CENTERS FOR MEDICARE AND MEDICAID SERVICES
CMS Office of Hearings

In the Matter of

Arkansas Superior Select, Inc.	*	
	*	
	*	Docket No. 2014 C/D App 2
Denial of Initial Application, H1587	*	
	*	

ORDER ON MOTIONS FOR SUMMARY JUDGMENT

Upon full review of the Applicant's Motion for Summary Judgment, CMS' Counter Motion for Summary Judgment and Reply to Applicant's Motion, and Applicant's Response to CMS' Motion, the Hearing Officer hereby orders as follows:

I. JURISDICTION

This appeal is provided pursuant to 42 C.F.R. § 422.660. The Centers for Medicare and Medicaid Services (CMS) Hearing Officer designated to hear this case is the undersigned, Brenda D. Thew.

II. ISSUE

Whether CMS properly denied Arkansas Superior Select, Inc.'s (ASSI or the Applicant) application to offer Medicare Advantage/Medicare Advantage - Prescription Drug (MA-PD) Health Maintenance Organization (HMO) plans and Health Maintenance Organization plans with a point of service (HMOPOS) option in 30 counties in Arkansas for contract year 2015.

III. PROGRAM BACKGROUND AND SUBSTANTIVE AUTHORITY

The Social Security Act authorizes CMS to enter into contracts with entities seeking to offer Medicare Advantage (MA) benefits[1] and Medicare outpatient prescription drug (Part D) benefits[2] to beneficiaries. In addition, MA organizations offering coordinated care plans must offer Part D benefits in the same service area.[3]

CMS does not enter into a contract with an applicant or MA organization that does not meet minimal enrollment requirements.[4] If an applicant organization cannot meet the

[1] Title XVIII of the Social Security Act § 1857, 42 U.S.C. § 1395w-27.
[2] Title XVIII of the Social Security Act § 1860D-12, 42 U.S.C. § 1395w-112.
[3] 42 C.F.R. § 422.4(c)(1).
[4] *Id.* § 422.514(a).

minimum enrollment requirements, CMS may waive those requirements.[5] To receive a waiver, a contract applicant or MA organization must demonstrate to CMS' satisfaction that the organization is capable of administering and managing the contract, and that the organization is able to manage the level of risk required under the contract.[6] Factors that CMS takes into consideration in making this evaluation include[7] the extent to which—

(1) The contract applicant or MA organization's 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 for the entity as described in 42 C.F.R. § 422.514(a), or

(2) The contract applicant or MA organization has the financial ability to bear the financial risk under an MA contract considering such factors as the organization's management experience and stop-loss insurance that is adequate and acceptable to CMS, and

(3) The contract applicant or MA organization is able to establish a marketing and enrollment process that allows it to meet the applicable enrollment requirement (in 42 C.F.R. § 422.514(a)) before completing the third contract year.[8]

IV. APPLICATION PROCESS

CMS has the regulatory authority to set the form and manner for the submission of applications by entities seeking to qualify as a MA organization offering a MA or MA-PD plan.[9] Specifically, CMS requires that applications be submitted through the Health Plan Management System (HPMS) and in accordance with instructions and guidelines that CMS may issue. Entities seeking to offer an initial MA coordinated care plan product such as an HMO or local Preferred Provider Organization must demonstrate that they meet regulatory qualifications. Those qualifications include appropriate State licensure, sufficient administrative capability to oversee the plan offerings, the capacity to enroll and dis-enroll beneficiaries, demonstrating that they hold contracts with a sufficient number and variety of medical service providers to ensure that all covered Medicare services will be available and accessible to their enrollees, and maintaining a minimum enrollment of beneficiaries.[10]

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[5] *Id.* § 422.514(b)(1).
[6] *Id.*
[7] The Hearing Officer notes that the term "includes" suggests that CMS may take additional factors, beyond those specified in 42 C.F.R. § 422.514(b), in reaching a determination regarding a contract applicant's qualification for a waiver.
[8] *See* 42 C.F.R. § 422.514(b)(1)(i)-(iii).
[9] *Id.* § 422.501(b)-(c).
[10] *Id.* §§ 422.501, 422.514(a).

After receiving a MA-PD application, CMS makes a determination as to whether the applicant organization meets all of the relevant program requirements. This determination is based solely on information contained in the application or obtained by CMS through methods such as onsite visits.[11]

As part of the application process, and prior to conducting the review required by regulation, CMS affords applicants an additional "courtesy" review and cure period. The 2015 Solicitation for Applications for Medicare Prescription Drug Plan 2015 Contracts (2015 Solicitation) provides:

> For those applicants with valid submissions, CMS will notify your organization via email of any deficiencies and afford a courtesy opportunity to amend the application(s)... Applicants failing to cure deficiencies following the courtesy cure period will be issued a Notice of Intent to Deny the application.[12]

The formal "Notice of Intent to Deny" (NOID) process is outlined at 42 C.F.R. § 422.502(c)(2)(ii) – (iii). If, after the "courtesy" opportunity to amend its application, CMS finds that an applicant does not meet the requirements for an MA organization, CMS issues a NOID. The NOID provides the basis for CMS' preliminary finding and gives the applicant ten days to cure the deficiencies in its application.

After the ten-day cure period, CMS will deny the application if the applicant does not submit a revised application, CMS still finds that the applicant does not appear qualified, or the applicant has not provided enough information to allow evaluation of the application.[13] If CMS denies the application, it gives written notice to the applicant indicating the reasons why the applicant is not qualified to contract as an MA organization.[14]

If CMS denies a MA-PD application, the applicant organization is entitled to a hearing before a CMS hearing officer.[15] In addition, the regulations governing the hearing process provide that either party may ask the hearing officer to rule on a Motion for Summary Judgment.[16]

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[11] *Id.* § 422.502(a).

[12] Centers for Medicare and Medicaid Services, 2015 Solicitation for Applications for Medicare Prescription Drug Plan 2015 Contracts (http://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/Downloads/2015PartDApplication.pdf), at 12.

[13] 42 C.F.R. § 422.502(c)(2)(iii).

[14] *Id.* § 422.502(c)(3).

[15] *Id.* § 422.660.

[16] *Id.* § 422.684. *See also* Medicare Program, Revisions to the Medicare Advantage and Part D Prescription Drug Contract Determinations, Appeals and Intermediate Sanctions Processes, 72 Fed. Reg. 68700, 68714 (December 5, 2007) (Preamble to final rule stating, "In ruling on such a [Summary Judgment] motion, we propose that the hearing officer would be bound by the CMS regulations and general instructions. Where no factual dispute exists, the hearing officer may make a decision on the papers, without the need for a hearing.").

V. STANDARD OF REVIEW

In this matter, ASSI has the burden of proving by a preponderance of the evidence that CMS' determination was inconsistent with MA and Part D requirements as defined in § 422.501, § 422.502, § 423.502, and § 423.503.[17]

VI. FACTUAL AND PROCEDURAL BACKGROUND

In response to CMS' solicitation of applications for MA and MA-PD plans, ASSI timely submitted its application on February 25, 2014, to operate an MA Only/MD-PD contract in 30 counties in Arkansas. In its application, ASSI informed CMS that it intended to apply for a minimum enrollment waiver. ASSI uploaded the waiver request into HMPS.[18]

On April 18, 2014, CMS issued a courtesy Deficiency Notice to ASSI which did not indicate a concern regarding the minimum enrollment waiver request.[19] On April 28, 2014, CMS issued a Notice of Intent to Deny to ASSI which identified the minimum enrollment deficiency in ASSI's application and set out ASSI's ten-day opportunity to cure this deficiency.[20] On May 8, 2014, ASSI submitted additional documentation in support of its Minimum Enrollment Waiver.[21] On May 28, 2014, CMS issued a formal Application Denial to ASSI based upon the following deficiency:

> Experience & Organization
>
> * Minimum Enrollment Waiver – your organization failed to submit all the necessary information to support the minimum enrollment waiver request. You failed to submit material to demonstrate that your organization has 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 42 C.F.R. 422.514(a).[22]

On May 29, 2014, ASSI filed a timely appeal from this determination.[23] On June 5, 2014, ASSI filed a Motion for Summary Judgment.[24] On June 13, 2014, CMS timely filed a Counter Motion for Summary Judgment and replied to ASSI's motion.

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[17] *Id.* §§ 422.660(b)(1), 423.660(b)(1).
[18] CMS Counter Motion for Summary Judgment and Reply at 5.
[19] *Id.* at 6.
[20] *Id.*, ASSI Motion For Summary Judgment Exhibit 3.
[21] CMS Counter Motion for Summary Judgment and Reply at 6-7.
[22] ASSI Motion For Summary Judgment Exhibit 1; CMS Counter Motion for Summary Judgment Exhibit B.
[23] CMS Counter Motion for Summary Judgment Exhibit C.
[24] Concurrently with its Motion for Summary Judgment, ASSI filed a Request for Production of Documents which was denied by Hearing Officer Benjamin Cohen on June 11, 2014.

On June 17, 2014, ASSI filed its Response to CMS' motion.

VII. ASSI's CONTENTIONS

ASSI contends that CMS failed to apply the criteria it was obligated to apply in evaluating whether ASSI met the waiver criteria under 42 C.F.R. § 422.514(b)(1). ASSI also argues that CMS failed to provide the "any specificity regarding the basis" for its preliminary finding that ASSI did not meet the waiver requirement "which impaired the ability of ASSI to respond appropriately ..."[25]

VIII. CMS' CONTENTIONS

CMS contends that it has authority to categorically deny the contract application of any applicant that does not meet CMS' enrollment requirements. CMS argues that regulations permit, but do not require, that it to grant a minimum enrollment waiver.[26] It emphasizes that it *may* grant a waiver if an application demonstrates *to CMS' satisfaction* that the organization is capable of administering and managing the contract and the level of risk.[27] CMS contends that the time for ASSI to submit relevant information regarding its request for minimal enrollment waiver has passed and that the Hearing Officer cannot now consider new information not previously in the record.[28]

IX. DECISION

The Applicant has met its burden of proof by showing through a preponderance of the evidence that CMS' determination was not consistent with the regulatory and sub-regulatory requirements and guidance.

The regulations provide that CMS may require applicants to complete their application in the form and manner established by the agency.[29] Accordingly, CMS annually publishes updated detailed instructions, directions, and application forms which serve as sub-regulatory guidance and policies. CMS' 2015 Solicitation establishes that applicants are afforded a "courtesy" review and cure period prior to the issuance of an official notice of intent to deny.[30] The Hearing Officer notes that CMS extends this "courtesy" to provide applicants an additional round of review and opportunity to cure prior to the formal regulatory review process.

The facts surrounding the process followed in evaluating ASSI's application are undisputed. While CMS followed the process set forth in regulation, it did not fully adhere to its sub-regulatory guidance. The Hearing Officer notes that CMS provided a "courtesy" review to ASSI, issued a Deficiency Notice, and provided a "courtesy" opportunity to cure. CMS acknowledges, however, that the deficiency upon which the

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[25] ASSI Motion for Summary Judgment at 4.
[26] CMS Motion for Summary Judgment at 5-6.
[27] *Id.* at 2; 42 C.F.R. § 422.514(b).
[28] CMS Motion for Summary Judgment at 4.
[29] 42 C.F.R. §§ 422.501, 423.502.
[30] *Supra* note 12.

denial was based was not identified in the Deficiency Notice issued following the "courtesy" review. As a result, ASSI was not afforded two opportunities to cure any deficiencies with respect to its request for waiver, as should have been provided by the full application process that CMS established.

In addition, 42 C.F.R. § 422.514(b) identifies factors that CMS takes into consideration in determining whether to waive the minimum enrollment requirement. To receive a waiver, a MA organization must demonstrate *to CMS' satisfaction* that it capable of administrating and managing a MA contract and the requisite level of risk.[31] When making a MA-PD contract determination, CMS is to specify the reasons for the determination.[32] It is undisputed that CMS' denial of ASSI's application was based solely on a lack of necessary information to support the minimum enrollment waiver request. The description of the missing information focused on the experience of the "organization." In that § 422.514(b) identifies additional factors[33] that CMS considers, it is not clear whether the information ASSI submitted satisfied those other factors or whether the analysis did not encompass those factors.

The Hearing Officer agrees that CMS is not obligated to grant a waiver, but the agency is required by regulation to consider certain factors specified by regulation and to provide the reasons for a contract denial. It is plausible that CMS may have provided more clarity as to the information it considered necessary to satisfy its evaluation of ASSI's waiver in a second round of review. It is equally plausible that ASSI may have been able to provide information sufficient to support its waiver request (with or without additional clarity of CMS' concerns) had it been afforded two opportunities to cure its deficiency as envisioned in the entire application process.

In conclusion, due to CMS' failure to follow the entire application process, ASSI was materially prejudiced as it effectively lost the opportunity to respond to CMS' concerns regarding its waiver request in the initial "courtesy" round review. ASSI proceeded reasonably throughout the application process in light of the circumstances. ASSI met its burden of proof in showing that the application process followed in this specific case was not consistent with a fair interpretation of the regulatory requirements. The Hearing Officer, however, has no authority to accept or review new information that was not included in ASSI's application.[34] Therefore, this matter is remanded for CMS to consider additional information, should ASSI choose to submit any, to support ASSI's request for waiver of the minimum enrollment requirement.

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[31] 42 C.F.R. § 422.514(b)(1) (emphasis added).
[32] *Id.* § 422.644(a), (b)(1); § 423.642(a), (b)(1).
[33] The Hearing Officer recognizes that CMS is not limited to considering only these factors.
[34] *See* 42 C.F.R. 422.501(c).

X. ORDER

The Applicant's Motion for Summary Judgment is granted in part and denied in part. CMS' Counter Motion for Summary Judgment is denied. This matter is remanded to CMS to (1) provide the Applicant with one additional opportunity to cure, (2) consider any information submitted by the Applicant in a manner that is consistent with the applicable regulations and the process CMS established for MD-PD applications, and (3) make a final contract determination on ASSI's application. The contract determination will include the right to appeal in accordance with 42 C.F.R. Part 422, Subpart N and Part 423 Subpart N. The actions taken under this remand shall conform to a schedule set as follows:

Within two business days of the date of this Order, the parties are directed to submit, or notify the undersigned that they are unable to agree upon, a Proposed Joint Scheduling Order that identifies

(1) The date by which CMS will provide more clarity on the basis for its denial of the Applicant's MA-PD application or confirm that the basis for denial will stand,

(2) The date by which the Applicant will supply additional information or notify CMS that it will not provide additional information,

(3) The date by which CMS will issue a final contract determination,

(4) A proposed briefing schedule to be followed in the event that ASSI appeals CMS' final contract determination, and

(5) A proposed hearing date, which shall be no later than August 11, 2014, to be set in the event that a hearing is required.

Brenda D. Thew
CMS Hearing Officer

Date: June 19, 2014