CENTERS FOR MEDICARE AND MEDICAID SERVICES
HEARING OFFICER DECISION

IN THE MATTER OF:

Gateway Health Plan of Ohio, Inc.	*	
	*	DOCKET NO. 2013 MA-PD 6
Denial of Initial Application to Qualify as a	*	
Medicare Prescription Drug Organization	*	
Contract Year 2014, Contract No. H9190	*	
	*	

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 Officer designated to hear this case are the undersigned, Benjamin R. Cohen and Michael J. McDougall.

II. ISSUE

Whether CMS properly denied the initial application submitted by Gateway Health Plan of Ohio, Inc. (Gateway Ohio or the Plan) to offer a Medicare Advantage – Prescription Drug (MA-PD) plan for contract year 2014.

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.
[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 (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 applicant organization must document that it has a provider network in place that meets CMS requirements.[7]

IV. APPLICATION PROCESS AND AUTHORITIES

MA-PD applications must be completed "in the form and manner required by CMS."[8] Presently, CMS requires the electronic submission of MA-PD applications via the Health Plan Management System (HPMS) program.[9] After receiving a MA-PD application, CMS makes a determination as to whether the applicant organization meets all of the relevant program requirements. This determination is based solely on information contained in the application or obtained by CMS through methods such as onsite visits.[10]

After initial applications are due, CMS affords applicants an additional "courtesy" review and cure period (prior to the regulatory review process associated with the Notice of Intent to Deny issuance). The 2014 Solicitation for Applications for Medicare Prescription Drug Plan 2014 Contracts (2014 Solicitation) provides:

> For those applicants with valid submissions, CMS will notify your organization via e mail of any deficiencies and afford a courtesy opportunity to amend the application(s)…. Applicants failing to cure deficiencies following the courtesy cure period will be issued a Notice of Intent to Deny the application. Applicants receiving notices of intent to deny have 10 days to remedy their applications. The end of the 10-day period is the last opportunity an applicant has to provide CMS with clarifications of corrections. CMS will only review the last submission provided during this cure period. Application materials will not be accepted after this 10 day time period.[11]

Before the final disapproval of an MA-PD application, CMS provides a formal "Notice of Intent to Deny," (NOID) which provides the basis for the denial and gives the applicant ten days to cure the deficiencies in its application. The regulatory requirement for curing an application is stated at 42 C.F.R. § 422.503(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

[6] 42 C.F.R. §§ 422.400 *et seq*., 422.503(b) *et seq.*
[7] 42 C.F.R. §§ 422.501(c)(2) and 422.502(c)(2).
[8] 42 C.F.R. §§ 422.501(c) and 423.502(c).
[9] *See* CMS Brief at 1-3.
[10] *See id*.
[11] http://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/Downloads/2014-Part-D-Application.pdf at 12.

> 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 denies the application. (Emphasis added.)

If, after the 10-day cure period, CMS denies an MA-PD application, the applicant has a right to a hearing before a CMS Hearing Officer in accordance with 42 C.F.R. §§ 422.660 and/or 423.650. The regulations dictate that, at a hearing, the applicant has the burden of proving by a preponderance of the evidence that CMS' determination was inconsistent with the requirements of §§ 422.501 and 422.502 for Part C and/or §§ 422.502 and 423.503 for Part D.

V. SUBSTANTIVE AUTHORITY

Part D 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. § 423.501[12] as follows:

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

The Part D regulations at 42 C.F.R. § 423.505(i) set out specific contract provisions that pertain to contracts with such entities. Subsection 1 of such regulation provides:

[12] *See also* 42 C.F.R § 423.4, which contains virtually identical language.

(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.

Moreover, 42 C.F.R §423.505(i)(3)-(5) provides that each and every contract a Part D sponsor has with a first tier, downstream, and related entities (or delegations to other parties) must contain various items, including provisions requiring other entities to perform services or activities in accordance with a Part D's sponsor's contractual obligations and the specification of delegated activities.[13]

Furthermore, the 2014 Solicitation requires applicants to identify all first tier, downstream and related entities that will be carrying out specific functions in a "First tier, Downstream and Related entities Function Chart." The 2014 Solicitation also instructs applicants to document their relationship with other entities that would be involved with plan administration. This requirement is 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 tier, downstream or related entity that contracts with any of the identified entities on the applicant's behalf. Unless otherwise indicated, each and every contract must:

1. Clearly identify the parties to the contract (or letter of agreement). If the applicant is not a direct party to the contract (e.g., if one of the contracting entities is entering into the contract on the applicant's behalf), **the applicant must be identified as an entity that will benefit from the services described in the contract.**

* * * * *

7. Be signed by a representative of each party with legal authority to bind the entity. (Emphasis in original)

* * * * *

[13] *See, e.g.*, 42 C.F.R §423.505(i)(3)(iii) and (i)(4)(i).

> Each complete contract must meet all of the above requirements when read on its own.[14]

VI. FACTUAL BACKGROUND

Gateway Ohio, the applicant in this case, and Gateway Health Plan, Inc., are wholly owned subsidiaries of Gateway Health Plan, LP (Gateway LP). Through documents executed in 2004 and 2005, Gateway Health Plan, Inc. had a contract with Argus Health Systems, Inc. (Argus) to provide Pharmacy Benefit Management (PBM) services.[15]

In February 2013 Gateway Ohio filed an application to qualify as a MA-PD plan for the 2014 contract year. In this application, Gateway Ohio indicated that it had contracted with Argus Health Systems, Inc. (Argus) to administer its PBM services.

In its initial review of Gateway Ohio's application, CMS found the application to be lacking in several respects. To this end, CMS issued a "courtesy deficiency notice" to the Plan on March 28, 2013.[16] This deficiency notice expressly highlighted fourteen perceived shortcomings in contract with "Argus Health Systems, Inc."[17] In addition, this notice indicated that CMS detected issues with Gateway Ohio's contracting structure but did not specify which contract was seen as deficient. Specifically, the courtesy deficiency notice provided:

> 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].[18]

The Plan testified that it believed such deficiency was related to the Argus contract and did not believe it was necessary to contact CMS to further discuss the "blank." Specifically, the Gateway employee who was responsible for the application testified:

> Q: …In the application, had Gateway Ohio identified Gateway LP as a first tier, downstream or related entity?
> A: No
> Q: In the application or in response to the Notice of Intent to Deny, had Gateway Ohio identified Gateway LP as its sole owner or corporate parent?
> A: Yes
> Q: Did Gateway---did CMS cite Gateway Ohio's failure to provide a first–tier agreement between Gateway Ohio and

[14] CMS Exhibit l0.
[15] Gateway Ohio Brief at 3, Gateway Ohio Exhibit 2 (Service Agreement Between Argus Health Systems, Inc. and Gateway Health Plan, Inc.) and Exhibit 3 (May 2005 Addendum to Service Agreement executed by Argus, Gateway Health Plan, Inc. and Gateway Health Plan, LP).
[16] CMS Brief at 3.
[17] CMS Exhibit 2.
[18] CMS Exhibit 2 at 2. CMS states that a "programming error" led to its failure to identify the deficient contract in this instance. *See* CMS Brief at 3.

Gateway LP in the deficiency letter, and that's the first letter that comes out after the contract review, that was sent by CMS to Gateway Health Plan on March 28?

A: No. There was an incomplete sentence in the deficiency letter, so that the issue was not identified from Gateway Ohio on March 28.

Q: Did you ask CMS about the incomplete sentence?

A: No

Q: Can you explain to us why you did not?

A: Because our first-tier entity for Part D is Argus as a PBM, and it was our understanding that the deficiency was related to the Argus contract. This item was included in a list of deficiencies that addressed the Argus contract.

Q: Was the issue identified accurately in the Intent to Deny letter?

A: Yes. For the first time, we saw that CMS was looking for a contract between Gateway LP and Gateway Ohio in the Notice of Intent to deny.[19]

In response to the courtesy deficiency notice, Gateway Ohio provided additional information to CMS on April 5, 2013. CMS acknowledged that this material "cured some of the deficiencies cited in the Argus contract," but concluded that the material "did not include an agreement between Gateway Ohio and Gateway LP."[20] For this reason, on April 26, 2013, CMS issued a NOID for the Gateway Ohio MA-PD application which listed five deficiencies including the following (filling in the "blank" that previously appeared in the courtesy deficiency notice with Gateway LP, *supra* note 18):

> 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 *Gateway Health Plan, LP*.[21]

Subsequently, during the ten day cure period window (which closed on May 7, 2013), Gateway Ohio and CMS communicated about the deficiencies CMS listed in the NOID. Initially, Gateway Ohio asked to schedule a call but CMS asked that the questions be submitted via email.

Throughout the email exchange that followed, CMS maintained that the Argus contract did not reference Gateway Ohio as the applicant or identify it as the "customer." In response, Gateway Ohio consistently referred CMS to the Addendum[22] it had uploaded. Gateway Ohio also relied on the Addendum to satisfy CMS' concern that it had not uploaded a contract between it and Gateway LP. Gateway Ohio explained and inquired:

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[19] Tr. 34-35, emphasis added.

[20] CMS Brief at 3.

[21] CMS Exhibit 5, emphasis added. In contrast to previous communications, the NOID contained CMS' first mention of the need for a contract between Gateway Ohio and Gateway LP.

[22] Gateway Ohio Exhibit 3.

> Gateway executed an Addendum with its PBM that assigned the Agreement to Gateway's corporate owner, Gateway Health Plan®, LP, the contracting entity on behalf of its wholly-owned subsidiaries, Gateway Health Plan® of Ohio, Inc. and Gateway Health Plan®, Inc. Gateway can provide an organization structure that demonstrates the Parent entity and its subsidiaries. Will CMS accept this organization structure to explain the structure and satisfy this deficiency?
>
> * * * * *
>
> Gateway did submit an executed contract with its PBM for Gateway Health Plan® of Ohio, Inc. Gateway executed an Addendum with its PBM in 2005 that assigned the Agreement to Gateway's corporate owner, Gateway Health Plan®, LP, the contracting entity on behalf of its wholly-owned subsidiaries, Gateway Health Plan® of Ohio, Inc. and Gateway Health Plan®, Inc. Gateway can provide an organization structure that demonstrates the Parent entity and its subsidiaries. Will CMS accept this organization structure to explain the structure and satisfy this deficiency?[23]

CMS responded that it had not seen the Addendum.[24]

To address CMS' concern that the Argus contract did not refer to Gateway Ohio as the "customer," Gateway Ohio offered:

> …. the introductory paragraph of the Addendum (pdf page 90) has the following "….and Gateway Health Plan®, LP ("Customer")." We will be submitting documentation that demonstrates link that Gateway Health Plan®, LP is the Parent entity contracting on behalf of its subsidiary, Gateway Health Plan® of Ohio, Inc and an Addendum to the PBM Agreement that clearly identifies Gateway Health Plan® of Ohio, Inc as a subsidiary of Gateway Health Plan®, LP. With this clarifying documentation, will this cure these 2 deficiencies?[25]

The email exchange culminated on May 2, 2013, when CMS responded "Yes."[26]

For context, the email exchange is set forth in its entirety in Appendix A attached hereto.

[23] CMS Exhibit 9.
[24] *Id.*
[25] *Id.*
[26] *Id.*

On May 1 and 2, 2013, representatives of Argus, Gateway Health Plan, Inc., and Gateway LP executed the following:[27]

> AMENDED ADDENDUM TO SERVICE AGREEMENT
>
> THIS AMENDED ADDENDUM is to the Services Agreement ("Agreement") effective as of January 1, 2004 between Argus Health Systems, Inc. and Gateway Health Plan, Inc. The effective date of this Addendum is January 1, 2004 (the "Effective Date").
>
> In compliance with Section 11.7 of the Agreement, all rights and obligations of Gateway Health Plan, Inc. shall be assigned to its corporate owner, Gateway Health Plan®, LP on behalf of itself and its wholly owned subsidiaries, Gateway Health Plan®, Inc. and Gateway Health Plan® of Ohio, Inc.
>
> The parties have caused this Addendum to be executed by their respective duly authorized officers or agents as of the date set forth below.

Gateway Ohio timely submitted the Amended Addendum prior to the May 7th cure deadline. On May 31, 2013 CMS issued a formal denial of Gateway Ohio's MA-PD application.[28] The lone deficiency from the official NOID, remained, as cited above:

> 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 Gateway Health Plan, LP.

By letter dated June 7, 2013, Gateway Ohio filed a timely appeal. A telephonic hearing was conducted on July 2, 2013. Gateway Ohio was represented by Kelli Back of the Law Offices of Mark S. Joffe. CMS was represented by Scott Nelson of the Medicare Drug Benefit Group. Benjamin R. Cohen and Michael J. McDougall served as the CMS Hearing Officers.

VII. GATEWAY CONTENTIONS

Gateway asserts that CMS' position regarding what constitutes a binding contract is too narrow.[29] Gateway posits that there are arrangements in which parties can enter into binding agreements other than those cited by CMS. It claims that Gateway Ohio demonstrated through its application that it has a binding relationship with Argus. Gateway Ohio, a wholly owned

[27] Gateway Ohio Exhibits 3 and 4. Exhibit 3 contains an Addendum to the Service Agreement signed in May, 2005 by the representatives of the same three organizations. The text in the 2005 Addendum mirrors that of the 2013 Amended Addendum shown in Exhibit 4. *See also* Gateway Ohio Exhibit at 5.
[28] Gateway Ohio Exhibit 1.
[29] Gateway Reply Brief at 2, 4.

subsidiary[30] of Gateway LP, timely filed a contract addendum with CMS which clearly provides that Gateway LP effectively entered into a binding contractual agreement with Argus on behalf of Gateway Ohio, thereby making Gateway Ohio a direct party to the agreement. Similarly, it contends that Gateway LP, in its role as corporate owner, only facilitated the contractual substitution of the parties to the Argus PBM Service Agreement.[31] For that reason, it argues that Gateway LP was not acting as a first tier or related entity under the regulatory definitions at 42 C.F.R. §§ 423.4 or 423.501; accordingly, the provision regarding the necessity for a contract or written arrangement between Gateway LP and Gateway Ohio under 423.505(i) does not apply.[32]

Gateway argues that its interaction with CMS on this issue led Gateway Ohio to believe that adding a reference to Gateway Ohio as it did would cure the deficiencies. It reiterates that in the initial courtesy deficiency letter, CMS failed to identify the contract that was at issue and that the first time that CMS' concern was correctly identified was in the Intent to Deny letter. After receiving the Intent to Deny letter, Gateway Ohio notes that it reached out to CMS to get clarification on what CMS required.[33]

Gateway also addresses CMS' concern that if Gateway Ohio, were sold, the contract would be invalidated because Gateway LP would no longer have authority to contract on behalf of Gateway Ohio. Gateway Ohio indicates that Medicare Advantage organization commonly undergo changes throughout a contract year, including changes in the PBM. Thus, Gateway Ohio represents that, like any other organization, it would simply take steps to ensure ongoing compliance. Regarding CMS' explanation that it may require Gateway Ohio to create certain contracting arrangements to provide CMS reasonable assurances in performance, Gateway Ohio asserts that CMS may not add requirements to the application process which are not supported by law.[34]

VIII. CMS CONTENTIONS

CMS argues that it expected the Plan to either submit an executed contract directly with Argus or CMS expected the Plan to submit a contract with a first tier entity[35] which in turn, would contract with Argus.[36] In turn, CMS expected that the first tier entity would contract with

[30] Gateway cites general state case law and codes involving instances in which non-signatory subsidiaries are held bound to the terms of a contract signed by a parent as well as the principle that a corporate parent is presumed to have power to direct a subsidiary. The Hearing Officer recognizes while these instructive concepts are fairly accepted, the task to determine if contract provisions are binding often requires a case specific analysis.
[31] Gateway Brief at 4.
[32] Tr. at 130-132. Gateway Ohio also submitted an Affidavit, signed in two parts (Gateway Exhibits 6 and 7), signed by a Gateway Ohio and Argus representative. It was not intended to cure a deficiency (it was not submitted to CMS before the cure deadline), but rather it was submitted as evidence to the Hearing Officer that Gateway Ohio and Argus intended to be contractually bound. The Hearing Officer notes that it was unnecessary to consider this affidavit and decide what weight, if any, this affidavit had on the case. Nevertheless, the undersigned takes the affidavit, which is consistent with other record materials, on face value that the organizations intended to be bound in a legally enforceable contract.
[33] Tr. at 9-10.
[34] Gateway Ohio Brief at 4.
[35] CMS argues that Gateway LP is a first tier entity (TR 18-92-94), even if it is not itself ultimately performing those select administrative functions but rather delegating completely to Argus. CMS argues that to not consider Gateway LP a first tier entity would render the definition of "first tier" meaningless.
[36] Tr. at 108-111.

Argus. CMS also contends that its omission in the initial courtesy notice deficiency was not prejudicial. CMS notes that the courtesy deficiency notice instructed the Plan to contact CMS with any questions, but that CMS has no record that Gateway Ohio took advantage of this opportunity to clarify any confusion it may have had regarding this deficiency.[37]

Moreover, CMS contends that the mere assertion that Gateway LP is undertaking to contract on Gateway Ohio's behalf is insufficient to establish a binding relationship between Argus and Gateway Ohio. In support, CMS argues that while it may generally be true that contracts "should be construed to effectuate the intent of the parties," (*quoting* Gateway Ohio Brief at 3), the parties' intent cannot create obligations in a third party unless the third party is itself a signatory to the contract or has authorized one of the signatories to act on its behalf.[38] While the Amended Addendum purports to assign the rights, CMS notes that Gateway Ohio is not itself a signatory to the agreement and thus CMS was not assured that the Plan made adequate arrangements to perform key functions.[39]

CMS maintains that Gateway LP's status as Gateway Ohio's parent organization was not sufficient to demonstrate that it has the authority to enter into contracts on Gateway Ohio's behalf. The organizations are legally distinct entities that are organized under the laws of separate states. CMS points to its obligation, pursuant to 42 CFR §423.502, to evaluate the Plan's qualifications to operate as a Part D sponsor independent of its corporate relationship with any other entity. Therefore, CMS asserts, it must "treat Gateway Ohio as an independent actor, not a supporting player to its parent."[40] It must be clear to CMS that Gateway Ohio can either perform required functions itself or can compel the performance of those functions by other parties acting on its behalf. CMS asserts that it cannot be adequately assured that Gateway Ohio can honor or enforce these obligations when, as a subsidiary organization, it must rely on the actions of its parent, over which it has no authority absent a binding contract, to compel performance on Gateway Ohio's behalf.[41]

CMS contends that the documents submitted by the Plan must demonstrate that the Plan has a binding relationship with each entity performing key functions. In support, CMS relies on 42 C.F.R. § 423.505(i) which requires that all contracts with these first tier, downstream, and related entities contain certain elements in order to ensure that these entities comply with the requirements of the Part D program. Accordingly, through the 2014 Solicitation, CMS requires applicants to identify the entities that will perform functions on their behalf and to submit contracts reflecting such.[42] The 2014 Solicitation specifically instructs applicants to provide executed contracts with each entity identified in the Part D function chart[43] and "with

[37] CMS Brief at 3; Tr. at 105-106.
[38] CMS Brief at 5.
[39] CMS Brief at 5; Gateway Ohio Exhibit 5 at 3.
[40] CMS Brief at 6.
[41] CMS Brief at 7. Moreover, without an express representation otherwise, CMS argues if Gateway LP were to sell Gateway Ohio; Gateway Ohio's rights, if any existed, would be extinguished. Sales of subsidiaries are a frequent occurrence in the Part D program and, because the contract is between CMS and the subsidiary, CMS does not have authority to review these transactions. In the absence of a contract between Gateway LP and the Plan, CMS maintains that it has no assurance that Argus would continue to provide services to Gateway Ohio if Gateway Ohio were to be sold. Tr. at 116-117.
[42] CMS Exhibit 10, § 3.1.1.C and 3.1.1.D.
[43] CMS Exhibit 1.

any first tier, downstream, or related entity that contracts with any of the identified entities on the applicant's behalf."[44] Simply put, CMS explains, the Plan must demonstrate that it has a binding contractual relationship, either directly or through other entities in its subcontracting chain, with each entity to which it has delegated responsibility for the identified Part D functions. At hearing, CMS noted that the binding contractual relationship must be shown in the language of "each and every contract," a term which is prevalent throughout 42 CFR 423.505(i). CMS explained that it relies upon this regulation when it looks for an express binding relationship between the sponsor and other entities within [PBM related] contracts rather than relying upon documentation which describes a corporate board structure to establish a binding relationship.[45]

Also, CMS asserts that its evaluation of contracting arrangements is not strictly limited to considering whether they are arguably enforceable. CMS contends that it is appropriate for it to require an applicant to create certain contracting arrangements with its delegated entities in order to provide CMS reasonable assurance that an applicant's direction to the entities "results in performance, not litigation."[46]

IX. DECISION

Gateway Ohio has met its burden of proof in showing that CMS determination was not consistent with the regulatory requirements.

The regulations provide that CMS may require applicants to complete their application in the form and manner established by the agency.[47] Accordingly, CMS annually publishes updated detailed instructions, guidance, and application forms. CMS' 2014 Solicitation establishes that applicants are afforded a "courtesy" review and cure period prior to the issuance of an official notice of intent to deny.[48] The Hearing Officer notes that CMS extends this "courtesy" to provide applicants an additional round of review and opportunity to cure beyond the regulatory review preceding the notice of intent to deny review and the final submission process.

In response to the 2014 Solicitation, Gateway Ohio submitted an application that included a contract, intended to be legally enforceable, to bind it with Argus (its first-tier entity and PBM).[49] CMS reviewed that contract[50] and issued a courtesy notice identifying multiple deficiencies. For fourteen of the fifteen contract related deficiencies, CMS noted, "The contract referenced is with Argus Health Systems, Inc."[51]

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[44] Gateway Ohio Reply Brief Exhibit 1.
[45] Tr. at 125-128.
[46] CMS Brief at 7. Moreover, without an express representation otherwise, CMS argues if Gateway LP were to sell Gateway Ohio, Gateway Ohio's rights, if any existed would be extinguished.
[47] 42 C.F.R. §§ 422.501 and 423.502.
[48] *Supra* note 11.
[49] Tr. at 61-63.
[50] To establish context, the Hearing Officer notes that CMS' review of contracts submitted through the application process entails more than an analysis of whether a contract would be legally enforceable. CMS systematically reviews each contract to ensure that certain terms are explicitly present in each and every contract in the interest of minimizing the risk that beneficiary access to care would be compromised or interrupted due to litigation regarding contractual obligations. Tr. at 26, 97, 101.
[51] CMS Exhibit 2.

The remaining contract related deficiency that is at the core of this appeal, however, was ill-defined and contextually ambiguous. In its courtesy notice, CMS intended to inform the Plan that its application did not contain a contract with Gateway, LP which CMS believed was Ohio's first tier, downstream or related entity. Instead, due to an error, the deficiency notice read:

> 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].[52]

The Plan testified that it assumed the deficiency was directed at its contract with Argus because Argus is its first-tier entity and the undefined deficiency was listed along with other deficiencies related to the Argus contract. Based on this assumption, Gateway Ohio did not seek clarification from CMS at this point in time regarding the incomplete sentence.[53] The Hearing Officer notes that Gateway Ohio took steps to address the fully defined deficiencies in the March 28 courtesy notice because CMS acknowledged that Gateway Ohio's resubmission cured some of the deficiencies.[54]

Thus, the first time the Plan understood that CMS, in fact, was "looking for a contract between Gateway LP and Gateway Ohio," was when the Plan received the official notice of intent to deny.[55] At that point, Ohio reached out to CMS and requested a telephone conference.[56] CMS declined, but offered to review questions submitted in writing. Ohio complied, submitting questions the very next day regarding the deficiencies CMS had identified.

On May 1, 2013, Gateway Ohio offered documentation and re-directed CMS to an existing contract addendum. Specifically, Gateway Ohio asked:

> Re:# 1& #2 below, the introductory paragraph of the Addendum (pdf page 90) has the following "….and Gateway Health Plan®, LP ("Customer")." We will be submitting documentation that demonstrates link that Gateway Health Plan®, LP is the Parent entity contracting on behalf of its subsidiary, Gateway Health Plan® of Ohio, Inc and an Addendum to the PBM Agreement that clearly identifies Gateway Health Plan® of Ohio, Inc as a subsidiary of Gateway Health Plan®, LP. With this clarifying documentation, will this cure these 2 deficiencies?[57]

CMS affirmed it would accept the materials listed in the Plan's email to cure deficiencies, stating simply "Yes."[58] Gateway Ohio then submitted the following:

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[52] *Id.*
[53] Tr. at 34-35.
[54] CMS Brief at 3.
[55] Tr. at 36.
[56] CMS Exhibit 6.
[57] CMS Exhibit 9.
[58] *Id.*

> THIS AMENDED ADDENDUM is to the Services Agreement ("Agreement") effective as of January 1, 2004 between Argus Health Systems, Inc. and Gateway Health Plan, Inc. The effective date of this Addendum is January 1, 2004 (the "Effective Date").
>
> In compliance with Section 11.7 of the Agreement, all rights and obligations of Gateway Health Plan, Inc. shall be assigned to its corporate owner, Gateway Health Plan®, LP on behalf of itself and its wholly owned subsidiaries, Gateway Health Plan®, Inc. and Gateway Health Plan® of Ohio, Inc.[59]

While CMS promptly responded and the parties engaged in what each apparently thought was a clear exchange, the Hearing Officer finds that the parties ultimately did not fully understand each other. The undersigned is convinced that if the applicant had received an error-free notice during the initial "courtesy" round of review, resulting in two opportunities to file its responsive cure materials (as envisioned in the 2014 Solicitation), Gateway Ohio and CMS would have bridged the remaining difference regarding the exact materials that CMS expected gateway Ohio to submit. Accordingly, considering the totality of the circumstances, the Hearing Officer finds that the Plan was materially prejudiced as a result of CMS's initial programming error within its March 28, 2013 courtesy deficiency notice.

The Hearing Officer notes that as opposed to less objective and widely understood requirement (e.g., licensure requirements), the contract review process may periodically require an elevated level of case-by-case analysis.[60] The Hearing Officer recognizes that the Plan's Amended Addendum is not what CMS envisioned and that CMS interpreted Gateway's May 1 question in light of its valid reading of the regulations and the email chain.[61] At the same time, the Hearing Officer finds that the text of the applicant's Amended Addendum encompasses the clarifying documentation it described in the May 1 email above and can hypothetically be read in context with the regulations in light of the circumstances. The Plan's interpretation of CMS' specific expectation and its corresponding final submission was reasonable, from its vantage point at the time.

Equally important, Gateway Ohio proceeded reasonably throughout the application process. The reasonableness of the Plan's understanding and course of action was further supported by the following three factors besides the error in the courtesy notice and the subsequent e-mail exchange. First, Gateway LP is the parent of Gateway Ohio. Second, the terms "first tier entity" and "related party" can tenably be read to exclude Gateway LP.[62] Third, the 14

[59] Gateway Ohio Exhibit 4.
[60] Tr. at 20-21.
[61] While CMS did not present a witness at the hearing, CMS argued that it expected the Plan to submit an executed contract between itself and Argus or expected the Plan to submit a contract between itself and a first tier entity to which it would have delegated responsibility for the identified Part D functions. Tr. at 28 ,19, 45-48,108-11, 140 .
[62] The Hearing Officer finds that the controversy regarding whether Gateway LP is a first tier and/or related party to Gateway Ohio pursuant to 42 CFR Part 423 is inconsequential in light of the holding in this appeal and that no finding on this issue is required.

contract-related deficiencies identified in the courtesy deficiency notice all referenced the contract with Argus as opposed to Gateway LP.

In conclusion, due to CMS' programming error, Gateway Ohio was materially prejudiced as it effectively lost the opportunity to respond to the initial courtesy round of feedback from CMS, which should have provided Gateway Ohio notice regarding that the core nature of CMS' concern. The Hearing Officer finds that the text of the Plan's Amended Addendum can be interpreted to encompass the clarifying documentation it offered in its May 1 email. Gateway Ohio proceeded reasonably throughout the application process in light of the circumstances. Gateway Ohio met its burden of proof in showing that CMS determination was not consistent with a fair interpretation of the regulatory requirements in the light of the case-specific procedural chain of events.[63]

CMS' May 31, 2013 CMS denial of Gateway Ohio's MA-PD application is reversed.

Benjamin R. Cohen
Michael J. McDougall
CMS Hearing Officers

Date: August 9, 2013

[63] The Hearing Officer notes that from a beneficiary perspective, there were no immediate or direct health and safety concerns. CMS presented a general concern that not obtaining the contract in the form it envisioned could hypothetically disrupt service of a potential enforceability question arose with Argus. Tr.at 113. The Hearing Officer notes that this is a legitimate general justification to support why CMS expects that "each and every contract" contain certain provisions. Nevertheless, given the record testimony in this particular case regarding how the parties intended to be bound, the possibility that such a dispute could arise and would lead to litigation during the one-year term of the Part D contract is merely speculative at this point.

APPENDIX A

From: [CMS Employee]
To: [gateway Employee]
Subject: RE: H9190 – Part D Application – Notice of Intent to Deny
Date: Thursday, May 02, 2013 8:27:00 AM

Yes.

From: [Gateway Employee]
Sent: Wednesday, May 01, 2013 7:25 PM
To: [CMS Employee]
Subject: RE: H9190 - Part D Application – Notice of Intent to Deny

Hello [CMS Employee],

Re:# 1& #2 below, the introductory paragraph of the Addendum (pdf page 90) has the following "....and Gateway Health Plan®, LP ("Customer")." We will be submitting documentation that demonstrates link that Gateway Health Plan®, LP is the Parent entity contracting on behalf of its subsidiary, Gateway Health Plan® of Ohio, Inc and an Addendum to the PBM Agreement that clearly identifies Gateway Health Plan® of Ohio, Inc as a subsidiary of Gateway Health Plan®, LP. With this clarifying documentation, will this cure these 2 deficiencies?

----Original Message----
From: [Gateway Employee]
Sent: Tuesday, April 30, 3:13 PM
To: [CMS Employee]
Subject: RE: H9190 - Part D Application – Notice of Intent to Deny

Hello [CMS Employee],

Gateway is seeking clarification on what information is needed to cure the identified contracting deficiencies. Please see our comments/questions below?

1. - The contract your organization submitted for key Part D functions does not contain language stating that your organization will monitor the first tier, downstream or related entity's performance on an ongoing basis. The contract referenced is with Argus Health Systems, Inc.

GATEWAY COMMENTS/QUESTION: The language is contained in the contract. This provision is noted in the Argus Health System, Inc. agreement, Medicare Part D Regulatory, Page 5, No. 7 as stated in the crosswalk. The crosswalk also notes the .pdf page number as 93 which is a typo and should be page 94. Does CMS need a corrected crosswalk with the .pdf typo corrected though the document and document page number is correct?

CMS RESPONSE: The issue is that the "Customer" is never defined in such a way to include the applicant, since the applicant is never referenced by name in the contract.

2. -The contract your organization submitted for key Part D functions does not contain language stating that your organization retains the authority to approve, suspend, or terminate any pharmacy arrangement made by the first tier, downstream or related entity on behalf of your organization. The contract referenced is with Argus Health Systems, Inc.

GATEWAY COMMENTS/QUESTION: The language is contained in the contract. This provision is noted in the Argus Health System, Inc. agreement, Appendix 1-C, Page 12, No.3 as stated in the crosswalk. The crosswalk notes the Appendix as C-1 and .pdf page number as 101which are typo and should be page 1-C and .pdf page 100. Does CMS need a corrected crosswalk with the typos corrected?

CMS RESPONSE: The issue is that the "Customer" is never defined in such a way to include the applicant, since the applicant is never referenced by name in the contract.

* * ** *

CMS RESPONSE: The crosswalk referred to the Participating pharmacy network agreement, not the PBM contract. We were unable to locate this language in the contract between the PBM and Gateway. The contract must require the PBM to abide by this provision of the regulation.

4. - The contract your organization submitted to perform key part D functions does not include a reference to your organization. The contract referenced is with Argus Health Systems, Inc.

GATEWAY COMMENTS/QUESTION: Gateway executed an Addendum with its PBM that assigned the Agreement to Gateway's corporate owner, Gateway Health Plan®, LP, the contracting entity on behalf of its wholly-owned subsidiaries, Gateway Health Plan® of Ohio, Inc. and Gateway Health Plan®, Inc. Gateway can provide an organization structure that demonstrates the Parent entity and its subsidiaries. Will CMS accept this organization structure to explain the structure and satisfy this deficiency?

CMS RESPONSE: We did not see this addendum in the document. The page number references (pp 88 and 89 of the pdf, according to the crosswalk) did not reference Gateway of Ohio.

5. - 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 Gateway Health Plan, LP

GATEWAY COMMENTS/QUESTION: Gateway did submit an executed contract with its PBM for Gateway Health Plan® of Ohio, Inc. Gateway executed an Addendum with its PBM in 2005 that assigned the Agreement to Gateway's corporate owner, Gateway Health Plan®, LP, the contracting entity on behalf of its wholly-owned subsidiaries, Gateway Health Plan® of Ohio, Inc. and Gateway Health Plan®, Inc. Gateway can provide an organization structure that demonstrates the Parent entity and its subsidiaries. Will CMS accept this organization structure to explain the structure and satisfy this deficiency?

CMS RESPONSE: See above. We did not see any such addendum.[64]

[64] CMS Exhibit 9.