CENTERS FOR MEDICARE AND MEDICAID SERVICES
Hearing Officer Decision

In the Matter of

Stonebridge Life Insurance Company, Inc.	*	
	*	Docket No. 2010 C/D App 7
Denial of Initial Application, S3502	*	
	*	

ORDER

Jurisdiction

This appeal is provided pursuant to 42 C.F.R. §422.650. 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 Stonebridge Life Insurance Company (Applicant) bore 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 (which also incorporate the contracting provisions of 42 C.F.R. §§423.504 and 423.505).

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. §423.500 et seq., CMS has established the general provisions for entities seeking to qualify as Medicare Advantage-Prescription Drug (MA-PD) plans.

If CMS denies an MA-PD applicant, an 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 regulations at §423.650(b)(i), state, 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 422.503.

The regulations at 42 C.F.R. §§422.684(b) and 423.662(b) state that either party to the hearing may ask the hearing officer to rule on a motion for summary judgment.[1]

[1] *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

Controlling Regulations and Agency Materials Related to the Alleged Deficiency relating to Contract Provision 3.1.1D13

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. [2]
> (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.

CMS provided its official regulatory interpretation in the Federal Register. The provision stated the following.

> We have chosen not to be proscriptive regarding whether first tier, downstream, and related entities must make their books and

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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."

[2] 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."

> 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 application, applicants must timely submit and file a Crosswalk of Citations to direct CMS to the location 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 (General)

In late February 2010, the Applicant timely filed with CMS initial applications for approval to offer Prescription Drug Plan Sponsor products beginning January 1, 2011. On June 7, 2010, the Applicant received a Notice of Denial listing six alleged contracting deficiencies (concerning a subcontract with TMG). The Applicant filed a timely appeal of the denial.

On July 6, 2010, CMS filed a Motion for Summary Judgment and a Memorandum and Motion for Summary Judgment. CMS notes that in accordance with the Final Rule published April 15, 2010 and effective June 7, 2010, 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. On July 9, 2010, the Applicant filed its Brief/Opposition to CMS' Motion to Summary Judgment.

Factual Background Related to the Alleged Deficiency at Contract Provision 3.1.1D13

In its June 7, 2010 letter, CMS identified one of the six deficiencies as follows:

> 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 Health, Inc.

The relevant TMG contractual provision relating to the alleged deficiency stated:[3]

> TMG agrees….(iv) to grant CMS, the Department of Health and Human Services (HHS), the Comptroller General, the State Attorney General, Department of Insurance (DOI), Department of Health (DOH) or their designees the right to inspect any pertinent records or information related to this Agreement during the contract term, and for up to ten (10) years from the final date of the contract period, and in certain instances, periods in excess of ten years, as legally required to the extent such records or information are still in the possession of TMG. [4]

(Emphasis added.)

CMS Contentions

Procedurally, CMS contends that pursuant to the October 2009 Proposed Rule and April 2010 Final Rule cited above, the burden of proof for the application review standards and the hearing is whether the applicant met all (not substantially all) of the Part D requirements.

Substantively, CMS generally argues that various contract(s) provisions submitted with the application did not include the requisite language and/or references to satisfy the controlling requirements of the controlling regulations.

Regarding the alleged deficiency relating to contract provision 3.1.1D13, the Applicant's actual contract language makes no declaration concerning TMG's authority to provide requested books and records directly to CMS or whether TMG should provide the records directly to the Applicant to deliver to CMS as required by 42 C.F.R. §423.505(i)(3)(iv). CMS reiterates the [initial] portion of the implementing Federal Register 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))."

Applicant's Contentions

Procedurally, the Applicant argues that it submitted its application while the "substantial compliance" standard was in effect, and that CMS [allegedly] corresponded and sought to

[3] Applicant Exhibit A at 4.

[4] 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 (issue 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.)

remedy deficiencies identified by CMS under the substantial compliance standard, the substantial compliance standard should apply.

Substantively, as a general argument relating to all of the alleged contractual deficiencies, the Applicant explained that no authority mandates the use of specific textual language and, accordingly, the executed contract contains the requisite specific[5] provisions which effectively bind it and its subcontractors into obligations which are enforceable in accordance with CMS' regulations. Additionally, the Applicant presented detailed analyses for each of the specific provisions at issue.

Moreover, regarding provision 3.1.1D13, the Applicant relies upon the portion of the December 5, 2007 Federal Register (which CMS did not cite) which indicates that, "[t]he parties could also decide to have such books and records made directly available to us, or our designee(s), through onsite access." The Applicant also cites a prior CMS Hearing Officer decision and the fact that CMS previously approved contracts with identical or similar language as additional support.

Decision

The Hearing Officer finds that the Applicant will bear the burden of proving by a preponderance of the evidence that CMS' determination was inconsistent with the requirements of 42 C.F.R. §§423.502-423.505). The Final Rule indicates that it is effective June 7, 2010 and applies from contract year 2011(the year at issue) forward. CMS' denial was issued on June 7, 2010, the effective date of CMS' new regulations. [6] Accordingly, pursuant to the unambiguous directive in the Final Rule, the Hearing Officer will apply the new burden of proof at hearing. [7]

The Hearing Officer finds that as the Applicant thoroughly responded to CMS motions regarding each of the separate provisions at issue, the matters regarding the alleged deficiencies (with the exception of the deficiency relating to contract provision 3.1.1D13 are not clearly resolved and additional legal argument may be presented at hearing addressing whether the contractual text

[5] The Hearing Officer notes that the Applicant alternatively argues that while it considers the specific provisions "straightforward, if an interpretation issue regarding a specific provision were to arise, the general provision in which TMG agrees to comply with all controlling legal authorities would be instructive.

[6] Proposed Rule, 74 Fed. Reg. 54634 (Oct. 22, 2009) and Final Rule, 75 Fed. Reg. 19678 (April 15, 2010). *See also* CMS Exhibit K (April 30, 2010 memorandum to applicants). Prior to June 7, 2010 (for hearings involving determination regarding contract year 2010), the burden of proof regulations at 42 C.F.R. §§422.660 and 423.650 required the sponsor "to demonstrate that it was in substantial compliance with the requirements" of the Part C and Part D programs.

[7] The Hearing Officer notes that the Applicant presented no compelling evidence to support its allegation that applying the new burden/standard was actually unduly harmful and prejudicial. The Final Rule was published on April 15, two weeks before the contract was actually executed (May 1, 2010) and a month before it was filed with CMS (May 15, 2010). Moreover, as early as October 2009, CMS indicated that it considering establishing a new burden of proof for future applications and 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.

contained the requisite legal provisions which bound and obligated Stonebridge and its subcontractors in accordance with the regulations.

The Hearing Officer finds that CMS' determination regarding contract provision 3.1.1D13 was inconsistent with the requirements of 42 C.F.R §423.502(i)(3)(iv). The TMG agreement 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 June 7, 2010 denial 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).

The regulatory text and deficiency notice alone 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. While reading the first sentence of the preamble language 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.)

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, pursuant to the language in the Federal Register, the Applicant has proved by a preponderance of the evidence that CMS' determination was inconsistent with the requirement of §§423.502 and 423.503.

Conclusion

The Hearing Officer denies CMS' request to dismiss based upon the summary motion provision. At hearing, the Applicant will bear the burden of proving by a preponderance of the evidence

that CMS' determination was inconsistent with the requirements of 42 C.F.R. §§423.502-423.505. The parties are expected to present arguments at hearing addressing whether the contractual text contained the requisite legal provisions to bind and obligate the Applicant and it subcontractors in accordance with the regulations. Regarding the alleged deficiency involving Provision 3.1.1D13, CMS' determination was inconsistent with the requirement of §§423.502 and 423.503 (and the implementing Federal Register).

Benjamin R Cohen
Hearing Officer

Date: July 13, 2010