DEPARTMENT OF HEALTH AND HUMAN SERVICES
Centers for Medicare & Medicaid Services

Decision of the Administrator

In the Case of:	*	
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Renal Payer Solutions, Inc.	*	**MA/PD Hearing Officer**
Contract Year 2023	*	**Docket No. H-22-00014**
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Contract No. H6207	*	
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This case is before the Administrator, Centers for Medicare & Medicaid Services (CMS), for review of the decision entered by the CMS Hearing Officer. Renal Payer Solutions, Inc. (RPS), the Applicant, requested that the Administrator elect to review and reverse the CMS Hearing Officer decision upholding the CMS denial of the Application. The Administrator elected to review the CMS Hearing Officer decision under 42 C.F.R. § 422.692(b) for Contract No. H6207. Accordingly, this case is now before the Administrator for final agency review under 42 C.F.R. §422.692.

Issue

This case involves the Applicant's appeal of CMS' denial of its Medicare Advantage (MA)/MA-Prescription Drug (PD) contract application for 2023 (Contract No. H6207) for services in seven counties in Nevada. The issue is whether the Applicant has proven by a preponderance of the evidence that CMS' determinations for Contract No. H6207 was inconsistent with the regulatory requirements. The contract denial was based on the following two deficiencies for the Part C application:

1. Failure to submit its health maintenance organization (HMO) certificate of authority (HMO COA) from the Nevada Division of Insurance (DOI).

2. Failure to submit the completed State Certification Form (State Certification) from the Nevada DOI.

On February 17, 2022, RPS filed an initial MA/MA-PD application with CMS to operate in seven counties in Nevada.[1] RPS's application concerns a chronic condition special needs MA-PD plan ("SNP") developed to address "the significant treatment issues for individuals with end stage renal disease ("ESRD")."[2] On March 21, 2022, CMS issued a courtesy notice to RPS informing the organization of several deficiencies in its Part C application. Among the deficiencies noted, CMS cited RPS's regarding: 1) "Copy of State Licensure - You failed to submit satisfactory evidence that your organization is licensed under State law as a risk-bearing entity eligible to offer health insurance or health benefits coverage, including the authority to offer the MA product

[1] CMS Memorandum and Motion for Summary Judgement (MSJ) at 1.
[2] RPS Brief at 1-2.

for which you are applying, across your entire service area."; and 2) "CMS State Certification Form - You failed to submit a fully and appropriately completed CMS State Certification For demonstrating that you meet the necessary requirements."[3] On April 18, 2022, CMS issued a Notice of Intent to Deny (NOID) for RPS's Part C application due to "RPS's failure to submit the HMO COA and the State Certification."[4] CMS specifically stated in the NOID, that "RPS had until 8pm Eastern Standard Time on April 28, 2022, to cure any application deficiencies."[5]

RPS asserted that the DOI's review of RPS's application for an HMO COA was impacted by staff shortages at the DOI. RPS stated that on April 28, 2022, DOI requested that RPS file an extension request with CMS.[6] In response, on April 28, 2022, RPS filed a request for an extension of time to file its documents, which was denied by CMS the same day.[7] On May 18, 2022, CMS issued RPS's contract determination in which CMS denied RPS's application for a new MA/MA-PD plan "under contract number H6207 due to the failure to submit a copy of the HMO COA and the [completed] State Certification[.]"[8]

CMS Hearing Officer Decision

The CMS Hearing Officer granted CMS' Motion for Summary Judgment. The Hearing Officer noted that the regulations are clear that an applicant must provide CMS with documentation of appropriate state licensure that the entity is able to offer health insurance or health benefits coverage that meets state-specified standards applicable to MA plans, and is authorized by the state to accept prepaid capitation for providing, arranging, or paying for the comprehensive health care services to be offered under the MA-PD contract.[9] RPS did not contest CMS' position that the controlling authority requires an applicant to submit the appropriate state licensure to be approved by CMS. Rather, RPS sought regulatory discretionary authority to allow RPS to cure its application in order to advance health equity specifically for the ESRD beneficiaries it hoped to serve. The Hearing Officer did not possess a broad scope of discretionary authority to provide the relief that RPS requested. Instead, the Hearing Officer determined that CMS' decision was consistent with regulatory requirements. The Hearing Officer found that RPS failed to timely meet CMS' application requirements and CMS' denial was an appropriate exercise of its delegated authority. Accordingly, the Hearing Officer granted CMS' Motion for Summary Judgement.

RPS's Request for Review

RPS submitted a request for Administrator's review of the decision by the Hearing Officer affirming the CMS denial of its Contract Year 2023 application to offer a new MA/MA-PD under contract number H6207. RPS stated that the Administrator should reverse the findings, as the deficiencies cited by CMS have all been cured, and there would be a significant benefit that would accrue to Medicare beneficiaries in RPS's intended service area from access to its MA-

[3] *Id*. at 2 and Exhibit A.
[4] *Id*. *at 2* and Exhibit B.
[5] Exhibit B. CMS Motion of Summary Judgement at 4.
[6] RPS Brief at 2.
[7] *Id*.
[8] RPS Brief, Exhibit D.
[9] 42 C.F.R. §422.501(c)(1)(i).

PD ESRD with Dialysis SNP plan.[10] RPS argued that throughout the CY 2023 application process, it worked diligently to respond to CMS's deficiency noticed and NOID.[11] It noted that at the time CMS issued the Part C NOID, RPS only had two deficiencies remaining: receipt of its health maintenance organization certificate of authority (HMO COA) and the completed State Certification Form. Both of these were issued from the Nevada Division of Insurance, and RPS continued to pursue securing its HMO COA and State Certification, but the DOI's review of its application was impacted by staff shortages, and beyond its control.[12]

RPS further attested that now that it has received both the HMO COA and the State Certification, it should be allowed to cure its application and offer its ESRD with Dialysis SNP for CY 2023. RPS noted it is fully prepared to perform the Contract for CY 2023 and has submitted its bid and other required submissions including: network for adequacy review, Opioid Management Program and Part D Transition Policy.[13]

RPS contended that the Administrator may review a Hearing Officer's decision and determine based on the decision, the hearing record, and any written arguments submitted whether the determination should be upheld, reversed, or modified.[14] RPS noted that even where a CMS denial and Hearing Officer decision are proper and correct, the Administrator may modify the denial in light of the facts and considerations in a specific case. RPS argued that the denial of its application would undermine CMS's effort to advance health equity in the Medicare Advantage Program. Race, social determinants of health, such as socioeconomic status and zip code has been shown to impact ESRD rates, and these health disparities can be explained in part due to barriers in accessing quality ESRD treatment. RPS's argued that it's ESRD with Dialysis SNP addresses these and other impediments to health equality through its innovative plan design that includes a transportation benefit, a food allowance, and a telehealth benefit that covers a nurse going to the member's home to improve the effectiveness of a telehealth visit.[15] RPS's focus on health equity for beneficiaries with ESRD, including through its benefit design and model of care, makes it critical that its ESRD with Dialysis SNP be available to its intended beneficiaries. For these reasons, RPS argued that the denial of its application would result in a serious disservice to Medicare beneficiaries in its proposed service area and would be inconsistent with CMS's health equity goals.

CMS' stated that had RPS timely submitted the documents, it would have worked with RPS to timely perfect them.

Discussion

Sections 1857 and 1860D-12 of the Social Security Act authorizes CMS to enter into contracts with entities seeking to offer Medicare Advantage (MA) (Part C) benefits and Medicare outpatient prescription drug (Part D) benefits to their plan enrollees. Pursuant to §§ 1857(a) and

[10] RPS attached copies of the missing HMO COA and State Certification documents that DOI issued on June 22, 2022, in its Reply Brief, (Exhibits J and K).
[11] RPS's Request for Administrator Review, dated July 18, 2022, page 1.
[12] RPS Appeal Brief, Exhibit C.
[13] RPS's Request for Administrator Review, dated July 18, 2022, page 3.
[14] 42 C.F.R. §422.692(d).
[15] RPS's Request for Administrator Review, dated July 18, 2022, page 7.

1860D-12(b)(1) an organization may not offer Part D benefits unless it has entered into a contract with CMS.

Under 42 C.F.R. §§422.501(c) and 422.503(b)(1), organizations seeking to contract as an MA organization must fully complete all parts of a certified application in the form and manner required by CMS. Specifically, CMS requires that an application be submitted through the Health Plan Management System ("HPMS") and in accordance with instructions and guidelines that CMS may issue. Among other requirements, an applicant must provide:

> Documentation of appropriate State licensure or State certification that the entity is able to offer health insurance or health benefits coverage that meets State-specified standards applicable to MA plans, and is authorized by the State to accept prepaid capitation for providing, arranging, or paying for the comprehensive health care services to be offered under the MA contract.[16]

Specifically, for state licensure, applicants must attest in their application that they are licensed under state law as a risk-bearing entity eligible to offer health insurance or health benefits coverage in each state in which the applicant wishes to offer one or more MA plans.[17] CMS requires applicants to verify this attestation by uploading an executed copy of the state license certificate with their application if the applicant was not previously qualified by CMS in that state.[18]

Applicants must also attest that the scope of their license or authority allows the applicant to offer the type of MA plan or plans that it intends to offer in the state (ie. Preferred Provider Organization, HMO, etc.). With the application, applicants must submit a CMS State Certification Form executed by the state that confirms and certifies that the plan type to be offered by the applicant is within the scope of the license.[19] The applications were due to CMS by February 17, 2022. Under current regulations and procedures, after receiving an application, CMS reviews the application for any issues.

CMS then notifies the applicant of any deficiencies by electronically sending a Deficiency Notice, and provides a "courtesy cure period" to the applicant. This is an applicant's first opportunity to amend its application. If an applicant fails to cure its deficiencies, CMS will issue a Notice of Intent to Deny (NOID).[20] The NOID affords an applicant a second opportunity to cure its application.[21] After a NOID is issued, an applicant has a final ten-day period to cure any deficiencies in order to meet CMS' requirements. If the applicant fails to do so, CMS will deny the application.[22]

If CMS denies the application, an applicant receives written notice of the determination and the basis for the determination. 42 C.F.R. §422.502(c)(3). Subsequently, applicants may request a

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[16] 42 C.F.R. §422.501(c)(1)(i).
[17] 42 C.F.R. §422.400(a).
[18] *See* Part C – MA and 1876 Cost Plan Expansion Application.
[19] *See* Part C – MA and 1876 Cost Plan Expansion Application at 50-56.
[20] 42 C.F.R. §422.502(c)(2)(i).
[21] 42 C.F.R. §422.502(c)(2)(ii).
[22] 42 C.F.R. §422.502(c)(2)(ii)-(iii).

hearing before a CMS Hearing Officer. 42 C.F.R. §§ 422.502(c)(3)(iii). Furthermore, the applicant has the burden of proving by a preponderance of the evidence that CMS' determination was inconsistent with the controlling requirements of 42 C.F.R. § 422.501 (application requirements) and §422.502 (evaluation and determination procedures).[23] In addition, either party may ask the Hearing Officer to rule on a Motion for Summary Judgment.[24] The CMS Hearing Officer decision is subject to Administrator review under 42 C.F.R. §422.666.

In this case, the Administrator finds that the record supports CMS' findings that the application had the foregoing deficiencies and was consequently properly denied. The CMS Hearing Officer properly found that the Applicant failed to demonstrate by a preponderance of the evidence that CMS' determinations for Contract No. H6207 was inconsistent with the requirements of 42 C.F.R. §422.501(c) and §422.503(b)(1).

The Administrator finds that the regulations make clear that an applicant must provide CMS with documentation of appropriate state licensure that the entity is able to offer health insurance or health benefits coverage that meets state-specified standards applicable to MA plans and is authorized by the state to accept prepaid capitation for providing, arranging, and paying for the comprehensive health care services to be offered under the MA-PD contract.[25] This is shown through the timely submission of the state licensing and state certification. The record shows that RPS failed to meet the application requirements when it submitted its initial application and failed to timely cure the deficiencies by April 28, 2022, the deadline established in the NOID.[26]

After a review of the record, the applicable law, CMS policy, and the parties' arguments and comments the Administrator finds that the CMS denial was proper and correct and in conformity with the regulations and application guidelines. The Applicant failed to demonstrate by a preponderance of the evidence that CMS' determinations were inconsistent with the requirements of 42 C.F.R. §422.501(c) and §422.503(b)(1).

The Administrator finds that the record supports CMS' denial of RPS's application for Contract Number H6207, as it failed to submit a copy of its State of Nevada Licensure and a State Certification Form for the State of Nevada. Thus, the Hearing Officer properly granted CMS' Motion for Summary Judgement. The CMS Hearing Officer does not possess a broad scope of discretionary authority to provide the relief that RPS sought in this case. Accordingly, the Administrator agrees with the Hearing Officer upholding the CMS deficiency finding and denial of the application, as CMS' determination was consistent with the regulatory requirements.[27]

However, pursuant to the Administrator's discretionary contractual authority, and for policy reasons, the Administrator modifies the CMS denial and the CMS Hearing Officer decision to allow the Applicant the opportunity to demonstrate that it meets the relevant MA/MA-PD regulatory and guidance application requirements in light of the policy considerations presented in this case. The Administrator further holds that, in allowing RPS the opportunity to correct the deficiencies in the application process at this time, the Applicant must promptly submit the

[23] 42 C.F.R. §422.660(b)(1).
[24] 42 C.F.R. §422.684(b).
[25] 42 C.F.R. §422.501(c)(1)(i).
[26] *See* CMS Motion for Summary Judgment at page 4.
[27] 42 C.F.R. §422.660 and 42 C.F.R. §422.688.

documentation required by CMS within the timeframes that CMS specifies pursuant to this decision to allow RPS to cure. CMS will review the documentation for whether the documentation cures the cited Application's deficiencies.[28] RPS must meet all necessary requirements as designated by CMS for its application to be approved. The CMS determination on whether the submitted documentation cures the Application's deficiencies, in conformity with requirements of the Medicare Program, is incorporated as the final decision of the agency on Contract No. H6207.

[28] For example, in Applicant's Reply Brief, the Applicant points to the following exhibits to demonstrate it has cured any deficiencies. *See,* RPS's Request for Administrative Review, and Reply Brief, at Exhibits J and K, the Nevada DOI's July 16, 2022 issuance of RPS's HMO COA and the State Certification.

DECISION

The Administrator modifies the decision of the Hearing Officer in accordance with the foregoing opinion.

THIS CONSTITUTES THE FINAL ADMINISTRATIVE DECISION OF THE SECRETARY OF HEALTH AND HUMAN SERVICES

Date: August 30, 2022

Jonathan Blum
Principal Deputy Administrator
Center for Medicare & Medicaid Services