DEPARTMENT OF HEALTH & HUMAN SERVICES

Centers for Medicare & Medicaid Services
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August 12, 2025

Via Electronic Delivery

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RE: Hearing Officer Order and Decision
Hearing Officer Docket Number: H-25-00005
Medicare Advantage/Prescription Drug Plan ("MA/PD"), Appeal Year: 2026
Healthy Mississippi, Inc., Contract Number: H7679

Dear Ms. Clements and Ms. Spaccarelli:

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

The Hearing Officers' 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 CMS OAA General Appeals at OAA_Appeal@cms.hhs.gov.

Sincerely,

Office of Hearings

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

HEALTHY MISSISSIPPI, INC., **Contract No. H7679** **Petitioner** **v.** **CENTERS FOR MEDICARE & MEDICAID SERVICES,** **Respondent**	* * * * * * * * * * * * * *	**CMS Hearing Officer Case No.:** **H-25-00005** **Denial of Application for a New Medicare Advantage /Medicare Advantage – Prescription Drug Plan, New Dual Eligible Special Needs Plan, and New Hybrid Institutional Special Needs Plan**

HEARING OFFICER ORDER GRANTING MOTION FOR SUMMARY JUDGMENT IN PART

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I. FILINGS

a) May 15, 2025, Appeal Submitted regarding the Centers for Medicare & Medicaid Services' ("CMS's") Initial Application Denials, filed by Healthy Mississippi, Inc. ("HMI");[1, 2]
b) May 20, 2025, Plan Hearing Brief ("Plan Hearing Brief") and Plan Exhibits P-1 through P-21;
c) May 27, 2025, CMS's Brief in Reply to the Applicant's Brief in the Matter of the Denial of the Medicare Advantage, Part D and Special Needs Plan Applications Submitted by [HMI] (Contract H7679), submitted with a Motion for Summary Judgment ("CMS Brief"), including CMS Exhibits C-1 through C-7; and
d) May 29, 2025, Plan Reply Brief ("Plan Reply Brief").

II. JURISDICTION

This appeal is provided pursuant to 42 C.F.R. §§ 422.660 and 423.650. The CMS Hearing Officers designated to hear this case are the undersigned, Amanda S. Costabile and Suzanne D. Rollins.

III. ISSUES

Whether CMS's denial of HMI's applications for a new Medicare Advantage/Medicare Advantage Prescription Drug MA/MA-PD plan, D-SNP, and a HI-SNP, under Contract No. H7679, based on the following determinations was inconsistent with regulatory requirements:

Issue 1: HMI had less than twelve months' experience operating its current MA-PD contract;

Issue 2: HMI failed to include Scripius's Pharmacy Provider Manual, which is incorporated into Scripius's network pharmacy contracts by reference; and

Issue 3: HMI failed to provide pharmacy network lists from Scripius, the Pharmacy Benefit Manager ("PBM") that it would use in 2026.

IV. DECISION SUMMARY

Issue 1: The Hearing Officers grant CMS's Motion for Summary Judgment based on Issue 1 (twelve-month performance history), thereby upholding CMS's denial of HMI's application. The Hearing Officers find that there are no material facts in dispute, as the record establishes that HMI admitted, within an attestation on its application, that it does not have the requisite performance history in the MA and Part D ("MA-PD") programs, and CMS's decision was consistent with the regulation at 42 C.F.R. §§ 422.502(b)(2) and 423.503(b)(2).

[1] The applications included a new Medicare Advantage/Medicare Advantage – Prescription Drug Plan ("MA/MA-PD Plan"), a new Dual Eligible Special Needs Plan ("D-SNP"), and a new Hybrid Institutional Special Needs Plan ("HI-SNP"), all under contract number H7679. *See* Plan Exhibits P-10 through P-12.

[2] Within this decision HMI is also referred to as "the Plan" and sometimes "the Applicant."

Issue 2: The Hearing Officers grant CMS's Motion for Summary Judgment based on Issue 2 (submission of Pharmacy Provider Manual) as it is undisputed that HMI's final submission did not include the required manual for its PBM, Scripius.

Issue 3: The Hearing Officers deny CMS's Motion for Summary Judgment on Issue 3 (pharmacy network list) due to unclear material facts. Specifically, the dates when the Plan may have filed materials into the Health Plan Management System ("HPMS")[3] and the exact date HMI was allegedly "precluded by CMS from uploading" its pharmacy network list into HPMS are still unclear. Plan Reply Brief at 3. As the approval of the Motions for Summary Judgment on Issues 1 and 2 each independently support CMS's denial of HMI's applications for Contract No. H7679, the Hearing Officers will not proceed with Issue 3.

V. AUTHORITIES, APPLICATION REVIEW PROCESS, PAST PERFORMANCE, PART D REQUIREMENTS, AND SUBREGULATORY GUIDANCE

A. Application Review Process

Under Title XVIII of the Social Security Act ("the 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, 1395w-112. Any entity seeking such a contract must fully complete all parts of a certified application in the form and manner required by CMS. 42 C.F.R. § 422.501(c)(1). CMS requires an entity seeking to contract as an MA organization to submit an application through HPMS. *See* "Part C-Medicare Advantage and 1876 Cost Plan Expansion Application" at https://www.cms.gov/files/document/cy2026-medicare-advantage-part-c-application.pdf (last visited May 29, 2025) ("Part C Application"). The "Part C-Medicare Advantage and 1876 Cost Plan Expansion Application" is specifically "[f]or all new applicants and existing Medicare Advantage organizations seeking to expand a service area[.]" *Id.* at 1.

The regulation at 42 C.F.R. § 422.501 sets forth the application requirements for entities that seek a contract as an MA organization offering an MA plan and additional application requirements for MA organizations seeking to offer a Specialized MA plan for Special Needs Individuals. Among other requirements, applicants must provide documentation of appropriate state licensure, demonstrate that they are licensed under state law as a risk-bearing entity eligible to offer health insurance or health benefits, and submit a properly executed CMS State Certification Form. *See* 42 C.F.R. § 422.400; Part C Application.

The Part C Application also contains a series of "required attestations that must be completed for each type of application and applicant." Part C Application at 17. Specific to the instant appeal, under the required attestations for "Management, Experience, and History," applicants must answer whether

[3] HPMS is the primary information collection vehicle within which MA organizations will communicate with CMS during the application process, bid submission process, ongoing operations of the MA program, reporting and oversight activities. https://www.cms.gov/files/document/cy2026-medicare-advantage-part-c-application.pdf at 7.

> The Medicare Advantage plan(s) currently offered by the applicant, applicant[']s parent organization, or subsidiary of the applicant[']s parent organization has been operational since January 1, 2024[,] or earlier.

Part C Application at 19 (Section 3.1.7).

MA organizations seeking to also offer prescription drug plans must, in addition to the requirements under part 422, follow the requirements of part 423 specifically related to the prescription drug benefit. 42 C.F.R. § 422.500; 42 C.F.R. § 423.500. CMS posted the final Solicitation for Applications for Medicare Advantage and Medicare Prescription Drug Plan 2026 Contracts on January 7, 2025, at https://www.cms.gov/files/document/2026-part-d-application-final.pdf (last visited July 14, 2025) ("Part D Application"). CMS Exhibit C-1; CMS Brief at 2.

The regulation at 42 C.F.R. § 423.502 sets forth the application requirements to qualify as a Part D sponsor, including that the applicant must fully complete all parts of a certified application in the form and manner required by CMS. 42 C.F.R. § 423.502(c)(1). MA organizations offering qualified prescription drug coverage are known as MA-PD plans. 42 C.F.R. § 423.4.

Like the Part C Application, the Part D application also contains a series of required attestations that must be completed, with CMS informing applicants that "[b]y providing such attestation, an applicant confirms that its organization complies with the relevant requirements as of the date its application is submitted to CMS[.]" Part D Application at 9. Specific to the instant appeal, under the required attestations for "Management and Operations," applicants must attest to and inform

> If applicant, applicant's parent organization, or any subsidiaries of applicant's parent organization has an existing contract(s) with CMS to provide Part D drug benefits, at least one of those contracts has been in continuous effect since January 1, 2024 or earlier. . . . 42 CFR § 423.503(b)(2).

Part D Application at 23 (Section 3.1.1).

CMS evaluates an entity's application, whether for an MA plan, Specialized MA plan, or for an MA-PD plan, solely based on information contained in the application itself and any additional information that CMS obtains through on-site visits and any essential operations test. 42 C.F.R. §§ 422.502(a)(1) and 423.503(a)(1). However, CMS may deny an MA, Specialized MA, or Part D application if the applicant failed to comply with Part C or Part D program requirements during the twelve months preceding the application deadline. 42 C.F.R. §§ 422.502(b)(1) and 423.503(b)(1).

After reviewing whether an application meets all requirements, CMS issues, if necessary, a Deficiency Notice in which CMS notifies an applicant of deficiencies within the application and allows a specific time within which the applicant may cure the deficiencies. *See* CMS Brief at 2. If the applicant fails to cure the deficiencies cited within the Deficiency Notice or if the applicant is otherwise unable to meet the pertinent regulatory requirements, CMS issues the applicant a Notice of Intent to Deny ("NOID"). 42 C.F.R. §§ 422.502(c)(2) and 423.503(c)(2). Pursuant to 42 C.F.R. §§ 422.502(c)(2)(ii) and 423.503(c)(2)(ii), the applicant will have ten days from the

NOID to respond in writing to correct deficiencies in the application.

If, in response to the NOID, the applicant either fails to submit a revised application within ten days from the date of the NOID, 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. 42 C.F.R. §§ 422.502(c)(2)(iii) and 423.503(c)(2)(iii). For an application denial, CMS provides the applicant with written notice of the determination and the basis for the determination. 42 C.F.R. §§ 422.502(c)(3) and 423.503(c)(3).

If CMS denies an MA or Part D 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's determination was inconsistent with the requirements of 42 C.F.R. §§ 422.501, 423.502 (application requirements) and 422.502, 423.503 (evaluation and determination procedures). 42 C.F.R. §§ 422.660(b)(1), 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), 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 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. Past Performance Review—Use Of Information From A Current Or Prior Contract

CMS may deny an MA, Specialized MA, or Part D Application if the applicant failed, during the twelve months preceding the application submission deadline, to comply with Part C or Part D program requirements. 42 C.F.R. §§ 422.502(b)(1) and 423.503(b)(1). 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, in the absence of twelve months of performance history, CMS may deny an application based on a lack of information available to determine an applicant's capacity to comply with the requirements of the MA or Part D programs. 42 C.F.R. §§ 422.502(b)(2) and 423.503(b)(2).

[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.

75 Fed. Reg. 19678, 19683 (Apr. 15, 2010).

Within its brief, CMS provides a comprehensive summary of the historic development of CMS's 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 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 amended its past performance requirements at 42 CFR §§ 422.502(b) and 423.503(b) in a final rule published in April 2011 to allow CMS to deny MA and Part D applications from an existing MA organization and/or Part D sponsor that did not have 14 months' performance history with the MA and/or Part D programs. 76 Fed. Reg. 21432 (April 15, 2011).

CMS Brief at 3.

The Hearing Officers observe that the Secretary further explained, within the preamble to the final rule, the following:

> Each year, as part of the application evaluation process, we conduct a comprehensive review of each Part C and D sponsor's past performance in the operation of its Medicare contract(s). Current regulations provide that organizations with current or prior contracts with CMS are subject to CMS denial of any new applications for additional or expanded Part C or D contracts if they fail during the preceding 14 months to comply with the requirements of the Part C or D programs, even if their applications otherwise demonstrate that they meet all of the Part C or D sponsor qualifications. In the absence of 14 months of performance, however, this leaves a gap whereby CMS must either assume full compliance and exempt the entity from past performance review or deny additional applications from such entities until the applicant has accumulated 14 months' experience, during which it complied fully with the requirements of the Part C and/or Part D programs.
>
> Our interest in protecting Medicare beneficiaries and limiting program participants to the best performing organizations possible strongly suggests that we take the latter approach. Our justification for proposing this change was two-fold. First, we would ensure that new entrants to the Part C or Part D program could fully manage their current contracts and books of business before further expanding. Second, this change would require that entities rightfully focus their attention on launching their new Medicare contracts in a compliant and responsible manner, rather than focusing attention almost immediately on further expansions.

76 Fed. Reg. 21432, 21524 (April 15, 2011).

CMS's brief further explains that

> CMS has modified past performance requirements in several subsequent rulemakings. In a final rule published in April 2018, CMS changed the past performance review period from 14 months to 12 months. 86 Fed. Reg. 16440 (April 16, 2018). CMS made several changes to the past performance requirements in a final rule published in January 2021, including codifying at 42 CFR §§ 422.502(b)(1)(ii) and 423.503(b)(1)(ii) the long-standing policy attributing the performance of existing MA organizations and Part D sponsors to inexperienced legal entities under the same parent organization. 86 Fed. Reg. 5864 (January 19, 2021).

CMS Brief at 3.

C. Part D Application And Contracting Requirements — First Tier, Downstream And Related Entity Requirements

The Part D Application requires Part D applicants to provide responses to a series of attestations related to Part D requirements and document their ability to meet the Part D program requirements. Among other document requirements, applicants must provide licensure information, contracts with subcontractors such as PBMs, contract templates for network pharmacies, a statement of corporate organization, and organizational compliance plans. The applications were due to CMS by February 12, 2025. *Id.* at 2.

Within subpart K of the Part D regulations, CMS describes its application procedures and contracts with Part D plan sponsors. Under 42 C.F.R. § 423.500, CMS specifically describes that the "subpart sets forth application procedures and contracts with Part D plans: application procedures and requirements; contract terms; procedures for termination of contracts; [and] reporting by Part D plans."

Under 42 C.F.R. § 423.505, CMS sets forth the contract provisions that must be specified in contracts between Part D plan sponsors and CMS. The regulation at 42 C.F.R. § 423.505(i) discusses a Part D plan sponsor's relationship with any first tier, downstream, or related entity, specifically listing the provisions that "[e]ach and every contract governing Part D sponsors and first tier, downstream, and related entities[] must contain[.]" 42 C.F.R. § 423.505(i)(3). Part D plan sponsors that delegate certain activities or responsibilities to first-tier, downstream, or related entities must also include the specific requirements and provisions listed under 42 C.F.R. § 423.505(i)(4)-(6) within their contracts.

Under Section 3.1.1.E, the Part D Application provides additional instruction as follows:

> [U]pload copies of executed contracts, fully executed letters of agreement, administrative services agreements, or intercompany agreements (in word-searchable .pdf format) with each first tier, downstream or related entity identified in Sections 3.1.1C . . . and with any first tier, downstream, or related entity that contracts with any of the identified entities on the applicant's behalf. As noted

above, this requirement applies even if an entity contracting on the applicant's behalf is the applicant's parent organization or a subsidiary of the applicant's parent organization. Unless otherwise indicated, each and every contract must:

1. Clearly identify the parties to the contract (or letter of agreement). If the applicant is not a direct party to the contract (e.g., if one of the contracting entities is entering into the contract on the applicant's behalf), the applicant must be identified as an entity that will benefit from the services described in in the contract.

CMS Exhibit C-1 at 30-31 (emphasis omitted).

The remainder of Section 3.1.1.E lists out an additional nineteen contract requirements that, "[u]nless otherwise indicated, each and every contract must" address. *Id*. at 30-32. More specifically, CMS states that "[e]ach complete contract must meet all of the above requirements when read on its own." *Id*. at 32.

D. Part D Network Access Requirements, Template Submissions And Pharmacy Network Lists

Section 1860D-4(b)(1)(C) of the Act establishes pharmacy access standards that Medicare Part D prescription drug plan ("PDP") sponsors must meet to ensure beneficiaries have adequate access to covered prescription drugs through contracted pharmacy networks. 42 U.S.C. § 1395w-104(b)(1)(C). *See* 42 C.F.R. § 423.120(a). Part D sponsors must "secure the participation in their pharmacy networks of a sufficient number of pharmacies to dispense drugs directly to patients (other than by mail order) to ensure convenient access to covered Part D drugs by Part D plan enrollees," and must provide adequate access to home infusion and several different types of pharmacies. CMS Exhibit C-1 at 14. Part D applicants that have contracted with a PBM to provide a pharmacy network are required to upload, in HPMS, all downstream contract templates. *Id.* at 44.

Within its brief, CMS further explains that

> Applicants must demonstrate that they have contracted pharmacy networks sufficient to meet Part D network adequacy standards. CMS requires applicants to submit lists of retail, long term care, home infusion, and, if applicable, mail order and Indian Health Service, Indian Tribe and Tribal Organization, and Urban Indian Organization ("I/T/U") pharmacies that are contracted to be in their Part D networks. Exhibit C-1, p. 14. An applicant may use its contracted PBM's current year Part D network to demonstrate compliance with network adequacy standards, but if it or its PBM does not have a current year network, the applicant must submit a list of pharmacies contracted to be in its network for the year for which it is applying. Exhibit C-1, p.15. For 2026 applications, this means that an applicant (or its PBM) that has an active Part D pharmacy network could submit the list of contracted pharmacies for 2025, and that if an applicant (or its PBM) did not have an active network, it would have to submit a list of pharmacies that had signed

> contracts for 2026. *Id*. Pharmacy access reviews are based on the service area in which the applicant is applying to operate. *Id*.

CMS Brief at 4-5.

The Part D Application explains

> CMS conducts the review of retail pharmacy access based on the service area that the applicant has provided in HPMS by the application deadline. The access review is automated. Applicants must input their pending service area into HPMS per the instructions at Section 3.3. As explained in Section 3.6.B, *applicants must upload the retail pharmacy list in HPMS* . . . .
>
> . . .
>
> With limited exceptions, this information gathered from the pharmacy lists will be used by CMS to geo-code the specific street-level locations of the pharmacies to precisely determine retail pharmacy access.

CMS Exhibit C-1 at 15 (emphasis added).

E. Additional Authority Cited By HMI Regarding Minimum Enrollment Waiver Regulations

HMI raises an argument, as seen *infra* pp. 11-12, that denying its application due to a lack of performance history conflicts with CMS's approval of its minimum enrollment waiver for H8879. Although the Hearing Officers reject this argument (*infra* p. 14), the legal authority regarding the minimum enrollment waiver is outlined below:

The minimum enrollment requirements are mandated by statute at 42 U.S.C. § 1395w–27(b), and "are necessary to enable organizations to adequately spread risk across enrolled populations." 65 Fed. Reg. 40170, 40271 (June 29, 2000). To be granted a waiver for minimum enrollment requirements, "a contract applicant must demonstrate to CMS's satisfaction that it is capable of administering and managing an MA contract and is able to manage the level of risk required under the contract[.]" 42 C.F.R. § 422.514(b). These waivers, if granted, are effective for the first three years of a contract. *Id.* When making a minimum enrollment waiver determination, CMS considers whether:

> (1) The contract applicant management and providers have previous experience in managing and providing health care services under a risk-based payment arrangement to at least as many individuals as the applicable minimum enrollment for the entity as described in paragraph (a) of this section; or
>
> (2) The contract applicant has the financial ability to bear financial risk under an MA contract. In determining whether an organization is capable of bearing risk, CMS considers factors such as the organization's management

> experience as described in paragraph (b)(1) of this section and stop-loss insurance that is adequate and acceptable to CMS; and
>
> (3) The contract applicant is able to establish a marketing and enrollment process that allows it to meet the applicable enrollment requirement specified in paragraph (a) of this section before completion of the third contract year.

42 C.F.R. § 422.514(b).

VI. PROCEDURAL HISTORY AND STATEMENT OF FACTS

HMI received its health maintenance organization license from the State of Mississippi on April 23, 2024. Plan Hearing Brief at 2. HMI operated an approved MA-PD plan under contract H8879 beginning in September 2024 for CY2025. *Id.;* CMS Brief at 5-6. HMI timely submitted MA, Part D, and two SNP applications for CY2026 under contract number H7679. Plan Hearing Brief at 3. One SNP application was for a preferred provider organization, D-SNP, and the other was a HI-SNP. *Id.*

Within its Part C Application, HMI "attested that its existing Medicare Advantage plan(s) with CMS have not been operational since January 1, 2024 or earlier." Plan Hearing Brief at 4 (quoting Part C Application Attestation 3.1.7 at 19).

Additionally, CMS states (and HMI does not dispute) that within HMI's initial application, "HMI accurately attested 'no' to the attestation: 'If the applicant, applicant's parent organization, or any subsidiaries of applicant's parent organization has an existing contract(s) with CMS to provide Part D drug benefits at least one of those contracts has been in continuous effect since January 1, 2024.'" CMS Brief at 5; *see* Plan Hearing Brief at 4.

Within HMI's documents submitted with its applications, CMS states that "the application stated that CapitalRx would perform key Part D functions on the applicant's behalf, including development and maintenance of a pharmacy network." CMS Brief at 5; CMS Exhibit C-2.

HMI submitted a letter ("Supplemental Letter") with its applications that stated

> [w]e are currently in the process of negotiating a new contract with a Pharmacy Benefit Manager (PBM) to enhance our prescription drug plan offerings for the upcoming contract year. This initiative is part of our ongoing commitment to improving the quality and efficiency of our services for Medicare beneficiaries. For this reason, we have submitted our current PBM contract and supplemental files [to] support compliance of the Part D requirements. We intend to provide updated documentation once the new PBM contract is finalized.

Plan Exhibit P-16 at 1; *see* Plan Hearing Brief at 7; CMS Brief at 5.

Following submission of the applications and CMS's subsequent review, CMS issued HMI March 13, 2024, Deficiency Notices for the MA-PD Part C and Part D applications, which cited numerous deficiencies. Plan Exhibits P-5 and P-6.

In response to the Deficiency Notices, HMI submitted materials on March 24, 2025. CMS Brief at 6. Following a review of the materials, on April 14, 2025, CMS issued NOIDs to HMI regarding its application. Plan Exhibits P-7, P-8 and P-9; CMS Brief at 6. CMS cited the lack of experience in addition to other deficiencies. *Id.* In response, on April 24, 2025, HMI submitted additional materials. *Id.* With respect to the April 24, 2025 materials submitted by HMI, CMS states that HMI

> [i]ncluded, for the first time, a contract between HMI and SelectHealth Benefit Assurance Company, Inc., DBA Scripius ("Scripius"). The April 24 submission also included pharmacy contract templates from Scripius. HMI did not update the Part D function chart in HPMS to indicate that Scripius would perform functions on its behalf or to remove CapitalRx from the chart. HMI also did not update the pharmacy network submissions to reflect its intent to use a different PBM than HMI used for its H8879 contract for its H7679 contract in 2026.[5]

Id. at 6.

On May 14, 2025, CMS issued a Denial Letter to HMI regarding its MA-PD application, citing eighteen deficiencies: one regarding Management, Experience, and History (existing Medicare Advantage plan has not been operational since January 1, 2024), one regarding Attestations, nine regarding Contracting, seven regarding Network Analysis, and one regarding Program Integrity. Plan Exhibit P-10. Pertinent to the instant appeal, CMS cited

> * Management, Experience and History-Your organization attested that its existing Medicare Advantage plan(s) with CMS have not been operational since January 1, 2024 or earlier. Your organization is therefore not eligible to apply for a new contract or service area expansion for 2026.

Plan Exhibit P-10.

> Attestations . . .
>
> -Your organization attested that its existing contract with CMS was not in continuous effect prior to January 1, 2024. Your organization is therefore not eligible to apply for a new contract or service area expansion for 2026.

Id.

[5] Within its Reply Brief, HMI generally states that it "was precluded by CMS from uploading the Scripius pharmacy network as part of its application curing submission in response to the NOID." Plan Reply Brief at 3.

Also on May 14, 2025, CMS issued separate Denial Letters to HMI regarding its D-SNP and HI-SNP applications. Each of these SNP Denial Letters cites a lack of at least twelve months of performance history with the Medicare Advantage program. Plan Exhibits P-11 and P-12.

On May 15, 2025, HMI timely requested a hearing regarding all three application denials. HMI filed its Hearing Brief and 21 exhibits on May 20, 2025, and CMS filed its Brief along with seven exhibits on May 27, 2025. Within its Brief, CMS articulated the following deficiencies[6] that it states continues to serve as the basis for its denial of HMI's application:

> Issue 1: HMI had less than twelve months' experience operating its current MA-PD contract;
>
> Issue 2: HMI failed to include Scripius's Pharmacy Provider Manual, which is incorporated into Scripius's network pharmacy contracts by reference; and
>
> Issue 3: HMI failed to provide pharmacy network lists from Scripius, the PBM that it would use in 2026.

CMS Brief at 7-10.

On May 29, 2025, HMI filed its Reply Brief.

On May 28, 2025, the Hearing Officer postponed the June 3, 2025, hearing to consider CMS's Motion for Summary Judgment.

VII. ISSUE 1 — LACK OF TWELVE MONTHS OF PERFORMANCE HISTORY

A. CMS's Basis For Denial

Pursuant to 42 C.F.R. §§ 422.502(b)(2) and 423.503(b)(2), CMS denied HMI's application as it had less than twelve months' experience operating its current MA-PD contract. CMS Brief at 5.

B. HMI's Contentions

HMI did not dispute that it had less than twelve months of performance history as its current contract with CMS (H8879) was not effective until September 2024. Plan Exhibit P-13; Plan Hearing Brief at 5. Nevertheless, HMI contends that CMS's denial based on the lack of twelve months of performance history is both arbitrary and capricious because it overlooks the potential benefits to Medicare beneficiaries and fails to assess the actual performance capabilities of HMI. HMI argues:

> [i]n implementing 42 C.F.R. § 422.502(b)(2) to deny MA organizations that are in their first year of operations from expanding regardless of their performance

[6] Within its Brief, CMS states that it would "not continue to rely on" the remaining deficiencies originally cited in the May 15, 2025 Denial Letter "as bases for denial of the H7679 application." *See* CMS Brief at 10.

> history, CMS has acted in an arbitrary and capricious manner in violation of the Administrative Procedure Act. Rather than advancing CMS' stated objective of protecting Medicare beneficiaries and limiting program participants "to the best performing organizations possible", the regulation deprives Medicare beneficiaries, particularly those in rural underserved areas, of much needed health plan options. Moreover, it cannot be said that 422.502(b)(2) limits beneficiaries' access to the best performing organizations since CMS makes no assessment of an MA organization's performance before denying the application in reliance on the regulation.

Plan Hearing Brief at 5.

HMI also alleges that the arbitrary and capricious nature of CMS's determination is "further demonstrated by the fact that had HMI's parent organization submitted the applications under a newly formed legal entity with no operational history with CMS, 422.502(b)(2) would not have prevented the new affiliate from expanding based on HMI's lack of 12 months of performance history." *Id*. at 6 (emphasis omitted).

HMI also contends that the application warrants approval because CMS, by approving a minimum enrollment waiver, has already recognized HMI's capability to operate as a Medicare Advantage Plan. HMI elaborates:

> [i]n addition, denying HMI's applications for lack of performance history is in direct conflict with CMS' approval of a minimum enrollment waiver for HMI in connection with HMI's initial MAPD application under H8879 for 2025. Pursuant to 42 C.F.R. § 422.514(a), unless the requirement is waived by CMS, CMS "does not enter into a contract" unless the organization meets the specified minimum enrollment requirement. However, pursuant to 422.514(b), CMS may waive the minimum enrollment requirement for the first 3 years of the contract if the "contract applicant [demonstrates] to CMS's satisfaction that it is capable of administering and managing an MA contract and is able to manage the level of risk required under the contract during the first 3 years of the contract . . . . Therefore, as a prerequisite to approving HMI's minimum enrollment waiver and its participation in the MA program for 2025, CMS determined that HMI was capable of performing its MA Program obligations—not just for 12 months but for three years.

Id. at 5-6 (emphasis and footnote omitted); Plan Reply Brief at 1-2 (emphasis omitted).

C. CMS's Contentions

CMS indicates that the denial should be upheld as it is undisputed that HMI did not have the requisite twelve months of experience as required by the controlling regulations. CMS also provides an explanation regarding the rationale for the twelve-month experience requirement. CMS explains:

> [f]or 14 years, CMS has prohibited entities from receiving new or expanded MA and Part D contracts until they have demonstrated the ability to operate their existing contracts for at least a single contract year. As CMS explained when it adopted the regulations at 42 CFR §§ 422.502(b)(2) and 423.503(b)(2), this restriction on immediately expanding their MA and Part D offerings was intended to encourage organizations to focus on the challenge of operating MA and Part D plans for the first time rather than immediately turning their attention to expanding their business. 76 Fed. Reg. 21524. HMI concedes that it has no prior experience operating MA or Part D plans and that its current MA-PD contract, H8879, has only been effective since September 2024 and only started serving beneficiaries on January 1, 2025. The fact that it does not have 12 months of experience operating MA and Part D plans is therefore undisputed. CMS therefore acted consistently with its longstanding regulations when it denied HMI's 2026 application for a new MA-PD contract under H7679.

CMS Brief at 7.

In addressing HMI's arguments that the subject application denial, based upon lack of performance history, conflicts with CMS's approval of HMI's minimum enrollment waiver. CMS asserts that

> [i]n adopting its current policy, CMS has sought to strike a balance between facilitating competition and innovation by contracting with organizations new to MA and Part D, and reducing the risk to beneficiaries posed by inexperienced plans. If CMS were to forbid all applications from newly formed legal entities or from entities with no current health insurance enrollment (as would be the case if CMS did not waive its minimum enrollment requirements in the manner described in HMI's brief), CMS would essentially eliminate new entrants into the MA and Part D markets. This would be unfair both to organizations wishing to operate in these markets and to beneficiaries who might benefit from lower costs or innovative practices by new insurance companies. Rather, CMS has opted to continue to allow inexperienced organizations to obtain MA and Part D contracts after demonstrating that they have met all other application requirements and to operate their business for a full year before applying for new contracts.

Id.

D. Hearing Officer Analysis And Decision

The Hearing Officers grant CMS's Motion for Summary Judgment based on Issue 1 (twelve-month performance history), thereby upholding CMS's denial of HMI's entire application. The Hearing Officers find that there are no material facts in dispute as the record demonstrates that HMI admitted within an attestation on its application that it does not possess the required twelve-month performance history in the MA-PD programs. Plan Hearing Brief at 4; CMS Brief at 5. Accordingly, CMS's decision was consistent with the regulation at 42 C.F.R. §§ 422.502(b)(2) and 423.503(b)(2).

HMI also argues that in granting HMI a minimum enrollment waiver for H8879, pursuant to 42 C.F.R. § 422.514(b), CMS had already determined that HMI "is capable of administering an MA contract and is able to manage the level of risk required under the contract during the first 3 years of the contract." Plan Hearing Brief at 4 (emphasis omitted). HMI similarly contends that the subject application denial is in direct conflict with CMS's prior grant of a minimum enrollment waiver.

The Hearing Officers reject HMI's argument that CMS's prior grant of a minimum enrollment waiver for contract H8879 warrants application approval here, finding that the minimum enrollment waiver requirements (42 C.F.R. § 422.514(b)) and CMS's past performance criteria (42 C.F.R. §§ 422.502(b)(2) and 423.503(b)(2)) are distinctly separate regulatory provisions and clearly serve different purposes in the MA program. CMS's minimum enrollment waiver determination concerns whether a new applicant has provided assurance, on a prospective basis, that it would be able to meet the initial requirements for a new MA contract. On the other hand, CMS's required past performance review is conducted as a part of the annual application evaluation cycle and is a retrospective-based assessment regarding whether an existing Plan has an established actual history to warrant an expansion.[7]

HMI also asserts that CMS acted in an arbitrary and capricious manner when applying 42 C.F.R. § 422.502(b)(2) to HMI as CMS made "no assessment of [HMI's] performance before denying [its] application[.]" Plan Hearing Brief at 5. HMI states that "CMS's denial harms [rather than protects] beneficiaries in Mississippi by depriving them" "of much needed health plan options." *Id*. at 1, 5.

The applicable appeals regulations direct the Hearing Officers to determine whether an applicant has proven by a preponderance of the evidence that CMS's determination was inconsistent with the requirements of 42 C.F.R. §§ 422.501, 423.502 and 422.502, 423.503. In exercising this authority, the Hearing Officers must comply with the provisions of title XVIII and related provisions of the Act, the regulations issued by the Secretary, and general instructions implementing the Act. 42 C.F.R. §§ 422.688 and 423.664. Accordingly, the Hearing Officers find that HMI's policy-related arguments, its claim that CMS's implementation of 42 C.F.R. § 422.502(b)(2) is arbitrary and capricious, and whether CMS chooses to exercise its discretion in a past performance review under 42 C.F.R. § 422.502(b) and/or 423.503(b)(2), are outside the scope of the Hearing Officers' authority under 42 C.F.R. §§ 422.688 and 423.664.

[7] As further support, in the preamble to the 2011 Final Rule, CMS states that the past performance requirement helps to ensure that new plans can "fully manage their current contracts . . . before further expanding[,]" and that new plans will focus on "launching their new Medicare contracts in a compliant and responsible manner, rather than focusing" on expanding. *Supra* p. 5. 76 Fed. Reg. at 21524. The Hearing Officers observe that within the preamble to the final rule for the minimum enrollment waiver regulation, in response to a commenter questioning the proposed expansion of the minimum enrollment waiver time period from one year to three years under 42 C.F.R. § 422.514(b), CMS drew a distinction between the minimum waiver request reviews and other forms of CMS oversight that are meant to protect beneficiaries and addressed the additional MA compliance requirements that continue to apply to organizations that are granted minimum enrollment waivers. 83 Fed. Reg. 16440, 16621 (April 16, 2018).

VIII. ISSUE 2—NON-SUBMISSION OF PHARMACY PROVIDER MANUAL

A. CMS's Basis For Denial

CMS found that HMI failed to timely submit the Pharmacy Provider Manual for its PBM, Scripius**.**

B. HMI's Contentions

At end, in its Plan Reply Brief, HMI acknowledged its "failure to submit the Scripius Pharmacy Provider Manual was an administrative oversight, which can be easily remedied." Plan Reply Brief at 3 n.4.

Of note, while HMI initially argued that it was materially prejudiced in the application process, CMS countered this argument in its brief. HMI did not further address the prejudiced argument in its Plan Reply Brief.

HMI indicated that it did not believe it was necessary to submit a Pharmacy Provider Manual when transitioning from its previous Pharmacy PBM, CapitalRx, to its new PBM, Scripius, based on its prior experience. Scripius stated:

> [t]he failure to submit the Pharmacy Provider Manual had not been previously identified as a deficiency by CMS in either the initial notice of deficiency or the NOID even though the Capital Rx template pharmacy contracts submitted with the initial application in February 2025 also referenced a Pharmacy Provider Manual, but HMI did not upload that manual when it uploaded the Capital Rx pharmacy contract templates for its Part D application submission [referencing Plan Exhibit P-20]. Since CMS did not identify the missing Capital Rx Pharmacy Provider Manual as a deficiency in either the initial deficiency notice or the NOID, HMI reasonably believed that it was not required to upload the Scripius Pharmacy Provider Manual. CMS' failure to issue a deficiency in connection with the Capital Rx submission, materially prejudiced HMI.

Plan Hearing Brief at 11.

C. CMS's Contentions

In its Brief, CMS provided background on why the missing Scripius Pharmacy Provider Manual was problematic, stressing that the absence of the manual prevented a comprehensive review of the pharmacy templates and verification of compliance with the solicitation requirements. CMS stated:

> CMS requires applicants for new Part D contracts to submit the pharmacy contract templates that they or their PBMs use to contract with pharmacies in their Part D networks. Exhibit C-1, p. 44. CMS reviews these templates to ensure that they meet the requirements for pharmacy contracts contained in the Part D regulation and the Solicitation. Although HMI did submit partial templates from Scripius, the

> submissions did not represent the complete pharmacy templates because they did not include the Scripius Pharmacy Provider Manual. The partial Scripius templates HMI provided in its April 24 submission incorporate the Pharmacy Provider Manual by referencing the requirements of that manual extensively. . . . The lack of a Pharmacy Provider Manual meant that CMS could not conduct a complete review of the actual templates used by Scripius to contract with Part D network pharmacies on HMI's behalf and therefore could not verify that the templates complied with the requirements set forth in the solicitation.

CMS Brief at 8.

Regarding HMI's allegation that it was materially prejudiced because CMS did not issue a NOID relating to an allegedly missing CapitalRx Pharmacy Provider Manual, CMS pointed out that HMI's premise was mistaken. CMS stated:

> [a]s HMI points out in its brief, CapitalRx's pharmacy contract templates, like Scripius's, do incorporate the CapitalRx Pharmacy Provider Manual by reference. . . . Which is presumably why HMI submitted the manual when it submitted CapitalRx's pharmacy contract templates with H7679's initial submission in February. *The manual appears on page 50 of Exhibit P-20, which is identical to the retail pharmacy template that HMI uploaded with its application in February. HMI cannot claim ignorance of the requirement to provide a Pharmacy Provider Manual based on CMS's failure to cite a deficiency that did not exist . . . .*
>
> While it is unfortunate that HMI's decision to not submit Scripius's templates until the third round of review deprived it of the opportunity to cure this deficiency, any lack of notice is solely due to this delay and not to any inconsistency in CMS's review of its application or miscommunication by CMS.

Id. (emphasis added).

D. Hearing Officer Analysis And Decision

As HMI did not timely submit the required Pharmacy Provider Manual, the Hearing Officers grant CMS's Motion for Summary Judgment, thereby upholding CMS's denial of HMI's entire application. HMI did not fully complete its certified application as required by CMS under 42 C.F.R. § 423.502(c)(1).

At end, HMI acknowledged its failure to submit the manual was an "administrative oversight." Plan Reply Brief at 3 n.4. Notably, the Hearing Officers find that HMI's initial allegation of material prejudice was weakened, given that CMS highlighted that HMI did, in fact, submit the CapitalRx pharmacy contract with its initial application.

IX. ISSUE 3—NON-SUBMISSION OF PHARMACY NETWORK LISTS

A. CMS's Basis For Denial

HMI did not provide the pharmacy network lists from Scripius, its PBM for H7679 in 2026.

B. HMI's Contentions

In its Hearing Brief, HMI states that in response to the NOID, it "submitted the new Scripius PBM contract, the Scripius template pharmacy contracts, and the pharmacy contract crosswalks for the Scripius pharmacy templates." Plan Hearing Brief at 8-9. HMI claims, however, that it was unable to "upload the Scripius pharmacy network[,]" because HPMS "included a message that the gates to submit the pharmacy network were closed." *Id*. at 9. As such, CMS's "review of HMI's pharmacy network was of HMI's current pharmacy network through Capital Rx." *Id*. HMI explains that "CapitalRx. . . was previously approved by CMS for CY2025 for [its contract] H8879, and again submitted on February 12, 2025 in connection with the application for H7679." *Id*. at 10. HMI asserts that "[d]espite the fact that HMI notified CMS that it was changing PBMs and had submitted the Scripius PBM contract and template pharmacy network contracts,[8] CMS did not afford HMI the opportunity to submit the Scripius pharmacy network before issuing the denial." *Id*. HMI claims that "CMS should be required to allow HMI to upload the Scripius pharmacy network to validate that the network satisfies applicable network adequacy requirements." *Id*.

HMI goes on to state that it "can immediately cure these alleged deficiencies as Scripius has a national pharmacy network of 45,000 pharmacies, with over 200 in Mississippi alone." *Id.* In addition, HMI states that "the Scripius network was previously approved by CMS for MAPD plans offered by Scripius' affiliates, H1994 and H2246." *Id*.

C. CMS's Contentions

Within its Brief, CMS responds that

> [a]s HMI acknowledges in its brief, the pharmacy network lists it submitted in February to demonstrate that it meets network adequacy standards in its proposed service area represent the CapitalRx network that HMI currently uses to serve its existing contract, H8879. [Plan] Brief, p. 10. However, as HMI also concedes, it does not plan to use CapitalRx as its PBM for H7679 in 2026. Rather, HMI plans to use Scripius's network. At no time prior to the April 24 submission did HMI indicate that the network it submitted in February was for a PBM other than the one it intended to use for H7679 in 2026. Based on the information provided with the February 12 and March 24 submissions, the PBM it intended to use for H7679 in 2026 was CapitalRx. HMI's decision to switch its PBM to Scripius for 2026 meant that none of the information it had submitted for CapitalRx's network had any

[8] The message contained within the Supplemental Letter is quoted *supra* Section VI, p.9.

> relevance to whether H7679 would be able to meet pharmacy network adequacy standards for 2026.
>
> . . .
>
> CMS concedes that both H1994 and H2246[9] currently meet Part D convenient access standards for their respective service areas based on network information that CMS reviews quarterly. However, these two facts are irrelevant to whether Scripius's pharmacy network meets Part D access standards for all types of pharmacies in the proposed service area for H7679. H1994 and H2246 service areas are limited to counties in Colorado, Idaho, Utha, and Nevada. Exhibits C-6 and C-7. HMI applied to operate H7679 in counties in Mississippi.
>
> . . .
>
> CMS Part D application reviewers had no way of knowing based on the information submitted with the application that HMI intended to use Scripius and not Capital Rx until CMS received the April application submission . . . [and] no way of knowing that the materials submitted with the application were anything other than a . . . representation of the PBM and pharmacy network HMI intended to use for 2026.

CMS Brief at 9-10.

D. Hearing Officer Analysis And Decision

The Hearing Officers deny CMS's Motion for Summary Judgment on Issue 3 (pharmacy network list). The record contains unclear material facts for the Hearing Officers to grant/deny CMS's Motion for Summary Judgment based upon this issue.

Specifically, the date that HMI was allegedly "precluded by CMS from uploading" its pharmacy network list is unclear. HMI states, within its Hearing Brief, that it "submitted the new Scripius PBM contract" and certain associated documents "in response to the NOID" on "April 23, 2025[.]" Plan Hearing Brief at 7-9. HMI then claims that "the CMS application submission process would not allow HMI to upload the Scripius pharmacy network[,] [as] CMS' Health Plan Management System ("HPMS") that is used by applicants to upload application materials included a message that the gates to submit the pharmacy network were closed." *Id*. at 9. However, the Hearing Officers note that HMI does not pinpoint the date on which it attempted to upload its pharmacy network list, nor is the record fully clear regarding the date(s) when HMI generally submitted its materials in response to the NOID.[10]

[9] HMI describes these contracts as being "MA[-]PD plans offered by Scripius' affiliates[.]" Plan Hearing Brief at 10.

[10] The record is unclear regarding whether HMI filed its materials in response to the NOID on April 23, 2025, April 24, 2024 (the last date to file curing materials), or on both days. Similarly, it is unclear if HMI alleges it attempted to file its pharmacy network on either of those days or at another time. CMS states that HMI submitted its materials in

The Hearing Officers will not proceed to hearing with Issue 3, as the approval of the Motions for Summary Judgment on Issues 1 and 2 each support CMS's denial of HMI's application for Contract No. H7679.

X. ORDER

The Hearing Officers find no material facts in dispute regarding Issues 1 and 2. HMI has not proven that CMS's determination was inconsistent with 42 C.F.R. §§ 422.501, 423.502 and 422.502, 423.503. Therefore, the Hearing Officers grant CMS's Motion for Summary Judgment for these two issues.[11] Each basis independently supports CMS's May 14, 2025, Denials of Application for a New Medicare Advantage/Medicare Advantage – Prescription Drug Plan, a New D-SNP, and a New HI-SNP for contract H7679. Although material facts remain in dispute for Issue 3, there is no need to proceed to a hearing on the Issue given the Motion for Summary Judgment's resolution on Issues 1 and 2.

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

Suzanne D. Rollins -S
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Date: 2025.08.12 14:59:40 -04'00'

Suzanne D. Rollins, Esq.
CMS Hearing Officer

Date: August 12, 2025

response to the NOID on April 24, 2025, not April 23, 2025. CMS Brief at 6. HMI states, within its Hearing Brief, that it "submitted the new Scripius PBM contract" and certain associated documents "in response to the NOID" on "April 23, 2025[.]" Plan Hearing Brief at 7-9. *See* CMS Exhibit C-5, Scripius Retail Template, was filed with an exhibit number "cover sheet" that identified it as CMS Exhibit C-5 and states that the template was "submitted April 24, 2025[,]" but the exhibit itself does not contain a filing date.

[11] CMS's Motion for Summary Judgment is located on page 12 of CMS's Brief.