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Office of the Attorney Advisor

SEP - 1 2010

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**VIA FACSIMILE AND
OVERNIGHT MAIL**

Vinod K. Shah, MD, MPH
Chief Operating Officer
American Health Alliance, Inc.
24035 Three Notch Road
Hollywood, MD 20636

Re: American Health Alliance, Inc., Docket No. 2010 C/D App 1

Dear Mr. Shah:

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:
American Health Alliance, Inc.	**Medicare Advantage Prescription Drug Plan** **Period Beginning: 2011** **Review of:** **Docket No. 2010-C/D-App-1** **H6037** **Dated: July 9, 2010**

This case is before the Administrator, Centers for Medicare & Medicaid Services (CMS), for review of the Hearing Officer's decision. The American Health Alliance, Inc., (the Applicant) timely requested Administrative review under 42 C.F.R. §§422.692(a) and 423.666(a). The Administrator initiated review under 42 CFR §§422.692 and 423.666. Comments were subsequently received from the Applicant requesting a reversal of the Hearing Officer's decision. Accordingly, this case is now before the Administrator for final administrative review pursuant to 42 C.F.R. §§422.692(d) and 423.666(d).

ISSUE

The issue involves whether CMS properly denied American Health Alliance's application to be a Medicare Advantage Prescription Drug (MA-PD) plan for the program year 2011.

HEARING OFFICER'S DECISION

The Hearing Officer granted CMS' Motion for Summary Judgment and found that CMS' denial of American Health's initial application was proper. The Hearing Officer found that, by the deadline for uploading information into the Health Plan Management System (HPMS), the Applicant failed to make a proper attestation and made numerous errors in submitting information concerning its organizational structure and the subcontractors performing various Part D functions, such that CMS could not assess the sufficiency of its arrangements to operate a Part D plan. The

Hearing Officer found these failures supported CMS' determination that the Applicant did not meet all of the program requirements under the regulations.

COMMENTS

The Applicant requested review by the Administrator under 42 C.F.R. §423.666(a). American Health argued that the cited deficiencies related to the Part D application represented clerical errors that can, and in some cases have been, efficiently resolved. The Applicant noted that no deficiencies were identified relating to the Part C Application. The Applicant disputed the judgment rendered regarding the relationships with first tier, downstream and related entities, and the contract between the Applicant and Envision Rx.

The Applicant contended that of the identified deficiencies, four have already been changed in the Part D Data or Business Functions Table in HPMS. The Applicant stated that in the final application upload on May 15, 2010 two formal signed contracts with MedStar and Envision were provided to the Part D reviewers. Each of these contracts identified the specific functions of the entities relative to Part D program requirements. Subsequent to the upload of these contracts, the appropriate changes were made in the Business Function Table of HPMS identifying the entities responsible for each of the four functions identified. Moreover, the Applicant argued that the Business Functions Table is designed to be updated outside the parameters of the application process when changes occur in contractual relations between the CMS contracted entity and the external third party delegated entities.

With regard to the attestation deficiency, the Applicant argued that it is clearly prepared to attest "yes" as opposed to "no" to the single item in the attestations referenced as recorded in error. The Applicant noted that it has, in previous documents, accepted and reported the attestation in the application as a typographical error and is fully capable and will be complying with the requirements. Finally, CMS' Notice of Denial stated that the executed contract with Envision was not for a term of at least the one-year contract period[1] and subsequently stated that the contracts are required to have a beginning date no later than November 15, 2010. The Applicant argued that although the effective date of the contract was the Envision contract began from the signing date on February 17, 2010, as Envision has been an integral part in the application process and is involved in the Part D formulary development, pharmacy network development, Part D component of the big process, and connectivity and beta testing of Part D data uploads. The Applicant contended that each of these functions represent a commitment to performance under the contract well in advance of the January 1,

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[1] *See* CMS Exhibit A.

2010 date when pharmacy claims are to be processed through Envision. The Envision contract is for a three year period, and has been given the permission for HPMS access from the Applicant's end since June 12, 2010.[2]

The Applicant argued that it was hoping to discuss the clerical errors at the hearing, but a summary judgment was issued. The Applicant concluded that the major substantive portions of the Part D application were submitted and approved, and that the administrative deficiencies, resulting from simple human error and oversight, have or could be resolved long before the establishment of a Part D contract between American Health Alliance and CMS.

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 Managed Care (MA) organizations under Part C, and/or Prescription Drug Plans (PDP) under Part D.[3] 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).

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 D application requirements at 42 C.F.R. §423.502(c)[4] states, in relevant part:

> (c) Completion of an application.
>
> > (1) In order to obtain a determination on whether it meets the requirement to become a Part D plan sponsor... the entity (the applicant) must complete a certified application, in the form and manner required by CMS,... "

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[2] *See* American Health Alliance, Inc. appeal to CMS, Exhibit 4.

[3] CMS has recently 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 (the year at issue) forward.

[4] *See* similar language for Part C at 42 C.F.R. §422.501.

> (2) The authorized individual must describe thoroughly how the entity is qualified to meet all requirements described in this part.

(Emphasis added).

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. §423.503 specifies the evaluation and determination procedures for applications to be determined qualified to act as a Part D sponsor, 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 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).[5]

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[5] 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. §423.503(c)(2).[6] The regulation at 42 C.F.R. §423.503 state, in relevant part:

> (b) *Notice of Determination.* * * *
>
> (1) *Approval of Application.* * * *
>
> (2) *Intent to Deny.*
>
> (i) If CMS finds that the applicant does not appear qualified to contract as a Part D plan sponsor 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 applicant may respond in writing to the issues or other matters that were the basis for CMS' preliminary finding and may 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 a Part D plan sponsor or has not provided enough information to allow CMS to evaluate the application, CMS denies the application.[7]

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[6] *See* similar language for Part C at 42 C.F.R. §422.502(c)(2).

[7] The preamble 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."

In the instant case, the Applicant timely filed an initial application to qualify as a MA-PD in February 2010, to offer CCPs in Calvert, Charles, Prince George's and St. Mary's counties in Maryland. CMS determined that the Applicant did not submit a complete Part D application and issued a deficiency notice to the applicant on March 19, 2010.[8] In this notice, CMS informed the Applicant that it had failed to correctly attest to certain requirement statements, presented inconsistent information in its Part D application and its HPMS file describing its organizational structure and contracting arrangements, and presented contracts that did not contain all of the provisions required under Part D. The Applicant also failed to execute the proper certification statement required in Section 4.0 of the Part D application. The Applicant responded to this deficiency notice on April 2, 2010, correcting one of the two attestations that were cited, but failed to correct the list of the entities responsible for performing Part D related functions on its behalf, leaving many of the deficiencies uncured.[9]

CMS issued a Notice of Intent to Deny the application by a letter, dated May 5, 2010, based on the remaining uncured deficiencies.[10] The Applicant responded to the notice on May 15, 2010, but none of the material that was uploaded into its HPMS Part D related functions list was responsive to its Part D application deficiencies. Rather, all of the submitted materials addressed deficiencies in its Part C application which CMS had identified on a separate notice.[11] CMS determined that the documentation necessary to show that this application was complete was not provided, and issued a MA-PD application denial notice based on the remaining application deficiencies.[12] CMS' denial was issued on June 7, 2010, the effective date of CMS revised regulations.[13] Accordingly, pursuant to the unambiguous directive in the Final Rule (and consistent with CMS' April 30, 2010 memorandum to applications,[14] CMS and the Hearing Officer applied this new burden of proof.

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[8] *See* CMS Exhibit B.

[9] Specifically, the organizational chart and history information provided in the application indicated that the Applicant would contract with TMG-Health, Inc. (TMG) to perform a series of functions. However, there was no indication of this in the Applicant's HPMS Part D-related functions lists, and the Plan failed to provide a copy of an executed contract with TMG. There were also discrepancies between the description of delegated functions in the Envision contract and those identified in the HPMS list of delegated key Part D functions. As part of its response to the deficiency notice, the Applicant left the Envision contact uncorrected.

[10] *See* CMS Exhibit C.

[11] *See* CMS Exhibit E.

[12] *See* CMS Exhibit E.

[13] *See supra,* note 1.

[14] *See* CMS Exhibit G.

Prior to June 7, 2010, for hearings involving determination regarding contract year 2010, the burden of proof regulations at 42 C.F.R. §422.660 and §423.650 required the sponsor "to demonstrate that it was in substantial compliance with the requirements" of the Part C and Part D programs.

American Health filed a timely request for a hearing concerning CMS' determination, and on June 18, 2010, CMS submitted a Memorandum and Motion for Summary Judgment in support of its denial. The Applicant subsequently submitted a response requesting relief from the deficiencies in the application denial and a hearing brief.

The Administrator notes that in order to obtain approval of an application for a MA-PD contract, applicants must demonstrate that they meet the application requirements to enter into such a contract. The record shows the Plan failed to cure, or adequately explain, all of the deficiencies cited in CMS' Intent to Deny letter. Specifically, there were several deficiencies found in the Plan's application, and the first deficiency concerns the attestation. The MA-PD application contains sets of statements shown in a series of tables concerning Part D program requirements to which organizations must attest. The applicants are clearly advised at the top of each table that they "must attest 'yes' to each of the following qualifications to be approved for a Part D contract." However, the Applicant attested "no" to the statement at Section 3.2.5, Item A.3 concerning the use of Prescription Origin Codes in the submission of its prescription drug event data to CMS. With respect to this requirement, the Applicant even acknowledged that it made an error in recording a "no" in this section of the application, and is fully ready and capable to attest yes, and comply with the requirements.

The remaining deficiencies occurred within the relationships with first tier, downstream, and related entities. The HPMS application instructions at Section 3.1.1, Item B requires that each applicant provide a chart showing its structure of ownership, subsidiaries, and business affiliates, and a chart that clearly depicts the placement of the Part D operations within its legal entity. The MA-PD application at Section 3.1.1, Item C, requires applicants to upload into HPMS a list that identifies the entities with which it will contract to perform Part D-related functions on its behalf. The instructions for the subsequent Item D then direct the applicant to provide copies of executed contracts with each first tier, downstream, and related entities it will use to carry out each of the functions listed in the function chart. CMS relies on applicants maintaining consistency between the chart in Item C and the materials provided in response to Item D, so that the agency can assess whether the contents of each contract accurately reflect the functions each subcontractor has agreed to perform on behalf of the applicant.

The record shows that there were several inconsistencies between the Applicant's HPMS list of subcontractor functions and the provisions of its contract with Envision. The Applicant also submitted a chart showing its organization structure and business relationships and a discussion of its organization history in response to Section 3.1.1.B of the MA-PD application. The Applicant stated that TMG would be performing enrollment/disenrollment, claims management, member services, fulfillment, and IT services on behalf of the Applicant, and the organization chart shows the same information. However, the Applicants list of subcontractors in HPMS fails to mention TMG, and indentifies other entities as performing the functions ascribed to TMG. Moreover, the Applicant failed to submit an executed contract with TMG. The record in this case shows that the Applicant initially planned to utilize TMG as a third party administrative management entity for various functions in its Part D plan, and thus, identified TMG both in the organization history and organization chart it submitted in response to Item B. However, it was unable to reach an agreement with TMG and instead signed a contract with MedStar, to perform the administrative functions initially associated with TMG. The Applicant indicated that it uploaded the MedStar contract into the HPMS by the May 15, 2010 deadline, but acknowledged that it failed to make the associated changes in the part D Function Chart or in its organization chart. The Applicant stated that subsequent to the upload of contract, the appropriate changes were made in the Business Function Table of HPMS identifying the entities responsible for each of the functions listed in the deficiency notice. [15] Moreover, the Applicant argued that the Business Function Table is a table designed to be changed outside the timeframes of the application process, and was updated relative to the uploaded contract.

The remaining deficiency concerned the contract between the Applicant and Envision. CMS' Notice of Denial stated that the executed contract with Envision was not for a term of at least the one-year contract period. The Applicant's June 24, 2010 response and hearing brief provided a copy of the contract, and indicates in Section 5.1 that the term of the contract was for a period of three years. The contract it executed with Envision, an organization identified as performing negotiation with prescription drug manufacturers, development and maintenance of a pharmacy network, and maintenance of a pharmacy and therapeutic committee, was entered into on February 17, 2010 for an effective date of January 1, 2011. CMS subsequently submitted a Memorandum and Motion for Summary Judgment, stating that the MA-PD application at Section 3.1.1, Item D, No. 7, requires that contracts between an applicant and any of its subcontractors for services used in preparation for the delivery of Part D benefits during the upcoming contract year have a term starting no later than November 15, 2010. The Applicant's brief did not address

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[15] *See* Applicant's Comments, dated August 24, 2010.

CMS' position. The Hearing Officer found that additional information would be needed to address this issue, however, there was no need to reach this issue, as the other errors in the application already precluded the application from being approved.[16] The Applicant provided a copy of the contract and Section 5.1 indicates that the term of the contract was for a period of three years.[17] The Applicant further explained that Envision has been an integral part of the application process and the contract began from the date of the signing, on February 17, 2010, as the functions Envision carried out represent a commitment to performance under the contract well in advance of the effective date when pharmacy claims are to be processed through Envision.[18]

Ultimately, American Health Alliance, Inc. failed to show it made a proper attestation by the application deadline and made numerous errors in submitting information concerning its organizational structure and subcontractors performing various Part D functions, such that CMS could not assess the sufficiency of its arrangements to operate a Part D plan. The totality of the discrepancies reasonably caused CMS to question whether the Applicant had in fact made final, binding arrangements within its own organization and with the subcontractors responsible for the operations of its Part D plan. Corrections should have been timely submitted by the Applicant in response to CMS' Intent to Deny letter, as the burden falls on the Applicant to show that it was in compliance with the stated requirements at the time of the application.

Thus, the Administrator finds that CMS and the Hearing Officer correctly found that the Application did not properly submit the required materials for approval of its MA-PD application. The record shows that the Applicant did not have valid documentation in place by the May 15, 2010 deadline, to cure the deficiencies cited by CMS and meet the application requirements. Moreover, the Applicant received enough information to complete a successful application and was given two opportunities with instructions to cure its deficiencies. However, the Administrator also finds that the Applicant's unique and extenuating circumstances combined with the benefit and best interest of the population served by the Applicant warrants the modifying of the Hearing Officer's decision to allow the Applicant to cure the remaining administrative deficiencies of its original application.[19]

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[16] *See* Hearing Officer Decision, page 11.

[17] *See* Applicant's Appeal to CMS, Exhibit 4.

[18] *See* Applicant's Appeal to CMS, Letter page 3.

[19] The Applicant's service area includes a county that, among other things, has a significantly low Medicare Advantage penetration percent. The county has the lowest Medicare Advantage penetration rate in Maryland and also amongst the lowest Medicare Advantage penetration rate of all counties in the United states

In this particular case, a review of the written arguments provided by the Application demonstrates that of the identified deficiencies, four have already been changed in the Part D Data or Business Functions Table in HPMS. With regard to the other deficiencies, the Applicant argued that it is clearly prepared to attest "yes" as opposed to "no" to the single item in the attestations referenced as recorded in error. The Applicant is also prepared to upload the already edited organizational table indicating MedStar as the third party delegated entity for administrative management services, as opposed to TMG-Health.

Accordingly, the Administrator finds that the CMS denial and the Hearing Officer affirmation were proper and correct. However, in light of the special and unique policy considerations presented in this specific case, the Administrator modifies the CMS denial and the Hearing Officer decision to allow the Applicant another opportunity to demonstrate that it meets the relevant MA-PD regulatory application requirements. The Administrator further holds that, in allowing the Applicant to correct the deficiencies in the application process at this time, the Applicant must promptly submit the documentation required by CMS within the timeframes CMS orders in light of this decision.

(excluding Alaska). Less than one percent of all counties in the United States have a similar Medicare penetration rate, with even significantly fewer counties having such a low rate and a population in excess of 10,000. This factor, amongst other factors, such as a significantly well below average number of plans for Medicare beneficiaries to chose from, indicates that the Medicare beneficiary population in this county may be best served at this time with an additional choice in MA/PD plans.

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: 8/31/10 Marilyn Tavenner

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