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Office of the Attorney Advisor

AUG 2 6 2011

VIA FACSIMILE

Eleanor Kolton, Esquire
Greenberg Traurig LLP
2101 L Street, NW, Suite 1000
Washington, DC 20037

Re: Senior Whole Health, LLC, Docket No. 2011-C/D-App-12

Dear Ms. Kolton:

Enclosed is a copy of the Administrator's decision in the above case modifying the decision of the Hearing Officer. This constitutes the final administrative decision of the Secretary of the Health and Human Services.

Sincerely yours,

Jacqueline R. Vaughn
Attorney Advisor

Enclosure

CENTERS FOR MEDICARE AND MEDICAID SERVICES

Decision of the Administrator

In the Matter of:	Claim for:
Senior Whole Health, LLC	**Medicare Advantage Prescription Drug Plan Period Beginning: 2012**
Denial of Service Area Expansion Application	**Review of: Docket No. 2011-C/D-App-12 H5992**
	Dated: July 13, 2011

This case is before the Administrator, Centers for Medicare & Medicaid Services (CMS), for review of the Hearing Officer's decision. The Plan timely requested administrative review under 42 C.F.R. §§422.692(a) and 423.666(a). The Administrator initiated review under 42 C.F.R. §§422.692(d) and 423.666(d). Additional comments were received from the Plan. Comments were also received from the Center for Medicare (CM) requesting affirmation. Accordingly, this case is now before the Administrator for final administrative review.

ISSUE

The issue involves whether CMS properly denied Senior Whole Health's application for a Medicare Advantage-Prescription Drug (MA-PD) Service Area Expansion (SAE).

HEARING OFFICER'S DECISION

The Hearing Officer granted CMS' Motion for Summary Judgment and found that CMS' denial of the Plan's initial application was proper. The Hearing Officer found that the facts of the case were not in dispute and, therefore, summary judgment based on the parties' written briefs was appropriate. The Hearing Officer noted that the record supported the fact that the license the Plan submitted into the Health Plan Management System (HPMS) by the Notice of Intent to Deny deadline did not authorize the Plan to operate in the four expansion counties. The Hearing Officer also noted that the record showed that the Plan obtained its certificate of authority to operate in the four expansion counties effective June 7, 2011. The Hearing Officer

found that the application instructions require applicants to demonstrate that their licenses authorize them to service the expansion areas, and that the required MA State Certification Request form elicits the critical information needed by CMS to ensure the applicant has the appropriate licensure for the proposed MA-PD contract, such as a list of geographic areas in the State that are covered within the authorization. The Hearing Officer found that the license that the Plan submitted by the Notice of Intent to Deny deadline did not include the four counties that it proposed to cover in its SAE application. The Hearing Officer also noted that the 2010 Final Rule modified the regulations by changing the standard for the MA-PD application from substantial compliance to meeting all of the requirements. In addition, the 2010 Final Rule clarified that CMS will only consider documents received by the Notice of Intent to Deny deadline. The Hearing Officer granted CMS' Motion for Summary Judgment and found that CMS' denial of the Plan's SAE application due to its failure to provide proof of licensure in the areas which it planned to serve was consistent with 42 C.F.R. §§422.501 and 422.502.

COMMENTS

The Plan requested review by the Administrator under 42 C.F.R. §422.692. The Plan stated that it is currently one of the few Fully-Integrated Dual-Eligible Special Needs Plans (FIDSNPs) in New York, and in order to serve additional dual eligible beneficiaries, it applied for a contract with CMS to expand its service area to include four additional counties. The Plan noted that its application was denied for a single reason – that New York State had not approved the expansion in time. However, the Plan alleged that at the time, the State was facing its budget deadline and working on a substantial Medicaid overhaul. As a result, the State missed the newly enacted earlier deadline for the requisite approval. The Plan noted that the State subsequently approved the expansion, and that the New York State Department of Health fully supports the Plan in this appeal.

The Plan recognized that CMS needs a uniform process, but requested a one-time exception due to four factors. First, the Plan argued that it is licensed to provide services in the SAE counties. It also alleged that it is one of the few FIDSNPs in New York, and in eight counties it is the only plan providing services to dual eligible beneficiaries. Second, the Plan noted that the timing for the completed process was changed and the deadlines were not clear to the State, which needed to grant the SAE much earlier than it had in the past. Moreover, the Plan stated that it did not have any control over the State's delay in approving the expansion. Third, the Plan contended that the State of New York supports the Plan's request for an exception to be made in this case. The Plan noted that given the Federal-State regulatory partnership that is required for Fully-Integrated Dual-Eligible Special Needs Plans, the State's position establishes legitimate grounds for an exception to be made

without disturbing the important general requirement and precedent to adhere to agency deadlines. Finally, the Plan argued that all requirements will have been met in advance of the final contracting timeline. The Plan noted that the deficiencies have been corrected, and that it had to have a contract with the State in place by July 1, 2011 for the Medicaid services to be provided. The Plan argued that it had obtained such a contract by mid-June of 2011, and as a result, there are no barriers to it being fully operable in accordance with the contracting timeline.

The Plan concluded by stating that it is a high quality plan that has been providing comprehensive health benefits to the most vulnerable populations. The Plan contended that granting the appeal would establish a narrow and limited exception in one instance that would apply only in this case where the contract at issue is an FIDSNP SAE in which the plan was already licensed by the State; the SAE was approved by the State by the final contracting deadline; and the State itself has taken the important step of requesting that CMS approve the SAE. Thus, the Plan requested the review and reversal of the SAE denial.[1]

CM submitted comments and stated that the sole basis for CMS' denial of the SAE application was the Plan's failure to submit the New York State licensure documentation authorizing the Plan to offer MA products in the four expansion counties of Kings, Queens, New York, and Bronx, for 2012. CM noted that the New York Certificate of Authority submitted by the Plan only authorized it to offer MA benefits in the twelve existing counties. CM argued that the Hearing Officer's decision creates a positive precedent as it reinforces CMS' authority to uphold its application deadlines and deny applications that do not meet the requirements by the final deadline. Moreover, CM noted that the State licensure requirement is fundamental to the overall application approval process because it ensures that applicants are solvent and have the capacity to operate as a risk-bearing entity. CM argued that the deadlines are critical to the application process in ensuring fairness, transparency, and equal treatment of all applicants. CM also noted that the deadlines are also needed so there is finality in plan offering in the fall and beneficiaries understand their plan options for the upcoming year.

DISCUSSION

The entire record furnished by the Hearing Officer has been examined, including all correspondence, position papers, exhibits, and subsequent submissions.

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[1] The Plan's Chief Executive Officer submitted further electronic comments in support of approval of the application. In addition, the State of New York and Congressman Rangel, Towns and Clarke, submitted letters in support of the Applicant.

Under the regulations at 42 C.F.R. §§422.500 and 423.500 et seq., CMS has respectively established the general provisions for entities seeking to qualify as Managed Care (MA) organizations under Part C, and/or Prescription Drug Plans (PDP) under Part D.[2] MA organizations offering coordinated care plans (CCPs) must offer Part D benefits in the same service areas. 42 C.F.R. §422.4(c)(1).

Pursuant to 42 C.F.R. §§422.501 and 423.502, organizations seeking to qualify as an MA-PD plan have their applications reviewed by CMS to determine whether they meet the application requirements to enter into such a contract. The regulation concerning the Part C application requirements at 42 C.F.R. §422.501[3] states, in relevant part:

> (c) Completion of an application.
>
> > (1) In order to obtain a determination on whether it meets the requirement to become an MA organization and is qualified to provide a particular type of MA plan, an entity, or an individual authorized to act for the entity (the applicant) must complete a certified application in the form and manner required by CMS, including the following:
> > i. 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.
> > ii. For regional plans, documentation of application for State licensure in any State in the region that the organization is not already licensed.
> > (2) The authorized individual must thoroughly describe how the entity and MA plan meet, or will meet, the requirements described in this part.

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[2] CMS has revised and/or clarified some of the regulatory text governing the Part C and Part D programs. *See* Proposed Rule, 74 Fed. Reg. 54634 (Oct. 22, 2009) and final Rule, 75 Fed. Reg. 19678 (April 15, 2010). The Rule is effective June 7, 2010 and applied from contract year 2011 forward.

[3] *See* similar language for Part D at 42 C.F.R. §423.501.

The regulation at 42 C.F.R. §422.400(c) further describes the State licensure requirements and state that each MA organization must:

(a) Be licensed under State law, or otherwise authorized to operate under State law, as a risk bearing entity (as defined in §422.2) eligible to offer health insurance or health benefit coverage in each State in which it offers one or more MA plans;

(b) If not commercially licensed, obtain certification from the State that the organization meets a level of financial solvency and such other standards that the State may required for it to operate as an MA organization; and

(c) Demonstrate to CMS that

(1) The scope of its license or authority allows the organization to offer the type of MA plan or plans that it intends to offer in the State; and

(2) If applicable, it has obtained the State certification required under paragraph (b) of this section. (Emphasis added.)[4]

In order to demonstrate that it meets these licensure requirements as authorized under 42 C.F.R. §422.501, CMS requires that Part C – MA applicants complete a table that states that the Applicant is licensed under State law as a risk-bearing entity eligible to offer health insurance and benefits in each State in which the Applicant proposed to offer the managed care product. In addition, the scope of the license or authority allows the Applicant to offer the type of managed care product that it intends to offer in the State(s). Applicants are required to upload into HPMS an executed copy of a State licensing certificate and the CMS State Certification Form for each State being requested. The application specifically states that "Applicants must meet and document all applicable licensure and certification requirements no later than the Applicants final upload opportunity, which is in response to CMS' Notice of Intent to Deny communication."[5]

With respect to the MA State Certification Request form, CMS required that an official from the MA organization make a certification regarding the type of the plan and identify the requested service area(s). Likewise, such form must be finalized by the State official(s) who certify that the applicant is licensed and/or the organization is authorized to bear the risk associated with the MA product. The instructions state that the form must be submitted with all Medicare Advantage applications, and that

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[4] *See* 42 C.F.R. §422.400.

[5] *See* 2012 Part C Medicare Advantage Application at http://www.cms.hhs.gov/MedicareAdvantageApps/attachment2010_PartC_MA_Cost Plan_Application_010411 (2011) at 62.

the MA State Certification Form demonstrates to CMS that the MA contract being sought by the applicant organization is within the scope of the license granted by the appropriate State regulatory agency, that the organization meets State solvency requirements and that it is authorized to bear risk. The determination is based on the organization's entire application as submitted to CMS, including documentation of the appropriate licensure.[6]

For the 2011 contract year, CMS established an online application process for both Part C and Part D plans called the Health Plan Management System (HPMS). All new applicants and requests to expand service areas had to submit their applications through the HPMS by the strict deadlines established by CMS. CMS provided training and technical assistance to plans in completing their application. Plan applications were evaluated solely on the materials that were submitted into the HPMS system within the CMS established windows and deadlines. After the applicant files its initial application, CMS reviews the application and notifies the applicant of any existing deficiencies. The applicant is then given the opportunity to correct the deficiencies.

The regulations at 42 C.F.R. §422.502 specifies the evaluation and determination procedures for applications to be determined qualified to act as an MA organization, and states in pertinent part:

> (a) *Basis for evaluation and determination.* (1) With the exception of evaluations conducted under paragraph (b) [Use of information from a current or prior contract], CMS evaluates an entities application for an MA contract solely on the basis of information contained in the application itself and any additional information that CMS obtains through on-site visits. (2) After evaluating all relevant information, CMS determines whether the application meets *all the requirements* in this part. (Emphasis added).[7]

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[6] *Id.* at 62. Also see Item 3 of the MA State Certification Request Form, at page 64, and the State Certification signature statement, at page 67.

[7] The preamble to the recent regulatory revision at 75 Fed. Reg. 19678, 19683 (April 15, 2010), states that "we specifically proposed to make explicit that we will approve only those applications that demonstrate that they meet all (not substantially all) Part C and Part D requirements." CMS also states that expecting applications to meet "all" standards is practical and explains that "applicants receive enough information to successfully apply and are given two opportunities with instructions to cure deficiencies."

However, if an applicant fails to correct all of the deficiencies, CMS will issue the applicant a Notice of Intent to Deny under the regulations at 42 C.F.R. §422.502(c)(2).[8] The regulation at 42 C.F.R. §422.502(c) states, in relevant part:

> (c) *Notice of Determination.* * * *
> (1) *Approval of Application.* * * *
> (2) *Intent to Deny.*
> (i) If CMS finds that the applicant does not appear to be able to meet the requirements for an MA organization and/or has not provided enough information to evaluate the application, it gives the applicant notice of intent to deny the application and a summary of the basis for this preliminary finding.
> (ii) Within 10 days of the date of the notice, the contract applicant may 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 the applicant does not appear qualified to contract as an MA organization or has not provided enough information to allow CMS to evaluate the application, CMS will deny the application.[9]

On January 4, 2011 CMS posted the 2012 Part C and Part D Applications on its website and provided notice to potential applications through the HPMS.[10] The application deadline was set for February 24, 2011.[11]

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[8] *See* similar language for Part D at 42 C.F.R. §423.503(c)(2).

[9] The preamble to the final regulation at 75 Fed. Reg. 19678, 19683 (April 15, 2010), states that "[w]e also proposed to clarify our authority to decline to consider application materials submitted after the expiration of the 10-day period following our issuance of a notice of intent to deny an organization's contract qualification application.... Further, we noted that consistent with the revisions to 42 C.F.R. §422.650(b)(2) and §423.660(b)(2) [sic - 42 C.F.R. §422.660(b)(2) and §423.650(b)(2)], which are discussed elsewhere in this final rule, the 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."

[10] *See* CMS' Motion for Summary Judgment, at pg. 2.

In this case, Senior Whole Health is a Special Needs Plan that presently participates in both Medicare and New York Medicaid Advantage programs, making it a dual-eligible Special Needs Plan (D-SNP). On February 24, 2011, the Plan filed a service area expansion application to offer MA-PD plans in Kings, Queens, New York, and Bronx counties within the State of New York. CMS determined that the application submitted by the Plan was incomplete and issued a Notice of Intent to Deny the application on April 28, 2011, citing the Plan's failure to demonstrate that it held appropriate licensure. The Plan was afforded ten days to "cure" the deficiency.[12] On May 9, 2011, within the curing period, the Plan uploaded a "Health Maintenance Organization Certification" issued by the State on September 30, 2009, into HPMS.[13] The Certification, however, only listed the twelve counties in which the Plan already provided services, not the proposed expansion areas.[14] On May 27, 2011, CMS notified the Plan that its MA-PD expansion application was denied due to the failure to timely submit a valid State licensure documentation authorizing it to offer plans in the four proposed expansion counties.[15] On June 6, 2011, the State informed the Plan that the licensure would be granted and Senior Whole Health received its State license on June 7, 2011.[16]

The Administrator finds that in order to obtain approval of an application for a MA-PD SAE contract, applicants must demonstrate that they meet the application requirements to enter into such a contract. The record shows the Plan failed to cure the deficiency cited in CMS' Intent to Deny letter by the May 9, 2011 deadline. The documentation provided by the Plan specifically limited its ability to offer MA products to the 12 counties specified in the Certificate of Authority, and did not include the 4 proposed expansion counties.[17] Thus, the Plan failed to timely obtain and submit evidence of a modification of its New York State Certificate of Authority which included the four expansion counties. Accordingly, the Administrator finds that the CMS denial and the Hearing Officer affirmation was proper and correct.

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[11] *Id.*

[12] *Id.* at pg. 4.

[13] *Id.* at Exhibit 4.

[14] *Id.*

[15] *Id.* at Exhibit 5.

[16] *See* Senior Whole Health's Opening Brief, at pg. 3.

[17] The license included the 12 counties of Albany, Columbia, Dutchess, Greene, Montgomery, Orange, Rensselaer, Saratoga, Schenectady, Warren, Washington, Ulster, but failed to include the proposed expansion counties of Bronx, Kings, New York, and Queens.

The Plan argued that it submitted the licensure documentation including the expansion areas on June 7, 2011, and requested that an exception be made for the untimely filing. The Administrator finds that the Applicant raises compelling policy arguments with respect to the beneficiary related value of the Plan's dually integrated SNP and cooperation with the State. The Administrator hereby exercises the broad contractual discretionary authority to allow the Applicant to cure its application.[18] Although the CMS denial and Hearing Officer's affirmation were proper and correct, in light of the special and unique facts and policy considerations presented in this specific case, the Administrator modifies the CMS denial and Hearing Officer decisions to allow the Applicant the opportunity to cure the application with submission of any documentation relating to the State licensure that is required to demonstrate full compliance with the Application provisions. CMS has not at this time reviewed and made a determination on such documentation of State licensure.[19] The Administrator holds that, in allowing the Applicant to cure its application, the Applicant must promptly submit the documentation required by CMS within the timeframes CMS orders. The CMS determination on that documentation and the determination on whether the application meets all the requirements and, thereby, whether the Applicant is qualified to contract with respect to the SAE application, will herein be incorporated as the final administrative decision under 42 CFR 422.692 and 423.666.

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[18] In addition, the Administrator exercises the broad authority under the regulations at 42 C.F.R. §422.692(d) and §423.666(d), which state that the Administrator may "review the hearing officer's decision and determine, based upon this decision, the hearing record, and any written arguments submitted by the MA organization or CMS, whether the determination should be upheld, reversed or modified."

[19] Pursuant to a June 6, 2011 State letter, the State issued a notification of an intent to approve the expansion counties. The Applicant was required to sign an attestation demonstrating an understanding and acceptance of the condition requiring additional infusion of capital in the month of June, and a further infusion of a lump amount and any other amounts the State deems necessary, by December 31, 2011. The record shows a copy of a "Organization and Certificate of Authority" issued June 7, 2011 with the inclusion of the additional expansion counties.

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: 8/25/11

Marilyn Tavenner
Principal Deputy Administrator and Chief Operating Officer
Centers for Medicare & Medicaid Services