CENTERS FOR MEDICARE AND MEDICAID ION SERVICES
HEARING OFFICER DECISION

IN THE MATTER OF:

Blue Cross Blue Shield of Montana, Inc.	*	
	*	DOCKET NO. 2013 MA/PD APP. 5
Denial of Initial Application to Qualify as a	*	
Medicare Prescription Drug Organization	*	
Contract Year 2014, Contract No. H0107	*	
	*	

I. JURISDICTION

This appeal is provided pursuant to 42 C.F.R. §§ 422.660 and 423.650. The Centers for Medicare and Medicaid Services (CMS) Hearing Officers designated to hear this case are the undersigned, Benjamin R. Cohen and Michael J. McDougall.

II. ISSUE

Whether CMS' denial of Blue Cross Blue Shield of Montana's (BCBSMT, or the Plan) initial application to offer a Medicare Advantage – Prescription Drug (MA-PD) plan for contract year 2014 was a proper application of its contracting authority.

III. PROGRAM BACKGROUND

The Medicare Advantage (MA or Part C) program offers Medicare beneficiaries the option of receiving health care benefits through a privately-operated coordinated care delivery system.[1] Medicare Part D offers an outpatient prescription drug benefit to Medicare beneficiaries.[2] Organizations that are approved to offer MA-PD benefits are required to maintain a provider network that ensures "adequate access to covered services" for its plan enrollees in each operative service area. This network must include a variety of providers, including primary care physicians, specialists, and hospitals.[3] In addition, MA organizations must offer a Part D benefit in the service areas in which they offer a Part C benefit.[4]

The Secretary of the United States Department of Health & Human Services (the Secretary) is authorized to contract with entities seeking to offer MA and MA-PD benefits.[5] Through

[1] *See* 42 U.S.C. § 1395w-21 *et seq.*
[2] *See generally*, 42 U.S.C. § 1395w-112. *See also* 42 C.F.R. Part 423 (Medicare Part D regulations).
[3] 42 C.F.R. § 422.112(a)(1).
[4] 42 C.F.R. § 422.4(c)(1). The Medicare Advantage Part C regulations (42 C.F.R. § 422 Subparts K and N) and Part D regulations (42 C.F.R. § 423 Subparts K and N) which govern applications, contract determinations, and appeals are analogous.
[5] 42 U.S.C. § 1395w-27.

regulation, the Secretary has delegated this contracting authority to CMS, which has established the general provisions for entities seeking to qualify as MA-PD plans.[6]

Potential MA-PD organizations submit applications to CMS, in which the organization must document that it has a provider network in place that meets CMS requirements.[7] Plan sponsors are permitted to utilize subcontractors (referred to as first tier, downstream and related entities) to fulfill some of their Part D responsibilities. These relationships are defined by regulation at 42 C.F.R. § 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.
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> * * * * *
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> *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.
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> * * * * *
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> *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;[8]

The Part D regulations at 42 C.F.R. §423.505(i) set out specific provisions that pertain to contracts with such entities:

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

[6] 42 C.F.R. §§ 422.400 *et seq.*, 422.503(b) *et seq.*
[7] *See* 42 C.F.R. §§ 422.501(c)(2); 423.502(c)(2).
[8] Identical language is also used at 42 C.F.R. § 423.501.

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 Soliciation), at Section 3.1.1, required plans to identify these entities in a "First tier, Downstream and Related entities Function Chart."[9] This solicitation also instructed applicants to document their relationship with other entities that would be involved with plan administration. This requirement was stated as follows:

> D. Except for [Service Area Expansion] applicants, upload copies of 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 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:
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> 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.
>
> * * * * *
>
> 5. Describe the payment the first tier, downstream, or related entity will receive for performance under the contract, if applicable.
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> * * * * *
>
> Each complete contract must meet all of the above requirements when read on its own.[10]

MA-PD applications must be completed "in the form and manner required by CMS."[11] Presently, CMS requires the electronic submission of MA-PD applications via the Health Plan Management System (HPMS) program.[12] Furthermore, the Solicitation requires applicants to

[9] Solicitation for Applications for Medicare Prescription Drug Plan 2014 Contracts (Contract Solicitation) at 26. *Available at* http://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/Downloads/2014-Part-D-Application.pdf (last visited August 8, 2013). *See also* CMS Initial Memorandum, Exhibit 7 (excerpts of Contract Solicitation).
[10] Contract Solicitation at 27-29 (emphasis omitted).
[11] 42 C.F.R. § 423.502(c)(1).
[12] CMS Initial Memorandum at 2.

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.[13]

Appendix X of the Contract Solicitation is titled "Crosswalks of Section 3.1.1D Requirements in Subcontracts submitted as Attachments to Section 3.1.1". 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.[14]

The HPMS crosswalk consists of a three-column table, portions of which are to be completed by the applicant. The two left-hand columns, which are titled "Section" and "Requirement," feature a number of contract items and terms that mirror the requirements set forth at Contract Solicitation Section 3.1.1.D.[15] The final column, titled "Location in Subcontract by Page number and Section" calls on applicants to specify the clause of each subcontract, and location within the uploaded file, that addresses the corresponding requirement. Of particular relevance to the present case, the crosswalk requires plans 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."[16]

After receiving a MA-PD application, CMS makes a determination as to whether the applicant organization meets all of the relevant program requirements.[17] This determination is based solely on information contained in the application or obtained by CMS through methods such as onsite visits.[18]

[13] Contract Solicitation at 29.
[14] CMS Hearing Exhibit B, HPMS Crosswalk of Section 3.1.1D Requirements in Subcontracts (HPMS Crosswalk) at 1 (emphasis in original)
[15] Id.
[16] *Id.* at 2.
[17] 42 C.F.R. § 423.503(a)(2).
[18] 42 C.F.R. § 423.503(a)(1).

Before final disapproval of an MA-PD application, CMS shall provide 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. The regulatory requirement for curing a Part D application is stated at 42 C.F.R. § 423.503(c)(2)(ii - iii) as follows:

> (ii) Within 10 days from 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 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.

If CMS denies a MA-PD application, the applicant organization is entitled to a hearing before a CMS hearing officer.[19] The regulation at 42 C.F.R. § 423.650(b)(1) dictates that "the applicant has the burden of proving by a preponderance of the evidence that CMS' determination was inconsistent with the requirements of [42 C.F.R. §§ 423.502 and 423.503]."[20]

IV. FACTUAL AND PROCEDURAL BACKGROUND

In February 2013, BCBSMT filed applications 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.[21] Following the initial "courtesy" review of BCBSMT's application, CMS determined that the application was not appropriately filed. In particular, CMS noted that certain of BCBSMT's purported contracts with first tier, downstream and related entities did not meet program requirements. Accordingly, on March 28, 2013, CMS issued a notice (the Deficiency Notice) that outlined these shortcomings.[22]

CMS noted that, at this stage, 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 with the application, CMS surmised that BCBSMT would be contracting with either Health Care Services Corporation (HCSC) or Health Care Services Corporation Insurance Services Company (HCSCISC), which would act as a first tier entity to

[19] 42 C.F.R. § 423.650.
[20] *See supra* p. 1. (The regulations at 42 C.F.R. §§ 423.503 and 423.503 establish the Part D contract application requirements and review procedures).
[21] CMS Initial Memorandum, Exhibit 1, List of Entities Performing Part D Functions on BCBSMT's Behalf.
[22] CMS Initial Memorandum, Exhibit 5, Courtesy Deficiency Notice Issued by CMS to BCBSMT (Deficiency Notice).

engage downstream contractors on BCBSMT's behalf.[23] However, CMS was not able to determine which entity the Plan had chosen to fill this role. CMS entered HCSCISC into its internal tracking system, but a "programming error" caused the company's name to be omitted from the Deficiency Notice.[24] The deficiency relating to the first tier contract, as issued in the March 28th notice, read as follows:

> Your organization did not upload an executed contract with one of the first tier, downstream or related entities that is performing a Part D function on your behalf. The first tier, downstream or related entity referenced is [blank][25]

On April 5, 2013 BCBSMT responded to this notice by providing additional contract materials for CMS review. These materials cured a number of deficiencies, but did not include a contract between BCBSMT and either HCSC or HCSCISC.[26] Internally CMS continued to refer to the missing contract as being between BCBSMT and HCSCISC.[27]

On April 26, 2013, CMS issued a formal Notice of Intent to Deny, based on the lack of a contract between BCBSMT and a first tier entity (either HCSC or HCSCISC), along with several other outstanding deficiencies.[28] This notice contained the following clause:

> Your organization did not upload an executed contract with one of the first tier, downstream or related entities that is performing a Part D function on your behalf. The first tier, related or downstream entity referenced is HCSC Insurance Services Company[29]

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).[30] The HCSC Contract is comprised of a Master Services Agreement, as well as three attached exhibits. Of those, Exhibit A is defined as a "Statement of Work".

The Master Services Agreement refers to HCSC as the "Services Vendor" and includes the following clause (Section 4) under the subheading "PAYMENT":

> 4.1 Payment. Services Vendor shall invoice BCBSMT monthly in accordance with the time schedules and other terms set out in the Exhibits that are attached to and incorporated into this Agreement. BCBSMT will pay undisputed, clear and complete invoices within forty-five (45) days after their receipt. Payment to

[23] CMS Initial Memorandum at 3. ("At this stage, the absence of BCBSMT as a party to any of these contracts led CMS to believe that BCBSMT was using HCSCISC or HCSC as a first tier entity to contract with downstream entities on its behalf, but it was unclear which entity it had chosen.").
[24] Id.
[25] CMS Initial Memorandum, Exhibit 5, Deficiency Notice at 2.
[26] CMS Initial Memorandum at 4.
[27] Id.
[28] Id.
[29] CMS Initial Memorandum, Exhibit 2, Notice of Intent to Deny at 2.
[30] CMS Initial Memorandum at 4.

> Services Vendor for the Professional Services provided to BCBSMT shall not include deductions for Federal Income Tax or Social Security. Services Vendor shall be responsible for the payment of all taxes of whatever kind or nature in connection with the performance of the Professional Services. Unless otherwise set out in an Exhibit A Attachment, BCBSMT shall reimburse Services Vendor for costs and expenses only in accordance with BCBSMT standard policies.[31]

The Statement of Work, Section 6 (Section 6) attached to the Master Services Agreement as Exhibit A, consists of the following clause, under the subheading "PROJECT FEES & EXPENSES":

> The parties will establish the fees and expense for this project by a separate agreement.[32]

The HPMS crosswalk for this HCSC Contract, as submitted by the Plan, indicated the payment terms of the agreement by noting, "Per page 21, Section 6, payment will be determined upon performance."[33]

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). This denial was based on the following two deficiencies, which were listed under the subheading "Contracting":

- The contract your organization submitted for a key Part D function does not contain the full underlying agreement. The contract referenced is with HCSC Insurance Services Company.

- The contract your organization submitted for key Part D functions does not contain finalized payment terms. The contract referenced is with HCSC Insurance Services Corporation.[34]

The denial notice did not identify any other application deficiencies.

On June 5, 2013, BCBSMT requested the current appeal. Following an initial round of briefs by the parties, the Plan filed a Motion for Summary Judgment on June 26, 2013. This motion was opposed by CMS and denied by Hearing Officer Benjamin Cohen on July 2, 2013.

On July 12, 2013 a live hearing was held at the CMS Office of Hearings in Baltimore, Maryland.

[31] CMS Initial Brief, Exhibit 6, Contract Between BCBSMT and HCSC (HCSC Contract) at § 4.1.
[32] HCSC Contract, Exhibit A; Statement of Work (Statement of Work) at § 6.
[33] CMS Hearing Exhibit B, HPMS Crosswalk at 2.
[34] BCBSMT Initial Brief, Exhibit 1, Denial Notice.

V. PREHEARING CONTENTIONS

The respective parties in this proceeding have each filed multiple briefs containing various assertions and responses. A chronological presentation will best frame these developments.

A. BCBSMT Initial Brief

In its Initial Brief, submitted on June 13, 2013, BCBSMT focuses its contentions on CMS' misidentification of the Plan's first tier contractor within the Denial Letter. The Plan notes that the denial indicates two contract deficiencies, both of which note that "The contract referenced is with HCSC Insurance Services Company."[35]

The Plan indicates that it was confused by the reference to HCSCISC:

> Because BCBSMT does not have a contract with HCSC Insurance Services Company and has not represented to CMS that HCSC Insurance Services Company will be performing any Part D functions on behalf of BCBSMT, BCBSMT did not understand the basis for this decision.[36]

The Plan indicates that it contacted CMS to address this confusion, and the agency responded via e-mail on June 7, 2013, again indicating that the deficient contract was between BCBSMT and HCSCISC.[37]

The Plan notes that no contract exists between it and HCSCISC, but instead offers a diagram indicating that HCSC was contracted to act on BCBSMT's behalf as a first tier entity. BCBSMT contends that CMS is, or should be aware, that HCSCISC and HCSC are separate legal entitites. The Plan also notes that its application did not indicate that HCSCISC would be acting on its behalf in any capacity.

The Plan summarizes its arguments, noting that:

> Because HCSC Insurance Services Company is not performing any delegated functions on behalf of BCBSMT, BCBSMT had no obligation under the Part D solicitation or the Part 423 (Part D) regulations to have a contract with HCSC Insurance Services Company, much less have that contract include those terms that may be required of agreements with delegated entities.[38]

BCBSMT concludes its initial brief by claiming that it "was not able to clarify these matters with CMS prior to the [Denial Letter] being issued as the reasons for denial had not been specifically raised prior to CMS issuing its denial."[39] The Plan contends that CMS erred in this case, and on that basis the denial should be overturned.

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[35] BCBSMT Initial Brief at 2 (citing BCBSMT Exhibit 1, Denial Notice).
[36] Id.
[37] *Id.* (citing BCBSMT Initial Brief, Exhibit 2, E-Mail Response from CMS).
[38] BCBSMT Initial Brief at 3.
[39] *Id.* at 4.

B. CMS Initial Memorandum

CMS responded to the Plan's Initial Brief with its Initial Memorandum, submitted on June 20, 2013. In this filing, CMS contends that the "clerical error" in naming HCSCISC instead of HCSC in the Denial Letter had no effect on CMS' review of the application.

CMS indicates that, during its first review of the Plan's application, it was unclear whether BCBSMT was contracting with HCSC or HCSCISC as a first tier entity. HCSCISC was entered in the agency's internal review tool.[40] However, CMS notes that the name of the contracting entity did not impact the analysis of the underlying contract:

> When a contract between HCSC and BCBSMT was finally provided during the third and final round of review, the review tool was not updated to reflect the fact that HCSC, and not the similarly named HCSCISC, was the name of the contracting entity. This clerical oversight played no role in CMS' ultimate denial of BCBSMT's application, which was based on deficiencies CMS identified in the HCSC contract.[41]

CMS further states that its incorrect naming of HCSCISC within the Denial Letter did not prejudice BCBSMT. As evidence, CMS notes that, following the Notice of Intent to Deny—which mistakenly identified HCSCISC as the deficient contract—the Plan provided a copy of the correct HCSC Contract for review.[42] CMS contends that this demonstrates that BCBSMT understood which contract was at issue.

Furthermore, CMS notes the nature and timing of deficiencies raised in the Denial Letter illustrate the lack of prejudicial harm to the Plan:

> Based on the similarity in names, its response to the Notice of Intent to Deny in providing the appropriate missing contract, and the fact that no contract with HCSCISC had been provided, BCBSMT knew or should have known that the substantive deficiencies cited [in the Denial Letter] concerned its contract with HCSC.[43]

Furthermore, while CMS notes that the Plan did not challenge the substance of the application denial, the agency addresses the review that led to the final determination. CMS points out that the Contract Solicitation requires all applicants to describe the Part D functions to be delegated to other entities, and to provide full copies of all contracts executed to this end. CMS notes that these contracts must contain certain elements, including "describing the payment the first tier, downstream[,] or related entity will receive for its performance under the contract, if applicable."[44]

[40] CMS Initial Memorandum at 4.
[41] Id.
[42] Id.
[43] *Id.* at 6.
[44] *Id.* (referencing Contract Solicitation, § 3.1.1D.5).

CMS offers a rationale for requiring applicants to describe the payment terms:

> Payment or consideration is a key element of any contract. Unless there are finalized payment terms, it is unclear that any meeting of the minds has occurred between the parties and therefore unclear whether an enforceable contract exists. Unless the applicant provides a contract that, on its face, is final and enforceable, CMS cannot determine whether a contract meets its requirements or be assured that the applicant has made adequate arrangements to perform key Part D functions.[45]

CMS notes that the HCSC Contract did not contain finalized payment terms, but rather states "The parties will establish the fees and expense for this project by a separate agreement."[46] CMS indicates that no other agreement was provided, and it therefore has no way to determine whether the parties have reached a final agreement regarding the services HSCC is to provide for the Plan. CMS further argues that the lack of a fixed payment term means that BCBSMT has no legally binding relationship with the downstream entities with which HCSC was to contract.[47]

CMS concludes by noting that BCBSMT's failure to provide a full contract that meets program requirements means that the Plan was unable to demonstrate its qualifications to act as a Part D sponsor.

C. BCBSMT's Motion for Summary Judgment and Reply Brief

On June 26, 2013, the Plan both moved for Summary Judgment of its appeal and offered a separate Reply Brief to address CMS' contentions.

In moving for Summary Judgment, the Plan contended that the undisputed facts of the case demonstrate that CMS' denial of its MA-PD application was erroneous. The Plan noted that the officially-stated reason for denying the application was BCBSMT's failure to provide a fully-executed contract with HCSCISC. However, the Plan argued, since it did not engage HCSCISC to act on its behalf, "there is currently no dispute that BCBSMT was not required to produce an agreement with HCSC Insurance Services Company. Therefore, the basis for CMS' denial is invalid and must be overturned."[48]

BCBSMT argued that the reason for CMS' misidentification of the HCSC Contract is of no import. Furthermore, the Plan argued that the degree of prejudice it experienced as a result of this error is not relevant to its Summary Judgment motion.

BCBSMT then addressed the issue of whether CMS' conduct prejudiced the Plan. BCBSMT contended that it was confused by the March 28th Deficiency Notice, particularly the previously-

[45] CMS Initial Memorandum at 6.
[46] Id.
[47] *Id.* at 7.
[48] BCBSMT Motion for Summary Judgment at 3.

noted deficiency that did not identify the contract at issue.[49] BCBSMT asserted that it contacted CMS to address this confusion:

> On April 1, 2013, two representatives of BCBSMT spoke with . . . the designated CMS contact on these issues, by telephone to obtain clarification of this issue. In response, [the CMS contact] stated that this Statement was a CMS systems glitch and the template deficiency message spit out by HPMS should be ignored.[50]

The Plan claimed that it relied on this information and did not make further inquiry into the issue during the time period between the Deficiency Notice and the issuance of the Notice of Intent to Deny. The Plan offered that a series of subsequent e-mail communications between BCBSMT and CMS demonstrate this fact, as the discussions address other outstanding application concerns but does not breach the topic of the incomplete deficiency.[51]

The Plan argued that these communications served to compound the impact of CMS' errors during the review process. BCBSMT contended that Deficiency Notice, Notice of Intent to Deny, and Denial Letter failed to identify the deficient contract (with HCSC) that led to CMS' final determination.

> While BCBSMT fully believes that its contract with HCSC was in full compliance with CMS' Part C and Part D requirements, it is also clear that if erroneous instructions had not been given by CMS on April 1 to disregard the [blank deficiency], BCBSMT would have further pursued and clarified this matter and through that process would have understood that a deficiency lay with the omission of the contract with HCSC, BCBSMT's actual first tier contractor, and would have clarified for CMS, <u>at that time and before the Notice of Intent to Deny was issued</u>, the name of that entity.[52]

BCBSMT claimed that the problems with its application could have been easily addressed if the Plan had not detrimentally relied on its communications with CMS. The Plan argued that this further demonstrated that CMS' denial of its MA-PD application was not made in accordance with the applicable rules, and that Summary Judgment was proper.

In its Reply Brief, filed along with the Summary Judgment Motion on June 26, 2013, BCBSMT addresses contentions raised in CMS' Initial Memorandum. At the outset, the Plan reiterates its belief that, in order to prevail in this appeal, it "need only show that CMS' conclusions in the notice of denial that was <u>actually issued</u> are inconsistent with CMS regulations."[53] However, BCBSMT also uses the Reply Brief to addresses the substantive issues of this dispute.

The Plan frames these underling concerns as follows:

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[49] BCBSMT Motion for Summary Judgment at 4. *See also* CMS Initial Memorandum, Exhibit 5, Deficiency Notice at 2.
[50] BCBSMT Motion for Summary Judgment at 4.
[51] *Id.* *See also* BCBSMT Motion for Summary Judgment, Exhibit 3 (E-Mail Communication).
[52] *Id.* (emphasis in original).
[53] BCBSMT Reply Brief at 2 (emphasis in original).

> The issues to be discussed for purposes of this reply brief are whether BCBSMT met the requirement in the Part D application that it "Describe the payment" that HCSC will receive under its Agreement with BCBSMT and whether BCBSMT supplied a contract with its application sufficient to constitute a complete, final, and enforceable agreement with a first-tier entity to provide Part C and Part D administrative services to BCBSMT.[54]

The Plan argues that CMS' construction of this requirement, which calls on plans to provide "finalized payment terms," exceeds what is established within the regulations and instructions.[55] The Plan believes that CMS' interpretation is incorrect and not in line with previous determinations by the agency.[56]

BCBSMT contends that language of the application requirement merely states that applicants must simply "describe the payment" terms of any subcontracts[57] The Plan argues that this does not require that such terms be "finalized," as stated by CMS, but rather "speaks more generally to a description of the payment, if applicable."[58]

BCBSMT notes that within Section 3.1.1D of the Contract Solicitation, there are 19 issues that need to be addressed within any applicant's submitted subcontracts. The Plan notes that 14 of these provisions directly correspond with a regulatory requirement, and that the remaining five are not mandated by regulation, but rather "pertain to assuring that the delegated entity has committed to performing Part D functions on behalf of the Part D sponsor." This concept, the Plan offers, indicates that CMS' interpretation requiring "finalized terms" is not properly rooted in the regulatory scheme.[59]

BCBSMT posits that CMS' interpretation is also at odds with the requirements of the Part C program, as demonstrated within the Medicare Managed Care Manual, which does not explicitly require payment terms within each contract.[60] The Plan argues that it would be inequitable for a Part C application to be approved, but a MA-PD application denied, based on the same contract.

However, the Plan also contends that the payment terms of the HCSC Contract meet CMS requirements. BCBSMT notes that the HCSC Contract consists of multiple elements, including

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[54] *Id.* at 3.
[55] *Id.* at 4 (citing CMS Initial Memorandum at 6, *supra* note 44).
[56] BCBSMT Reply Brief at 5. The Plan notes that the Hearing Office found for the applicant in 2010, *In the Matter of Arkansas Blue Cross and Blue Shield*, Docket No. 2010 C/D App. 3. In that case, BCBSMT contends that the Hearing Officer determined that a contract clause stating that a first tier entity would "make its books and other records available" satisfied the requirement that records be made directly available to CMS.
[57] BCBSMT Reply Brief at 5 (citing Contract Solicitation at 28).
[58] *Id.*.
[59] *Id.* at 6.
[60] *Id.* (citing Medicare Managed Care Manual, Chapter 11), *available at* http://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/mc86c11.pdf (last visited August 12, 2013)).

a Master Services Agreement and Statement of Work. The Plan offers that CMS based its determination that the HCSC Contract lacked payment terms solely on the Statement of Work, Section 6, which indicates that payment will be determined by a separate agreement.

BCSMT contends that the purpose of Section 6 was "to signify the contemplation and intention of the parties to be able to supplement and add to the existing [Statement of Work] terms, including those relating to payment and fees."[61] Furthermore, the Plan notes several clauses within the HCSC Contract that address the payment that HCSC will receive. First the Plan notes that Section 2.1 of the Master Services Agreement identifies both the services that will be required under the contract as well as the "fees, expenses and any other compensation BCBSMT will pay." In addition, this clause also contemplates a system by which Exhibit A, the Statement of Work could "be supplemented or added from time to time by mutual agreement of the parties."[62] The Plan further notes that, according to Section 4 of the HSCC Contract, BCBSMT is to "reimburse HCSC its 'costs and expenses' in accordance with BCBSMT's policies."[63]

BCBSMT points to other contract clauses, before concluding that,

> These provisions clearly satisfy the application requirement that [the HCSC Contract] describe payment to first-tier, downstream and related entities. This conclusion is not undermined by the fact that the parties decided not to include in the executed [HCSC Contract] specific payment amounts for the functions to be performed by HCSC beyond a reimbursement of its costs.[64]

Furthermore, the Plan contends that the contract, on its face, creates reciprocal rights and obligations that constitute sufficient consideration to form a contract under applicable state law. The Plan notes that the parties to the agreement, are in the midst of an "impending acquisition" by which HCSC will assume ownership of BCBSMT, and, "[i]t is inconceivable to speculate under these circumstances that HCSC and BCBSMT do not consider the [HCSC Contract] final and enforceable."[65]

Finally, the Plan voices policy and equitable concerns in support of its contract application, noting the potential benefits of additional plan options for MA enrollees in the Montana marketplace.

D. CMS' Reply Brief Opposing Summary Judgment

On July 2, 2013, CMS filed a Reply Brief that opposed the Plan's Motion for Summary Judgment. CMS argued that BCBSMT raised disputed factual issues in its Motion. CMS challenged the Plan's contention that the error in the Deficiency Notice and Denial Letter prejudiced BCBSMT. Furthermore, CMS opposed the Plan's account of its efforts to seek clarification following the issuance of the Deficiency Notice on March 28, 2013. "CMS disputes

[61] BCBSMT Reply Brief at 7.
[62] *Id.* at 8 (citing HCSC Contract, § 2.1).
[63] *Id.* (citing HCSC Contract, § 4.1).
[64] *Id.* at 9.
[65] *Id.* at 10.

both that this advice [to disregard the incomplete deficiency citation] was given and the characterization of the conversation contained in the motion for summary judgment."[66]

The existence of a factual dispute led the Hearing Office to deny the Motion for Summary Judgment on July 5, 2013.[67]

VI. HEARING AND ORAL ARGUMENTS

On July 12, 2013, a live hearing was held with all parties in attendance. Presenting for BCBSMT was Mr. Mark Joffe, Esq.. Responding on behalf of the CMS Medicare Drug Benefit Group was Mr. Scott Nelson. The proceeding was conducted by the undersigned hearing officers.

Prior to the parties' opening statements a summation of the prehearing proceedings and filings was read into the record. This summary included a cursory explanation of the reasoning behind the denial of BCBSMT's Motion for Summary Judgment.

As the appellant bearing the burden of proof in this proceeding, BCBSMT was required to present its case first. At the outset of this presentation, the Plan indicated that it would not pursue the line of argument that culminated in its Motion for Summary Judgment. Speaking for the Plan, Mr. Joffe stated:

> Blue Cross Blue Shield of Montana has decided to focus its attention in this manner and at this hearing on the substantive issue of whether it has been in full compliance with the requirements themselves under Part D. Accordingly, we are no longer--while we believe the notice was defective and while we believe we were prejudiced by the conversation with Ms. Spaccarelli, at this time at this hearing, we are no longer pursuing those arguments, those positions.[68]

When asked to clarify whether the Plan was fully declining to pursue these contentions or simply opting not to present testimony, Mr. Joffe replied, on behalf of BCBSMT, "We're dropping the contention."[69]

With BCBSMT no longer pursuing the contentions set forth in its Motion for Summary Judgment, the hearing focused on the issue of whether the HCSC Contract met CMS program requirements. BCBSMT framed the issue as follows:

> [T]he ultimate issue is, does the language in this document, this contract, meet that specific requirement regarding describing payment. So that's a legal issue.[70]

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[66] CMS Reply Brief at 3.
[67] *See* Order Denying Summary Judgment, July 5, 2013.
[68] Transcript of July 12, 2013 Hearing (Tr.) at 8-9.
[69] Tr. at 10. This point was later reiterated by Mr. Joffe, when in revisiting the facts in dispute he noted that "[BCBSMT is] providing this information for background but we're no longer arguing the underlying substance." Tr. at 23.
[70] Tr. at 63.

During oral argument concerning this legal issue, both parties largely reiterated their prehearing contentions. BCBSMT argued that CMS read the contract "payment terms" requirement too narrowly, and that the essence of the requirement is that the parties demonstrate a "legal commitment to participate in the program and to continue for a year."[71] The Plan's representative explained that the parties to the HCSC Contract had such an aim, and this intent is particularly relevant in light of HCSC's pending acquisition of BCBSMT.[72] This commitment was also evident in the composition of the Plan's subcontracts, as each of the ten subcontractors identified by the Plan as performing Part D functions on its behalf had contracted with HCSC prior to the application submittal. The Plan summarized this configuration, noting "So basically, [BCSBMT]'s intention was to develop a collaborative agreement to be able to access the arrangements that HCSC had developed in order to implement the program." [73]

The Plan argued the terms of the Master Services Agreement essentially establish a "cost contract" that can be augmented by the Statement of Work payment clause:

> What was intended here [in the Statement of Work, Section 6] is if the parties wanted to establish an additional payment component, margin cost plus *X*, some manner of payment in addition to the base cost, they could.[74]

Accordingly, BCBSMT stated that the phrase, "The parties will establish the fees and expenses for this project by a separate agreement" was discretionary in nature.[75] However, the Plan also conceded that the language of Section 6 was "not drafted as clearly as it should be."[76]

CMS disputed this interpretation of the contract terms. First, CMS noted that the use of the term "will" within the Statement of Work, Section 6, indicated that the payment and fees for the HSCS contract had not been agreed to at the time of contract execution. In addition, CMS noted that in its application crosswalk the Plan indicated that the payment terms for the HCSC Contract were contained in the Statement of Work, Section 6.[77]

Furthermore, CMS argued that the terms of the Master Service Agreement, Section 4 and the Statement of Work, Section 6 cannot be read in tandem as establishing the payment terms of the contract. CMS noted that the introductory language of Section 4 contains the phrase, "unless otherwise set out in an Exhibit A attachment." Therefore, CMS argued, the presence of an Exhibit A "trumps or negates anything that follows the introductory clause," including the cost

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[71] Tr. at 25.
[72] Tr. at 12 ("Last September, HCSC and Blue Cross Blue Shield of Montana announced an arrangement where HCSC would be acquiring the assets of Blue Cross Blue Shield of Montana."). The relationship between HCSC and BCBSMT was not raised or explained during the application process.
[73] Tr. at 17-18. 126-127.
[74] Tr. at 42. At Hearing, BCBSMT's representative opined that the amount of payment to be added to the cost component was "miniscule," (Tr. at 126) and estimated to be "one to two percent" of the contract value (Tr. at 130). Furthermore, given the nature of collaboration between BCBSMT and HCSC, counsel offered that "whether they decide to add a margin component is insignificant." (Tr. at 127). BCBSMT declined to call a witness to attest these figures. *See* Tr. at 130.
[75] Tr. at 58-59.
[76] Tr. at 137.
[77] Tr. at 79. At hearing CMS introduced BCBSMT's crosswalk for the HCSC Contract as Hearing Exhibit B. *Supra* note 33.

language cited by BCBSMT.[78] CMS sees the language at Section 6 as indicating that the parties "clearly contemplated or acknowledged that there were to be payments of some sort, and that was to be negotiated later."[79]

VII. DETERMINATION

The Hearing Officer finds that the Plan has not met its burden in demonstrating that CMS' denial of BCBSMT's MA-PD application was inconsistent with the program regulations at 42 C.F.R. §§ 423.502 and 423.503.

As a preliminary matter, the Hearing Officer notes that the procedural issues raised by BCBSMT were withdrawn from consideration at the live hearing. These issues, therefore, played no role in reaching the determination on this appeal. Nonetheless, it is noted that the Hearing Officer believes that the Plan's prehearing briefs did not demonstrate that BCBSMT was materially prejudiced by the procedural defects in the application review process. In addition, by failing to provide a first tier contract at the outset of its application submission in February 2013, the Plan forfeited an opportunity for additional CMS review. While the initial Deficiency Notice, issued on March 28th, erroneously omitted the name of HCSC, the Plan knew, based on the composition of its subcontractors, that HCSC was acting as a first tier entity on its behalf. In fact, the stated intent of BCBSMT was "to be able to access the arrangements that HCSC had developed in order to implement the [Part D plan] program." [80] Accordingly, the Plan knew, or should have known, that the submission of a contract with HCSC was a required element of the MA-PD application. Furthermore, the Plan was also on notice that its failure to timely submit all contracts and appropriate contract crosswalks from the outset of the application submission process would limit CMS' initial review, and thus impact any deficiency notice that was subsequently issued.[81]

Next, the incorrect identification of HCSCISC on the April 26th Notice of Intent to Deny and May 31st Denial Letter did not actually prejudice the Plan. This is evidenced by the fact that, on May 6th, BCBSMT provided the proper HCSC contract in response to the Notice of Intent to Deny, which incorrectly listed HCSCISC as the deficient contract. The Plan's action demonstrates that BCBSMT understood CMS' expectations.[82] Again, it is evident that the Plan knew that a contract with HCSC was a vital component of its application. Therefore, when the Denial Letter referenced a contract with HCSCISC that did not exist, the Plan could not plausibly claim that it misunderstood the basis for the determination.

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[78] Tr. at 83.
[79] Tr. at 92.
[80] *Supra* note 73.
[81] *Supra* note 13. The Contract Solicitation instructs applicants that, "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." The Hearing Officer notes that the Plan's failure to provide a first tier contract in February may have led to the reference to HCSCISC in the April 26th and May 31st notices.
[82] *Supra* notes 30 and 42.

The question before the Hearing Officer is whether the HCSC Contract as submitted within the Plan's MA-PD application, meets CMS program requirements. In particular, the parties agree that the core question on appeal is whether the HCSC Contract adequately addresses the requirement that Part D subcontracts "Describe the payment the first tier, downstream, or related entity will receive for performance under the contract, if applicable."[83]

BCBSMT argues that, in totality, the HCSC Contract constitutes a "cost contract" and that the payment terms of Section 6 of the Statement of Work create a mechanism by which the parties may add payment elements to the contract as needed.[84]

CMS argues that the payment provision at in the Master Services Agreement does not apply when, as here, there is a payment term contained in the incorporated Exhibit A Statement of Work. Because the Statement of Work, at Section 6, indicates that the parties "will" negotiate payment through a separate agreement, CMS contends that the payment terms of the contract are not adequately described in the submitted contract.

In a general sense, the parties offer competing visions as to the nature of payment terms that would be required in this sort of contract. At hearing, the Plan offered that an exchange of promised actions could suffice to create a legally enforceable agreement between BCBSMT and HCSC, and that the entirety of the HCSC Contract creates binding obligations on both parties. CMS argued that finalized, financial payment terms are a material element of the HCSC Contract, and without such terms the agreement between HCSC and BCBSMT is not a true, binding contract at all.

While the Plan contends that Section 6 of the Statement of Work was intended to establish a "cost plus" payment structure that builds on the payment clause at Section 4 of the Master Services Agreement, CMS' interpretation of these items was reasonable. First, as CMS noted the payment language at Section 4 of the Master Services Agreement is applicable, on its face, "Unless otherwise set out in an Exhibit A Attachment…." Next, within the Statement of Work, which was appended to the Master Services Agreement as an Exhibit A attachment, the parties agree that they "will establish the fees and expense . . . by a separate agreement." Despite the Plan's contentions to the contrary, the use of the word "will" in this clause is reasonably read to have the effect of creating an obligation to reach an agreement concerning payment, not an option to do so.[85] Under this construction the Master Services Agreement directs to the Statement of Work, which in turn directs to a separate agreement that, if executed, was not provided to CMS for review prior to the application deadline. The Contract Solicitation clearly required that "Each complete contract must meet all of the [program] requirements when read on its own."[86] The HCSC Contract, which references a "separate agreement" that was not submitted with its application, does meet this standard.

[83] *Supra* note 10 (emphasis added).
[84] It is noted that this construction is at odds with the HPMS Crosswalk submitted for the HCSC Contract, in which the plan indicated that the payment description was found in "Section 6" and that "payment will be determined upon performance." *Supra* note 14.
[85] At hearing, BCBSMT acknowledged that Section 6 was "not drafted as clearly as it should be." *Supra* note 76.
[86] *Supra* note 10.

In conclusion CMS properly read and applied its mandate requiring Part D applicants who contract with others to perform services to "describe the payment" in such subcontract. The Hearing Officer recognizes, and CMS conceded, that this mandate does not expressly require the submission of a fixed dollar figure.[87] Moreover, even in commercial transactions, a valid contract could hypothetically contain reciprocal "consideration" that is not monetary in nature. Nevertheless, it is clear that monetary payment is a core element of the subject HCSC Contract, and from CMS' application review perspective, at the time of the final submission deadline, the final amount of payment in this contract could not be determined.

VIII. CONCLUSION

Blue Cross Blue Shield of Montana did not prove by a preponderance of the evidence that CMS' determination was inconsistent with the regulations at 42 C.F.R. §423.502 and 423.503. CMS' decision to deny the application is sustained.

Benjamin R. Cohen
Hearing Officer
August 12, 2013

Michael J. McDougall
Hearing Officer
August 12, 2013

[87] *See* Tr. at 77.