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Office of the Attorney Advisor

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SEP - 3 2013

Mike Frank, President
Blue Cross Blue Shield Montana, Inc.
560 North Park Avenue
Helena, MT 59601

Re: Blue Cross Blue Shield of Montana, Inc, Docket No. 2013 MA/PD App. 5

Dear Mr. Frank:

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: Danielle R. Moon, J.D., M.P.A., Director, CMS
Cynthia G. Tudor, Ph.D., Director, CMS

CENTERS FOR MEDICARE AND MEDICAID SERVICES

Decision of the Administrator

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PROVIDER REIMBURSEMENT REVIEW BOARD

In the Matter of:	**Claim for:**
Blue Cross Blue Shield of Montana, Inc.	**Medicare Advantage Prescription Drug Plan** **Period Beginning: 2014**
Denial of Initial MA-PD Application	**Review of:** **Docket No. 2013-C/D-App-05** **H0107** **Dated: August 12, 2013**

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). Further comments were received from the Plan requesting reversal of the Hearing Officer's decision. Comments were also received from the CMS Center for Medicare (CM) stating that the CMS Hearing Officer's decision was appropriate and within the scope of its authority. Accordingly, this case is now before the Administrator for final administrative review.

ISSUE AND CMS HEARING OFFICER'S DECISION

The issue is whether CMS' denial of Blue Cross Blue Shield of Montana, Inc. (BCBSMT's) initial application to offer a Medicare Advantage-Prescription Drug (MA-PD) plan for contract year 2014 was a proper application of its contracting authority.

The Hearing Officer found that BCBSMT did not prove by a preponderance of the evidence that CMS' determination was inconsistent with the regulations at 42 CFR 423.502 and 423.503. The Hearing Officer sustained CMS' decision to deny the application based on the fact that the Plan failed to "describe the payment" of services arrangement with its subcontractor and the final amount of payment to the Plan's subcontractor could not be determined.

COMMENTS

The Plan requested review by the Administrator under 42 C.F.R. §422.692. The Plan submitted comments stating that the Administrator should use its broad discretion to reverse the Hearing Officer's decision because it is in the best public policy interests of Montana's Medicare beneficiaries. The Plan argued that reversal of the Hearing Officer's decision would enable the Plan to offer enhanced choice, the availability of high quality plans, and affordable premiums compared to most of the MA-PD coordinated care plans that are currently available.

The Plan reiterated that the MA-PD application did meet CMS requirements and that the CMS Part D denial was improper. The Plan stated that the decision of the CMS Hearing Officer was incorrect because the Plan did meet the requirement that its contract with HCSC describes the payment terms. The Plan points out that the HCSC contract constitutes a cost contract and the payment terms contained in the Statement of Work create a mechanism by which parties may add payment elements to the contract as needed. Moreover, the Plan stated that, as of August 1, 2013, following State regulatory approval, BCBSMT now operates as a division of HCSC, rendering moot the need for the BCBSMT/HCSC contract, the accompanying Statement of Work, and any additional pricing agreement that caused the denial. As such, the Plan requests that the contract be awarded directly to HCSC or facilitate a novation of the contract to HCSC.

CMS submitted comments stating that it did not object to the Administrator taking public policy considerations into account under the Administrator's broad discretionary authority in this case. CMS requested however that, should the Administrator find that public policy considerations support a determination that BCBSMT be permitted to offer an MAPD in Montana in 2014, the finding should also acknowledge that the Hearing Officer correctly determined that BCBSMT did not meet the requirements set forth in the application to become a Part D sponsor.

CMS acknowledged that BCBSMT coordinated care plan, if offered for 2014 enrollees in the most rural of 39 counties, would have a major impact on the population's access to Medicare managed care options and choice. Of the 39 proposed service area counties, the 13 least populated counties have either one or no MA-PD coordinated care plans available to their Medicare eligible residents. Further, CMS noted that the BCBSMT characterization of the quality of the plans it has offered is accurate.

CMS also requested that the Administrator make any finding in favor of BCBSMT conditional upon the organization submitting to CMS the materials necessary to demonstrate that it has cured the deficiencies identified in the denial of its

application to become a Part D sponsor. Specifically, CMS requested that BCBSMT be required to submit a contract between itself and HCSC that complies with the requirements described in the Part D application.

DISCUSSION

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

The Secretary is authorized to contract with entities seeking to offer MA and MA-PD benefits. As reflected at 42 CFR 422.400 and 422.503(b), the Secretary has delegated this contracting authority to CMS, which has established the general provisions or entities seeking to qualify as MA-PD plans.

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 Advantage (MA) organizations under Part C, and/or Prescription Drug Plans (PDP) under Part D.[1] The regulation at 42 C.F.R. §422.4(c)(1) requires that MA organizations offering coordinated care plans (CCPs) must offer Part D benefits in the same service areas. Under 42 C.F.R. §422.4(c)(1)(iv) defines a specialized MA plan for special needs individuals (SNP) as including any type of coordinated care plan that meets CMS' SNP requirements and exclusively enrolls special needs individuals as defined by 42 C.F.R. §422.2 of this subpart. All MA plans wishing to offer a SNP are required to be approved by the National Commission of Quality Assurances (NCQA), effective January 1 2012.

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 regulations at 42 C.F.R. 423.502 and 423.50 set forth the application and general requirements for an entity to qualify to contract as a sponsor of a Part D plan.

Organizations submit applications to CMS, in which the organization must document that it has a provider network in place that meets CMS requirements.[2] Plan sponsors are permitted to utilize subcontractors (referred to as first tier,

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[1] CMS has revised and/or clarified some of the regulatory text governing the Part C and Part D programs. See, e.g., Proposed Rule, 74 Fed. Reg. 54634 (Oct. 22, 2009) and final Rule, 75 Fed. Reg. 19678 (April 15, 2010); 77 Fed. Reg. 22072, April 12, 2012 (final rule with comment period.)

[2] *See* 42 CFR 422.501(c)(2) and 423.502(c)(2).

downstream and related entities) to fulfill some of their Part D responsibilities. These relationships are defined by regulation at 42 CFR 423.4 as follows:

> *Downstream entity* means any party that enters into a written arrangement, acceptable to CMS, with persons or entities involved with the Part D benefit, below the level of arrangement between a Part D plan sponsor (or applicant) and a first tier entity. These written arrangements continue down to the level of the ultimate provider of both health and administrative services.
>
> *****
>
> *First tier entity* means any party that enters into a written arrangement, acceptable to CMS, with a Part D plan sponsor or applicant to provide administrative services or health care services for a Medicare eligible individual under Part D.
>
> *****
>
> *Related entity* means any entity that is related to the Part D sponsor by common ownership or control and
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> (1) Performs some part of the Part D plan sponsor's management functions under contract or delegation;
> (2) Furnishes services to Medicare enrollees under an oral or written agreement.

The Part D regulations at 42 CFR 423.505(i) set out specific provisions that pertain to contracts with such entities:

> (1) Relationship with first tier, downstream, and related entities (1) <u>Notwithstanding any relationship(s) that the Part D plan sponsor may have with first tier, downstream, and related entities</u>, the Part D sponsor maintains ultimate responsibility for adhering to and otherwise fully complying with all terms and conditions of its contract with CMS. (Emphasis added)

Pursuant to the regulations at 42 CFR 423.505(i) (2) (i) – (iv) the Part D sponsor agrees to require all first tier, downstream and related entities to comply to the provisions contained therein and under paragraph (j) "to include in the contract other terms and conditions as CMS may find necessary and appropriate in order to implement requirements in this part."

Consistent with the 42 CFR 423.502(c), requirement tha6t MA-PD applications must be completed "in the form and manner required by CMS," CMS requires the electronic submission of MA-PD applications via the Health Plan Management (HPMS) program. Applicants are required to identify all first tier, downstream, and related entities that will be carrying out specific functions on their behalf. The 2014 MA-PD Contract Solicitation (the Contract Solicitation), at Section 3.1.1, requires plans to identify these entities in a "First tier, Downstream and Related entities Function Chart."[3] This solicitation also instructs applicants to document their relationship with other entities that would be involved with plan administration. This requirement was stated as follows:

> D. Except for SAE [Service Area Expansion] applicants, upload copies executed contracts, fully executed letters of agreement, administrative services agreements, or intercompany agreements (in word-searchable .pdf format) with each first tier, downstream or related entity identified in [the Function Chart] and with any first tier, downstream or related entity that contracts with any of the identified entities on the applicant's behalf. Unless otherwise indicated, each and every contract must:
>
> 1. Clearly identify the parties to the contract (or letter of agreement). If the applicant is not a direct party to the contract (e.g., if one of the contracting entities is entering into the contract on the applicant's behalf), the applicant must be identified as an entity that will benefit from the services described in the contract.
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> *****
>
> 5. Describe the payment the first tier, downstream, or related entity will receive for performance under the contract, if applicable.
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> *****

[3] Solicitation for Applications for Medicare Prescription Drug Plan 2014 Contracts (Contract Solicitation) at 26. See CMS June 20, 2013 brief, Exhibit 7, (Complete version available at: www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/Downloads/2014-Part-D-Application.pdf)

> Each complete contract must meet all of the above requirements when read on its own.[4]

Furthermore, the Solicitation requires applicants to provide certain information via HPMS in order to assist CMS in the review process. Section 3.1.1.E of the Solicitation instructs applicants as follows:

> Except for [Service Area Expansion] applicants, upload electronic lists of the contract/administrative service agreement/intercompany agreement citations demonstrating that the requirements of Section 3.1.1.D are included in each contract and administrative service agreement. Submit these data by downloading the appropriate spreadsheet found in HPMS that mimics the crosswalk in Appendix X of this solicitation. If the applicant fails to upload crosswalks for executed agreements and contract templates, CMS cannot guarantee that the applicant will receive notice of any deficiencies in the contracting documents as part of this courtesy review.[5]

In addition, the Appendix X of the Contract Solicitation is titled "Crosswalks of Section 3.1.1.D Requirements in Subcontracts submitted as Attachments to Section 3.1.1."[6] A version of this crosswalk, bearing the same title, is also available to applicants via the HPMS portal. In the HPMS version of the crosswalk, plans are instructed as follows:

> Applicants must complete and upload in HPMS the following chart for each contract/administrative services agreement submitted under Section 3.1.1D. Applicants must identify where specifically (i.e., the pdf page number) in each contract/administrative services agreement the following elements are found.[7]

The HPMS crosswalk consists of a three-column table, applicable portions of which are to be completed by the applicant. The first two columns, which are titled "Section" and "Requirement," feature contract items and terms that mirror the requirements set forth at Contract Solicitation Section 3.1.1.D, with the final column, titled "Location in Subcontract by Page number and Section" requiring

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[4] Contract Solicitation at 27-29 (emphasis in original omitted).

[5] Contract Solicitation at 29.

[6] *See* Transcript of Oral Hearing, dated July 12, 2013, CMS Hearing Exhibit B.

[7] *See* Transcript of Oral Hearing, dated July 12, 2013, CMS Hearing Exhibit B. HPMS Crosswalk of Section 3.1.1D Requirements in Subcontracts (HPMS Crosswalk) at 1 (emphasis in original omitted).

applicants to specify the corresponding subcontract clause for each requirement and its location within the uploaded file. This includes the need to specify the contract item that addresses "The payment the first tier, downstream, or related entity will receive for performance under the contract, if applicable."

After receiving a MA-PD application, CMS makes a determination as to whether the applicant organization meets all of the relevant program requirements. This determination is based solely on information contained in the application or obtained by CMS through methods such as onsite visits.[8] Before final disapproval of an MA-PD application, CMS provides a formal "Notice of Intent to Deny," which sets out the basis for the denial and gives the applicant ten days to cure the deficiencies in its application. 42 CFR 423.503(c)(2) provides that if CMS does 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 that the applicant does not appear qualified to contract as a Part D plan sponsor or has not provided CMS enough information to allow CMS to evaluate the application, CMS will deny the application.

In February 2013, BCBSMT filed an application to qualify as a MA-PD plan sponsor for the 2014 contracting year. In its Part D application, BCBSMT indicated that it would contract with a variety of other entities to perform Part D-related functions on its behalf. Following the initial review of BCBSMT's application, CMS determined that the application was not appropriately filed. In particular, CMS noted that certain of BCBSMT's contracts with first tier, downstream, and or related entities did not meet program requirements. On March 28, 201, CMS issued a notice (Deficiency Note) that outlined the BCBSMT's application shortcomings.

CMS noted that, BCBSMT was not named as a party to any of the submitted contracts. Based on its review of the application submission, including the parties to each of the downstream contracts included in the application, CMS surmised that BCBSMT would be contracting with either Health Care Services Corporation (HCSC) or Health Care Services Corporation (HSCS) Insurance Services Company, which would act as a first tier entity to engage downstream contractors on BCBSMT's behalf. However, CMS was not able to determine which entity the Plan had chosen to fill this role. CMS entered HSCS Insurance Services Company into its internal tracking system, but a "programming error" caused the company's name to be omitted from the Deficiency Note.

On April, 2013 BCBSMT responded to the Deficiency Note by providing additional contract materials for CMS review. These materials cured a number of deficiencies, but did not include the contract between BCBSMT and either HCSC or HCSC

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[8] 42 CFR 423.503(a).

Insurance Services Company. On April 26, 2013, CMS issued a formal Notice of Intent to Deny with a 10 day cure period, based on the lack of a contract between BCBSMT and a first tier entity (either HCSC or HCSC Insurance Services Company), along with several other outstanding deficiencies.

On May 6, 2013, the Plan responded to the Notice of Intent to Deny by providing additional materials for CMS review. These materials included a contract between BCBSMT and HCSC (the "HCSC Contract").[9] The HCSC Contract is comprised of a Master Services Agreement, as well as three attached exhibits which includes Exhibit A as a "Statement of Work." The "Statement of Work", Exhibit A, contained the following clause under the subheading "Project Fees and Expenses": that "the parties will establish the fees and expense for this project by a separate agreement." The "HPMS crosswalk" explained the payment terms of this contract by noting, "Per page 21, Section 6, payment will be determined upon performance."[10]

CMS reviewed the HCSC Contract and determined that it did not include finalized payment terms. Therefore, CMS determined that the BCBSMT application did not contain the full agreement between the Plan and HCSC. On May 31, 2013 CMS issued a final, formal denial of the Plan's application (the Denial Letter), because the contract the Plan submitted for a key Part D function did not contain the full underlying agreement.. The contract the Plan submitted for key Part D functions did not contain final payment terms.

In this case, the Hearing Officer properly found that BCBSMT's did not meet the required burden of proof. Despite the Plan's arguments regarding CMS' use of HSCISC as the incorrectly named contractor, the Administrator finds that the core issue in this case is whether the Plan's application adequately addresses the requirements that Part D subcontracts "describe the payment the first tier, downstream, or related entity will receive for performance under the contract." In this case, the Hearing Officer properly found that the Plan application failed to provide the necessary elements to be an enforceable contract under the MA-PD program. The Hearing Officer also properly concluded that the record demonstrates that the Plan was not prejudiced by the clerical error in the name of the first tier contractor and the action by the Plan clearly indicated it was aware of the contract at issue prior to the denial date.

As properly determined by the Hearing Officer, the Plan's Statement of Work indicates that the parties "will negotiate payment through a separate agreement."

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[9] CMS June 20, 2013 Brief, Exhibit 6, HCSC Contract.

[10] *See* Transcript of Oral Hearing, dated July 12, 2013, CMS Hearing Exhibit B.

The "separate agreement" was not submitted as part of the Plan's application and the general statement made by the Plan indicting that the specific terms were "forthcoming" in a future agreement is insufficient and inadequate in order to satisfy the Part D application requirements. The final financial payment terms are a material element of a first tier, downstream or related entity contract (in this case the HCSC Contract), and without such terms the agreement between HCSC and BCBSMT cannot be seen as a complete, final and enforceable for purposes of the MA/PD program. Importantly, such a payment requirement is necessary under the Medicare Advantage/Part D program as CMS must be assured that the Plan has made adequate arrangements to perform key Part D functions in order to protect Medicare beneficiaries.[11]

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 that the documentation provided by the Plan was insufficient to qualify for a MA-PD Contract since the HCSC contract did not include the required financial payment terms. Accordingly, the Administrator finds that the CMS denial and the Hearing Officer affirmation were proper and correct.

The Plan, however, argued that allowing for an MA-PD contract would enable the Plan to offer enhanced choice, increase the availability of high quality plans, and affordable premiums compared to most of the MA-PD coordinated care plans that are currently available in Montana. CMS concurred in stating that a contract for 2014 would have a significant major impact on the population access to Medicare managed care options and choice. The Administrator finds compelling public policy arguments with respect to the beneficiary related value of the Plan's services provided to populations within the State of Montana.

The Administrator hereby exercises the broad contractual discretionary authority to allow the Plan to cure its application.[12] The Administrator finds that the CMS denial and Hearing Officer's affirmation were proper and correct. However, in light of the special and unique facts and public policy considerations presented in this specific

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[11] Consequently, while general contract law as applied to specific cases may be instructive, such cases are not controlling as the issue in this case involves the contractual requirements CMS determines are necessary for an organization to participate in the Federal Medicare Advantage/Part D program.

[12] 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."

case, the Administrator modifies the CMS and Hearing Officer decisions in order to allow the Plan the opportunity to cure the application with submission of documentation CMS requires for the Applicant to demonstrate full compliance with the provisions previously found deficient.

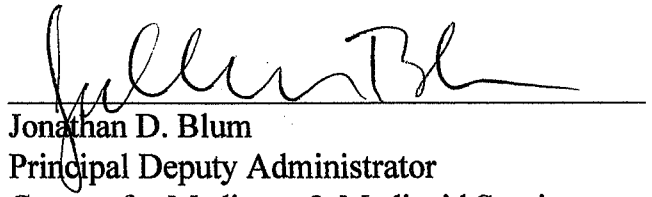
The Administrator holds that, in allowing the Applicant to cure its application, the Applicant must promptly submit the documentation required by CMS within the timeframes CMS orders. The CMS determination on that documentation and on whether the application subsequently meets all the requirements necessary to qualify the Applicant to contract with CMS under the MA-PD program, will herein be incorporated as the final administrative decision in this case under 42 CFR 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: 8/29/2013



Jonathan D. Blum
Principal Deputy Administrator
Centers for Medicare & Medicaid Services