DEPARTMENT OF HEALTH & HUMAN SERVICES

Centers for Medicare & Medicaid Services
Office of Hearings
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August 31, 2023

VIA ELECTRONIC DELIVERY

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-23-00017
Medicare Advantage/Prescription Drug Plan Contract Denial
Molina Healthcare of Nebraska, Inc., Contract Number: H8426

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

Molina Healthcare of Nebraska, Inc., Contract No. H8426,	*	**Denial of Application for a Medicare Advantage / Medicare Advantage-Prescription Drug Plan**
Appellant	*	
v.	*	
Centers for Medicare & Medicaid Services,	*	**Contract Year 2024**
Respondent	*	**Hearing Officer Docket No. H-23-00017**

ORDER GRANTING CMS' MOTION FOR SUMMARY JUDGMENT

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I. FILINGS

This Order is being issued in response to the following:

(a) Molina Healthcare of Nebraska, Inc.'s ("Molina-Nebraska's") Hearing Request and exhibits filed on June 1, 2023;
(b) Molina-Nebraska's Hearing Brief and exhibits filed on June 15, 2023; and
(c) Centers for Medicare & Medicaid Services' ("CMS'") Brief in Reply to Applicant's Brief in the Matter of the Denial of the Molina Healthcare of Nebraska, Inc. Application, Contract Number H8426 ("CMS Brief") and exhibits filed on June 22, 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 Molina-Nebraska's Medicare Advantage ("MA")/MA-Prescription Drug ("MA-PD") plan and dual-eligible Special Needs Plan ("D-SNP") initial applications (contract H8426), based on (1) parent organization Molina Healthcare, Inc.'s failure to comply with the terms and conditions of a current or previous year's contract with CMS because it met or exceeded 13 points for compliance actions as calculated in accordance with 42 C.F.R. § 423.503(b)(1)(i) (2022); and (2) Molina-Nebraska's failure to meet CMS' network adequacy requirements under 42 C.F.R. § 422.116 was inconsistent with regulatory requirements. [1]

IV. DECISION SUMMARY

The Hearing Officer grants CMS' Motion for Summary Judgment. The Hearing Officer finds that there are no material facts in dispute. Molina-Nebraska's application did not timely demonstrate, by the final submission date communicated on CMS' Notice of Intent to Deny ("NOID"), that it met CMS' network adequacy requirements pursuant to 42 C.F.R. § 422.116(a)(1)(ii). Additionally, Molina-Nebraska's application is subject to the past performance regulations at 42 C.F.R. §§ 422.502(b) and 423.503(b). The Hearing Officer finds that CMS applied and followed

[1] Although CMS' May 17, 2023 Denial Notice also lists "Letters of Intent" as a deficiency, Molina-Nebraska states that it received a communication from CMS, on May 18, 2023, informing Molina-Nebraska that CMS had "validated the resubmitted LOIs, and the LOI deficiency has been removed from your application." Molina-Nebraska Brief at 9; *see* Molina-Nebraska Exhibit P-11. However, within CMS' Brief here, CMS continues to list "failure to meet CMS' Letter of Intent (LOI) requirements per 42 CFR § 422.116(d)(7)" as one of the deficiencies that resulted in the application denial. CMS Brief at 1. Despite this discrepancy, the Hearing Officer finds that CMS' denial is supportable under the regulations based on two, separate application deficiencies, either of which, alone, suffices to uphold the denial. As Molina-Nebraska both requested a record hearing and decided not to submit a reply brief after CMS' assertions in its Brief, the Hearing Officer makes no determination regarding the purported LOI deficiency.

the controlling regulations in effect at the time and upholds CMS' denial of Molina-Nebraska's applications.

V. PROCEDURAL HISTORY AND STATEMENT OF FACTS

Molina-Nebraska is a subsidiary of Molina Healthcare, Inc., and is currently licensed in Nebraska as a health maintenance organization. Molina Healthcare, Inc., currently offers health plans in nineteen states. Molina-Nebraska Hearing Brief at 2. In September 2022, Molina-Nebraska was awarded a contract to be a managed care organization in Heritage Health, Nebraska's Medicaid managed care program. *Id.* As required by the contract, Molina-Nebraska filed initial applications to offer MA, MA-PD plans and a D-SNP for calendar year ("CY") 2024. *Id*.

On February 13, 2023, Molina-Nebraska filed its initial application to offer an MA-PD plan and D-SNP under contract number H8426. Subsequently, CMS issued Molina Part C and Part D Deficiency Notices dated March 20, 2023, in which CMS cited certain deficiencies that included network adequacy. *See* Molina-Nebraska Exhibit P-7; CMS Exhibit C-5. Within both Deficiency Notices, CMS warns that past performance related deficiencies will be provided in the NOID at the end of April. *Id.* Molina-Nebraska submitted curing materials to CMS by the March 28, 2023, deadline. CMS Brief at 7.

On April 17, 2023, CMS issued Molina-Nebraska NOIDs for its Part C, Part D and SNP applications. *See* Molina-Nebraska Exhibits P-2, P-3 and P-4. All three NOIDs listed past performance as a deficiency, while the Part D NOID also identified contracting deficiencies and the Part C NOID also identified state licensure and network deficiencies. *Id*. With respect to the Past Performance deficiency, the Part C/Part D NOIDs state the following:

> CMS has determined, pursuant to 42 C.F.R. § 422.502(b)[/42 CFR § 423.503(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 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.

Molina-Nebraska Exhibits P-2, P-3

The Part C and Part D NOIDs informed that Molina-Nebraska had until April 27, 2023, to submit changes to its applications. *Id*. Molina-Nebraska submitted curing materials in the form of revised provider and facility HSD tables and LOI submissions by the April 27, 2023 deadline. CMS Brief at 7.

On May 17, 2023, CMS issued Molina-Nebraska a Denial Notice regarding its application to offer a new MA, MA-PD plan, citing the following deficiencies: past performance, MA provider and facility networks, and LOIs. Molina-Nebraska Exhibit P-5. Within the Denial Notice, CMS further explains its past performance determination, stating that "[y]our organization failed to comply with the terms of a current or previous year's contract with CMS because it met or exceeded 13 points for compliance actions as calculated in accordance with 42 CFR § 423.503(b)(1)(i)." *Id.*

On June 1, 2023, Molina-Nebraska filed its Request for Hearing with the Office of Hearings. On the same date, the Office of Hearings acknowledged the request and provided the parties with a hearing date and briefing schedule. The parties submitted their respective briefs pursuant to the briefing schedule. 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 Molina[-Nebraska]'s application[,]" thus it is entitled to summary judgment in its favor. CMS Brief at 15.

Additionally, within its Brief, CMS provided a detailed summary of the compliance actions that comprised the basis for the past performance deficiency. *Id*. at 7-8. CMS states that "[s]ince [Molina-Nebraska] did not hold a Part C or D contract at the time of application submission, the past performance of one of its sibling contracts (H2879)[, Molina Healthcare of Wisconsin,] was imputed to its application in accordance with 42 CFR §§ 422.502(b)(1)(ii) and 423.503(b)(1)(ii)." *Id.* at 7. CMS provides that "H2879 received two [Corrective Action Plans ("CAPs")], one warning letter, and one [Notice of Non-compliance ("NONC")] during the performance period for CY 2024 applications, for a total of 16 points[,]" detailed as follows:[2]

[2] CMS Brief at 7. Although CMS was not clear as to whether it imputed two additional contracts to Molina-Nebraska's application, CMS nonetheless provided compliance points-related contract details for two additional Molina Healthcare affiliates – Molina Healthcare of Florida and Molina Healthcare of New Mexico:

> Molina Healthcare of Florida received 13 compliance points under contract H8130 for three compliance actions issued between March 1, 2022 and February 28, 2023. The compliance actions consisted of the following:
>
> - CAP issued May 26, 2022 for failure to comply with requirements related to operating a customer service call center. Exhibit C-8, p. 1-2;

Molina Healthcare of Wisconsin received 16 compliance point under contract H2879 for four compliance actions issued between March 1, 2022 and February 28, 2023. The compliance actions consisted of the following:

> - CAP issued May 26, 2022 for failure to comply with requirements related to operating a customer service call center. Exhibit C-10, p. 1-2;
>
> - NONC issued December 7, 2022 for failure to comply with requirements related to timely response to calls to the customer service call center in the second quarter of 2022. Exhibit C-10, p. 3-5;
>
> - Warning Letter issued January 26, 2023 for failure to comply with requirements related to timely response to calls to the customer service call center in the third quarter of 2022. Exhibit C-10, p. 6-8; and
>
> - CAP issued February 22, 2023 for earning a Part D summary Star Rating of less than 3 Stars for 2023. Exhibit C-10, p. 9-10.

> - NONC issued December 7, 2022 for failure to comply with requirements related to timely response to calls to the customer service call center in the second quarter of 2022. Exhibit C-8, p. 3-5; and
>
> - CAP issued February 24, 2023 for earning a Part D summary Star Rating of less than 3 Stars for 2023. Exhibit C-8, p. 6-7.

Molina Healthcare of New Mexico received 14 compliance points under contract H9082 for four compliance actions issued between March 1, 2022 and February 28, 2023. The compliance actions consisted of the following:

> - NONC issued March 4, 2022 for failing to ensure that Annual Notices of Changes were delivered to enrollees in a timely manner in September 2021. Exhibit C-9, p. 1-2;
>
> - CAP issued May 26, 2022 for failure to comply with requirements related to operating a customer service call center. Exhibit C-9, p. 3-4;
>
> - NONC issued October 25, 2022 for failure to connect at least 80% of calls requiring TTY services for the hearing and speech impaired to TTY within 7 minutes. Exhibit C-9, p. 5-6; and
>
> - CAP issued February 24, 2023 for earning a Part D summary Star Rating of less than 3 Stars for 2023. Exhibit C-9, p. 7-8.

CMS Brief at 8.

CMS Brief at 7.

On June 26, 2023, Molina-Nebraska requested a decision on the written record that the Hearing Officer granted on June 27, 2023.

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 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 Coordinated Care Plan ("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.[3]

Beginning with contract year 2024, an MA organization's application for a new or expanding service area must demonstrate compliance with the network adequacy requirements set forth under 42 C.F.R. § 422.116 as part of its application. 42 C.F.R. § 422.116(a)(1)(ii) (2023). Within a new or expanding service area application, an MA organization must demonstrate that the number and type of providers available to plan enrollees are sufficient to meet projected needs of the population to be served. 42 C.F.R. § 422.112(a)(4). As such, the MA organization must meet maximum time and distance standards and contract with a specified minimum number of each provider and facility-specialty type. 42 C.F.R. § 422.116(a)(2). To demonstrate compliance with these network adequacy standards, applicants must upload, as part of the application, Provider and Facility HSD Tables into HPMS. *See* "Part C-Medicare Advantage and 1876 Cost Plan Expansion Application" at https://www.cms.gov/files/document/cy-2024-medicare-advantage-part-c-application.pdf-1 at

[3] The Medicare Modernization Act of 2003, Public L. No. 108-173, established an MA CCP specifically designed to provide targeted care to individuals with special needs. MA CCPs established to provide services to these special needs individuals are called "Specialized MA plans for Special Needs Individuals," or SNPs. Special needs individuals and specialized MA plans for special needs individuals are defined at 42 C.F.R. § 422.2. SNPs are expected to follow existing MA program rules, including MA regulations at 42 C.F.R. § 422, as modified by guidance, with regard to Medicare-covered services and Prescription Drug Benefit program rules. Every applicant that proposes to offer a SNP must obtain additional CMS approval as an MA-PD plan. A CMS MA-PD contract that is offering a new SNP, or that is expanding the service area of a CMS-approved SNP, needs to complete only the SNP application portion of the MA application if CMS has already approved the service area for the MA contract. Otherwise, if the MA organization is planning to expand its contract service area, it must complete both a SNP application and an MA SAE application for the approval of the MA service area. *See* https://www.cms.gov/Medicare/Health-Plans/SpecialNeedsPlans and https://www.cms.gov/medicare/health-plans/specialneedsplans/snp-application.

27; *see also* December 2022 Instructions, CMS Exhibit C-2 at 2. Furthermore, under 42 C.F.R. § 422.116(a)(1)(ii), CMS may deny an application on the basis of an evaluation of the applicant's network for the expanding service area.

Under 42 C.F.R. § 422.116(b)-(e), CMS sets forth its specific requirements regarding provider and facility-specialty types; county type (i.e., metro, rural, etc.) designations; maximum time and distance standards; and minimum number standards for each provider and facility specialty type. Under 42 C.F.R. § 422.116(f), CMS provides the conditions under which an MA plan may request an exception to network adequacy criteria in 42 C.F.R. § 422.116(b)-(e), as well as its considerations in evaluating such requests. Additionally, under 42 C.F.R. § 422.116(d)(7), CMS provides that

> [b]eginning with contract year 2024, an applicant for a new or expanding service area receives a 10-percentage point credit towards the percentage of beneficiaries residing within published time and distance standards for the contracted network in the pending service area, at the time of application and for the duration of the application review. In addition, applicants may use a Letter of Intent (LOI), signed by both the MA organization (MAO) and the provider or facility with which the MAO has started or intends to negotiate, in lieu of a signed contract at the time of application and for the duration of the application review, to meet network standards. As part of the network adequacy review process, applicants must notify CMS of their use of LOIs to meet network standards in lieu of a signed contract and submit copies upon request and in the form and manner directed by CMS. At the beginning of the applicable contract year, the credit and the use of LOIs no longer apply and if the application is approved, the MA organization must be in full compliance with this section, including having signed contracts with the provider or facility.

When evaluating an applicant's network, CMS explains that its "network review is performed through an automated tool within HPMS that compares the network data submitted by each applicant against standardized CMS network adequacy criteria published in the annual Reference File[.]" CMS Brief at 3. CMS states that the automated tool "generates two reports," called the Automated Criteria Check ("ACC"), for "Provider" and "Facility," "that show whether a provider in a given county is passing the network adequacy requirements." *Id*. Lastly, CMS asserts that "[t]he ACC reports are accessible within the system to reflect where the applicant stands with respect to meeting the standardized criteria." *Id*; *see also* December 2022 Instructions, CMS Exhibit C-2 at 2.

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). However, CMS may deny an application submitted by an organization that does not hold a Part C or Part D contract at the time of the submission when the applicant's parent organization or another subsidiary of the parent organization meets the criteria for denial stated in paragraph (b)(1)(i). 42 C.F.R. §§ 422.502(b)(1)(ii) and 423.503(b)(1)(ii).

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. CMS Brief at 3.

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 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."[4]

B. Compliance Actions and Consideration of Performance Under an Applicant's Current or Prior Year Contract

Under 42 C.F.R. §§ 422.504(m)(1) and 423.505(n)(1), CMS may take compliance actions if it determines that an MA organization or Part D sponsor has not complied with the terms of a current or prior Part C or D contract with CMS. Within the preamble to the 2022 Final Rule, CMS clarifies that, for purposes of the regulation, compliance actions are NONCs, CAPs and warning letters. 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, 27816 (May 9, 2022). CMS may take one of the aforementioned three types of compliance actions based on the nature of the noncompliance. 42 C.F.R. §§ 422.504(m)(3) and 423.505(n)(3). CMS bases its decision on whether to issue a compliance action and what level of compliance action to take on an assessment of the circumstances surrounding the noncompliance, including all of the following: (i) the nature of the conduct; (ii) the degree of culpability of the MA organization; (iii) the adverse effect to beneficiaries which resulted or could have resulted from the conduct of the MA organization; (iv) the history of prior offenses by the MA organization or its related entities; (v) whether the noncompliance was self-reported; and (vi) other factors which relate to the impact of the underlying noncompliance or the lack of the MA organization's oversight of its operations that contributed to the noncompliance. 42 C.F.R. §§ 422.504(m)(2) and 423.505(n)(2).

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. Additionally, CMS may deny an application based on the applicant's failure to comply with the requirements of the Part C or Part D program under any current or prior contract with CMS even if the applicant currently meets all of the regulatory requirements. *Id*. Specific to the instant appeal, applicants may be considered to have failed to comply with a contract for

[4] Within the preamble to the 2010 Final Rule, the Secretary provided additional clarification regarding the hearing process:

> [T]he applicant would not be permitted to submit additional revised application material to the Hearing Officer for review should the applicant elect to appeal the denial of its application. Allowing for such a submission and review of such information would, in effect, extend the deadline for submitting an approvable application.

Policy and Technical Changes to the Medicare Advantage and Medicare Prescription Drug Benefit Programs, 75 Fed. Reg. 19678, 19683 (April 15, 2010).

purposes of application denial if, during the review period, the applicant met or exceeded 13 points for compliance actions on any one contract. 42 C.F.R. §§ 422.502(b)(1)(i)(E) and 423.503(b)(1)(i)(E). CMS determines the number of points each MA organization accumulated during the performance period[5] for compliance actions based on the following point values:[6]

> (i) Each corrective action plan *issued* during the performance period under § 422.504(m) counts for 6 points.
>
> (ii) Each warning letter *issued* during the performance period under § 422.504(m) counts for 3 points.
> (iii) Each notice of noncompliance *issued* during the performance period under § 422.504(m) counts for 1 point.

42 C.F.R. § 422.502(b)(1)(i)(E)(1)(i)-(iii)[7] (emphasis added).

CMS further explains its application of the past performance methodology as follows:

> 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. 5999.

CMS Brief at 5.

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

[5] As noted above, for the CY 2024 application cycle, the performance or review period ran from March 1, 2022, through February 28, 2023. CMS Brief at 6.

[6] CMS adds all the point values for each MA organization to determine if any organization meets CMS' identified threshold. 42 C.F.R. §§ 422.502(b)(1)(i)(E)(2) and 422.503(b)(1)(i)(E)(2).

[7] For Part D contracts, the identical provision is located at 42 C.F.R. § 422.502(b)(1)(i)(E)(1)(i)-(iii).

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 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). 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 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). In the 2021 final rule, CMS also amended its Part C and Part D past performance regulations to codify the long-standing policy attributing the performance of existing MA organizations and Part D sponsors to inexperienced legal entities under the same parent organization. 42 CFR §§ 422.502(b)(1)(ii) and 423.503(b)(1)(ii).
>
> CMS again amended its past performance regulations in a final rule published in May 2022. 87 Fed. Reg. 27704 (May 9, 2022). 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.

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.

VII. DISCUSSION, FINDINGS OF FACT AND CONCLUSIONS OF LAW

The Hearing Officer grants CMS' Motion for Summary Judgment. The Hearing Officer finds that there are no material facts in dispute as Molina-Nebraska admits that its provider and facility networks submitted with its application do not meet CMS' network adequacy requirements and that Molina-Nebraska's parent company, Molina Healthcare, Inc., had an affiliated health plan contract that met or exceeded 13 points for compliance actions as calculated in accordance with 42 C.F.R. § 423.503(b)(1)(i). CMS Brief at 6; Molina-Nebraska Hearing Brief at 1. Instead, Molina-Nebraska argues that neither it "nor its parent organization, Molina Healthcare, Inc., is a high-risk organization[.]" Molina-Nebraska Hearing Brief at 1. Molina-Nebraska also argues that CMS has not considered that the shortened timeline associated with its amended application requirements made it "extraordinarily difficult for new plans . . . to timely establish a Medicare network[,]" and requests that CMS allow it to demonstrate that it has now "satisfied network adequacy in all of the counties in its proposed service area." *Id.* Lastly, Molina-Nebraska asserts that as CMS interprets its amended past performance regulation as not including two opportunities to cure past performance deficiencies, the regulation is arbitrary and capricious and impermissibly retroactive. *Id.* at 6. The Hearing Officer's findings regarding these arguments are set forth below.

A. <u>The Hearing Officer finds that Molina-Nebraska's network submitted with its application did not timely meet CMS' network adequacy requirements and CMS' decision to deny Molina-Nebraska's application based on CMS' review of that network was consistent with the controlling regulations.</u>

Molina-Nebraska argues that "CMS imposed an untenable deadline to expand in Nebraska that disadvantaged new entrants like Molina[-Nebraska]." Molina-Nebraska Hearing Brief at 8 (emphasis omitted). Specifically, Molina-Nebraska states that

> The timeline was effectively illusory for new entrants like Molina[-Nebraska], because providers often will not engage with managed care organizations ("MCOs") until the state publicly announces the Medicaid award or the Medicaid MCO contract is much closer to the start date. To address this reluctance of Nebraska providers, [Nebraska Department of Health and Human Services ("DHHS")], at Molina[-Nebraska]'s request, issued a Provider Bulletin in February 2023 informing providers in the state of the award and that awardees may be contacting providers to contract for healthcare services. [*See* Molina-Nebraska Exhibit P-9.] Incumbent MCOs did not need DHHS's bulletin since they already had an established provider network in the state. Similarly, CMS' new timeframe gave Medicaid MCOs already operating in the state an advantage in establishing network adequacy, while severely hampering the ability of new Medicaid MCOs (like Molina[-Nebraska]) to timely build a Medicare network prior to operations.

Molina-Nebraska Hearing Brief at 8-9.

Molina-Nebraska argues that despite its "use of LOIs and the 10 percentage point credit, these temporary actions were insufficient relief for applicants like Molina[-Nebraska], because of the reluctance from providers to execute binding agreements or even LOIs so far in advance of the actual start date for the provision of, and payment for, healthcare services for CY2024." Molina-Nebraska Hearing Brief at 9.

Molina-Nebraska states that despite the "untenable deadline" and difficulties in establishing its network in a new state, "[s]ince the time Molina submitted curing materials in response to the NOID, Molina[-Nebraska] has closed all network gaps." *Id*. at 10 (emphasis omitted). Molina-Nebraska concludes that "[g]iven the difficulties new plans to a state reasonably faced in establishing an adequate network within CMS's abbreviated timeframe, Molina should be permitted to demonstrate that it has cured all network deficiencies." *Id*.

In its response, CMS asserts that "[t]here is no factual dispute that Molina[-Nebraska] failed to comply with CMS' application requirements for network adequacy." CMS Brief at 13 (emphasis omitted). CMS states that after it "conducted its final review of Molina's application materials[,] [it] found that Molina[-Nebraska] did not have an adequate network in Antelope, Blaine, Dawson,

Hall, Holt, Jonson, Knox, Lancaster, Logan, Nemaha, and Wayne counties[.]" *Id*. Further CMS argues that "[t]he period for Molina[-Nebraska] to submit relevant information regarding documentation of an adequate provider network has passed. CMS requires that all required network adequacy documentation be provided by the final submission deadline." *Id*. at 14.

Although Molina-Nebraska states that it has now "cured all network deficiencies," CMS has not reviewed Molina-Nebraska's updated network and the Hearing Officer's authority is limited in this appeal. Molina-Nebraska Hearing Brief at 10; *see* 42 C.F.R. § 422.688 and 423.664. Molina-Nebraska was required to demonstrate, in the form and manner required by CMS, compliance with CMS' network adequacy requirements as part of its application. 42 C.F.R. § 422.116(a)(1)(ii); 42 C.F.R. § 501(c)(1). Further, CMS may deny an application on the basis of an evaluation of the applicant's network. 42 C.F.R. § 422.116(a)(1)(ii). Here, Molina-Nebraska does not dispute that its as-submitted network did not timely demonstrate compliance with CMS' network adequacy requirements. As such, the Hearing Officer finds that CMS' denial of Molina-Nebraska's application was consistent with the regulatory requirements.

B. Molina-Nebraska has neither demonstrated that it was materially deprived of an opportunity to cure its past performance deficiencies 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.

Molina-Nebraska asserts that "CMS's denial should be reversed because CMS failed to provide Molina the requisite opportunity to cure the Past Performance Deficiency[,]" and that "CMS incorrectly interpreted its regulations requiring opportunities to cure as inapplicable to Past Performance Deficiencies." Molina-Nebraska Hearing Brief at 3 (emphasis omitted). Specifically, Molina-Nebraska argues that "[t]he CMS application process explicitly affords two opportunities to cure any deficiencies: first, in response to Deficiency Notices, and second, in response to [NOIDs]." *Id*. at 4. Molina-Nebraska asserts, however, that it was denied both of its opportunities to cure the past performance deficiencies as CMS did not identify any past performance deficiency in the Deficiency Notice and then, "when CMS ultimately identified the past performance deficiency in the NOID, CMS prohibited Molina[-Nebraska] from even attempting to show that it had cured, or could cure, the deficiency[.]" *Id*.; *see* Molina-Nebraska Exhibits P-2, P-3 ("No material can be submitted to cure this issue.").

Molina-Nebraska argues that "CMS cited to no authority that exempts past performance deficiencies from the regulatory framework that affords applicants two opportunities to cure[,]" and that "it is entitled by regulation and CMS's application process" to be "provided with the cure opportunities[.]" *Id*. In support of its argument, Molina 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*.") Molina asserts that *Arkansas Superior Select* stands for the proposition that a Hearing Officer will reverse CMS' denial if an applicant is "not afforded two opportunities to cure any deficiencies." *Id*. at 3. Additionally, Molina states that it "will be able to demonstrate that the . . . past performance issues cited by CMS—all of which relate to other

Molina Healthcare, Inc. health plans outside of Nebraska—have either been fully remediated already or remediation is underway." *Id*. at 4 (emphasis omitted).

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 10. 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*. at 10-11. CMS states that "the 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*. at 11. 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 Molina-Nebraska'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. Molina[-Nebraska] 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.

Id. at 10.

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." *Id*. at 11; Medicare and Medicaid Programs; Contract Year 2022 Policy and Technical Changes to the Medicare Advantage Program, Medicare Prescription Drug Benefit Program, Medicaid Program, Medicare Cost Plan Program, and Programs of All-Inclusive Care for the Elderly, 86 Fed. Reg. 5864, 6002 (Jan. 19, 2021).

The Hearing Officer notes that Molina-Nebraska does not argue that CMS' past performance analysis was cited in error. Instead, Molina-Nebraska asserts that CMS should take into consideration that the deficiencies upon which the application denial is based, "have either been fully remediated already or remediation is underway." Molina-Nebraska Hearing Brief at 4. Moreover, although Molina-Nebraska argues that it was "never afforded . . . an opportunity to cure the past performance deficiency" (Molina-Nebraska Hearing Brief at 3), the Hearing Officer notes that the activity underlying the compliance actions used within the analysis (e.g., actual violations and noncompliance resulting in CAPs/warning letters/NONCs) cannot be undone. Indeed, Molina-Nebraska's NOID specifically warns that "[n]o material can be submitted to cure this issue." Molina-Nebraska Exhibits P-2, P-3. Thus, while Molina-Nebraska complains that it has not been afforded any opportunity to cure the past performance deficiencies, the Hearing Officer finds that the violations and noncompliance findings are based on *historical* information from past years. Although Molina Healthcare, Inc., may take steps to try to avoid receiving CAPs/warning letters/NONCs in the future, it is impossible to take remedial steps to "undo" the past. 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 Molina-Nebraska 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' violations and noncompliance, 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 deficiencies relating to historical performance as the performance-related activity itself cannot be changed.

Furthermore, 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 mitigating factors or exception requests. *See generally* 42 C.F.R. § 422.502(b).

C. Molina-Nebraska'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 and 423.664.

Molina-Nebraska argues that as "CMS interpreted 42 C.F.R. § 422.502(c)(2)'s cure provisions as inapplicable to past performance deficiencies[,]" CMS' denial here, based upon CMS' CY2023 Past Performance Methodology, renders the methodology "arbitrary and capricious and impermissibly retroactive." *Id*. at 6. Molina-Nebraska states that "the CY2023 Past Performance Methodology is arbitrary and capricious because, by CMS's own admission, organizations do not have an appeal right in connection with the underlying compliance actions included in the methodology's applicable review period, with the exception of intermediate sanctions." *Id*. at 7 (quoting the preamble to the May 9, 2022 Final Rule, "CMS appreciates the need to ensure that compliance actions taken against MA organizations are accurate and appropriate. However, we do not believe an appeal process is necessary." 87 Fed. Reg. at 27818).

Additionally, Molina-Nebraska further asserts that CMS' interpretation of the methodology "undermines [CMS'] stated purpose" of "protecting the Part C and Part D programs and beneficiaries[.]" *Id*. at 6. Specifically, Molina-Nebraska explains that by "increasing the scope of past compliance actions included in the CY2023 Past Performance Methodology, without affording applicants the opportunity to show that those past compliance issues had been remediated, would exclude qualified applicants like Molina[-Nebraska] and, therefore, harm Medicare beneficiaries." *Id.* at 6-7. Molina-Nebraska concludes that "[b]y adopting a regulation in the face of evidence demonstrating that it would effectively countermand its stated policy objective, CMS acted arbitrarily, capriciously, and unlawfully. *Id*. at 7.

With respect to its assertion that "CMS's interpretation of its notice and cure regulation also gives the methodology impermissible retroactive effect[,]" Molina-Nebraska states that "[a]ll of the issues and activities that resulted in the cited past performance deficiencies *preceded* the effective date of the CY2023 Final Rule[.]" *Id*. Molina-Nebraska argues that "[f]ederal law prohibits CMS from promulgating retroactive rules absent a statutory requirement, significant public safety concern, or other critical need–none of which are present here." *Id*. (quoting that 42 U.S.C. § 1395hh(e)(1)(A) provides that "A substantive change in regulations . . . shall not be applied (by extrapolation or otherwise) retroactively to items and services furnished before the effective date of the change, unless the Secretary determines that- (i) such retroactive application is necessary to comply with statutory requirements; or (ii) failure to apply the change retroactively would be contrary to the public interest." Molina-Nebraska Hearing Brief at 7, n.19.).

CMS argues that its application of the 2022 Past Performance Methodology is not a retroactive application of an agency regulation as "[d]enying an application for a new contract in the future, 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." CMS Brief at 9.

CMS' response to Molina-Nebraska's argument that "organizations do not have an appeal right in connection with the underlying compliance actions included in the methodology's applicable review period, with the exception of intermediate sanctions" (Molina-Nebraska Hearing Brief at 7) is as follows:

> CMS explains the process for compliance actions in the 2022 final rule, stating that "when requested by an organization, CMS reviews information provided by the organization and re-reviews the compliance action to determine if the action was appropriate. CMS has a long-standing history of discussing compliance actions with organizations and retracting or modifying compliance actions when necessary." 87 Fed. Reg. 27818. Molina[-Nebraska] is correct to say that, in the 2022 rule, CMS stated that it does not feel that a formal appeals process is necessary for compliance actions based on our existing process. However, CMS further notes in that same rule that "a formal appeal process is available for applicants whose application has been denied for past performance reasons specified in this rule." 87 Fed. Reg. 27818.

CMS Brief at 12-13.

Additionally, CMS argues that the current past performance rule is not inconsistent with CMS' policy objectives, explaining that

> CMS has repeatedly emphasized the importance of ensuring that beneficiaries have access to high quality plans. This policy goal was reflected in the past performance regulation as originally adopted in 2010, when it updated that regulation in 2018, in all of its past performance methodologies, and in the most recent regulation changes in 2021 and 2022. CMS' 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 compliance.

Id. at 13.

In refuting Molina-Nebraska's claim that the 2022 Past Performance Methodology constitutes a retroactive application of an agency regulation, CMS argues that it has

> issued compliance letters for noncompliance with Part D requirements since the inception of the Part D program. Up until the 2021 amendment to the past performance regulation, compliance letters were used to assess past performance for purposes of evaluating Part C and Part D applications. CMS announced that it was planning to resume the use of compliance actions in evaluating past performance in a proposed rule published January 12, 2022, prior to the start of the past performance review period for 2024 applications. 87 Fed. Reg. 1842. Molina[-Nebraska] was therefore on notice for the entirety of the past performance review period that compliance actions issued during that period might be used to evaluate any 2024 applications. The final rule, where the past performance changes were made official, was published May 9, 2022, still more than 9 months before the 2024 applications were due.

Id. at 9.

Further, CMS states

> Even if CMS were to disregard compliance actions issued before the 2022 final rule was published, Molina[-Nebraska]'s application would still have been subject to denial for its affiliates' poor performance. Molina Healthcare of Florida's contract H8130 earned 13 points for compliance actions released after May 9, 2022

> – on May 26, 2022, December 7, 2022, and February 22, 2023. Molina Healthcare of New Mexico's contract H9082 also earned 13 points for compliance actions issued during the same time period – on May 26, 2022, October 25, 2022, and February 24, 2023. Finally, Molina Healthcare of Wisconsin's contract H2879 earned all 16 of its compliance points for compliance actions issued during that time period – on May 26, 2022, December 7, 2022, January 26, 2023, and February 22, 2022.

Id.

CMS concludes 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 repeated noncompliance." *Id.*

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 applications. While Molina-Nebraska argues that "[a]ll of the issues and activities that resulted in the cited past performance deficiencies *preceded* the effective date of the CY2023 Final Rule," the regulation itself assigns points for compliance actions (CAPs, warning letters, and NONCs, *not* the underlying noncompliance itself), that CMS *issues* within the applicable review period at the time that the underlying noncompliance was *identified*, regardless of when the noncompliance actually occurred. CMS argues that this approach is consistent with "all previous applications of . . . past performance authority, both before and after CMS began publishing annual past performance methodologies[.]"[8] *See* CMS Brief at 5.

At end, the Hearing Officer's authority, however, 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. 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 Hearing Officer grants CMS' Motion for Summary Judgment and upholds CMS' denial of Molina-Nebraska's application. The Hearing Officer finds that no material facts are in dispute and that Molina-

[8] The Hearing Officer notes that Molina-Nebraska has not indicated what it would have done differently if it had known that failing to comply with the terms of an existing contract—when it occurred—would result in application denial at a later date.

Nebraska has not proven by a preponderance of the evidence that CMS' denial of its application was inconsistent with regulatory requirements.

Amanda S. Costabile -S
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Amanda S. Costabile, Esq.
CMS Hearing Officer

Date: August 31, 2023