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Office of the Attorney Advisor

SEP - 1 2015

VIA ELECTRONIC AND
FIRST CLASS MAIL

Bruce Romanello, CEO
Eden Health Plans
7925 NW 12th Street, Suite 324
Doral, FL 33126

Re: Eden Health Plan, Docket No. 2015 MA/PD App. 3

Dear Mr. Romanello:

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

cc: Kathryn A. Coleman, Director, CM/CMS
Cathy Baldwin, MCAG/CM/CMS

CENTERS FOR MEDICARE AND MEDICAID SERVICES

Decision of the Administrator

In the Matter of:	Claim for:
Eden Health Plan	**Medicare Advantage Plan** **Period Beginning: 2015**
Denial of Initial Application **Medicare Advantage** **Prescription Drug Organization**	**Review of:** **Docket No. 2015-MA/PD-App.3**
	Dated: July 31, 2015

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. §§422.660 and 423.650. The Administrator initiated review under 42 C.F.R. §§422.692(d) and 423.666(d). CMS submitted Comments requesting the Administrator's affirmation of the Hearing Officer's decision. Accordingly, this case is now before the Administrator for final administrative review.

ISSUE

The issue involves whether Eden Health Plan ("Eden" "Applicant" or "Plan") proved by a preponderance of the evidence that the Centers for Medicare and Medicaid Services' ("CMS") denial of its Medicare Advantage ("MA") plan application-on the grounds that it failed to document appropriate State licensure, provide adequate evidence of fiscal solvency, and demonstrate network adequacy-was inconsistent with regulatory requirements.

BACKGROUND AND 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 was appropriate since Eden's 2015 MA-PD Application No. 3 did not meet the program requirements by virtue of its failure to include the critical documentation, among other things, of State licensure, fiscal solvency, and CMS' network standards by the

established deadlines. Therefore, Eden did not meet its burden of proof, set forth at 42 CFR 422.660(b)(1), in demonstrating that CMS' determination was inconsistent with program contracting requirements.

On February 18, 2015, Eden submitted to CMS an initial MA application and application to offer a special needs plan. Eden's requested service area was comprised of eight counties in Florida. In its initial review, CMS noted several deficiencies with Eden's application, including failures to upload State licensure and documentation demonstrating fiscal solvency under State law, and failures in Eden's provider services network. CMS informed Eden of its deficiencies in the Deficiency Notice, e-mailed to the Plan on March 11, 2015. The Deficiency Notice also informed Eden that it had until March 17, 2015 to submit its revisions.

Although Eden timely submitted revisions to CMS, Eden continued to have deficiencies in State licensure, fiscal solvency, and its provider services network. Therefore, on April 20, 2015, CMS issued its Notice of Intent to Deny ("NOID"). The NOID gave Eden a final ten day cure period to correct any deficiencies in its application.

Eden submitted revised materials by the deadline, April 30, 2015; however, its deficiencies in State licensure, fiscal solvency, and its provider services network remained. Consequently, on May 27, 2015, CMS issued its formal denial of Eden's application.

On July 8, 2015, Eden filed a Motion for Summary Judgment with the Hearing Officer. CMS filed its Memorandum and Cross-Motion for Summary Judgment on July 17, 2015. Eden elected not to file an optional response.

The Hearing Officer stated that the regulations are clear that an applicant must have a State license, meet fiscal solvency requirements, and that its contracted network must meet CMS' standards. As such, Eden failed to meet these application requirements when it submitted its initial application, and failed to cure these deficiencies during the application process. The Hearing Officer found that Eden failed to submit the required materials by CMS' established deadlines.

The parties do not dispute these facts. In its Motion for Summary Judgment, Eden does not offer an argument or explanation regarding its deficiencies. Instead, Eden stated that the deficiencies will be corrected in the near term. Eden concedes that it did not meet CMS' requirements and essentially requested an extension to cure its deficiencies. The Hearing Officer found that CMS' denial was an appropriate exercise of its delegated authority. Therefore, Eden did not meet its burden of proof

in demonstrating that CMS' determination was inconsistent with controlling authority.

COMMENTS

The Plan requested review by the Administrator under 42 C.F.R. §422.692. The Plan submitted additional information in the form of an HMO Certificate of Authority issued by the State of Florida, Department of Insurance which authorizes the Plan to transact business as a Medicare Advantage plan in the State of Florida. The Plan also submitted documentation demonstrating compliance with CMS requirements for Network adequacy.

Regarding its fiscal solvency, Eden stated that it has invested approximately two million dollars to meet the requirements for application approval by both CMS and the State of Florida. Eden also stated that it has 14 employees and are in the process of adding an additional five that are in standby mode as they await final CMS approval. They are also in the midst of preparing marketing materials and model documents for open enrollment. Finally, Eden states that, once the Plan receives approval from CMS, it will be completely ready and meet compliance requirements for open enrollment by October 1, 2015.

Based on this submission, the Plan stated that it believes that it has met all of the MA-PD application requirements and request that the Administrator grant conditional approval for the Plan's MA-PD application.

CM recommended that the Administrator uphold the Hearing Officer's determination in support of CMS's application denial based on the continued failure of the applicant to meet CMS's requirements for State licensure, financial solvency and network adequacy. According to CMS, there are no policy grounds for overturning CMS's denial because there is adequate access in the service area. However, if the Administrator decides to modify the decision and approve Eden's MA-PD application, CMS recommends that the Administrator require Eden to upload their Health Services Delivery ("HSD") Provider and Facility tables to CMS' Health Plan Management System ("HPMS"), in order to demonstrate to CMS that Eden meets network adequacy standards under 42 C.F.R. §422.112.

Finally, CMS recommends the Administrator consider whether or not Eden has secured the required State licensure to meet licensing and financial solvency requirements under 42 C.F.R. §§422.384 and 422.501. CMS has not seen evidence that Eden has secured the proper State license. If the Administrator were to pursue this course of action, CM recommends that the Administrator require Eden to

demonstrate that it fully meets state licensing, financial solvency requirements and network adequacy standards no later than September 11, 2015.

DISCUSSION

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

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 Medicare Advantaged organizations (MAO) under Part C, and/or Prescription Drug Plans (PDP) under Part D.[1] The MA organizations may be a coordinated care plan, a combination of an MA medical savings account. (MSA) plan and a contribution into an MA MSA established in accordance with § 422.262, or an MA private fee-for-service plan. 42 C.F.R. §422.4.

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[2] 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

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[1] The regulations controlling Part C Applications are set forth at Title 42, Chapter IV, Part 422 and the corresponding regulations controlling Part D aspects of the Application are set forth at Part 423.

[2] *See* similar language for Part D at 42 C.F.R. §423.501. *See also* 42 C.F.R. 422.503(b)(2).

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.

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.

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.

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 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.

In addition, relevant to this case, 42 C.F.R. § 422.112 states in part that:

> (a) *Rules for coordinated care plans.* An MA organization that offers an MA coordinated care plan may specify the networks of providers from whom enrollees may obtain services if the MA organization ensures that all covered services, including supplemental services contracted for by (or on behalf of) the Medicare enrollee, are available and accessible under the plan. To accomplish this, the MA organization must meet the following requirements:
> (1) *Provider network.* (i) Maintain and monitor a network of appropriate providers that is supported by written agreements and is sufficient to provide adequate access to covered services to meet the needs of the population served. These providers are typically used in the network as primary care providers (PCPs), specialists, hospitals, skilled nursing facilities, home health agencies, ambulatory clinics, and other providers.
> (ii) *Exception*: MA regional plans, upon CMS pre-approval, can use methods other than written agreements to establish that access requirements are met.
> (2) *PCP panel.* Establish a panel of PCPs from which the enrollee may select a PCP. If an MA organization requires its enrollees to obtain a referral in most situations before receiving services from a specialist, the MA organization must either assign a PCP for purposes of making the needed referral or make other arrangements to ensure access to medically necessary specialty care.
> (3) *Specialty care.* Provide or arrange for necessary specialty care, and in particular give women enrollees the option of direct access to a women's health specialist within the network for women's routine and preventive health care services provided as basic benefits (as defined in § 422.2). The MA organization arranges for specialty care outside of the plan provider network when network providers are unavailable or inadequate to meet an enrollee's medical needs.

CMS requires applicants to demonstrate compliance with 42 C.F.R. §422.112, among other things, by submitting HSD Tables through Health Plan Management System or HPMS.[3] CMS established an online application process for both Part C and Part D plans called the 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 CMS network review is done largely through an automated tool within HPMS that compares the network data submitted by each applicant against standardized criteria and generates two reports accessible within the system to reflect where the applicant stands with respect to meeting the standardized criteria. The criteria assessed were minimum numbers of providers and facilities within a certain time and distance, which are based on market share assumptions for new applicants. Time and distance requirements are based on providers/facilities type and type of geographic area. Applicants are able to review their network after uploading their Provider and Facility tables, before the deadline for submission of tables.

Further, in addition to meeting State fiscal and certification requirements, 42 C.F.R. § 422.384 states that:

> Financial plan requirement. (a) *General rule.* At the time of application, an organization must submit a financial plan acceptable to CMS. (b) *Content of plan.* A financial plan must include—
> (1) A detailed marketing plan;
> (2) Statements of revenue and expense on an accrual basis;
> (3) Cash-flow statements;
> (4) Balance sheets;
> (5) Detailed justifications and assumptions in support of the financial plan including, where appropriate, certification of reserves and actuarial liabilities by a qualified actuary; and

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[3] *See also* CMS Exhibit A, November 11, 2014 "Release of Contract Year 2016 Medicare Advantage Health Services Delivery Guidance and Reference Tables"; Exhibit B, "CY MA HSD Provider and Facility Specialty and Network Criterion Guidance"; Exhibit C, "HSD Instructions for CY 2016 Applications."

> (6) If applicable, statements of the availability of financial resources to meet projected losses.

Under 42 C.F.R. §§422.503(b)(1) and 422.501(c), any entity seeking to contract as an MA organization ("MAO") must fully complete all parts of a certified application in the form and manner required by CMS. CMS requires that applications be submitted through HPMS and in accordance with the instructions and guidelines that CMS may issue. Applicants must demonstrate that they meet qualifications including appropriate State licensure, sufficient administrative capability to oversee the plan offerings, the capacity to enroll and dis-enroll beneficiaries, and an ability to offer sufficient medical services to their enrollees. With regard to medical services, an applicant must demonstrate it "maintain[s] and monitor[s] a network of appropriate providers that is supported by written agreements and is sufficient to provide adequate access to covered services to meet the needs of the population served."

The regulations at 42 C.F.R. §422.502 specify 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.

However, if an applicant fails to correct all of the deficiencies, under the timeframes set forth at 42 C.F.R. §422.502(c), CMS will issue the applicant a Denial of the Application consistent with 42 C.F.R. §422.502(c)(3).[4]

In this case, the Plan's application to become a Medicare Advantage Organization was denied because the Plan did not provide several of the required documents by the deadline iincluding demonstrating it had the necessary Certification of Authority and State Certification from the State of Florida; fiscal solvency; and the necessary network sufficiency. The Plan anticipated certification as a risk bearing entity, however, it experienced a significant delay from the State of Florida to certify the Plan as a risk bearing entity for Medicare Advantage. The Plan stated that it was in

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

possession of both these documents at the time of the Administrator review. In addition, the Plan submitted documentation showing a 100 percent passing rate for the CMS Network adequacy requirements.

According to the Plan, there have been a number of entities placed in receivership over the past few years within the State of Florida. This has led to a significant increase in the scrutiny of all applications. This caused the application period to be significantly longer than what was previously experienced for these plans. Hence, the Plan's application was under review with the State since February of 2015 and was finally approved on August 3, 2015 and was simultaneously granted approval to receive the State Certification of Authority.

The Administrator finds that in order to obtain approval of an application for a MA-PD contract, applicants must demonstrate that it meets the application requirements to enter into such a contract. The record shows the Plan failed to cure the deficiencies cited in CMS' NOID letter by the required deadline. The documentation provided by the Plan was insufficient to qualify for a MA-PD Contract since the Plan was not licensed and certified by the State of Florida as an HMO nor had the Plan demonstrated fiscal solvency and cured its network issues. Accordingly, the Administrator finds that the CMS denial and the Hearing Officer affirmation were proper and correct.

The Plan argued that it subsequently obtained and submitted all of the licensure documentation that were lacking in its original application, and requested that an exception be made for the untimely filing. The Administrator notes that the Plan raised the issue of the State backlog and increased scrutiny placed on health maintenance organizations within the State of Florida necessary for receiving MA certification and that it has completed this process as of this date. In addition, the Plan now maintains it can demonstrate fiscal solvency and has cured its network deficiencies.

The Administrator hereby exercises the broad contractual discretionary authority to allow the Plan to cure its application. Although the CMS denial and Hearing Officer's affirmation were proper and correct, in light of the facts and considerations presented in this specific case, the Administrator modifies the CMS denial and Hearing Officer decisions to allow the Plan the opportunity to cure the application with submission of any documentation relating to the State licensure, fiscal solvency and network requirements that are 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, the fiscal solvency documentation, or whether the Plan has met

the network requirements. 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 MA-PD application, will herein be incorporated as the final administrative decision under 42 C.F.R. §422.692 and 423.666.

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: 8/27/15

Patrick Conway, M.D.
Acting Principal Deputy Administrator
Centers for Medicare & Medicaid Services