CENTERS FOR MEDICARE AND MEDICAID SERVICES

Hearing Officer Decision

In the Matter of

Senior Whole Health, LLC	*	
	*	Docket No. 2011 C/D App 12
Denial of Service Area Expansion Application, H5992	*	
	*	
	*	

ORDER GRANTING
MOTION FOR SUMMARY JUDGMENT

Jurisdiction

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

Issue

Whether CMS' denial of Senior Whole Health's (SWH) Medicare Advantage –Prescription Drug (MA-PD) Service Area Expansion (SAE) application for the State of New York based on lack of appropriate state licensure was proper.

Statutory and Regulatory Background

Section 101 of the Medicare Prescription Drug Improvement and Modernization Act of 2003 (MMA) (Pub.L. 108-173), amended title XVIII of the Social Security Act (the Act) by establishing a voluntary prescription drug benefit and made changes to the Medicare managed care program known as Medicare Advantage (MA). Pursuant to 42 C.F.R. §§ 422.500 and 423.500 *et seq*., CMS has established the general provisions for entities seeking to qualify as MA-PD plans.

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 at 42 C.F.R. § 422.501(c)[1] states, in relevant part:

> (c) *Completion of an application.*
>
> > (1) In order to obtain a determination on whether it meets the requirements 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

[1] *See also* 42 C.F.R. § 423.502(c).

> 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; or
> >
> > (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.

(Emphasis added). [2]

Further State licensure requirements are described at 42 C.F.R. § 422.400 as follows:

> …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 require 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).[3]

In order to demonstrate that it meets these licensure requirements as authorized under 42 C.F.R. § 422.501, CMS has the following requirements for applicants with regard to licensure.

For Part C – MA Applicants, CMS requires applicants to complete a table that states:

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[2] 42 C.F.R. § 423.502(c)(1)(i).
[3] 42 C.F.R. § 422.400.

1. Applicant is 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 proposes 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 or states.
    - If "Yes", upload in HPMS an executed copy of a state licensing certificate **and** the CMS State Certification Form for each state being requested.

    Note: Applicant must meet and document all applicable licensure and certification requirements no later than the Applicant's final upload opportunity, which is in response to CMS' Notice of Intent to Deny communication.

(Emphasis added).[4]

With respect to the MA State Certification Request form, CMS requires 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 for the MA State Certification Request form state:

> **This form is required to be submitted with all Medicare Advantage (MA) applications**. The MA organization is required to complete the items above the line (items 1-3), then forward the document to the appropriate State Agency Official who should complete those items below the line (item 4-7). After completion, the State Agency Official should return this document to the applicant organization for submission to CMS as part of its application for a MA contract.
>
> The questions provided must be fully completed. If a space is needed to respond to the questions, please add pages as necessary. Provide additional information whenever you believe further explanation is will clarify the question.
>
> **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**. A determination will be based on the organization's entire application as submitted to CMS, including documentation of appropriate licensure.

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

(Emphasis added).[5]

Item 3 of the MA State Certification Request form states:

> 3. Type of MA application filed by the Applicant with the Centers for Medicare & Medicaid Services (CMS): (Circle all that are appropriate)
> - HMO - PPO - MSA - PFFS - Religious Fraternal
> Requested Service
> Area:_____[6]

The State Certification signature page states:

> By signing the certification, the State of _____ is certifying that the organization is licensed and/or that the organization is authorized to bear the risk associated with the MA product circled in item 3 above. The State is not being asked to verify plan eligibility for the Medicare managed care products(s) or CMS contract type(s) requested by the organization, but merely to certify to the requested information based on the representation by the organization named above.[7]

If CMS denies an MA-PD applicant, it has a right to a hearing before a CMS Hearing Officer under 42 C.F.R. § 422.660(a) and 423.650(a). Under the regulation at 422.660(b), the applicant has the burden of proving by a preponderance of the evidence that CMS' determination was inconsistent with regulatory requirements.[8]

The regulation at 42 C.F.R. §422.684(b) and 423.662(b) states that either party to the hearing may ask the hearing officer to rule on a motion for summary judgment.[9]

Factual and Procedural Background

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

SWH is a Special Needs Plan that participates in both Medicare and New York Medicaid Advantage programs, making it dual-eligible (D-SNP).[12] On February 24, 2011, SWH timely

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[5] *Id*. at 62.
[6] *Id*. at 64.
[7] *Id*. at 67.
[8] 42 C.F.R. § 422.660(b)(1). *See also* 42 C.F.R. § 423.650(b)(1).
[9] *See* 72 FR 68700, 68714, 68725 (December 5, 2007). The preamble to the Final Rule further explains that "In ruling on such a 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."
[10] CMS *MSJ* at 2-3.
[11] *Id*. at 3.

filed a service area expansion application, H5992, to offer MA-PD plans in Kings, Queens, New York, and Bronx counties within the State of New York.[13] At that time, SWH's application to the New York Department of Health (NYDOH) for expansion into the four counties listed was still pending.[14]

By electronic mail and through a Notice of Intent to Deny (NOID) dated April 28, 2011, CMS informed SWH of the deficiency regarding its failure to demonstrate that it held appropriate licensure.[15] The NOID also stated that CMS would deny the SAE application if the curing materials were not submitted within ten days.[16] Within the curing period, on May 9, 2011, SWH uploaded a "Health Maintenance Organization Certification" issued by NYDOH into HPMS.[17] The Certification, however, listed only the twelve counties in which SWH currently provides services, not the proposed expansion areas.[18]

On May 27, 2011, again by electronic mail, CMS notified SWH that its MA-PD application was denied due to SWH's failure to submit valid state licensure documentation authorizing it to offer plans in the four proposed expansion counties.[19] On June 6, 2011 NYDOH informed SWH that the license would be granted.[20] SWH received its State license on June 7, 2011.[21]

SWH timely filed a request for a hearing concerning CMS' determination. On June 21, 2011, SWH filed its opening brief requesting a reversal of CMS' denial. On June 24, 2011, CMS filed its brief in support of its denial which addressed the lack of licensure. On June 28, 2011, CMS submitted a motion for summary judgment (MSJ) and memorandum in support of its denial of SWH's SAE application based solely on SWH's failure to provide evidence of appropriate state licensure. On June 30, 2011, SWH submitted its opposition to CMS' Opening Brief and Motion for summary judgment. On July 6, 2011, CMS submitted a response to SWH's Cross-MSJ.[22] On July 7, 2011, SWH submitted a reply to CMS' response to SWH's Cross-MSJ.

CMS' Contentions

CMS Denied SWH's Application due to SWH Missing the Certification Deadline:
CMS contends that SWH failed to timely acquire and submit the proper license, and thus CMS' denial of SWH's application should be upheld.[23] CMS states that under 42 C.F.R. §422.400(a), the applicant must be licensed under State law as a risk bearing entity eligible to offer health insurance in the State where it intends to operate. Further, CMS asserts that §422.400(c) requires

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[12] SWH *Reply Brief* at Exhibit 1.
[13] CMS *MSJ* at 3.
[14] SWH *Opening Brief* at 2.
[15] CMS *MSJ* Exhibit 2.
[16] *Id*. at 3.
[17] *Id*. at Exhibit 3.
[18] *Id*.
[19] *Id*. Exhibit 1.
[20] SWH *Opening Brief* at 3.
[21] *Id*.
[22] CMS' *Response in Opposition to SWH's Cross-MSJ* was dated July 9, 2011 but submitted July 6, 2011.
[23] CMS *Reply Brief* at 11-12.

the applicant to demonstrate that the scope of the license allows the organization to offer the plans which the applicant intends to offer.[24] CMS also states that in accordance with 42 C.F.R. §422.501(c)(1)(i), an applicant must have an appropriate State license certifying that the applicant has met State requirements for offering health insurance plans.[25]

CMS points out that the Hearing Officer has previously held, in 2008, that the State licensure component is a fundamental application requirement or "threshold requirement."[26] CMS continues by referencing a 2009 Hearing Officer Decision which found that the "regulations contemplate that applicants must demonstrate to CMS that such requirements will be met for the time period and areas that the applicant seeks to expand."[27]

Next, CMS argues that the documentation provided by SWH specifically limited SWH's ability to offer Medicare Advantage products to the 12 counties specified in the Certificate of Authority.[28] CMS argues that New York's limitation of authority to specific counties is evidence that, under New York law, a valid and appropriate State license must include a Certificate of Authority which specifies the counties in which the product is being offered.[29]

CMS concludes that due to SWH's failure to timely obtain and submit evidence of a modification of its New York State Certificate of Authority which included the four expansion counties, CMS denied the SAE.[30] CMS concludes that SWH's July 7, 2011 submission of the licensure documentation, nearly a month after the May 9, 2011 deadline constituted a failure to meet the application requirements; thus CMS correctly denied the SWH SAE application.[31]

CMS Applied its Regulatory Authority Properly:
CMS contends that SWH has the burden of proving by a preponderance of the evidence that the CMS determination was inconsistent with the requirements of federal regulations.[32] CMS states that it has the regulatory authority under 42 C.F.R. §422.501(b) and 42 C.F.R. §423.502(b) to set the form and manner for the submission of applications for qualification as a Medicare Advantage Organization (MAO) and to offer a Part D plan.[33] CMS argues that in order to appropriately administer the Part C and Part D programs, CMS must have established deadlines for applicants to complete their applications. CMS argues that absent such deadlines, uncertainty regarding qualified MA plans would have negative implications for beneficiaries and various components within CMS.[34] CMS states that the instructions of the MA application require the applicant to meet and document all applicable licensure and certification requirements by the

[24] CMS *MSJ* at 4.
[25] *Id*.
[26] *Id*. at Exhibit 4.
[27] *Id*. at 5, Exhibit 5.
[28] CMS *Reply to Applicant's Brief* at 6.
[29] *Id*.
[30] CMS *MSJ* at 7.
[31] *Id*. at 7-8.
[32] CMS *Reply to Applicant's Brief* at 2.
[33] *Id*. at 1-2. *See also* 42 C.F.R. §422.501 and 42 C.F.R. §423.502.
[34] CMS *Reply to Applicant's Brief* at 7.

upload deadline.[35] CMS contends that the April 15, 2010 Final Rule (2010 Final Rule) did not change the long standing documentation requirements of §422 and §423.[36]

CMS asserts that it followed 42 C.F.R. §422.501(c) concerning the application requirements by sending via e-mail a NOID which identified multiple deficiencies in the H5992 SAE application, including the lack of an appropriate license.[37] CMS states that the NOID notified SWH that there was a ten-day period in which SWH could cure the identified deficiencies.[38] CMS asserts that under the plain language of 42 C.F.R. §422.502(c)(2)(iii), CMS "will deny the application" when the materials provided within the established timeframe indicate that the applicant does not appear qualified.[39] CMS argues that SWH uploaded a license which did not list the expansion counties, and thus CMS was compelled to deny the SAE for H5992.[40]

Further, CMS contends that the denial of SWH's MA application is entirely separate and distinct from SWH's application to offer a Special Needs Plan.[41] CMS states that SWH completed and received conditional approval for a separate SNP application.[42]

The Final Rule did not Require a Federalism Summary under Executive Order 13132:
CMS contends that, contrary to SWH's belief, it did follow appropriate procedures under Executive Order 13132 when promulgating regulatory changes in the 2010 Final Rule.[43] CMS asserts that the revisions to 42 C.F.R. §422.502(c)(2) in the 2010 Final Rule did not require a Federalism summary impact statement under Executive Order 13132.[44] CMS states that the modification made explicit that CMS will only approve those applications that demonstrate that they meet **all** Part C and Part D requirements, not merely "substantially all" of the requirements.[45] CMS argues that the regulation does not impose a substantial or direct compliance cost on the State as the rule only changes the MA program and does not dictate any State rights or responsibilities.[46] CMS asserts that the States remain free to determine their own standards, processes, and timelines for issuing and expanding health plans' licenses as they see fit.[47] CMS also argues that the change which provides for CMS' authority to deny applications which fail to meet all requirements does not have a preemptive effect on any State licensing laws or State laws relating to plan solvency.[48]

CMS Motion for Summary Judgment and Response to SWH's Cross-Motion for Summary Judgment

[35] *Id*. at 7 (citing the MA Application at 4).
[36] *Id*. at 5-6.
[37] CMS *MSJ* at 5.
[38] *Id*. at 6.
[39] CMS *Opposition to SWH's Cross-MSJ* at 2. *See also* 42 C.F.R. §422.502(c)(2)(iii).
[40] *Id*.
[41] *Id*. at 1.
[42] *Id*.
[43] CMS *Reply to Applicant's Brief* at 8.
[44] *Id*. at 8-9.
[45] *Id*. at 9.
[46] *Id*. at 9-10.
[47] *Id*. at 10.
[48] CMS *Reply to Applicant's Brief* at 11.

CMS contends that summary judgment is appropriate in this case because the facts are not in dispute.[49] CMS asserts that the license that SWH submitted by the NOID deadline did not cover the expansion areas, that SWH did not, in fact, obtain such a license until after the NOID deadline and that as a matter of law CMS is entitled to summary judgment.[50] CMS argues that this matter concerns the MA application and that SNP application rules and policies are not relevant to this case.[51] CMS posits that SWH's policy arguments concerning the role of SNPs in New York are also outside the scope of the MA application.[52] CMS further supports its position with the language in 42 C.F.R. §422.502(c)(2)(iii) which states that CMS "will deny the application" when the materials provided within the established time frame indicate that the applicant is not qualified.[53] CMS states that it has no flexibility and was required to deny the application.[54]

Senior Whole Health's Contentions

SWH Satisfied Statutory Criteria at the Time of its Application:
SWH contends that that it satisfied the requirements of the current regulations with the documents that it submitted with its application to CMS.[55] SWH asserts that §1855(a)(1) of the Social Security Act requires only a State license to be offered to the agency.[56] SWH stresses that it has been licensed to offer MA-PD benefits in the State of New York since 2006 and submitted its supporting documentation prior to CMS' denial.[57] SWH argues that no provision requires a "county-by-county" license nor must it demonstrate that such authority as part of the application process.[58]

SWH notes the "will meet" language of 42 C.F.R. §422.501(c)(2) and argues that this language permits a plan to speak about the future within their application.[59] SWH contends that it was allowed to inform CMS that SWH had applied for an expansion certification with NYDOH and supplement its CMS application with supporting documentation after the deadline.[60] SWH points out that it obtained the expansion certification prior to filing this appeal.[61]

Further, SWH contends that its State license was within the "scope"[62] of what was required by the regulation. SWH argues that the word, "scope," in 42 C.F.R. § 422.400(c)(1) refers to the

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[49] CMS *MSJ* at 1.
[50] *Id*. at 7-8.
[51] CMS *Opposition to Cross-MSJ* at 1-2.
[52] *Id*. at 2.
[53] *Id*.
[54] *Id*.
[55] SWH *Opening Brief* at 4.
[56] *Id*. (Citing the language "be organized and licensed under State law as a risk-bearing entity eligible to offer health insurance or health benefits coverage in each State in which it offers a… plan." *See also* 42 C.F.R. §423.504(b)(2).)
[57] SWH *Opening Brief* at 2, 4.
[58] SWH *Reply Brief* at 3.
[59] SWH *Opening Brief* at 4-5.
[60] *Id*.
[61] *Id*. at 5.
[62] *See* 42 C.F.R. § 422.400 (c)(1).

type of license not the geographical reach of the license.[63] SWH concludes that as there is no language in the regulation requiring a county-by-county license, therefore the documents which SWH submitted to CMS were satisfactory.[64]

The Final Rule Violates the Concept of Federalism:
SWH contends that the 2010 Final Rule creates a bureaucratic inconsistency and violates the concept of federalism.[65] SWH argues that federalism implications are created that when a final rule compels States to alter their operations.[66] SWH maintains that the 2010 Final Rule forces the States to complete their review processes more rapidly than they would have otherwise done and New York was not fully aware of this change.[67] SWH explains that New York traditionally has not issued expansion licenses for its Medicaid/Medicare plans until late in the CMS application process.[68]

Further, SWH contends that the Final Rule does not comply with the requirement of Executive Order 13132 for a federalism analysis.[69] SWH asserts that when a rule affects the operations of a State, an agency must consult with State officials and provide a federalism impact analysis.[70] SWH concludes that since the 2010 Final Rule does not provide a federalism impact analysis and thus the agency did not properly alert State officials of the change, the rule should not be accorded deference.[71]

CMS Retains Discretion to Allow SWH's Application:
SWH contends that although the preamble to the rule states that the agency will be inflexible, that inflexibility is not reflected in the rule itself.[72] In SWH's view, the phrase "meet, or will meet" in 42 C.F.R. §422.501(c)(2) provides the agency with the ability to be flexible in order to accommodate documents that are not submitted by the CMS deadline.[73] SWH observes that CMS previously allowed Plans to amend their applications late in the process.[74] SWH argues that CMS retains the flexibility to treat the application as complete because the expanded license was issued before SWH filed this appeal.[75]

SWH also contends that CMS should use its discretion and approve the application because SWH is the only fully-integrated D-SNP operating in eight counties in the State of New York.[76] SWH states that the D-SNP program is subject to different constraints and deadlines than an

[63] SWH *Reply Brief* at 4.
[64] *Id*. at 6.
[65] *Id*. at 3.
[66] *Id*. at 6.
[67] *Id*. at 5.
[68] SWH *Opening Brief* at 1.
[69] *Id*. at 5-6.
[70] *Id*. at 6. (Citing Executive Order 13132 §6(c)).
[71] *Id*.
[72] SWH *Reply Brief* at 7.
[73] *Id*.
[74] SWH *Opening Brief* at 1.
[75] *Id*. at 5.
[76] SWH *Opposition to MSJ* at 4.

ordinary MA plan.[77] SWH argues that it makes little administrative sense to hold a D-SNP plan to the same deadline as an MA plan.[78]

SWH's Objection to CMS' Motion for Summary Judgment, Cross-Motion for Summary Judgment and Response to CMS' Response to its Cross-Motion for Summary Judgment

SWH contends that CMS' motion for summary judgment should be denied for three reasons.[79] First, SWH finds a dispute over two material facts, specifically (1) what is sufficient under New York State law to satisfy its licensure requirement and (2) whether SWH's submission by the NOID deadline was sufficient to document that it would be able to fulfill all of the conditions of an MA plan.[80] Second, SWH argues it fully meets the statutory and regulatory licensure requirements.[81] Third, SWH contends that CMS is not required to automatically deny SWH's application where the documentation is submitted in early June rather than mid-May. In sum, SWH believes that CMS should have exercised its discretion and accepted SWH's application because SWH is currently the only fully integrated SNP serving dual-eligible residents in eight counties in New York and its expansion is beneficial to that special population.[82] SWH maintains that no rule eliminates CMS' discretion to approve SWH's application, that the supposed inflexibility is based on the preamble to the 2010 Final Rule, which is an interpretive rule that cannot obliterate an agency's discretion.[83]

Decision

The Hearing Officer finds that the facts in this case are not in dispute and therefore, a summary judgment based on the parties' written briefs is appropriate.[84]

Preliminarily, the Hearing Officer notes that SWH sees two material facts in dispute: (1) what is sufficient under New York state law to satisfy its licensure requirement and (2) whether its submission by the NOID deadline was sufficient to document that it would be able to fulfill timely all of the conditions of a Medicare Advantage Plan.[85] The Hearing Officer disagrees that facts are in contention. First, the Hearing Officer notes that the record is clear that the license that SWH submitted into the HPMS by the NOID deadline does not authorize SWH to operate in the four expansion counties.[86] Second, the record is also clear that SWH obtained its certificate of authority to operate in the four expansion counties effective June 7, 2011.[87] The Hearing Officer finds that the issue of whether regulatory requirements are satisfied by submission of a license that does not include the expansion counties by the NOID deadline, followed by

[77] *Id*. at 4-5.
[78] *Id*. at 5.
[79] *Id*. at 1-2.
[80] *Id*.
[81] SWH *Opposition to MSJ* at 1-2.
[82] *Id. See also* Exhibit 2.
[83] SWH *Reply to CMS' Opposition to Cross-MSJ* at 1.
[84] 42 C.F.R. §422.684(b).
[85] *See* SWH *Opposition to MSJ* at 1-2.
[86] SWH *Opening Brief* at Exhibit 1.
[87] *See Id*.

obtaining a license for the expansion counties after the NOID deadline, is a question of law on which a summary judgment can be granted.

Statutory Requirements:
The Hearing Officer notes that pursuant to 42 C.F.R. § 422.501(c), CMS may set deadlines and dictate the form and manner of the application process (i.e., CMS has the right to specify documentation requirements and due dates). In addition, 42 C.F.R. § 422.502(c)(2)(ii) requires that applicants revise their applications within 10 days from the date of the Notice of Intent to Deny letter. The Hearing Officer notes that 42 C.F.R. § 422.502(c)(2)(iii) further clarifies that "[i]f CMS does not receive a revised application within the 10 days for 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 a MA organization or has not provided enough information to allow CMS to evaluate the application, CMS will deny the application." Therefore, in deciding if SWH was in compliance with program requirements, the Hearing Officer will evaluate only materials timely and properly filed with the agency by the May 9, 2011 deadline.

The Hearing Officer notes that 42 C.F.R. §§ 422.501(c)(1)(i) and 422.400 explicitly require that an applicant be licensed. The Hearing Officer finds that appropriate State licensure (or certification) and meeting State solvency standards are essential cornerstones of the application.[88] SWH indicates that it was licensed as an MA plan in twelve counties, that it provided a copy of its existing license by the cure date, and that there is no statutory or regulatory requirement that its license specify the four counties it planned to operate in its SAE application. The Hearing Officer notes that 42 C.F.R. § 442.501(c)(i) requires proof that the applicant is authorized to provide services "to be offered under the MA contract," and 42 C.F.R. § 422.400(c) requires that the applicant "demonstrate to CMS that… [t]he scope of its license or authority allows the organization to offer the type of MA plan or plans it intends to offer in the State..."[89] The Hearing Officer finds that the requirements of 42 C.F.R. § 442.501(c)(i) and 42 C.F.R. § 422.400(c), read together or independently, reasonably contemplate that the license or certification permit the applicant to provide services in the areas it plans to cover in its SAE application.

The Hearing Officer finds that the application instructions require applicants to demonstrate that their licenses authorize them to serve the expansion areas. The Hearing Officer finds 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. [90]

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[88] 42 C.F.R. §§ 422.501(c)(1)(i) and 422.400.
[89] 42 C.F.R. §422.400(c).
[90] The MA State Certification Request form asks for the following information: type of license or certificate of authority held by the applicant; the requested service areas the applicant plans to serve; the name of the state agencies whose approval is required for licensure; the name of the state agencies that assess the financial solvency of the applicant; and the signature of the appropriate State Agency Official certifying that the applicant is licensed or otherwise authorized to operate in the state and has meet the state financial solvency requirements. (*See supra* text accompanying notes 5-6.)

In addition, the Hearing Officer notes that prior to issuing the final denial, CMS warned SWH that it was deficient with respect to licensure because SWH had not uploaded a valid license for the proposed expansion area and, in order to cure the deficiency, was required to upload the information into the HPMS by the cure date.[91] The Hearing Officer finds that the license that SWH submitted did not include the four counties that SWH proposed to cover in its SAE application. While SWH maintains that it was licensed for other counties in the State of New York since 2006 and was in the process of expanding the license, SWH acknowledged that the licensing authority was still reviewing its expansion application well after the May 9, 2011 deadline.[92] As a result, the Hearing Officer finds that CMS' denial of SWH's application due to SWH's failure to provide proof of licensure in the areas which SWH planned to serve was consistent with 42 C.F.R. §§422.501 and 422.502.

Effect of the April 15, 2010 Final Rule:

The Hearing Officer notes that the 2010 Final Rule modified the regulations by changing the standard for the MA-PD applications 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 NOID deadline.[93] The Hearing Officer notes that the 2010 Final Rule made no changes to the general requirement that applicants complete a certified application in the form and manner required by CMS or to the substantive licensure requirements.

SWH contends that the 2010 Final Rule compels the States to alter their operations and that CMS failed to conduct a federalism impact analysis as required by Executive Order 13132.[94] The Hearing Officer disagrees. The Hearing Officer finds that the regulatory changes in the 2010 Final Rule do not impose a substantial or direct compliance cost on any State, nor affect the States' licensing processes. Instead, the revisions affect what private MA-PD applicants are required to submit by the application deadline. The Hearing Officer finds that it is the responsibility of the applicant to ensure that all the steps in the application process, including obtaining appropriate State licensure, are completed by the deadline required by CMS.

Flexibility in CMS' Discretion:

The Hearing Officer also notes that SWH claims that language in the preamble to the 2010 Final Rule removed the flexibility that CMS had to accept documentation after the deadline pursuant to the "meet, or will meet" language in 42 C.F.R. §422.501(c)(2).[95] The Hearing Officer disagrees. The Hearing Officer notes that the regulation at 42 C.F.R. §422.501(c) allows CMS to set deadlines and dictate the form and manner of the application process. The language in 42 C.F.R. §422.501(c)(2), which states that the MA plan's "authorized individual must thoroughly describe how the entity and MA plan meet, or will meet, all the requirements in this part," pertains to the applicant's responsibility and does not limit CMS's authority to specify which application requirements must be met and when. Under this section, CMS has the discretion to determine which application requirements must be met by the application deadline and which requirements the applicant can attest will be met later. The Hearing Officer finds that CMS used

[91] CMS *MSJ* at Exhibit 2.
[92] SWH *Opening Brief* at 2-3.
[93] See 42 C.F.R. § 422.502(c)(2)(iii).
[94] SWH *Opening Brief* at 5-6.
[95] SWH *Reply Brief* at 7.

this authority to specify in the application instructions that applicants must meet and document licensure by the NOID deadline.[96]

The Hearing Officer acknowledges the fact that SWH is a fully-integrated D-SNP and that SNPs may submit contracts with the State later than the May 9, 2011 CMS application deadline. The Hearing Officer finds, however, that the State SNP contract deadline does not negate the licensure requirement for the MA application.[97]

Conclusion

The Hearing Officer grants CMS' Motion for Summary Judgment and finds that CMS' denial of SWH's SAE application for Kings, Queens, New York, and Bronx counties within the State of New York was consistent with the regulations at 42 C.F.R. §§422.501 and 422.502.

Brenda D. Thew
Hearing Officer

Date: July 13, 2011

[96] *See supra* text accompanying notes 4-6.

[97] The Hearing Officer acknowledges that SWH is a fully integrated special needs plan that covers the dual-eligible population in eight counties in New York and that its expansion to four additional counties is supported by a letter from the Medicaid Director and Deputy Commissioner of the Office of Health Insurance Programs, NYDOH. (SWH's *Opposition to MSJ* at 5. *See also* Exhibit 2.) The Hearing Officer, however, cannot consider these factors and must follow the statute, regulations and CMS instructions. (42 C.F.R. §422.688.)