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 29, 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-22-00016
Medicare Advantage/Prescription Drug Plan Contract Denial
Vitality Health Plan of California, Contract Number: H1426

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

Vitality Health Plan of California Contract No. H1426,	*	
	*	**Denial of Application to Offer Medicare Advantage/Medicare Advantage-Prescription Drug Plan**
Appellant	*	
	*	
v.	*	
	*	**Contract Year 2023**
Centers for Medicare & Medicaid Services,	*	
	*	**Hearing Officer Docket No. H-22-00016**
Respondent	*	
	*	

ORDER GRANTING MOTION FOR SUMMARY JUDGMENT

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I. FILINGS

This Order is being issued in response to the following:

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

II. JURISDICTION

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. ISSUE

Whether CMS' denial of Vitality's service area expansion application for its existing Medicare Advantage/Medicare Advantage-Prescription Drug contract (H1426) (hereinafter "MA-PD"), based on an intermediate sanction imposed due to Vitality's failure 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. DECISION SUMMARY

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. Vitality'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 on July 2, 2020, CMS issued a Notice of Intermediate Sanction as the Department of Managed Health Care ("DMHC") of the State of California filed an Order to Cease and Desist accepting new enrollees on the basis that Vitality did not meet financial requirements. DMHC did not lift the Order until January 18, 2022 (retroactive to January 4, 2022) and CMS, accordingly, lifted the intermediate sanction on January 20, 2022 (also effective January 4, 2022). Vitality's intermediate sanction fell within 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 Vitality's applications.

Moreover, the Hearing Officer notes that Vitality 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:[1]

> (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.

[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. Consideration of Performance Under an Applicant's Current or Prior Year 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).[2] Under the amended regulation, an applicant may be considered to have failed to comply with a contract for purposes of an application denial under §§ 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

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

§§ 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).

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 §§ 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 case of intermediate sanctions in particular, CMS included in its past performance analysis intermediate sanctions that were "imposed **or in place**" during the performance period. Exhibit C-1, p. 6 (emphasis added).

> 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 years 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 Reply Brief at 2-4.

C. Authority Cited - Retroactive Application of an Agency Regulation

Vitality's primary argument is that CMS' reliance on 42 C.F.R. §§ 422.502(b) and 423.502(b) is impermissibly retroactive. Vitality 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 [Health and Human Services "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

[3] CMS distinguishes *Bowen* as follows: "These facts contrast sharply 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. Vitality is not being penalized for conduct that was compliant when it took place or being deprived of anything to which it is entitled under

> 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.

Vitality Hearing Brief at 6-7.

VI. STATEMENT OF FACTS

Vitality is a health maintenance organization that has contracts with CMS to operate MA plans in certain geographic areas in California, and is a wholly owned subsidiary of Commonwealth Care Alliance, Inc. ("CCA"). Vitality Hearing Brief at 1. Both parties agree that the facts are undisputed. Vitality provides an uncontested outline of its organization's history as follows:

> On June 30, 2020, the Department of Managed Health Care of the State of California ("DMHC") issued a Cease and Desist Order, effective July 2, 2020, against the Applicant (the "2020 Order"). The 2020 Order stated that the Applicant failed to comply with certain state financial requirements pursuant to the Knox-Keene Act. The 2020 Order stated that "effective July 2, 2020, Vitality shall immediately cease and desist from offering contracts or accepting new applications from any new enrollees or subscribers who are not currently in contract with Vitality."
>
> On July 2, 2020, CMS issued a letter to the Applicant noting as a result of the DMHC 2020 Order, the Applicant was non-compliant with CMS's contract requirements to accept new enrollments. 42 C.F.R. § 422.504(a)(1). CMS further informed the Applicant that it was imposing an intermediate sanction on the MA-PD Contract H1426, suspending Applicant's ability to enroll Medicare beneficiaries. *See* Exhibit A.

its current contract. Vitality is merely being denied a new service area expansion of its contract based on that contract being under an intermediate sanction during part of the past performance review period, a consequence that has been a potential result of intermediate sanctions for many years." CMS Brief at 7.

On July 30, 2020, the DMHC filed a motion requesting an order to revoke Applicant's health plan license for failure to maintain minimum financial requirements.

On December 18, 2020, Applicant filed a voluntary petition for relief under Chapter 11 of the Bankruptcy Code in order to, among other things, resolve and restructure its debts and concurrently satisfy the DMHC's Tangible Net Equity (TNE) requirement. Applicant planned to satisfy the TNE requirement via a change of control and planned to discharge its indebtedness through a Chapter 11 plan of reorganization.

On August 27, 2021, the DMHC withdrew its request to revoke Applicant's license in light of the bankruptcy proceedings. The DMHC stated "in the event the [DMHC] approves [Applicant's] request for Change in Control that is contemplated as the mechanism for successful reorganization under a Chapter 11 Plan of Reorganization, the [DMHC] will lift the Cease and Desist Order on the date of that approval, or any date listed as a condition of that approval, whichever is later."

On October 10, 2021, Applicant's MA-PD contract H1426 earned a 4 Star Rating for CY 2022. *See* Exhibit B.

Subsequent to Applicant's bankruptcy filing, CCA and Applicant entered into discussions regarding CCA's proposal to acquire Applicant. CCA and Applicant agreed to terms and entered into discussions with the DMHC seeking approval for the change in control.

On December 31, 2021, DMHC issued a letter to the Applicant approving the change in ownership of Applicant and contract H1426 to CCA. *See* Exhibit C. As part of this approval, CCA agreed to comply with a Letter of Undertakings. Notably, the letter provided that "[w]ithin 3 business days following the date of closing, CCA, CCAC and the Plan agree to file … third party supporting documentation of sufficient capital infusion to maintain the Plan's Tangible Net Equity (TNE) at two hundred percent (200%) of the minimum amount required by section 1300.76, title 28 of the California Code of Regulations" and that "[t]he Parties shall ensure that the Plan, at all times, maintains a minimum 200% of required TNE through June 30, 2024." *See* Exhibit D.

On January 18, 2022, as a result of the change in ownership and CCA's commitment to maintain 200% of the minimum TNE requirement, DMHC notified the Applicant that it was lifting the Cease and Desist Order retroactively effective January 4, 2022. *See* Exhibit E. Soon thereafter, on January 20, 2022, CMS issued a letter notifying the Applicant that it was retroactively releasing its intermediate sanction against contract H1426, also effective January 4, 2022. *See* Exhibit F.

> On February 14, 2022, Applicant submitted an application to CMS for approval of the service area expansion. On March 3, 2022, Applicant submitted to the state of California a request for approval to expand its service area into Stanislaus County and Merced County for its Medicare Advantage line of business for CY 2023. On March 30, 2022, DMHC approved the application for H1426 service area expansion into the two contiguous counties for 2023. *See* Exhibit G.[4]
>
> However, on May 18, 2022, CMS issued a notice of denial of Applicant's SAE 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 (May 23, 2022), a representative from CMS confirmed that: "CMS denied Vitality Health Plan of California's application for a service area expansion under contract H1426 because H1426 was under an intermediate sanction (pursuant to 42 CFR §§422.756 and 423.756) from July 2, 2020 through January 4, 2022."

Vitality Hearing Brief at 3-5.

VII. DISCUSSION, FINDINGS OF FACT AND CONCLUSIONS OF LAW

The Hearing Officer grants CMS' Motion for Summary Judgment. There are no material facts in dispute. Vitality 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 which was published on January 19, 2021, and effective 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 had been subject to the imposition of an intermediate sanction under Part 422 Subpart O or Part 423 Subpart O of the regulations. Vitality alleges that CMS' application of the regulations is impermissibly retroactive because the 12-month past performance review period for its February 2022 contract application began in February 2021. Vitality explains that "most of the actual conduct, including the imposition of intermediate sanction that served as the sole basis for the application denial, occurred in 2020, long before the effective date of the pertinent regulation." Vitality Hearing Brief at 8.

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[4] CMS provides further background:

> On March 21, 2022, CMS issued application Part C and Part D deficiency notices to Vitality stating that CMS had determined, pursuant to 42 CFR §§ 422.502(b) and 423.503(b), that the organization failed to comply with the terms of a current or previous year's contract with CMS. Exhibit C-2. . . . On April 18, 2022, CMS issued Part C and Part D NOIDs to Vitality, citing the same deficiency as was identified in the March 21 notice. Exhibit C-3.

CMS Reply Brief at 5-6.

Vitality 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 Supreme Court found that a rule may not "increase a party's liability for past conduct." 511 U.S. 244, 280 (1994).[5] Vitality claims that § 422.502(b)(1) represents a "substantive change" that imposed new legal consequences on its past conduct. Vitality Hearing Brief at 8. Vitality indicates that prior to the regulation, intermediate sanctions were only a single factor that CMS considered as it reviewed past performance, and the presence of one factor alone was usually not determinative. Vitality Hearing Brief at 8-9.

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 methodologies[6] in which the issuance of intermediate sanctions 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). The 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. The Hearing Officer finds that in considering the intermediate sanctions that were in place during the past performance period, CMS applied and followed the controlling regulations which were in effect as it reviewed Vitality'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 Vitality's applications.

Aside from the Hearing Officer's holding above upholding the denial on the basis that CMS applied and followed the controlling authorities in effect, the Hearing Officer notes that Vitality has simply not established that the denial is otherwise fundamentally unfair or contrary to law. With regards to the *Landgraf* decision that Vitality 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

[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 intent favoring such result."

Landgraf, 511 U.S. at 280.

[6] *See supra* Part V.B.

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 highly unlikely that Vitality would have treated its financial difficulties that prompted the intermediate sanctions with less urgency if it knew for certain that the sanctions alone would disqualify it from expanding its service area. CMS Reply Brief at 7. The 2021 final rule did not change CMS' general expectation relating to the importance of maintaining fiscally stable operations. At most, the regulation modified the weight that fiscal issues and intermediate sanctions could carry in past performance reviews. Such weight was always subject to fluctuation, as CMS updated its methodologies over the years.

Vitality argues that while 42 C.F.R. §§ 422.688 and 423.664 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. Vitality Reply Brief at 2-3. 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, Vitality 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 and considering this material fact in its application decision, 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.

Vitality Reply Brief at 3-5.

CMS explains:

> 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. . . . CMS explicitly declined to disregard intermediate sanctions that were lifted during the review period in its

> comments to the 2021 final rule.[7] Denying Vitality's application here was therefore entirely consistent with the policy underlying CMS' past performance requirements.
>
> Moreover, as discussed previously, Vitality's fiscal problems were ongoing throughout much of the past performance review period. As documented in its brief and exhibits, Vitality was working throughout 2021 to improve its financial situation. The State of California did not lift its Cease and Desist Order until January 2022.
>
> 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 Vitality's application for a service area expansion 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 Vitality has a new parent as of December 2021, Vitality 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 Reply Brief at 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 Vitality's application is not inconsistent with such rationale.

[7] "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. at 6000.

VIII. ORDER

Vitality 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 Cohen -S

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Date: 2022.07.29 17:39:02 -04'00'

Benjamin R. Cohen, Esq.
CMS Hearing Officer

Date: July 29, 2022