application requirements) and 42 C.F.R. §§ 422.503 and 423.504 (evaluation and determination procedures). 42 C.F.R. §§ 422.660(b)(1) and 423.650(b)(1). In addition, either party may ask the Hearing Officer to rule on a Motion for Summary Judgment. 42 C.F.R. §§ 422.684(b) and 423.662(b). The authority of the Hearing Officer is found at 42 C.F.R. §§ 422.688 and 423.664, which specifies that "[i]n exercising his or her authority, the hearing officer must comply with the provisions of title XVIII [of the Social Security Act ("Act")] and related provisions of the Act, the regulations issued by the Secretary, and general instructions issued by CMS in implementing the Act."

B. <u>Consideration of Performance Under an Applicant's Current or Prior Year</u> Contract

While the parties disagree regarding whether CMS' application of the past performance criteria in the current version of 42 C.F.R. §§ 422.502(b) and 423.503(b) constitutes an impermissible retroactive application of an agency regulation under section 1871(e)(1) of the Social Security Act, the parties do not have a disagreement regarding the historical development of the controlling authorities that have provided CMS the general authority to consider an MA-PD organization's past performance while reviewing annual MA-PD contract applications. CMS provides a thorough background as follows:

CMS may deny an MA and/or Part D application if the applicant failed, during the 12 months preceding the application submission deadline, to comply with the requirements of the Part C and/or D programs. Applicants may be considered to have failed to comply with a contract for purposes of application denial if they were subject to an intermediate sanction under 42 CFR Part 422 Subpart O and/or 42 CFR Part 423 Subpart O or if they failed to maintain a fiscally sound operation as required by 42 CFR §§ 422.504(b)(14) and 423.505(b)(23). CMS may rely on this basis even if the applicant demonstrates through its submitted application that it

otherwise meets all of the requirements for qualification as a Part C or Part D sponsor. 42 CFR §§ 422.502(b) and 423.503(b).

CMS first adopted the authority to deny Part C contract qualification applications from current Medicare contractors through the interim final rule published in June 1998 as part of the implementation of the Medicare+Choice program, the predecessor to the current MA program. 63 Fed. Reg. 34975-34976 (June 28, 1998). CMS incorporated the same provision into the Part D implementing regulations published in January 2005. 70 Fed. Reg. 4554 (January 28, 2005).

CMS made clarifications to the past performance authority through a final rule published in April 2010. 75 Fed. Reg. 19684 (April 15, 2010). There, CMS amended 42 C.F.R. §§ 422.502(b) and 423.503(b) to state that in conducting its analysis of a contracting organization's past performance, it would look back over the 14-month period immediately preceding the deadline for the submission of contract qualification applications. CMS stated in the preamble that it would develop a methodology for conducting the analysis of organizations' past Medicare contract performance and that it would make it available through publication in its manuals. CMS published the first Past Performance Methodology in final on December 13, 2010 for use during the CY 2012 application cycle that commenced in February 2011. The past performance review period for the 2012 application cycle was January 2010 through February 2011, a time period that began five months before the June 7, 2010 effective date of the rule.

CMS made additional clarifications to past performance authority in a final rule published in April 2018. [83] Fed. Reg. 16440 (April 16, 2018). In that rule, CMS changed the past performance review period from 14 months to 12 months.

CMS issued past performance methodologies for application cycles after the 2012 cycle in the late fall or early winter immediately prior to the application due date for the respective cycle. The latest a [sic] methodology was released was February 11, 2015, for the 2016 application cycle that commenced later that month, and the earliest was December 2, 2011[,] for the 2013 application cycle that commenced in February 2012. CMS last issued a past performance methodology on January 25, 2019[,] for the 2020 application cycle that commenced in February 2019.

CMS subsequently amended its regulations at 42 CFR §§ 422.502(b) and 423.503(b) in a final rule published in January 2021. 86 Fed. Reg. 5864 (January 19, 2021). Under the amended regulation, an applicant may be considered to have failed to comply with a contract for purposes of an application denial under 42 CFR §§ 422.502(b)(1) or 423.502(b)(1) if during the 12 month review period prior to submitting an application it had (1) been subject to the imposition of an intermediate sanction under Part 422 Subpart O or Part 423 Subpart O of the regulation, or (2) failed to maintain a fiscally sound operation as required by 42

² The effective date of the regulation is March 22, 2021. 86 Fed. Reg. at 5864.

CFR §§ 422.504(b)(14) or 423.505(b)(23). 42 CFR §§ 422.502(b)(1)(i) and 423.503(b)(1)(i).

Each of these bases, on its own, "represents significant noncompliance with an MA or Part D contract." 86 Fed. Reg. at 5999. Intermediate sanctions can suspend Medicare beneficiary enrollment into plans, plan communication with beneficiaries, and/or CMS payment to the plan for beneficiaries enrolled after the sanction date. 42 CFR §§ 422.750(a) and 423.750(a). CMS imposes intermediate sanctions for certain substantial violations of the organization's contract with CMS described in 42 CFR §§ 422.752(a) and 423.752(a) or, pursuant to 42 CFR §§ 422.752(b) and 423.752(b), when CMS makes a determination that could lead to a contract termination under 42 CFR §§ 422.510(a) or 423.509(a). Organizations subject to intermediate sanctions are afforded the administrative appeals rights in Part 422 Subpart N and Part 423 Subpart N. 42 CFR §§ 422.756(b) and 423.756(b).

The fiscal solvency requirement requires that organizations "[m]aintain a fiscally sound operation by at least maintaining a positive net worth." 42 CFR §§ 422.504(b)(14) and 423.505(b)(23). As CMS stated in the 2021 final rule, failure to meet the program's fiscal solvency requirements "places in jeopardy the organization's ability to even meet its current contractual requirements." 86 Fed. Reg. at 6000.

In adopting these bases for application denial, CMS noted that its "overall policy with respect to past performance remains the same." 86 Fed. Reg. at 5999. CMS adopted the changes so that it could continue to deny applications where "the level of previous noncompliance is such that granting additional MA or Part D business opportunities to the responsible organization would pose a high risk to the success and stability of the MA and Part D programs and their enrollees." 86 Fed. Reg. at 5999. Both of these bases had, in fact, been important elements of the prior past performance methodology — in the 2020 Application Cycle Methodology, a negative net worth would result in an organization receiving two negative performance points and an intermediate sanction could result in from two to seven points, depending on the type of sanction and whether it was lifted during the review period. Exhibit C-1. CMS adopted these two bases instead of the type of multifactor analysis it had used in the past performance methodology because each one by its "nature already capture[s] significant and comprehensive information about an applicant's past contract performance." 86 Fed. Reg. at 6000.

As had been the case in all previous applications of its past performance authority, both before and after CMS began publishing annual past performance methodologies, CMS declared that it would assess past performance based on noncompliance that was identified or actions that were taken during the applicable review period, regardless of when the underlying noncompliance took place. As CMS stated in the proposed rule, "the relevant non-compliance must be documented by CMS (through the issuance of a letter, report, or other publication)

during the 12-month review period established at 42 CFR §§ 422.502(b)(1) and 423.503(b)(1). Thus, CMS may include in [its] analysis conduct that occurred prior to the 12-month past performance review period but either did not come to light, or was not documented, until sometime during the review period." 86 Fed. Reg. at 5999.

In the 2021 final rule, CMS also amended its past performance regulation to codify the longstanding policy attributing the performance of existing MA organizations and Part D sponsors to inexperienced legal entities under the same parent organization. So as not to discourage parent organizations from acquiring troubled plans, CMS also codified its two year "grace period" for organizations acquiring MA organizations or Part D sponsors, during which the poor past performance of a newly acquired legal entity would not be attributed to other legal entities held by the same parent organization. 86 Fed. Reg. at 6001. Under the new provision at 42 CFR §§ 422.502(b)(1)(ii) and 423.503(b)(1)(ii), if, for example, the MA organization MAO1 were under sanction in December 2021 and its parent organization formed NewCo to apply for a 2023 MAPD contract in February 2022, MAO1's performance would ordinarily be attributed to NewCo and prevent CMS from approving the application. However, if the parent had just acquired MAO1 in January 2022, it would fall within the grace period and NewCo's application would be unaffected by MAO1's poor performance. However, MAO1, as the legal entity that had itself failed to comply with a prior year's MA or Part D contract, would still be impacted by its own performance and any 2023 application would be denied on past performance grounds"

CMS Brief at 2-4.

C. Authority Cited - Retroactive Application of an Agency Regulation

Reliance's primary argument is that CMS' reliance on 42 C.F.R. §§ 422.502(b) and 423.502(b) is impermissibly retroactive. Reliance presents the legal authority in support of its contention as follows:

Section 1871(e)(1) of the Act provides that a substantive change in regulations and policy must not be applied retroactively, except for two narrow circumstances: 1) the HHS Secretary determines that such retroactive application is necessary to comply with statutory requirements; and 2) the HHS Secretary determines that failure to apply the change retroactively would be contrary to the public interest. The statute further provides that "[n]o action shall be taken against a provider of services or supplier with respect to noncompliance with such a substantive change for items and services furnished before the effective date of such a change." 42 U.S.C. § 1395hh(d)(1)(C).

This statutory framework is reflective of a congressional intent to narrow the scope of the retroactive applicability of Medicare rules, and is consistent with the strong

presumption against retroactivity established by the Supreme Court in *Bowen v. Georgetown Univ. Hosp.* 488 U.S. 204 (1988).³ This presumption is grounded in the principle that "[e]lementary considerations of fairness dictate that individuals should have an opportunity to know what the law is and to conform their conduct; accordingly, settled expectations should not be lightly disrupted." *Landgraf v. USI Film Products*, 511 U.S. 244, 265 (1994).

Notably, the Medicare statute's prohibition on the retroactive applicability of Medicare regulations focuses on regulations that amount to "substantive changes." 42 U.S.C. § 1395hh(e)(1)(A). This approach is consistent with the principle that a rule operates retroactively only when it imposes "new legal consequences" for past conduct. *Landgraf*, 511 U.S. at 269–70. According to the Supreme Court, a rule "is not made retroactive merely because it draws upon antecedent facts for its operation." *Cox v. Hart*, 260 U.S. 427, 435 (1992). Only where a rule creates "new legal consequences" for prior actions is it retroactive. *Landgraf*, 511 U.S. at 269-70. Whether a rule imposes "new legal consequences" is guided by "familiar considerations of fair notice, reasonable reliance, and settled expectations." *Id.* at 270.

Reliance Hearing Brief at 7-8.

VI. STATEMENT OF FACTS

Reliance is a health maintenance organization that has contracts with CMS to operate MA plans in certain geographic areas in Michigan, and is controlled by Commonwealth Care Alliance ("CCA"), a Massachusetts non-profit corporation. Reliance Hearing Brief at 1. Both parties agree that the facts are undisputed. Reliance provides an uncontested outline of its organization's financial related history as follows:

The Applicant was formed on January 7, 2017. On April 3, 2019, Applicant obtained a certificate of authority to operate as a state-licensed health maintenance organization with the ability to provide medical services to persons in Michigan who subscribe as recipients of federal health benefits under MA plans contracted by CMS. Applicant began enrolling members in 2019 for coverage beginning in January 2020.

In its first year, Applicant enrolled approximately 500 members. Applicant had scheduled a series of meetings with providers to attempt to increase the number of members. Unfortunately, this coincided with the onset of the COVID-19 pandemic

³ CMS distinguishes *Bowen* as follows: "The facts contrast to those in *Bowen v. Georgetown Univ. Hosp.*, 488 U.S. 204 (1988), where a retroactive application of a rate reduction would have resulted in CMS attempting to recoup payments already made to hospitals under rates in effect when the services were rendered. Reliance is not being penalized for conduct that was compliant when it took place or being deprived of anything to which it is entitled under its current contract. Reliance is merely being denied a new MAPD contract based on its noncompliance with its current contract, a consequence that has been a potential result of noncompliance for many years." CMS Brief at 7.

in the United States. The State of Michigan issued an Emergency Declaration on March 10, 2020. The Emergency Declaration and subsequent orders following the declaration restricted access to places of public accommodation, limited gatherings and travel, and required workers deemed "non-essential" to remain at home. These actions significantly interfered with Applicant's ability to attract new members, including through in-person marketing events. As a result, it was not possible to meet with prospective members for the rest of 2020 and the better part of 2021. This caused the Applicant to be unable to meet its enrollment projections, which led to a shortfall in the premium deficiency reserve ("PDR") of almost \$4 million.

On July 29, 2020, the Michigan Department of Insurance and Financial Services ("DIFS") issued a Notice and Order of Supervision, Order No. 2020-18-M ("2020 Order") pursuant to Michigan Insurance Code, MCL 500.3551. See Exhibit A. According to the 2020 Order, Applicant was operating with inadequate levels of capital and surplus, and ongoing operating losses. The 2020 Order directed Applicant to "take immediate action to restore financial soundness" and placed Applicant under the supervision of the DIFS Director. Such supervision included compliance with specified reporting requirements and required the Applicant to seek permission to pay certain expenses and provide notice if providers refuse service. The 2020 Order further directed the Applicant to "actively seek out new capital sources or pursue the possibility of an affiliation, joint venture, or merger in whole or in part with another entity" in order to "give [Applicant] access to additional capital to adequately support its business operations" subject to the Director's approval in accordance with Michigan law.

By December 30, 2020, Applicant was able to raise additional capital in the amount of \$3,915,000.

On January 6, 2021, DIFS issued an amendment to the 2020 Order (the "Amendment"), finding that the Applicant "continued to operate in good faith pursuant" to its obligations under the original order. See Exhibit B. As part of this Amendment, DIFS revised certain requirements in the 2020 Order. Specifically, DIFS required Applicant to "provide a listing of all disbursements along with the regular reporting made under this Order" and required that "any disbursement in excess of \$25,000.00 [] receive prior approval of the Director or her designee."

After the 2020 Annual Enrollment Period ("AEP"), DIFS reported that Applicant had a financial deficit and required an additional \$4 million to correct the deficiency. The required funds were raised by April 30, 2021 through additional capital contributed by Applicant's shareholders, bringing the total raised to \$8,380,000.00.

On September 21, 2021, a Form A statement was submitted on behalf of CCA, seeking approval for acquisition of control of Applicant. On December 1, 2021,

via Order No. 2021-45-M, the Director approved the acquisition of control of Applicant by CCA in accordance with the Form A statement. *See* Exhibit E.

On December 10, 2021, Applicant entered into an Agreement with CCA. CCA acquired 70% of the stock of Applicant and is the majority shareholder, thus meeting the requirement that Applicant merge in whole or in part with another financially sound organization. *See* Exhibit E.

CCA made a \$4 million capital contribution which appeared on the December 31, 2021 financial statement. CCA provided an additional \$2 million cash infusion to Applicant on March 22, 2022. These capital contributions have ensured that Applicant meets the minimum legal requirements for risk-based capital. CCA has also obtained a surety bond in the amount of \$5 million on behalf of Applicant as financial security in the event of Applicant's insolvency. CCA additionally has acquired reinsurance for excess loss to cover Applicant's members. See Exhibit C.

On February 16, 2022, the Applicant filed with CMS an application to offer a new Medicare Advantage/Medicare Advantage Prescription Drug (MA/MA-PD) contract under contract number H4306.

As of March 31, 2022, Applicant reported a capital surplus of \$3,172,444. As a result, on April 29, 2022, CCA made a request to DIFS to remove the Order of Supervision for Applicant. *See* Exhibit C. Also on April 29, 2022, CMS issued a notice of non-compliance to Applicant "regarding the organization's failure to meet CMS' fiscal soundness requirement." *See* Exhibit D. The CMS notice noted that "Federal regulations at 42 C.F.R. §422.504(a)(14) and §423.505(b)(23) require organizations ensure a fiscally sound operation by maintaining a positive net worth (total assets exceeding total liabilities). [Applicant's] independently audited annual financial statements as of December 31, 2020 show a negative net worth of (\$2,753,666)."⁴

On May 18, 2022, CMS issued a notice of denial Applicant's Application. In the denial, CMS stated generally that "CMS has determined, pursuant to 42 CFR §422.502(b) and 42 CFR §423.503(b), that your organization failed to comply with the terms and conditions of a current or previous year's contract with CMS. Organizations that experience such problems are considered high-risk organizations for purposes of application approvals and beneficiary protection." In subsequent communications, a representative from CMS confirmed that: "the

CMS Brief at 5.

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⁴ CMS provides further background that led up to the April 29, 2022 notice. CMS indicates:

On January 20, 2022, Reliance submitted its complete 2020 audited financial statement to CMS as required for its contract H9862. Exhibits C2 and C3. This statement had been due in April 30, 2021 (Exhibit C-4) and appears to have been completed by the auditor on June 24, 2021. Exhibit C-3, p. 4. Some information had been provided in the intervening months between June 2021 and January 2022, but the required documentation and information was not provided in full until January 20, 2022. Exhibit C-2, p.1.

reason for the denial of [Applicant's] H4306 application was that as part of its financial reporting for contract H9861, [Applicant] submitted financial statements to CMS in 2021 showing that [Applicant] had a negative net worth."

On May 20, 2022, Michigan's DIFS issued an Order to the Applicant terminating its previous Order of Supervision. *See* Exhibit E. According to DIFS, "[Applicant] has met the requirements to abate the hazardous conditions identified in the July 20, 2020 Order of Supervision." DIFS further notes that Applicant had "reasonably complied with the requirements of the Notice and Order of Supervision" and that "[t]he December 1, 2021 Order Approving Acquisition, allowing Commonwealth Care to assume control of [Applicant] in accordance with the Form A statement, sufficiently meets the requirements necessary to abate the hazardous conditions identified in the Notice and Order of Supervision."

Reliance Hearing Brief at 3-6.

VII. <u>DISCUSSION, FINDINGS OF FACT AND CONCLUSIONS OF LAW</u>

The Hearing Officer grants CMS' Motion for Summary Judgment. The parties agree that there are no material facts in dispute. Reliance Reply Brief at 3; CMS Brief at 11-12.

At issue in this matter, CMS amended its regulations at 42 C.F.R. §§ 422.502(b) and 423.503(b) through a final rule published on January 19, 2021, and effective on March 22, 2021. 86 Fed. Reg. 5864 (January 19, 2021). The amendment provides, in relevant part, that an applicant may be considered to have failed to comply with a contract for purposes of an application denial if, during the 12-month review period prior to submitting an application, it failed to maintain a fiscally sound operation as required by 42 C.F.R. §§ 422.504(b)(14) and 423.505(b)(23). Reliance alleges that CMS' application of the regulations are impermissibly retroactive because the 12-month past performance review period for its February 2022 contract application began in February 2021, prior to the March 22, 2021 effective date of the regulation. Reliance Hearing Brief at 8.

Reliance explains that the Medicare statute generally prohibits retroactive application of regulations and that CMS' view is inconsistent with *Landgraf v USI Film Products*, in which the Court found that a rule may not "increase a party's liability for past conduct." 511 U.S. at 280.⁵ Reliance Reply Brief at 4-5. Reliance claims that 42 C.F.R. § 422.502(b)(1) represents a "substantive change" that imposed new legal consequences on its past conduct. Reliance MSJ at 1. Reliance explains that for over a decade, CMS, through its past performance methodology,

Landgraf, 511 U.S. at 280.

intent favoring such result.

⁵ For fuller context, the Court generally explained factors it considers when evaluating if a *congressional statute* is impermissibly retroactive. The Court explained that when a statute does not expressly prescribe its "proper reach" the court must determine whether the new statute would have retroactive effect, *i.e.*, whether it would impair rights a party possessed when he acted, increase a party's liability for past conduct, or impose new duties with respect to transactions already completed. If the statute would operate retroactively, our traditional presumption teaches that it does not govern absent clear congressional

developed a "settled expectation" that a fiscal unsoundness determination alone was insufficient for CMS to deny a contact application. Reliance Reply Brief at 3-4. Reliance argues that the fact that lack of fiscal soundness has historically been treated as a negative factor in a past performance reviews does not overcome its claim of an impermissible retroactive application.

In review, the Hearing Officer notes that for over a decade, CMS regulations have established that CMS may consider an MA-PD organization's past performance in evaluating contract determinations. In evaluating contract applications, CMS has issued a series of past performance methodologies⁶ in which a past failure to maintain a fiscally sound operation resulted in the assignment of negative performance points, which, in turn, may have resulted in the denial of future applications in accordance with the requirements of 42 C.F.R. §§ 422.502(b) and 423.503(b).

The Hearing Officer must comply with the provisions of Title XVIII of the Act — Health Insurance for the Aged and Disabled — and related provisions of the Act, regulations issued by the Secretary of Health and Human Services, and general instructions issued by CMS in implementing the Act. 42 C.F.R. §§ 422.688 and 423.664. The MA-PD organization maintains the burden of proof by a preponderance of the evidence that CMS' determination was inconsistent with regulatory requirements. See 42 C.F.R. §§ 422.660(b)(1) and 423.650(b)(1). regulations at issue, 42 C.F.R. §§ 422.502(b) and 423.503(b) were published on January 19, 2021 and effective on March 22, 2021, well before the 2023 application review cycle, which ran from February 2022 through May 2022. Reliance's fiscal problems were ongoing through the 12-month past performance review period. The Hearing Officer finds that here, CMS applied and followed the controlling regulations which were in effect as it reviewed Reliance's applications. Accordingly, applying the scope of authority provided under 42 C.F.R. §§ 422.660(b)(1) and 423.650(b)(1), the Hearing Officer upholds CMS' denial of Reliance's applications.

Aside from the Hearing Officer's holding above upholding CMS' denial on the basis that CMS applied and followed the controlling authorities in effect, the Hearing Officer notes that Reliance has simply not established that the denial is otherwise fundamentally unfair or contrary to law. With regards to the Landgraf decision that Reliance cites, the Court provided factors to consider when evaluating if a congressional statute (as opposed to a regulation here) is impermissibly retroactive. The Court noted "[e]lementary considerations of fairness dictate that individuals should have an opportunity to know what the law is and to conform their conduct." 511 U.S. at 265. Whether a rule imposes "new legal consequences" is guided by "familiar considerations of fair notice, reasonable reliance, and settled expectations." Id. at 270. As CMS notes, it is inconceivable that Reliance "treated its financial problems less urgently than it would have if it knew for certain that the failure to maintain fiscal soundness would disqualify it from expanding its offerings in 2023." CMS Brief at 7. Reliance's failure to maintain a fiscally sound operation violated its contract with CMS at the time it occurred. At that time, it was clear that such failure, at the very least, could potentially impact future applications. The 2021 final rule did not change CMS' general expectation relating to the importance of maintaining fiscally sound and stable operations. At most, the regulation modified the weight that failure to maintain fiscal soundness

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⁶ See supra Part V.B.

could carry. Such weight was always subject to fluctuation as CMS updated it methodologies over the years.

Reliance argues that while 42 C.F.R. § 422.688 indicates that the Hearing Officer must comply with the controlling authorities, the Hearing Officer is not precluded from reversing a contract application denial on policy grounds, especially when the Hearing Officer would not be acting inconsistently with regulations. Reliance Reply Brief at 5, 6. As noted above, however, this is not a case in which CMS was allegedly acting inconsistently with regulations or polices which were in effect through the application review cycle.

Similarly, from a policy perspective, Reliance stated:

Although CMS is correct to say that problems that occurred in the past have a bearing on future performance, it completely disregards the relevance of whether the problems have been cured, as well as other factors such as the emergence of a new parent organization with high standards of quality and prior adherence to CMS regulatory requirements of MA-PD plans, inherent in the predictive component of past performance reviews.

. . . .

[I]nstead of following its own policy rationale, CMS takes an inflexible approach that dismisses this future harm in its calculation, and focuses almost exclusively on its finding of past fiscal soundness issues. This narrow approach is both impracticable and inconsistent with the policy rationale for these regulations, and ultimately would deprive Medicare beneficiaries of the opportunity to have an additional high quality plan in their service area for which they can enroll.

Reliance Reply Brief at 7, 8.

CMS, in turn, responds:

The very nature of past performance is that problems that occurred or were discovered in the past impact CMS' decision to approve an application for a future year, regardless of whether the problems are ongoing. In response to a comment on the 2021 proposed rule asking that CMS not deny applications for organizations that were subject to intermediate sanctions during the review period if the sanctions were lifted, CMS observed, "CMS expects all sanctioned organizations to move promptly to complete the necessary corrective action to have a sanction removed, we believe that in any instance, the fact that a sanction had to be imposed at all speaks to the stability of the organization and is relevant to whether it should be approved for a new contract." 86 Fed. Reg. 6001. The same reasoning applies to organizations that were found to be fiscally unsound during the review period. Regardless of whether the applicant eventually cured the underlying performance problem, the noncompliance with the current or prior year's contract occurred and

CMS properly takes it into account when determining whether to approve an application.

Moreover, as discussed previously, Reliance's fiscal problems were ongoing throughout much, if not all, of the past performance review period. As documented in its brief and exhibits, Reliance was working throughout 2021 to improve its financial situation. The State of Michigan did not release Reliance from the Order of Supervision first issued in July 2020 until May 20, 2022, three months after Reliance submitted its 2023 application.

Finally, CMS' stated desire not to discourage the acquisition of troubled MA organizations and Part D sponsors by new parent organizations does not justify exempting Reliance's application for a new contract from past performance requirements. As previously noted, CMS adopted the two-year grace period in 42 CFR §§ 422.502(b)(1)(ii) and 423.503(b)(1)(ii) for subsidiaries of parents that acquired troubled MA organizations and Part D sponsors so that the acquired organization's performance problems would not negatively impact other subsidiaries of the new parent. CMS did not in any way indicate that it intended to further encourage acquisitions by exempting the MA organization or Part D sponsors that itself failed to comply with a current or prior year's contract from past performance requirements. While CMS acknowledges that Reliance has a new parent as of December 2021, Reliance itself is the organization with which CMS has a contract and that demonstrated its failure to comply with its existing contract. CMS does not regulate or in any way control whether an organization is acquired by a new parent and thus has no reason to exempt the organization with which it contracts from the consequences of its past performance merely because it has a new parent organization.

CMS Brief at 10-11.

While the Hearing Officer has no authority to weigh the relative merits regarding the parties competing policy relating arguments, the Hearing Officer finds that CMS' stated policy rationale is logical and the denial of Reliance's application is not inconsistent with such rationale.

Finally, Reliance also notes that in its Hearing Brief, it pointed out that its financial issues coincided with the COVID 19 pandemic as during such time, it became difficult for Reliance "to conduct the necessary outreach to increase its number of members" but now "the worst of the COVID-19 pandemic is behind us." Reliance Hearing Brief at 14-15. Reliance indicates that it is "odd" that CMS did not reply to this point in its brief, considering the extent to which the agency has implemented policies to mitigate COVID 19 on MA plans. Reliance Reply Brief at 8-9; Reliance Hearing Brief at 14-15. Nevertheless, the Hearing Officer does not have the authority to consider the root cause of the financial difficulties to overturn CMS' determination, which was issued in accordance with the controlling authorities.

VIII. ORDER

Reliance has not established by a preponderance of the evidence that CMS' determination was inconsistent with the controlling legal authorities. CMS' Motion for Summary Judgment is granted.

Benjamin R. Cohen, Esq. CMS Hearing Officer

Date: July 28, 2022