CENTERS FOR MEDICARE AND MEDICAID SERVICES

Hearing Officer Decision

In the Matter of

Arkansas Blue Cross and Blue Shield	*	
	*	Docket No. 2010 C/D App 3
Denial of Initial Application, H8091	*	
	*	

ORDER GRANTING ARKANSAS BLUE CROSS AND BLUE SHIELD'S MOTION FOR SUMMARY JUDGMENT

Jurisdiction

This appeal is provided pursuant to 42 C.F.R. §423.650. The Centers for Medicare and Medicaid Services (CMS) Hearing Officer designated by the CMS Administrator to hear this case is the undersigned, Benjamin R. Cohen.

Issue

Whether CMS' denial of the Applicant's MA-PD initial application for calendar year 2011 was consistent with the requirements of 42 C.F.R. §§423.502 and 423.503.[1]

Statutory and Regulatory Background

The Social Security Act (SSA or the Act) authorizes CMS to enter into contracts with entities seeking to offer Medicare Advantage (MA) benefits (Part C) and Medicare outpatient prescription benefits (Part D) to Medicare beneficiaries. SSA §§1857 and 1860D-12. Pursuant to 42 C.F.R. §§422.500 and 423.500 et seq.,[2] CMS has established the general provisions for

[1] All of the deficiencies cited by CMS relate to the Part D portion of the application. CMS Memorandum and Motion for Summary Judgment, June 25, 2010 at 2.

[2] CMS has recently revised and/or clarified some, but not all 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 Final Rule states in part that "This final rule makes revisions to the regulations governing the Medicare Advantage (MA) program (Part C) and prescription drug benefit program (Part D) based on our continued experience in the administration of the Part C and D programs. The revisions strengthen various program participation and exit requirements; strengthen beneficiary protections; ensure that plan offerings to beneficiaries include meaningful differences; improve plan payment rules and processes; improve data collection for oversight and quality assessment, implement new policies and clarify existing program policy." The Rule is effective June 7, 2010 and applies from contract year 2011(the year at issue) forward.

entities seeking to qualify as Medicare Advantage-Prescription Drug (MA-PD) plans. 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. *See* 42 C.F.R. §§422.501 and 423.502.

The current regulation concerning the Part D application requirements at 42 C.F.R. §423.502 states, in relevant part:

> (c) Completion of an application.
>
> > (1) In order to obtain a determination on whether it meets the requirements to become a Part D plan sponsor, an entity, or an individual authorized to act for the entity (the applicant) must fully complete all parts of a certified application, **in the form and manner required by CMS**, . . .
> >
> > (2) The authorized individual must describe thoroughly how the entity is qualified to meet **all requirements** described in this part.

(Emphasis added).

CMS has established an online application process for both Part C and Part D plans called the Health Plan Management System (HPMS). All new applications and requests to expand service areas had to submit their applications through the HPMS by deadlines established by CMS. CMS provided training and technical assistance to plans in completing their applications and plan applications were evaluated solely on the materials they submitted into the HPMS by the deadline established by CMS.

The regulation 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. It states, in relevant 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 entity's 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 applicant meets **all the requirements** in this part.

(Emphasis added).[3]

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[3] In the preamble to the recent regulatory revision at 75 Fed. Reg. 19678, 19683 (April 15, 2010), CMS indicated that "we specifically proposed to make explicit that we will approve only those applications that

After an applicant files its initial application, CMS reviews the application, notifies the applicant of deficiencies and the applicant is given an opportunity to correct the deficiencies.

If the applicant fails to correct all of the deficiencies, CMS issues the applicant a Notice of Intent to Deny under the regulation at 42 C.F.R. §423.503(c)(2).[4] The regulations at 42 C.F.R. §423.503 state, in relevant part:

> (c) *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.[5]

If CMS denies an MA-PD applicant, the applicant has a right to a hearing before a CMS Hearing Officer under 42 C.F.R. §§422.660(b) and 423.650(b). The current Part D regulation at §423.650(b)(i), states, at hearing, the applicant has the burden of proving by a preponderance of the evidence that CMS' determination was inconsistent with the requirements of §§423.502 and 423.503.

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demonstrate that they meet all (not substantially all) Part C and Part D requirements." CMS also states that expecting applicants 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."

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

[5] The preamble to 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 § 422.650(b)(2) and § 423.660(b)(2) [sic §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."

The regulation at 42 C.F.R. §422.684(b) and 423.662(b) states that either party to the hearing may ask the hearing officer to rule on a motion for summary judgment.[6]

Specific Regulations and Other Rules Related to the Alleged Deficiencies

Part D sponsors are permitted to utilize subcontractors (referred to as first tier, downstream and related entities) to fulfill some of their Part D responsibilities. The Part D regulations at 42 C.F.R. §423.505(i) sets out specific contract provisions that pertain to contracts with the first tier, downstream and related entities. In this case, the following portion of the regulation is at issue.

> (i) *Relationship with first tier, downstream, and related entities*.
> (1) * * *
> (2) The Part D sponsor agrees to require all first tier, downstream, and related entities to agree that –
> (i) HHS, the Comptroller General, or their designees have the right to audit, evaluate, and inspect any books, contracts, records, and documentation of the first tier, downstream, and related entities involving transactions related to CMS' contract with the Part D sponsor. [7]
> (ii) * * *
> (3) All contracts and written arrangements between Part D sponsors and first tier, downstream, and related entities, must contain the following:
> (i) * * *
> (ii) * * *
> (iii) * * *
> (iv) A provision requiring the Part D sponsor's first tier, downstream, and related entities to produce upon request by CMS, or its designees, any books, contracts, records including medical records and documentation of the Part D sponsor, relating to the Part D program, to either the sponsor to provide to CMS, or directly to CMS or its designees.

The Hearing Officer notes that CMS provided its official regulatory interpretation in the Federal Register. The provision stated the following.

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[6] *See* 72 Fed. Reg. 68700, 68714, 68725 (December 5, 2007). The preamble to the Final Rule further explains that "In ruling on such a motion, we propose that the hearing officer would be bound by the CMS regulations and general instructions. Where no factual dispute exists, the hearing officer may make a decision on the papers, without the need for a hearing."

[7] In the recent changes to the regulations at 75 Fed. Reg. 19678, 19821 (April 15, 2010), this section was modified by adding language related to computer and other electronic systems including medical records. It now states, "HHS, the Comptroller General, or their designees have the right to audit, evaluate, and inspect any books, contracts, computer and other electronic systems, including medical records and documentation of the first tier, downstream, and related entities involving transactions related to CMS' contract with the Part D sponsor."

> We have chosen not to be proscriptive regarding whether first tier, downstream, and related entities must make their books and records available to us directly or through the Part D sponsor. It is our opinion that this is considered to be part of the negotiation process between the Part D sponsor and its first tier, downstream, and related entities. The provision must be clear as to whether or not the requested documentation is to be submitted through the Part D sponsor to us (or our designee(s)), or submitted directly to us (or our designee(s)). The parties could also decide to have such books and records made directly available to us, or our designee(s), through onsite access.

72 Fed. Reg. 68700, 68708 (Dec. 5, 2007) (Emphasis added).

As part of their applications, applicants must timely submit a Crosswalk of Citations of Section 3.1.1.D to location in their contracts of the required regulatory language. The CMS crosswalk language referring to Section 3.1.1D13 requests the location of:

> Language indicating that any books, contracts, records, including medical records and documentation relating to the Part D program will be provided to CMS or its designees or will be provided directly to CMS or its designees. 42 CFR §423.505(i)(3)(iv)

Factual and Procedural Background

In February 2010, Arkansas Blue Cross and Blue Shield, Inc. (the Applicant) timely filed an initial application (H-8091), to offer PPO plans in Pulaski County, Arkansas. CMS reviewed the application, and issued a March 19, 2010 Part D Deficiency notice.[8] Relevant to the ultimate narrow issue in the subject appeal (involving the contract language between the Applicant and its designee TMG Health (TMG)), the notice stated:

> The executed contract/administrative services agreement/intercompany agreement your organization submitted for key Part D functions does not indicate if books, contracts, records, including medical records and documentation relating to the part D program will be provided to your organization to provide to CMS or will be provided directly to CMS or its designees. The executed contract/administrative service agreement/intercompany agreement is with TMG.

The Applicant responded to the notice on April 1, 2010 but neglected to resubmit the TMG contract as CMS required.[9] Accordingly, on May 5, 2010 CMS issued the Applicant a Notice of

[8] CMS Exhibit B.
[9] CMS Exhibit C.

Intent to Deny its MA-PD application[10] which generally noted that the Applicant failed upload the required [resubmitted and revised] contract with TMG. The notice indicated that the deadline to file curing materials was May 15, 2010.

In an effort to address the alleged deficiency noted above, on May 12, 2010 the Applicant executed a [Second] Amendment [11] to the TMG Agreement containing the following language:

> TMG acknowledges that HHS, the Comptroller General, or their designees have the right to inspect any books, contracts, patient care documentation, and other records of TMG, or its subcontractors or transferees involving transactions related to the ABCBS Medicare Advantage and Prescription Drug Contract through 10 years from the final date of the contract period or from the date of the completion of any audit, or for such longer period provided for in 42 CFR§422.504((e)(2); 422.504(e)(3); 422.504(e)(4); 422.504(i)(2)(ii) or other applicable law, whichever is later. [12]

(Emphasis added.)

On May 14, 2010, the Applicant filed the Second Amendment (with the revised corresponding crosswalk[13]).

On June 7, 2010, CMS issued a Denial stating the contract provision was insufficient.[14]

The Applicant filed a timely request for a hearing concerning CMS' determination. On June 25, 2010, CMS submitted a Memorandum and Motion for Summary Judgment. On June 30, 2010, the Applicant submitted a Cross Motion for Summary Judgment with Brief. On June 30, the undersigned Hearing Officer advised the parties that he concurs with the parties' representations that as no material facts were disputed, adjudicating this case via summary judgment would be appropriate.

CMS' Contentions

[10] CMS Exhibit D.

[11] Applicant Exhibit G. The original Agreement was executed in March, 2006 and the First Amendment was effective November, 2007.

[12] The Hearing Officer notes language similar to TMG's Part D contract is contained in the guidance for the Part C program in the Medicare Managed Care Manual, Chapter 11 – Medicare Advantage Application Procedures and Contract Requirements, Section 100.5 – Administrative Contracting Requirements (issued 2-17-06), where it provides that the "following provisions must be addressed in the administrative service contracts: * * * The person or entity must agree to grant DHHS, the Comptroller General, or their designees the right to inspect any pertinent information related to the contract during the contract term, for up to 10 years from the final date of the contract period, and in certain instances described in the MA regulations, periods in excess of 10 years, as appropriate." (emphasis added.)

[13] CMS Exhibit J.

[14] CMS Exhibit A. CMS used the same explanation quoted above in the March 19, 2010 Part D Deficiency Notice.

Procedurally, CMS explains that applicants must demonstrate that they meet all Part D program requirements to qualify as an MA-PD sponsor in their proposed service area. Pursuant to 42 C.F.R. §423.502(c)(1), applicants are required to complete all parts of a certified application in the form and manner required by CMS. Furthermore, the applicant must describe thoroughly how it meets all Part D program requirements. 42 C.F.R. §423.502(c)(2). CMS limits its review to that information contained in the application and determines whether the application meets all Part D requirements. 42 C.F.R. §423.503(a)(1) and (2). If CMS does not receive a revised application or the revised application still does not demonstrate that the applicant is qualified to act as a Part D sponsor, CMS denies the application. 42 C.F.R. §423.503(c)(2)(iii). CMS also indicated that in accordance with the current version of 42 C.F.R. §423.505 (as well as holdings in previous Hearing Officer decisions) neither CMS nor the Hearing Officer may consider information provided after the expiration of the 10-day period following the Notice of Intent to Deny. Finally, CMS notes that the applicant must prove by a preponderance of the evidence that CMS' determination was inconsistent with the requirements of 42 C.F.R. §§423.502 and 423.503.

Substantively, the Applicant's contract with TMG submitted to CMS did not contain the language required by the regulation and Section 3.1.1, Item D of the MA-PD Application. The Applicant provided a crosswalk that it had developed itself, rather than the one provided by CMS in Appendix III of the MA-PD Application. Moreover, the actual contract language makes no declaration concerning TMG's authority to provide requested books and records directly to CMS or to the Applicant for distribution to CMS. Moreover, CMS indicates that language in the TMG contract [Second Amendment] is inconsistent with the [initial] portion of the implementing Federal Register which states that, "[t]he provision must be clear as to whether or not the requested documentation is to be submitted through the Part D sponsor to us (or our designee(s)) or submitted directly to us (or our designee(s))."[15] Moreover, CMS notes that the TMG contract erroneously references a non-existent regulation in 42 C.F.R. 422 (which references Part C) rather than the controlling regulation at 42 C.F.R. 423 (which references Part D), and therefore, there is no evidence that the contract met Part D requirements.

Applicant's Contentions

The Applicant indicates that it has been an approved Part D sponsor since the inception of the program in 2006. The Applicant notes that it has contracted with TMG in previous plan years and submitted copies of the original Part C contract from 2006 and an amended contract that covers Part D in 2007.[16] The Applicant states that these contracts were approved by CMS for plan years 2008, 2009 and 2010.[17] The Applicant notes that for this year's application, it received a notice of intent to deny pertaining to language concerning the issue of production of records to CMS or its designees. The Applicant asserts that the contract with language it submitted by the deadline complied with the regulatory requirements at 42 C.F.R. §423.505(i)(3)(iv).[18]

[15] 72 Fed. Reg. 68700, 68708 (Dec. 5, 2007).
[16] *See* Plan Exhibits A and B.
[17] *See* Applicant Exhibit C.
[18] *See* Applicant Exhibit G.

The Applicant first contends that the burden of proof in this case for the 2011 application process should be "substantial compliance" with the requirements of the Part D regulations. The Applicant points out that this was the standard when it submitted its application in February of 2010 during the application process for the 2011 contract year. The Applicant asserts that the change in the regulations announced in 75 Fed. Reg. 19678 (April 15, 2010) state that:

> [t]hese regulations are effective June 7, 2010, the rules published in the April 15, 2010. However, we note that because health and drug plans under the Part C and D programs operate under contracts with CMS that are applicable on a calendar year basis, the provisions will not be applicable prior to contract year January 1, 2011 except where otherwise noted.

The Applicant indicates that the Secretary never intended to apply the new standard midway through the application approval process, to the harm and detriment of plan sponsors and that any attempt to apply this section retroactively to application that were filed before the change in rules constitutes an impermissible attempt to apply the new rule retroactively.

The Applicant also contends that a careful review of the contract with TMG indicates that it does meet the requirements of the regulation at 42 C.F.R. §423.505(i)(3)(iv). In the TMG contract in Section 7, (I.C) (quoted above), the Applicant states it contains a "right to inspect" which necessarily includes the obligation to produce books and records to CMS or its designees. Moreover, it requires TMG to produce those records directly to CMS, thus providing CMS notice that, upon its request any records are to be produced directly by TMG to CMS. In addition, the Applicant refers to Section 6 of the Second Amendment (amending Section I.B) contains a contract requirement in which TMG agrees that any services it or its subcontractors provided will be consistent with and will comply with the Applicant's MA-PD contractual obligations and other laws, regulations, rules and orders. This section provides further support that the parties clearly intend to comply with all regulatory requirements including those contained in 42 C.F.R. §423.505(i)(3)(iv).

Finally, the Applicant points out that the same TMG agreement which is now purportedly deficient was approved for two new applications for contract year 2010. Since it had no reason to know or suspect that the TMG agreement was deficient in this regard, the Applicant's reasonable reliance, to its detriment, on CMS' previous approvals provides an additional basis on which the denial should be reversed.

Decision

The Hearing Officer finds that the Applicant has proved by a preponderance of the evidence that CMS' determination was inconsistent with the requirements of 42 C.F.R §423.502(i)(3)(iv),[19] the

[19] The Hearing Officer notes that the Applicant presented no actual evidence to support its allegation that applying the new burden/standard at hearing (effective June 7, 2010) was unduly harmful and prejudicial as it forced the Applicant to in effect "change horse in midstream" from its initial February 2010 submission. While CMS' deficiency notice to the Applicant stating CMS' position regarding the subject

provision which CMS contends that the plan did not comply with. The amended agreement between the Applicant and TMG contains a section in which TMG acknowledges that HHS, the Comptroller General or their designee would have the right to "inspect" its records or documentation. The regulatory text at 42 C.F.R §423.502(i)(3)(iv) indicates that contracts with other entities are required to contain provisions requiring the entities to "produce" records (to either the sponsor to provide to CMS or directly to CMS or its designees). Likewise, the case specific March 19, 2010 Deficiency Notice from CMS to the Applicant as well as excerpts from the Solicitation for 2011 Applications for New Medicare Advantage Drug Plans closely, but do not exactly mirror the regulation as both indicate the contracts must contain provisions requiring entities to "provide" records (to either the sponsor to provide to CMS or directly to CMS or its designees).[20]

The regulatory text and deficiency notice are somewhat ambiguous as to whether the obligation to produce (or provide) records is satisfied by producing (or providing) such records for viewing at an onsite "inspection," or whether this obligation carries a higher burden (e.g. "submission" to CMS). Certainly, if the right to inspect records satisfies the regulatory "production" requirement, the records would necessarily be made directly available to CMS (and it would be unnecessary to further declare whether or not TMG would directly submit records to CMS).

The Hearing Officer notes that CMS provided its official regulatory interpretation in the Federal Register.[21] While reading the first sentence from the preamble to the revisions to the regulation alone supports CMS' position, as it refers to the obligation to declare which entity would submit records to CMS to satisfy the regulation, the following sentence provides an alternative way to satisfy the regulation (making records directly available through onsite access). The provision stated the following.

> The provision must be clear as to whether or not the requested documentation is to be submitted through the Part D sponsor to us (or our designee(s))or submitted directly to us (or our designee(s)). The parties could also decide to have such books or record made directly available to us, or our designee(s) through onsite access.

(Emphasis added.)[22]

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contract language was issued in March, the final rule was published on April 15, nearly a month before the revised contract provision was actually executed (May 13, 2010). Moreover, as early as October 2009 CMS indicated that it considering establishing a new burden of proof for future hearings (although no effective date was established). Finally, the Applicant makes no allegation that it would have actually drafted the disputed contract provision differently under the previous substantial compliance standard.

[20] CMS Exhibit J. The Hearing Officer also notes that the application states "Nothing in this application is intended to supersede the regulations at 42 CFR Part 423. Failure to reference a regulatory requirement in this application does not affect the applicability of such requirement, and MA-PD sponsors and/or Applicants are required to comply with all applicable requirements of the regulations in Part 423 of 42 CFR. In particular, the attestation in this application is intended to highlight examples of key requirements across a variety of functional and operational areas, but are in no way intended to reflect a complete or thorough description of all Part D requirements."

[21] 72 Fed. Reg. 68700, 68708 (Dec. 5, 2007).

[22] *Id.*

Thus, as TMG has acknowledged that CMS has the right to inspect, CMS has onsite access under the contract, and accordingly, CMS would necessarily receive records directly from TMG (not through the Applicant). Accordingly, the Applicant has proved by a preponderance of the evidence that CMS' determination was inconsistent with the requirement of §§423.502 and 423.503.[23]

Conclusion

The Applicant's Motion for Summary Judgment is granted.

Benjamin Cohen
Hearing Officer

Date: July 13, 2010

[23] While CMS notes that the Agreement between the Applicant and TMG refers to 42 C.F.R. Part 422 (the Part C Portion of the Medicare contract) as opposed to Part 423 (the Part D Portion of the Medicare contract), the Hearing Officer finds this legally constitutes a harmless "scrivener's error" which would not effectively change TMG's clear intention and legal binding obligation to have its records inspected (and accordingly would still satisfy all regulatory requirements). Moreover, there is no legal obligation to precisely cite the exact regulation in such contract (See Introductory language within Solicitation for Application, infra, n. 19).

Likewise, (consistent with the Introductory Note, CMS' current suggestion that the Applicant could have lessened its risk if it followed the crosswalk language (which does not exactly mirror the regulation) is misplaced. If this case did not ultimately rest on the Federal Register instruction at 72 Fed. Reg. 68700, 68708 (April 5, 2007), the Hearing Officer would have evaluated whether the Applicant proved by a preponderance of the evidence that the contractual text effectively addressed all of the legal requirements of the regulation and bound and obligated the parties accordingly. Moreover, but for the regulatory reference in CMS Crosswalk (CMS Exhibit J at 33 (Instruction) and at 107 (Crosswalk Section 3.1.1D13), the text of the Provider's Crosswalk (CMS Exhibit L, 3.1.1D13) are the same.