DEPARTMENT OF HEALTH & HUMAN SERVICES

Centers for Medicare & Medicaid Services
Office of Hearings
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August 9, 2023

Christine Clements
Sheppard Mullin Richter & Hampton LLP
2099 Pennsylvania Avenue, NW
Washington, DC 20006

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

RE: Hearing Officer Decision
Hearing Officer Docket Number: H-23-00011
Medicare Advantage/Prescription Drug Plan Contract Denial
Lasso Healthcare Insurance Company, Contract Number H9618

Dear Ms. Clements 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

Lasso Healthcare Insurance Company **Contract No. H9618**	**Denial of Application to Expand Medicare Advantage / Medicare Advantage-Prescription Drug Plan**
Appellant	
v.	**Contract Year 2024**
Centers for Medicare & Medicaid Services,	**Hearing Officer Docket No. H-23-00011**
Respondent	

ORDER GRANTING CMS' MOTION FOR SUMMARY JUDGMENT

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I. FILINGS

This Order is being issued in response to the following:

(a) Lasso Healthcare Insurance Company's ("Lasso Healthcare") Hearing Request and exhibits filed on June 1, 2023;
(b) Lasso Healthcare's Hearing Brief and exhibits filed on June 12, 2023; and
(c) Centers for Medicare & Medicaid Services' ("CMS'") Brief in Reply to Applicant's Brief in the Matter of the Denial of the Lasso Healthcare Application of its Medicare Advantage ("MA")/MA-Prescription Drug ("MA-PD") Contract, Contract Number H9618 ("CMS Brief") and exhibits filed on June 19, 2023.

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, Amanda S. Costabile.

III. ISSUE

Whether CMS' denial of Lasso Healthcare's MA/MA-PD initial application (contract H9618), based on Lasso Healthcare's failure to comply with the terms and conditions of a current or previous year's contract with CMS in accordance with 42 C.F.R. § 422.502(b) (2022) and 42 C.F.R. § 423.503(b) (2022), was inconsistent with regulatory requirements.

IV. DECISION SUMMARY

The Hearing Officer grants CMS' Motion for Summary Judgment. The Hearing Officer's authority is limited to deciding whether CMS' determination was consistent with regulatory requirements. *See* 42 C.F.R. §§ 422.660 and 423.650. Lasso Healthcare'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 May 9, 2022, and effective June 29, 2022, well before the 2024 application review cycle that ran from February 2023 through May 2023. The parties do not dispute that Lasso Healthcare's contract number H1924 received Part C summary Star Ratings of 2 for both of its most recent Star Rating periods, namely, Contract Years ("CY") 2022 and 2023. The Hearing Officer finds that CMS applied and followed the controlling regulations in effect at the time. Accordingly, the Hearing Officer upholds CMS' denial of Lasso Healthcare's applications.

V. PROCEDURAL HISTORY AND STATEMENT OF FACTS

On February 15, 2023, Lasso Healthcare applied "for a new MAPD Coordinated Care Plan ("CCP") contract under contract number H9618." CMS Brief at 6. Lasso Healthcare "currently offers Medicare Medical Savings Account ("MSA") plans in 35 states[,]" including, since January 1, 2019, contract number H1924. Lasso Healthcare Hearing Brief at unnumbered page 1; CMS Brief at 6. An MSA, such as H1924, "does not offer Part D coverage[,]" therefore, Lasso Healthcare "did not have any Part D contracts with CMS as of the date it filed its 2024 H9618 application." CMS Brief at 6.

In October 2021, CMS released the contract-level Part C and Part D Star Ratings for CY 2022. In October 2022, CMS released the contract-level Part C and Part D Star Ratings for CY 2023. For both CYs, Lasso Healthcare's contract number H1924 received Part C summary ratings of 2 stars. *Id*. at 5.

CMS issued Lasso Healthcare Deficiency Notices dated March 20, 2023, in which CMS cited deficiencies in both its Part C and Part D applications. Lasso Healthcare Exhibit P-1. Specifically, the deficiencies communicated within the notice involved (1) Experience and History Document; (2) state licensure—CMS State Certification Form for Missouri; (3) MA Provider Table; (4) MA Facility Table; (5) certain attestations (Part D only); and (6) contracting (Part D only). *Id*. Within the Deficiency Notices, CMS states that it "will provide information related to our analysis of your past performance and minimum enrollment waiver in the Notice of Intent to Deny (NOID)," and "[a]ny past performance-related deficiencies will be provided to applicants at the end of April." *Id*. On March 28, 2023, Lasso Healthcare submitted documentation to CMS to cure its application deficiencies. Lasso Healthcare Hearing Brief at unnumbered page 2.

On April 17, 2023, CMS issued Lasso Healthcare Part C and Part D NOIDs. *Id*. The deficiencies listed within the NOIDs involved (1) MA Provider Table; (2) MA Facility Table; (3) MA Letters of Intent; and (4) Past Performance. Lasso Healthcare Exhibit P-3; CMS Exhibit C-2. With respect to the Past Performance deficiency, the NOIDs state the following:

> CMS has determined, pursuant to 42 CFR § 422.502(b)[/42 CFR § 422.503(b)] that your organization failed to comply with the terms of a current or previous year's contract with CMS. Therefore, within the next several weeks, CMS will be issuing your organization a final notice of denial of your organization's Part C[/Part D] application regardless of the presence or absence of deficiencies in your submitted application materials. No material can be submitted to cure this issue. You may either withdraw your organization's pending Part C[/Part D] application or, once you have received the formal Denial Notice, you may appeal this determination pursuant to 42 CFR § 422.660[/42 CFR § 423.650(a)(1)]. If any deficiencies (identified below) other than those related to past contract performance still exist with your organization's pending Part C[/Part D] application, you may submit corrected materials per the instructions outlined in this letter. If you intend to appeal the denial of your application, you must use this cure period to submit corrected materials to address any application deficiencies. Materials submitted after this cure period will not be considered during the administrative appeals process governing CMS' application determinations.

Id.

CMS' Part D NOID also informed that "[y]our organization failed to comply with the terms of a current or previous year's contract with CMS because it received any combination of Part C or

Part D summary ratings of 2.5 or less in both of the two most recent Star Rating periods, as identified in 42 CFR § 423.186." CMS Exhibit C-2.

On April 27, 2023, Lasso Healthcare submitted materials in response to the NOIDs. Lasso Healthcare Brief at unnumbered page 3.

On May 17, 2023,[1] CMS issued Lasso Healthcare a Denial Notice regarding its MA, MA-PD application. Lasso Healthcare Exhibit P-5. Within the Denial Notice, CMS "identified two years of Part C or Part D summary ratings of 2.5 or less as the basis of the past performance denial." CMS Brief at 6.

On June 1, 2023, Lasso Healthcare filed its Hearing Request with the Office of Hearings. Lasso Healthcare Exhibit P-6. On the same date, the Office of Hearings acknowledged the request and provided the parties with a hearing date and briefing schedule. Lasso Healthcare Exhibit P-7. The parties submitted their respective briefs pursuant to the briefing schedule then subsequently filed a joint "Request for Decision of Written Record" on June 21, 2023. The Hearing Officer granted the parties' request on June 22, 2023.

Within its June 12, 2023, Hearing Brief, Lasso Healthcare argues as follows: (1) CMS failed to give Lasso Healthcare an opportunity to cure its past performance deficiency; (2) "CMS' adoption of the current past performance methodology for application denials is arbitrary and capricious"; and (3) the current past performance methodology is prohibited retroactive rulemaking. Lasso Healthcare Hearing Brief at unnumbered pages 3-9. Lasso Healthcare asserts that "denying [its] application . . . would deny historically underserved beneficiaries . . . access to personalized care delivered with a cutting-edge approach focused on social determinants of health . . . and designed to achieve exceptional outcomes for racial and ethnic minority group." *Id*. at unnumbered page 1.

Within its responsive brief, CMS asserts that it "has correctly applied to the undisputed facts the regulatory authority it adopted through the rulemaking process in denying Lasso [Healthcare's] application[,]" thus it is entitled to summary judgment in its favor. CMS Brief at 12.

VI. BACKGROUND AND AUTHORITY

A. Application Process

Under Title XVIII of the Social Security Act (codified at 42 U.S.C. §§ 1395-1395lll), CMS is authorized to enter into contracts with entities seeking to offer Medicare Part C and Part D benefits

[1] CMS' Exhibit C-3 includes a Denial Notice dated May 30, 2023. Although CMS does not specifically explain why the Denial Notice dates are different, Lasso Healthcare footnotes the following:

> The original Contract Determination issued by CMS also identified a deficiencies for MA Provider Table and MA Facility Table: Appellant uploaded information that did not support its attestation for MA Letters of Intent – NMM Review. However, CMS subsequently reissued the Contract Determination without these deficiencies.

Lasso Healthcare Brief at unnumbered page 3 n.7.

to beneficiaries. 42 U.S.C. § 1395w-27, 112. Any entity seeking to contract as an MA/MA-PD 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). In order to offer an MA CCP in an area, an MA organization must offer qualified Part D coverage, thus must meet all Part D program requirements to qualify as an MA-PD sponsor in a service area. *See* 42 C.F.R. § 422.500. As such, CCP applicants must submit a separate Part D application as well as a Part C application as a condition for approval of the CCP application. https://www.cms.gov/files/document/cy-2024-medicare-advantage-part-c-application.pdf-1 (last visited July 19, 2023); https://www.cms.gov/files/document/2024-part-d-application-final.pdf-0 (last visited July 19, 2023); *see* 42 C.F.R. § 422.500.

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(a)(2) 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 as part of the application itself and any 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) (2022).

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 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.
>
> (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/MA-PD 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. §§ 422.502 and 423.503 (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

Currently, CMS may deny an MA and/or Part D application if the applicant failed, during the twelve months preceding the application submission deadline, to comply with the requirements of the Part C and/or D programs. Under 42 C.F.R. § 423.503(b)(1)(ii), CMS may deny an application submitted by an organization that does not hold a Part D contract at the time of submission when the applicant's parent organization or another subsidiary of the parent organization meets the criteria for denial.[2] Specific to the instant appeal, applicants may be considered to have failed to comply with a contract for purposes of application denial if any one of the criteria delineated in 42 C.F.R. §§ 422.502(b)(1)(i) or 423.503(b)(1)(i) apply, including if the organization received any combination of Part C or D summary ratings of 2.5 or less in both of the most recent Star Rating periods, as identified in 42 C.F.R. §§ 422.166 and 423.186. 42 C.F.R. §§ 422.502(b)(1)(i)(D) or 423.503(b)(1)(i)(D) (2022). Additionally, CMS may deny an application based on the applicant's failure to comply with the requirements of the Part C/Part D program under any current or prior contract with CMS even if the applicant otherwise meets all of the requirements for qualification as a Part C or Part D sponsor. 42 C.F.R. §§ 422.502(b)(1) and 423.503(b)(1).

Within its Brief, CMS provides a comprehensive summary of the historic development of CMS' past performance regulations up to and including the 2022 amendments:

> 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

[2] The regulation 42 C.F.R. § 422.502(b)(1)(ii) contains the same language with respect to Part C evaluations.

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 CFR §§ 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 the past performance authority in a final rule published in April 2018. [83] Fed. Reg. 16440 (April 16, 2018).[3] 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 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 §§ 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 §§ 422.502(b)(1) or

[3] Medicare Program; Contract Year 2019 Policy and Technical Changes to the Medicare Advantage, Medicare Cost Plan, Medicare Fee-for-Service, the Medicare Prescription Drug Benefit Programs, and the PACE Program, 83 Fed. Reg. 16440 (April 16, 2018).

> 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 §§ 422.504(b)(14) or 423.505(b)(23). 42 CFR §§ 422.502(b)(1)(i) and 423.503(b)(1)(i).
>
> CMS again amended its past performance regulations in a final rule published in May 2022. 87 Fed. Reg. 27704 (May 9, 2022).[4] In this final rule, CMS adopted three additional grounds for denying an application based on an applicant's performance under a current or prior contract: (1) the organization currently being in State bankruptcy proceedings; (2) *the organization earning a Part C or Part D summary Star Rating of 2.5 stars or fewer in each of the two most recent Star Ratings periods*; and (3) the organization earning a total of 13 points for compliance actions under any one contract. 42 CFR §§ 422.502(b)(1)(i)(C)–(E) and 423.503(b)(1)(i)(C)–(E).

CMS Brief at 3-4 (emphasis added).

CMS' amendment to the past performance regulation was published as a final rule on May 9, 2022, with an effective date of June 29, 2022.

C. Star Ratings

As the Secretary explains in the preamble to the April 16, 2018 Final Rule, "[t]he MA and Part D Star Ratings measure the quality of care and experiences of beneficiaries enrolled in MA and Part D contracts, with 5 stars as the highest rating and 1 star as the lowest rating." 83 Fed. Reg. 16440, 16520 (Apr. 16, 2018). The Star Ratings and data reporting are at the contract level for most measures, with those measures reflecting structure, process, and outcome indices of quality, including Part D measures that reflect beneficiary experiences and benefit administration. *Id.* at 16532, 16526; 42 C.F.R. § 423.182(c)(1). CMS calculates an overall Star Rating, a Part C summary rating, and a Part D summary rating for each MA-PD contract using the 5-star rating system. 42 C.F.R. §§ 422.162(b) and 423.182(b).

Star Ratings play a role in CMS' "oversight, evaluation, and monitoring of MA and Part D plans to ensure compliance with the respective program requirements and the provision of quality care and health coverage to Medicare beneficiaries." 83 Fed. Reg. at 16520-21. As such, in April 2012, the Secretary "finalized regulations to use consistently low summary Star Ratings—meaning 3 years of summary Star Ratings below 3 stars—as the basis for a contract termination for Part C

[4] Medicare Program; Contract Year 2023 Policy and Technical Changes to the Medicare Advantage and Medicare Prescription Drug Benefit Programs; Policy and Regulatory Revisions in Response to the COVID–19 Public Health Emergency; Additional Policy and Regulatory Revisions in Response to the COVID–19 Public Health Emergency, 87 Fed. Reg. 27704 (May 9, 2022).

and Part D plans."[5] *Id*. at 16520; 42 C.F.R. §§ 422.510(a)(4)(xi) and 423.509(a)(4)(x). Under 42 C.F.R. § 423.186(h)(2), CMS conducts plan preview periods before each Star Ratings release during which time plan sponsors can preview their Star Ratings data in the Health Plan Management System prior to display on the Medicare Plan Finder.[6]

CMS calculates Star Ratings for a particular contract year based on data from the contract year two years prior to the Star Ratings year. CMS Brief at 5. For example, Lasso Healthcare's 2023 Star Ratings were based primarily on data from Contract Year 2021 and released in October 2022. *Id*.

VII. DISCUSSION, FINDINGS OF FACT AND CONCLUSIONS OF LAW

The Hearing Officer grants CMS' Motion for Summary Judgment. The Hearing Officer finds as follows:

[5] Within the 21st Century Cures Act which became Pub. L. No. 114-225 on December 13, 2016, Congress mandated, under section 17001, that "[u]ntil plan year 2019, the CMS may not terminate a [MA] plan solely because the plan failed to achieve a specified minimum quality rating." https://www.congress.gov/bill/114th-congress/house-bill/34 (last visited on August 2, 2023). Subsequently, on February 6, 2019, CMS issued a memorandum to all Part C and Part D Plan Sponsors regarding the "End of [the] Moratorium on Authority to Terminate Medicare Advantage Organization Contracts Based on Low Star Ratings." www.hhs.gov/guidance/sites/default/files/hhs-guidance-documents//star_rating_termination_timing_hpms_final.pdf (last visited on August 2, 2023). Specifically, CMS states that "[g]iven the expiration of [the 21st Century Cures Act moratorium] on December 31, 2018, CMS will resume its authority to terminate Part C and Part D contracts that have consistently failed to achieve good Star Ratings." *Id.* at 1.

[6] 42 C.F.R. § 423.186(h)(2). Within the preamble to the April 16, 2018 final rule, the Secretary explains the overall purpose of the two preview periods provided by CMS:

> During the first plan preview, we expect Part C and D sponsors to closely review the methodology and their posted numeric data for each measure. The second plan preview includes any revisions made as a result of the first plan preview. In addition, our preliminary Star Ratings for each measure, domain, summary score, and overall score are displayed. During the second plan preview, we expect Part C and D sponsors to again closely review the methodology and their posted data for each measure, as well as their preliminary Star Rating assignments.

83 Fed Reg 16588 (Apr. 16, 2018).

Furthermore, the Secretary emphasized how important it is

> that Part C and D sponsors regularly review their underlying measure data that are the basis for the Part C and D Star Ratings. For measures that are based on data reported directly from sponsors, any issues or problems should be raised well in advance of CMS' plan preview periods.

Id.

A. <u>Lasso Healthcare has neither demonstrated that it was materially deprived of an opportunity to cure its past performance deficiencies or prejudiced by not receiving its past performance analysis until issuance of its NOID, nor demonstrated that the regulations and pertinent subregulatory guidance require CMS to consider any other factors when assessing an applicant's past performance.</u>

Lasso Healthcare argues that it was not given an opportunity to cure its past performance deficiencies despite the fact that CMS' "application process . . . affords applicants two opportunities to cure any deficiencies." Lasso Healthcare Hearing Brief at unnumbered page 4. In support of its argument, Lasso Healthcare points to a June 19, 2014, Hearing Officer decision concerning *Arkansas Superior Select, Inc.*, Docket No. 2014 C/D App. 2 (hereinafter, "*Arkansas Superior Select*"). Lasso Healthcare asserts that *Arkansas Superior Select* stands for the proposition that

> [a]n applicant is entitled to an application process "consistent with a fair interpretation of the regulatory requirements," and where an applicant is "not afforded two opportunities to cure any deficiencies . . . as should have been provided by the full application process that CMS established[,]" a Hearing Officer will reverse CMS' denial.

Lasso Healthcare Hearing Brief at unnumbered pages 3-4.

Additionally, Lasso Healthcare asserts that "CMS confirmed the availability of two curing opportunities" "to cure any deficiencies" within the applicable CMS training,[7] but that "CMS did not identify [Lasso Healthcare's] Past Performance deficiency in the Deficiency Notice. . . . Therefore, [Lasso Healthcare] was effectively denied its initial opportunity to cure the deficiency." *Id*. at unnumbered pages 4-5. Lasso Healthcare argues that even though CMS provided information related to its analysis of Lasso Healthcare's past performance in the NOID, it was not afforded "any opportunity to cure the deficiency before issuing the Contract Determination. Therefore, [Lasso Healthcare] was afforded no opportunity at all to cure the past performance deficiency." *Id*. at unnumbered page 5.

Lasso Healthcare also argues that "CMS has broad contractual and regulatory discretionary authority to allow an applicant to cure its application." *Id*. at unnumbered page 4. In considering such, Lasso Healthcare explains that in reviewing its Star Ratings at issue here, it

> has analyzed these results and concluded that they are closely related to its commitment to its mission to serve needy and high risk populations who often experience greater barriers to care, which create significant obstacles to achievement of many of the Star Rating measures. [Lasso Healthcare states that it] is dedicated to

[7] *See* Lasso Healthcare Exhibit P-8 at 5.

> resolving these barriers, but the benefits of its efforts take time to realize.

Id. at unnumbered page 5.

Thus, Lasso Healthcare states that it is curing the deficiencies cited in the Contract Determination and that it "is dedicated to resolving" its Star Rating results and "has committed substantial resources to improve [its] performance on Part C and Part D measures[.] *Id*. Lasso Healthcare projects "that it will have Part C and Part D star ratings of 3 Stars for CY2024[,]" and asserts that "[i]n light of the foregoing, it cannot be reasonably concluded that [Lasso Healthcare] is a 'high-risk organization' for purposes of application approvals and beneficiary protection as indicated in the Contract Determination." *Id*.

In response, CMS states that it "has historically not reported the results of the past performance analysis until the second stage of review." CMS Brief at 8. CMS asserts that "[a] past performance deficiency is not cited in response to any deficiency in an applicant's response to the solicitation; rather, it is the result of an analysis CMS performs in accordance with the regulation to determine if the applicant has failed to comply with the requirements of a current or prior contract during the past performance review period." *Id*. CMS states that "[t]he past performance deficiency in the NOID provides applicants an opportunity to withdraw their application or inform CMS of any errors the applicant believes were made in assessing their past performance[.]" *Id*. CMS claims that "the very nature of past performance means that it is not 'curable' during the review period." *Id*.

Additionally, CMS argues that *Arkansas Superior Select* is distinguishable from the Lasso Healthcare's issue in the instant appeal as follows

> [In *Arkansas Superior Select*,] CMS failed to provide two opportunities to cure deficiencies in the applicant's request for an enrollment waiver as called for in the solicitation, in that case, the failure to provide two cure periods prejudiced the applicant. . . . CMS was required by the regulation to consider certain factors in deciding whether to grant a waiver of the minimum enrollment requirement and depriving the applicant of one of the usual opportunities to present information relating to those factors materially prejudiced them. *Arkansas Superior Select*, at 6. In contrast, neither the regulation nor the subregulatory guidance indicate that CMS will consider requests for exemptions from the results of the past performance analysis as part of the application review process. Lasso [Healthcare] was not deprived of a full opportunity to "cure" the past performance deficiency because nothing short of demonstrating that the deficiency was cited in error would cure it.

CMS Brief at 8.

In support of CMS' policy, CMS points to the preamble of the January 19, 2021, final rule in which CMS "has indicated . . . that [it] intends to deny an applicant that meets the bases for past performance denial and that organizations should not expect that [CMS] would consider requests for exceptions to such denials." CMS Brief at 9; 86 Fed. Reg. 6002 (Jan. 19, 2021).

The Hearing Officer notes that Lasso Healthcare does not argue that its past performance analysis was cited in error. Instead, Lasso Healthcare asserts that CMS should take into consideration that it is curing the deficiencies cited in the Contract Determination. Lasso Healthcare Hearing Brief at unnumbered page 5. Moreover, although Lasso Healthcare argues that it "was afforded no opportunity at all to cure the past performance deficiency[,]" the Hearing Officer notes that the information (e.g., actual violations and deficiencies) upon which contract number H1924's CY 2022 and 2023 summary Star Ratings are based cannot be undone. Indeed, the April 17, 2023, NOID specifically warns that "[n]o material can be submitted to cure this issue." Lasso Healthcare Exhibit P-3. While Lasso Healthcare claims that it is, in fact, "curing the deficiencies cited in the contract determination[,]" the Hearing Officer finds that, as the Star Ratings were already issued based on historical information from past years, it is impossible for Lasso Healthcare to take remedial steps to change the CY 2022 and 2023 Star Ratings.[8] Accordingly, the Hearing Officer agrees with CMS that the decision in *Arkansas Superior Select* is distinguishable from the facts in the instant appeal. Thus, the question of whether Lasso Healthcare was prejudiced by not receiving the notices that are described in *Arkansas Superior Select* does not apply to situations such as the one present here, i.e., the prior years' Star Ratings, in which it is not possible for an MA plan to "cure" the underlying past performance determinations. In other words, the Hearing Officer finds that the general right to cure application deficiencies (e.g., clerical errors, network deficiencies, documentation requirements) does not extend to past history as it cannot be changed.

Furthermore, with respect to Lasso Healthcare's argument that the past performance methodology ignores an applicant's remediation of past performance issues (to ensure that past performance issues are not repeated), although 42 C.F.R. § 422.502(b)(1) grants CMS the discretion to determine whether or not to deny an application based on the applicant's past performance, the Hearing Officer finds that neither the regulation nor CMS' subregulatory guidance require CMS to consider any remediation efforts or exception requests. Lasso Healthcare Hearing Brief at unnumbered page 6; *see generally* 42 C.F.R. § 422.502(b).

[8] Of note, CMS states that Lasso Healthcare "did not challenge its Star Ratings for 2022 or 2023 when they were released in Fall of 2021 and 2022, respectively." CMS Brief at 6. As Lasso Healthcare does not challenge, in the instant appeal, that the underlying information that CMS relied upon to calculate the ratings was incorrect and/or whether the ratings were otherwise incorrectly calculated back in 2021 and 2022, the Hearing Officer will not reach or analyze whether failure to raise a concern or formal challenge to the Star Rating during the preview period would negate the Plan's opportunity to do so under a future contract determination appeal which arises years after the ratings were issued.

B. Lasso Healthcare's arguments that the Secretary's CY 2023 Past Performance Methodology regulation is arbitrary and capricious and that it is prohibited retroactive rulemaking are outside the scope of the Hearing Officer's authority under 42 C.F.R. § 422.688.

Lasso Healthcare states that "CMS' denial of [its] application is as a result of changes made by CMS to its past performance methodology at 42 C.F.R. §§ 422.50[2](b)(1)(i)(E)[9] and 423.503(b)(1)(i)(E) in the CY2023 Policy and Technical Changes to the Medicare Advantage and Medicare Prescription Drug Benefit Programs rulemaking (the "CY2023 Past Performance Methodology")." 87 Fed. Reg. 27704 (May 9, 2022) (the "CY2023 Final Rule"). Lasso Healthcare Hearing Brief at unnumbered page 6. Lasso Healthcare asserts that

> [i]n the CY2023 Final Rule, CMS exponentially expanded the grounds on which it could choose to deny a Part C or Part D application to include any circumstances wherein, during the applicable review period, the applicant met or exceeded 13 points for compliance actions for any one contract. The CY2023 Past Performance Methodology assesses points based on the type of compliance action issued by CMS. The "applicable review period" is the 12 months preceding the deadline established by CMS for the submission of contract qualification applications. The CY2023 Past Performance Methodology was first effective for the CY2024 application cycle. The applicable review period was March 1, 2022 through February 28, 2023.

Id.

Lasso Healthcare argues that

> [t]he CY2023 Past Performance Methodology is a draconian approach to evaluating applicants that utilizes an arbitrary point system, which does not sufficiently account for disparate reasons underlying particular compliance actions, and fails to consider whether an organization has remediated its past performance issues before denying an application. As a result, the CY2023 Past Performance Methodology denies applications submitted by organizations, like [Lasso Healthcare], that can fully manage their current contracts and books of business and are in the process of successfully implementing measures necessary to achieve excellent health outcomes for needy and high risk populations. In addition, contrary to CMS' assertions, the CY2023 Past Performance Methodology will impact beneficiary access by limiting the number

[9] Within its Hearing Brief, Lasso Healthcare discusses changes to "42 C.F.R. § 422.504(b)(1)(i)(E)" but the Hearing Officer notes that the past performance methodology regulatory subsection that Lasso Healthcare discusses is located at 42 C.F.R. § 422.502(b)(1)(i)(E).

> of qualified plans available to them, and by effectively denying underserved populations access to plans that have been most focused on and are best able to address their particular needs.

Id. at unnumbered page 7.

Lasso Healthcare adds that "the CY2023 Past Performance Methodology made no assessment regarding [its] ability to provide health care services to beneficiaries and deemed [Lasso Healthcare] a "poor performer" without providing [it with] an opportunity to rebut that false and unfair characterization." *Id*.

Additionally, Lasso Healthcare states that "[a]doption of the CY2023 Past Performance Methodology is arbitrary and capricious in violation of the Administrative Procedure Act ("APA") because it undermines – rather than advances – CMS' stated objective of protecting the Part C and Part D programs and beneficiaries." *Id*. at unnumbered page 8. Lasso Healthcare argues that

> CMS ignored the impact that increasing the scope of past compliance actions included in the CY2023 Past Performance Methodology, without affording applicants the regulatorily required opportunity to show that those past compliance issues had been remediated, would have on beneficiary access to qualified plan choices. The CY2023 Past Performance Methodology is also arbitrary and capricious because it violates CMS' own regulations, since organizations do not have an appeal right in connection with the compliance actions included in the methodology, with the exception of intermediate sanctions.

Id.

With respect to its claim that the CY2023 Past Performance Methodology is prohibited retroactive rulemaking, Lasso Healthcare argues that "[f]ederal law prohibits the imposition of retroactive rules absent a statutory requirement, significant public safety concern, or other critical need – none of which are present here." Lasso Healthcare Hearing Brief at unnumbered page 9 (citing to 42 U.S.C. § 1395hh(e)(1)(A)). Lasso Healthcare asserts that based on "the chronology of CMS' past performance methodology[,] . . . the CY2023 Past Performance Methodology clearly effects a substantive change from CMS' prior regulation." *Id*. *See Ne. Hosp. Corp. v. Sebelius*, 657 F.3d 1, 14 (D.C. Cir. 2011) ("To determine whether a rule is impermissibly retroactive, [a court] first look[s] to see whether it effects a substantive change from the agency's prior regulation or practice.").

Additionally, Lasso Healthcare asserts that

> CMS cites no statutory requirements to justify the retroactive application of the CY2023 Past Performance Methodology. Nor did CMS assert that failure to apply the regulatory change retroactively would be contrary to the public interest. Moreover, a public-interest

> determination under section 1395hh(e)(1)(A)(ii) is, at a minimum, subject to review under the arbitrary-and-capricious standard of the APA.

Id. (*see, e.g., Sec'y Br. at 43, St. Francis Med. Ctr. v. Azar*, 894 F.3d 290 (D.C. Cir. 2018)).

Lasso Healthcare states that "the Contract Determination cannot stand because of its reliance on an unlawfully adopted regulation–the CY2023 Past Performance Methodology." *Id*.

Lastly, Lasso Healthcare cites to a number of Administrator decisions in which the Administrator exercised "discretion to allow a plan to cure an application, even when the CMS denial was not arbitrary or capricious." *Id*. at unnumbered pages 9-10. Lasso Healthcare argues that such discretion has been applied when there are "compelling public policy arguments with respect to the beneficiary related value of the Plan's services provided to vulnerable Medicare populations[.]" *Id.* at unnumbered page 9 (citing to *In the Matter of Community Care Alliance of Illinois*, Docket No. 2013-MA/PD-App-07, Adm'r Dec. at 7 (Aug. 4, 2013)). Lasso Healthcare goes on to discuss the many ways in which it asserts that its plan meets the needs of the communities that it serves. *See id*. at unnumbered pages 10-11.

In its response, CMS argues that although Lasso Healthcare states that its application was denied based on "compliance actions," this characterization is "incorrect" and that Lasso Healthcare's application denial was "based on two consecutive years of low Star Ratings." CMS Brief at 7-8.

Nonetheless, CMS asserts that

> While the revised rule does assign points for compliance actions, it largely replaces the point system that was used prior to 2021 with a list of criteria, any one of which could result in a past performance denial. It is not clear why a point system adopted by subregulatory guidance, as was used prior to the 2021 rule, is less arbitrary than a list of criteria that was adopted after notice and comment rulemaking, as the 2021 and 2022 rules were.

Id. at 10.

With respect to Lasso Healthcare's argument that the CY2023 Past Performance Methodology does not afford applicants the opportunity to show that those past compliance issues have been or are being remediated, CMS states that it "is under no obligation to consider such information." *Id.* Furthermore, CMS argues that the CY2023 Past Performance Methodology is not inconsistent with CMS' policy objectives as "CMS has repeatedly emphasized the importance of ensuring that beneficiaries have access to high quality plans." *Id*. CMS also explains that its "policy goal has never been simply to increase the number of plans available to Medicare beneficiaries, but to ensure that those plans provide high quality services as reflected in such performance indicators as Star Ratings." *Id*.

CMS asserts that denying an application "based on conduct that demonstrated poor performance under CMS rules both when it occurred and when it was reported to CMS[] is prospective, not

retroactive." *Id*. at 6. Further, CMS argues that "[t]he changes to the past performance regulation in the 2022 final rule do not violate traditional notions of fair notice, reasonable reliance, or settled expectations with respect to the consequences of poor Star Ratings." *Id*. at 6-7.

CMS explains that "Star Ratings for MAPD contracts were first published in 2008[,]" and "[s]ince that time, CMS has displayed" the Star Ratings "so that Medicare beneficiaries can use the information about the plan's quality in making enrollment decisions." *Id.* at 7. Further, "MA organizations and Part D sponsors agree to maintain Part C and Part D summary ratings of at least 3 stars as a condition of their contracts with CMS[,]" and "MA and Part D contracts have been subject to termination for earning Part C or Part D summary ratings of less than 3 stars for three consecutive years since 2013." *Id*.; *see* 42 C.F.R. §§ 422.504(a)(17), 423.505(b)(26); 422.510(a)(4)(xi) and 423.509(a)(4)(x). Moreover,

> While the 2021 final rule temporarily ended the longstanding use of Star Ratings in assessing past performance for purposes of reviewing applications, the more severe consequence of low Star Ratings was not lifted at that time. Lasso [Healthcare] certainly would not have performed better in 2020 and 2021, the contract years on which its 2022 and 2023 Part C Star Ratings were based, if it were confident that the consequence of poor Star Ratings would include application denial in addition to the much more severe consequence of contract termination and lower quality bonus payments.

Id.

Lastly, CMS argues that "it is hardly unfair to prohibit an organization that is at risk of termination if it earns one more year of low Star Ratings from expanding its business in the year prior to that possible termination." *Id*. CMS concludes that

> The denial of Lasso [Healthcare]'s application was therefore not an impermissible exercise of retroactive rulemaking. The requirement to maintain Part C summary ratings of at least 3 stars is a longstanding regulatory requirement and it is not inconsistent with other consequences for low Star Ratings, such as contract termination. Lasso [Healthcare] neither could have nor should have relied on CMS not using Star Ratings as a factor in past performance review for 2023 applications in making decisions that affected 2022 and 2023 Star Ratings or 2024 applications.

Id. at 7-8.

The Hearing Officer notes that CMS published its most recent amendments to its past performance methodology in May 2022, providing notice to CY 2024 applicants of the potential impact of the 2023 Star Ratings on CY 2024 applications. Following publication of the amended past

performance methodology in May 2022 and CMS' release of the CY 2023 Star Ratings in October 2022, applicants with Star Ratings of 2.5 or below were on notice, prior to the application deadlines, that their applications may be denied.

Additionally, for over a decade, CMS regulations have established that CMS may consider an MA-PD organization's past performance in evaluating contract applications,[10] and that, as noted, as a condition of a contract with CMS, MA organizations and Part D sponsors agree to maintain Part C and Part D summary ratings of at least 3 stars. 42 C.F.R. §§ 422.504(a)(17) and 423.505(b)(26). Regardless, however, the Hearing Officer's authority is limited in the instant appeal and the Hearing Officer does not have the authority to consider policy-related arguments that challenge the application or substance of controlling regulations. Under 42 C.F.R. § 422.688, the Hearing Officer "must comply with the provisions of title XVIII and related provisions of the Act, *the regulations issued by the Secretary*, and general instructions issued by CMS in implementing the Act." 42 C.F.R. § 422.688 (emphasis added). The Secretary's CY2023 Past Performance Methodology was published within a final rule issued on May 9, 2022, with an effective date of June 29, 2022. *See* 87 Fed. Reg. 27704 (May 9, 2022). The CY 2024 application cycle at issue in the instant appeal commenced in February 2023, thus was subject to the regulatory provisions promulgated within the CY 2023 final rule. *See* CMS Brief at 2.

VIII. DECISION AND ORDER

The parties agree that there are no material facts in dispute as Lasso Healthcare concedes that it received Part C summary Star Ratings of 2 stars in both 2022 and 2023. Lasso Healthcare has not demonstrated by a preponderance of evidence that CMS' denial of its initial application for H9618 based on its past performance analysis regarding its Star Ratings for 2022 and 2023 was inconsistent with this controlling regulation. Thus, the Hearing Officer grants CMS' Motion for Summary Judgment.

Amanda S. Costabile -S
Digitally signed by Amanda S. Costabile -S
Date: 2023.08.09 10:30:24 -04'00'

Amanda S. Costabile, Esq.
CMS Hearing Officer

Date: August 9, 2023

[10] *See* CMS Brief at 3-4 for a detailed discussion of the Secretary's past performance methodologies.