CENTERS FOR MEDICARE & MEDICAID SERVICES
HEARING OFFICER DECISION

IN THE MATTER OF:	*	
	*	
eternalHealth, Inc.	*	
Contract Year 2022	*	
Contract Nos. H1280 and H1294	*	**Hearing Officer Docket Nos.:**
	*	**H-21-0013**
Denial of Initial Applications to Offer	*	**H-21-0014**
Medicare Advantage/Medicare Advantage-	*	
Prescription Drug Plans	*	
	*	

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I. FILINGS

This Decision is being issued in response to the following:

(a) eternalHealth, Inc.'s ("Appellant") Hearing Request dated June 8, 2021.

(b) Appellant's Hearing Brief dated June 17, 2021 ("Appellant's Brief").

(c) Centers for Medicare & Medicaid Services' ("CMS") Brief in Reply to Appellant's Brief dated June 30, 2021 ("CMS' Brief").

(d) Appellant's Reply Brief dated July 6, 2021 ("Appellant's Reply").

II. ISSUE

Whether Appellant has proven by a preponderance of the evidence that CMS' determinations for contract numbers H1280 and H1294 were inconsistent with the requirements of 42 C.F.R. § 423.503. Each of the contract denials are based on the following four alleged deficiencies:[1]

1. New documents provided on April 29, 2021, failed to demonstrate a contractual relationship between OptumRx and United Health Services, Inc. ("UHS"), the entity referenced in the downstream contracts (hereinafter "Sub-Issue 1");

2. The contract between eternalHealth and OptumRx did not have an effective date prior to January 1, 2022, which was essential as OptumRx had consented to provide services prior to the start of the 2022 benefit year (hereinafter "Sub-Issue 2");

3. eternalHealth failed to produce the Pharmacy Provider Agreement referenced in the pharmacy contract templates it submitted (hereinafter "Sub-Issue 3"); and

4. eternalHealth's downstream entity contracts failed to specifically identify eternalHealth as the Part D entity for which they would be performing delegated functions (hereinafter "Sub-Issue 4").

See CMS' Brief at 4. *See also* eternalHealth's Exhibit P-10 at 775-77.

III. SUMMARY OF DECISION

The Hearing Officer upholds CMS' determinations for contract numbers H1280 and H1294. In its final opportunity to cure its application, Appellant filed a new relationship chart identifying OptumRx as its first tier pharmacy benefit manager ("PBM"), with OptumRx contracting with several downstream entities. However, the corresponding downstream contracts are structured so

[1] CMS further explains that "[b]ecause CMS must determine that 'an application meets all the requirements' described in the Part D regulations, CMS may deny an application when there is even one deficiency remaining uncured at the end of the cure period following the issuance of the [Notice of Intent to Deny]. [42 C.F.R.]§ 423.503(a)(2)." CMS' Brief at 2.

that UHS (an affiliate of OptumRx) enters into those contracts "on behalf of itself and its affiliates," yet UHS was not identified on the relationship chart.

Additionally, the effective date of the contract between Appellant and OptumRx, which can be fairly read to include marketing and enrollment services, was January 1, 2022. However, contracts relating to the performance of delegated Part D functions necessary to support an applicant's pre-benefit year operations enrollment-related services must have an effective date no later than October 15, 2021. Based on these findings, the Hearing Officer affirms CMS' denial of Appellant's application to offer new Medicare Advantage Prescription Drug products under contract numbers H1280 and H 2694.

IV. GENERAL AUTHORITY GOVERNING APPLICATION AND CONTRACTING PROCESS

The Social Security Act ("SSA" or "the Act") authorizes CMS to enter into contracts with entities seeking to offer Medicare Advantage ("MA"), or Part C, benefits and Medicare outpatient prescription drug ("PD"), or Part D, benefits to their plan enrollees. SSA §§ 1857 and 1860D-12. An organization may not offer Part D benefits unless it has entered into a contract with CMS. SSA §§ 1857(a) and 1860D-12(b)(1).

Organizations intending to offer Part D benefits must complete a certified application in the form and manner required by CMS and demonstrate that they meet all Part D program requirements to qualify as a Part D sponsor in their proposed service area for the product. 42 C.F.R. § 423.502(c).

CMS posted the final Solicitation for Applications for Medicare Prescription Drug Plan 2022 Contracts ("Solicitation") on its website on December 30, 2020.[2] The Solicitation required Part D contract applicants to provide responses to a series of attestations related to Part D requirements as well as documentation demonstrating their ability to meet program requirements. The documentation included licensure information, contracts with subcontractors such as PBMs, contract templates for network pharmacies, a statement of corporate organization and organizational compliance plans. Organizations were to submit their applications through the Health Plan Management System ("HPMS"), CMS' electronic system of record for the administration of the MA-PD programs. Solicitation at § 3.1.1. The applications were due to CMS by February 17, 2021.

CMS conducts a review of all submitted Part D applications pursuant to 42 C.F.R. § 423.503 and issues determinations consistent with § 423.503(c). Organizations that offer Part D benefits through a Prescription Drug Plan ("PDP") are a type of Part D sponsor known as a "PDP sponsor." 42 C.F.R. § 423.4. Once qualified as a Part D sponsor, PDP sponsors execute a PDP contract with CMS.

Under current regulations and procedures, after receiving an application, CMS reviews the application for any issues. CMS then notifies the applicant of any deficiencies by electronically sending a Part D Deficiency Notice, and provides a "courtesy cure period" to the applicant.

[2] *Available at* https://www.cms.gov/files/document/2022-part-d-application.pdf.

Solicitation at § 2.4.1.3. This is an applicant's first opportunity to amend its application. If an applicant fails to cure its deficiencies, CMS will issue a Notice of Intent to Deny ("NOID"). *Id.*; 42 C.F.R. § 423.503(c)(2). The NOID affords an applicant a second opportunity to cure its application. After a NOID is issued, an applicant has a final ten-day period to cure any deficiencies in order to meet CMS' requirements; otherwise, CMS will deny the application. 42 C.F.R. § 423.503(c)(2)(ii)–(iii).

If, after review, CMS denies the application, an applicant receives written notice of the determination and the basis for the determination. 42 C.F.R. § 423.503(c)(3). Subsequently, applicants may request a hearing before a CMS Hearing Officer. 42 C.F.R. §§ 423.503(c)(3)(iii) and 423.650. Furthermore, the applicant has the burden of proving by a preponderance of the evidence that CMS' determination was inconsistent with the overarching requirements of 42 C.F.R. §§ 423.502 (application requirements) and 423.503 (evaluation and determination procedures). 42 C.F.R. § 423.650(b)(1).

The Hearing Officer must comply with the provisions of Title XVIII of the Act — Health Insurance for the Aged and Disabled — and related provisions of the Act. Additionally, the Hearing Officer is bound by regulations issued by the Secretary of Health and Human Services and general instructions issued by CMS in implementing the Act. 42 C.F.R. § 423.664.

V. PROCEDURAL HISTORY

In connection with Contract Year 2022, eternalHealth submitted an application to CMS for a new MA-PD product under Contract H1280. The application included an executed first tier contract between the Appellant and RxAdvance, a company that offers a range of services to insurers and managed care organizations, to serve as the Appellant's PBM. The Appellant also submitted a downstream contract between RxAdvance and Medical Review Institute of America ("MRIoA Contract"), however, the Appellant was not directly identified in the MRIoA Contract. eternalHealth Exhibit P-1 at P 002. The Medicare Addendum to the MRIoA Contract provided that MRIoA may operate as a downstream entity to MA organizations. *Id.* at P 033. The submission also included template contracts for certain pharmacy services to be provided by downstream entities.

The Appellant also included a crosswalk between the MRIoA Contract and certain CMS requirements in its application. eternalHealth Exhibit P-2 at P 037-39. One requirement for subcontracts is "[t]he parties to the contract. *If the applicant is not a party to the contract, it must be identified by name as an entity that will benefit from the services described in the contract*." *Id.* at P 037 (emphasis added). In an attempt to meet this requirement, Appellant cited to the first page of the MRIoA Contract (which included only MRIoA and RxAdvance as parties to the contract). Appellant's Brief at 3; *see also* eternalHealth Exhibit P-1 at P 002.

Appellant also included downstream contract templates of RxAdvance for retail, mail order, home infusion and long-term care pharmacy services. *See* eternalHealth Exhibit P-3 at P 045 – P 211. Each of these templates contained multiple references to the RxAdvance Manual, and specifically required that downstream pharmacies comply with the manual, which is expressly incorporated

into the downstream pharmacy agreements. No provider manual was uploaded with the application. Appellant's Brief at 3.

On March 22, 2021, CMS issued a Part D Deficiency Notice with respect to Contract H1280. eternalHealth Exhibit P-4 at P 215-17. The Appellant states that this notice did not point out the types of alleged deficiencies that CMS later identified as problematic in its final May 27, 2021 application denial. Appellant's Brief at 3. The Appellant notes that the March 22, 2021 Part D Deficiency Notice did not reference any alleged deficiency relating to its failure to include a pharmacy manual (*see* Sub-Issue 3) or failure to include a reference to eternalHealth in the MRIoA Contract (*see* Sub-Issue 4). *Id.*

On March 31, 2021, the Appellant responded to the Part D Deficiency Notice. On April 19, 2021, CMS issued a NOID for Contract H1280, listing the same deficiencies and, again, cited no deficiencies relating to Sub-Issues 3 or 4. *Id.* at 3-4; eternalHealth Exhibit P-5 at P 223-26.

On April 20, 2021, Appellant (through a consultant) reached out to CMS to seek clarity on some of the cited deficiencies. eternalHealth Exhibit P-6 at P 228-29. On April 29, 2021, the last day of the cure period, Appellant responded to the Part D Deficiency Notice and NOID and submitted materials, including a new subcontractor relationship chart and five subcontracts, that it had not been submitted previously. Such submission indicated eternalHealth had made significant changes to its delegated entity structure. Notably, the Appellant changed its PBM from RxAdvance to OptumRx. Accordingly, the Appellant submitted new documentation of its first tier contract with OptumRx, including the OptumRx pharmacy contract templates. The Appellant also submitted a set of downstream contracts that did not expressly name OptumRx as a party. Rather, the contracts were between UHS and several downstream entities: MRIoA, TeleTech Healthcare Solutions, R.R. Donnelly and Sons, West Notifications and MCMC. eternalHealth Exhibit P-8 at P 280 - P 768. The Appellant explained that OptumRx was an affiliate of UHS, and that UHS contracted for services with downstream entities. Appellant's Brief at 12. The Appellant claimed that the change in PBM was "necessitated by CMS' demands" relating to its PBM meeting experience related requirements. Appellant's Reply at 1-2.

On May 27, 2021, CMS denied applications H1280 and H2694.[3] eternalHealth Exhibit P-10 at P 775-80. For both of these applications, CMS identified four core deficiencies (i.e., Sub-Issues 1, 2, 3, 4, *supra* p. 1) which were not identified in the earlier Part D Deficiency Notice or NOID for H1280. Noting that the Appellant "switched its PBM from RxAdvance to OptumRx between the issuances of the NOID and the denial notice" CMS contends that the deficiencies "all . . . arose for the first time with the documents submitted initially during the last cure period following the issuance of the NOID." CMS' Brief at 4.

[3] CMS did not issue an identification number for Contract H2694 in November 2020 because of a CMS programming error. Because of this error, CMS allowed the Appellant to submit application materials for Contract H2694 by May 19, 2021, on the condition that all application materials submitted would be the same as the H1280 materials submitted in response to the NOID. Therefore, Appellant submitted materials, relying as it had for H1280 on the deficiencies cited in the NOID, and which were corrected by these materials. *See* eternalHealth Exhibit P-9 at P 770-74; Appellant's Brief at 4; CMS' Brief at 3-4.

By letter dated June 8, 2021, eternalHealth appealed CMS' May 27, 2021 denial of applications H1280 and H2694. eternalHealth Exhibit P-12 at P 786.

VI. DISCUSSION, FINDINGS OF FACT AND CONCLUSIONS OF LAW

A. Sub-Issue 1 — Failure To Demonstrate A Contractual Relationship Between OptumRx And UHS.

As noted above, through its final cure submission, eternalHealth indicated for the first time that it switched its PBM to from RxAdvance to OptumRx. eternalHealth Exhibit P-7 at P 231-41. eternalHealth also filed a new relationship chart that identified OptumRx as its first tier entity that contracted with several downstream entities. CMS Exhibit C-2. However, the actual downstream contracts were structured so that UHS enters into those contracts "on behalf of itself and its Affiliates" and the downstream entity "will provide certain services to [UHS] and its Affiliates" (*e.g.*, eternalHealth Exhibit P-8 at P 281 and P 727). OptumRx is an affiliate of UHS, but UHS does not appear on the relationship chart. *See* Appellant's Brief at 12; CMS Exhibit C-2. Moreover, the version of the downstream contracts which were filed with CMS contain a supplemental red header which alerts CMS to Appellant's position relating to whether the document is obtainable through the Freedom of Information Act ("FOIA") process. The supplemental header states "UHS/OptumRx Confidential Trade Secret & Commercial Financial Information – FOIA Exemption 4." eternalHealth Exhibit P-8 at P 281; CMS' Brief at 6-7.[4]

The Appellant maintains that because OptumRx is an affiliate of UHS, the UHS contracts with the downstream entities sufficiently provide the legal link in its chain of delegation of Part D functions as required by CMS. The Appellant argues that no separate contract between OptumRx and UHS is necessary because the language "itself and its Affiliates" in the downstream contracts found in eternalHealth Exhibit P-8 "very clearly encompasses OptumRx, and creates a legally binding obligation on the downstream entities to furnish services to OptumRx." Appellant's Brief at 12.[5]

The Hearing Officer finds that Appellant's as-filed application did not demonstrate by a preponderance of the evidence that CMS' interpretation of its policy was inconsistent with the requirements of 42 C.F.R. § 423.503. The Hearing Officer finds merit in CMS' position that the submissions Appellant provided through the application filing windows were not acceptable because they did not clearly demonstrate the legal chain of delegation to its identified first tier and downstream entities. Notably, UHS was not identified as a downstream entity within the relationship chart, CMS Exhibit C-2, yet the corresponding downstream contracts expressly identify UHS as a party, not OptumRx. While the downstream contracts might, as the Appellant contends, constitute a legally binding obligation between the entities, CMS' determination that they do not satisfy the criteria laid out in the controlling authority is reasoned.

[4] The Hearing Officer finds that the supplemental marking is a purely administrative task performed to prepare the documents for submission to CMS and provide CMS with limited information regarding the relationship between UHS and OptumRx.

[5] The hearing record also contains a May 27, 2021 letter which outlines the relationship between eternalHealth, UHS and OptumRx. eternalHealth Exhibit P-18 at P 983; Appellant's Brief at 17. However, the letter was not presented to CMS by the close of the final application deadline for consideration.

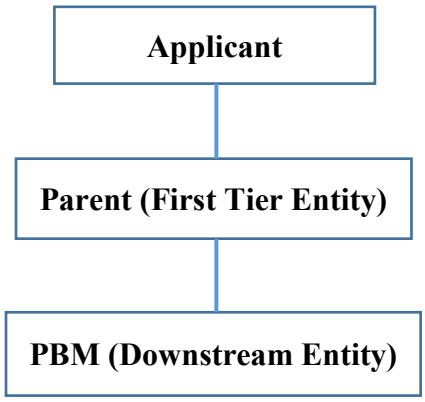
The Appellant alleges that neither the regulation nor the Solicitation "squarely address" a situation where an affiliate of the first tier contractor enters into downstream contracts on behalf of the first tier contractor. Appellant's Reply at 3. The Hearing Officer, however, notes that in reviewing an application, the regulatory definition of downstream entity expressly grants CMS a level of discretion in determining acceptability. 42 C.F.R. § 423.501. Moreover, the regulation envisions that the application materials clearly demonstrate the necessity for clear contractual links and delegation chains between entities. The definitions state:

> *Downstream entity* means any party that enters into a written arrangement acceptable to CMS, below the level of the 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. (emphasis added).

Moreover, the Part D Solicitation at Section 3.1.1.C advises applicants that they may meet Part D requirements by delegating certain functions to first tier or downstream entities. *See* CMS Exhibit C-1 at 5. Section 3.1.1.C instructs applicants as follows:

> Where an applicant has elected to use subcontractors to meet Part D requirements, it must demonstrate that it has binding contracts in place that reflect these relationships. These contracts serve as the *legal links that form the applicant's "chain of delegation,"* extending from the applicant to the entities (first tier or downstream) that will actually perform the stated function on the applicant's behalf. Where the function is to be performed by a downstream entity, there must be contracts in place through which the applicant has delegated a function to a first tier entity, *which has in turn* delegated that function to the downstream entity.
>
> Applicants must identify in the HPMS the first tier and downstream entities with which it has contracted to perform the listed Part D functions. The chart below is provided to assist applicants in identifying the information that must be provided in HPMS.
>
> **Note concerning parent and subsidiary relationships:** In establishing its subcontracting arrangements, an applicant must clearly demonstrate that it has elected to delegate certain Part D functions to first tier and downstream entities . . . .
>
> **Instructions:** In HPMS, on the Contract & Management/Part D Information/Part D Data Page, provide names of the first tier, downstream, and related entities you will use to carry out each of the functions listed in this chart[.]

Sections 3.1.1.D and E, CMS Exhibit C-1 at 7, states:

> **D. First Tier, Downstream, and Related Entity Relationship Chart** Prepare and upload into HPMS a chart showing the relationship between the applicant and each first tier, downstream, and related entity identified in section 3.1.1 C. This chart must include the names of all entities in the contracting chain between the applicant and the entity performing the identified function. An example of a chart is provided below for reference.
>
> 
>
>
> **E.** Except for SAE applicants, upload copies of executed contracts, fully executed letters of agreement, administrative services agreements, or intercompany agreements . . . with each first tier, downstream or related entity identified in Sections 3.1.1 C . . . and with any first tier, downstream, or related entity that contracts with any of the identified entities on the applicant's behalf.

Accordingly, Appellant has not demonstrated by a preponderance of the evidence that CMS' decision to deny contract applications H1280 and H2694 was improper. Based upon Applicant's failure to demonstrate a contractual relationship between OptumRx and UHS, CMS' denial of the applications, in their entirety, is upheld.[6]

B. Sub-Issue 2 — OptumRx Contract Effective Date Deficiency

After receipt of the NOID, Appellant submitted a contract with OptumRx to act as its PBM. The contract term was for three years with an effective date of January 1, 2022. eternalHealth Exhibit P-7 at P 231. The services which OptumRx agreed to provide were set forth in Exhibit B of the

[6] The Appellant notes that CMS has been inconsistent in previous applications as it allegedly identified similar deficiencies involving OptumRx and UHS, in which CMS either accepted or permitted a correction. Appellant's Reply at 4. The Hearing Officer notes that Section 2.4 of the 2022 Solicitation specifically states that "**Applicants should not rely on their understanding of prior years' applications and review standards in determining whether they are complying with application requirements.**"

contract. *Id.* at P 246-51. Pursuant to Section 1.2.1 of Exhibit B, OptumRx agreed to establish and maintain a pharmacy network to provide services to Appellant, as follows:

> Pharmacy Network. OptumRx will establish and maintain a network of pharmacies to provide the Services to Client ("***Pharmacy Network***"). Upon request, OptumRx will make available to Client a current list of Network Pharmacies in the Pharmacy Network. OptumRx may add or remove Network Pharmacies from the Pharmacy Network. OptumRx will retain cash management responsibilities to help support prompt payment of Network Pharmacies.

Id. at P 247.

CMS contends that the contract between Appellant and OptumRx "*provides for the performance of delegated Part D functions necessary to support EternalHealth's pre-benefit year operations enrollment-related services and therefore should have been effective no later than October 15, 2021.*" CMS' Brief at 7. Section 3.1.1.E.6 of the 2022 Solicitation[7] provides:

> ". . . .Unless otherwise indicated, each and every contract must:
>
> . . . .
>
> 6. Clearly indicate that the contract is for a term of at least the initial one-year contract period (i.e., January 1 through December 31) for which this application is being submitted. Where the contract is for services or products to be used in preparation for the next contract year's Part D operations (e.g., marketing, enrollment), the initial term of such contract must include this period of performance (e.g., contracts for enrollment-related services must have a term beginning no later than October 15 extending through the full contract year ending on December 31 of the next year).

Additionally, CMS cites to an authority relating to the requirement to display pharmacy networks for beneficiaries to review in advance of enrollment. CMS' Brief at 7. The Part D regulations require sponsors to provide "[a]t the time of enrollment" information concerning "[t]he number, mix, and distribution (addresses) of network pharmacies from which enrollees may reasonably be expected to obtain covered Part D drugs and how the Part D sponsor meets the requirements of

[7] The May 27, 2021 denials of Appellant's applications stated that "[t]he contract your organization submitted [with OptumRx] is not for a term of at least the one-year contract period for which this application was submitted." eternalHealth Exhibit P-10 at P 776 (Contract H1280) and P 779 (Contract H2694). The Hearing Officer notes that this narrative draws upon the requirement provided in the initial sentence of Solicitation § 3.1.1.E.6, which addresses the contract term. Appellant explains that since the contract term with OptumRx was for three calendar years, it believes it met CMS' stated requirements. Appellant's Brief at 11. Through a subsequent phone call between the Appellant and CMS, CMS clarified its concern that the contract required an effective date no later than October 15, 2021 (which draws upon the requirement provided within the second sentence of Solicitation § 3.1.1.E.6). *See id.*

§423.120(a)(1) for access to covered Part D drugs[.]" 42 C.F.R. §§ 423.128(a)(3) and (b)(5). More specifically, Part D sponsors must post their pharmacy directory, among other plan-related information, on their website "by October 15 prior to the beginning of the plan year[.]" 42 C.F.R. § 423.2265(c)(1)(iv). Likewise, pharmacy networks are included in the Part D plan information displayed on the Medicare Plan Finder website[8] during the annual election period that begins October 15 each year. *See* CMS Exhibit C-3 at 10 ("Pharmacy network submissions . . . must be a full representation of the Part D sponsor's contracted retail and mail order network pharmacies. All pharmacies submitted . . . must be identified as either retail or mail order based on the sponsor's retail and mail order pharmacy network contracts.").

The Appellant contends that the October 15, 2021 effective date required by CMS is inapplicable here based upon OptumRx's function. The Appellant states that it is not clear that any aspect of OptumRx's contract is for services or products to be used in preparation for the next contract year's Part D operations. The Appellant suggests that there is no deficiency based on Section 3.1.1.E.6 of the Solicitation on the basis that OptumRx allegedly does not furnish marketing and enrollment services. Appellant's Brief at 11; Appellant's Reply at 5.

With regard to the start date, Appellant explains that OptumRx has assisted with, among other things, the formulary development and submission, pharmacy network development and was "equally prepared to be available as needed to support responses to any information requests by potential beneficiaries prior to January 1, 2022." Appellant's Brief at 11. Additionally, the OptumRx contract requires OptumRx to provide the client a readiness plan no later than June 1 of the preceding year, which is well in advance of October 1. eternalHealth Exhibit P-7 at P 268 § 1.12.1; *see also* Appellant's Reply at 6. Appellant adds that, for all practical purposes, the contract has been in effect well in advance of October 15, 2021, and that "the parties always intended that comprehensive beneficiary support would be available." Appellant's Brief at 11.

The Hearing Officer finds merit in CMS' argument that in order to comply with the requirement to display pharmacy networks for beneficiaries to review in advance of enrollment as described above, the Appellant would need to have the details of OptumRx's Part D pharmacy network finalized no later than October 15, 2021. Additionally, pursuant to Section 3.1.1.E.6 of the Solicitation, the effective date for the OptumRx contract needed to be no later than October 15, 2021, because the contract is for services or products to be used in preparation for the next contract year's Part D operations.[9] Indeed, this is further evidenced in Appellant's acknowledgement that OptumRx has assisted with, among other things, the formulary development and submission, pharmacy network development and was "equally prepared to be available as needed to support responses to any information requests by potential beneficiaries prior to January 1, 2022." Appellant's Brief at 11. Accordingly, the Hearing Officer finds that the January 1, 2022 effective

[8] Medicare Plan Finder, *available at* https://www.medicare.gov/plan-compare/#/?lang=en&year=2021.
[9] The Hearing Officer also finds that the services OptumRx provides can fairly be characterized as marketing and enrollment services. Further, the "marketing and enrollment" functions referenced in Section 3.1.1.E.6 are merely examples of broader preparatory operations, services or products as the functions are introduced by the term e.g.

date in the contract between Appellant and OptumRx did not meet the requirements set forth in the controlling authority.

C. Sub-Issue 3 — Failure To Provide Pharmacy Provider Agreement And Sub-Issue 4 — Failure To Reference eternalHealth In Downstream Contracts

For Sub-Issues 3 and 4, the Appellant argues that it was prejudiced by CMS' application review on the basis that CMS did not flag the same type of alleged deficiencies during its first two rounds of review of application materials (albeit, as CMS notes, at a time when Appellant had an arrangement with a different PBM).[10] Appellant's Reply at 1-2. As the Hearing Officer upholds CMS' determination based on Sub-Issues 1 and 2, it is unnecessary to reach a substantive decision regarding the parties' competing arguments relating to Sub-Issues 3 and 4.[11]

[10] CMS responds to the Appellant's allegation as follows:

> CMS concedes that during the first two rounds of review, it failed to cite the RxAdvance pharmacy contract templates for not including the pharmacy manual and the contract between RxAdvance and MRIoA for failing to name EternalHealth. However, once EternalHealth completely changed its subcontracting arrangements and submitted completely new documents for CMS to review, it rendered moot any prior deficiency notices related to subcontracting arrangements CMS had issued earlier in the application review process. With the change in business arrangements, EternalHealth was no longer working to "remedy any defects CMS identified." 423.503(c)(2)(ii). It had effectively submitted a new application, making the results of any other review of previous, unrelated documents involving largely different parties inapplicable to the review of the new documents. Similarly, CMS' prior review cannot be considered to alter the application requirements in any way, making it unreasonable for EternalHealth to treat CMS' prior deficiency notices as new guidance.

CMS' Brief at 8.

[11] While Appellant's arguments that it was prejudiced are largely presented in relation to Sub-Issues 3 and 4, the Hearing Officer further clarifies that Sub-Issues 1 and 2 cannot be attributed to a CMS miscommunication. As CMS articulates:

> Even without these deficiencies in the OptumRx pharmacy contract templates and the various subcontracts, EternalHealth's applications were deficient in a way that cannot be attributed to any miscommunication by CMS in its deficiency notice and NOID. The failure to provide a contract between EternalHealth and [United Health Service] and the failure of the OptumRx contract to have a start date prior to January 1, 2022 were not deficiencies that were present in the contract between EternalHealth and RxAdvance or in the contract between RxAdvance and MRIoA, and did not apply to the RxAdvance pharmacy contract templates.

Id.

VII. ORDER

CMS' denial of eternalHealth's applications to offer new MA-PD products under Contract Numbers H1280 and H 2694 is affirmed.

_____
Benjamin R. Cohen, Esq.
CMS Hearing Officer

Date: August 31, 2021

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Centers for Medicare & Medicaid Services

Decision of the Administrator

In the Case of:	*	
	*	
eternalHealth, Inc.	*	**MA/PD Hearing Officer**
Contract Year 2022	*	**Docket Nos. H-21-0013**
	*	**H-21-0014**
Contract Nos. H1280 and H2694	*	
	*	

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This case is before the Administrator, Centers for Medicare & Medicaid Services (CMS), for review of the decision entered by the CMS Hearing Officer. The eternalHealth Inc., the Applicant, requested that the Administrator elect to review and reverse the CMS Hearing Officer decision upholding the CMS denial of the Applications. The Administrator elected to review the CMS Hearing Officer decision under 42 C.F.R. § 423.666(b) for Contract Nos. H1280 and H2694.[1] Pursuant to the Notice to Elect Review, the Applicant and CMS submitted supplemental comments. Accordingly, this case is now before the Administrator for final agency review under 42 C.F.R. §423.666.

Issue

This case involves the Applicant's appeal of CMS' denial of its Part D contract applications to provide Medicare Prescription Drug Plan Benefits for 2022 (Contract Nos. H1280 and H2694) for Middlesex, Suffolk, and Worcester Counties, Massachusetts. The issue is whether the Applicant has proven by a preponderance of the evidence that CMS' determinations for Contract Nos. H1280 and H2694[2] were inconsistent with the requirements of 42 C.F.R. § 423.503. Each of the contract denials are based on the following four deficiencies:

1. New documents provided on April 29, 2021, failed to demonstrate a contractual relationship between OptumRx and United Health Services, Inc. (UHS), the entity referenced in the downstream contracts;

2. The contract between eternalHealth and OptumRx did not have an effective date prior to January 1, 2022, which was essential as OptumRx had consented to provide services prior to the start of the 2022 benefit year;

[1] The CMS Hearing Officer decision had a singular inadvertent error in the heading referring to H1294, instead of H2694, as did the Administrator's Notice to Elect Review of Docket Nos. H-21-0013 and H-21-0014.

[2] CMS did not issue an identification number for Contract H2694 in November 2020 because of a CMS clerical/programming error. CMS allowed the Applicant to submit application materials for Contract H2694 by May 19, 2021, on the condition that all application materials submitted would be the same as the H1280 materials submitted in response to the NOID.

3. eternalHealth failed to produce the Pharmacy Provider Agreement referenced in the pharmacy contract templates it submitted; and

4. eternalHealth's downstream entity contracts failed to specifically identify eternalHealth as the Part D entity for which they would be performing delegated functions.

On February 17, 2021, eternalHealth submitted an application for a Medicare Advantage (MA) Health Maintenance Organization Point of Service (HMOPOS) contract to offer MA and Part D plans in Massachusetts under Contract No. H1280. The application stated that eternalHealth had contracted with RxAdvance as its first-tier entity providing Pharmacy Benefit Management (PBM) services. RxAdvance, in turn had contracted with the Medical Review Institute of America (MRIoA) plus the pharmacies in its contracted network that would participate in eternalHealth's Part D benefit plan.

On March 22, 2021, CMS issued a courtesy notice to eternalHealth informing the organization of several deficiencies in its Part D application, including those related to its documentation of its relationships with first tier and downstream entities (Exhibit P-4) to which eternalHealth responded on March 31, 2021.

CMS issued a Notice of Intent to Deny (NOID) eternalHealth's Part D application based on, among other things, remaining subcontracting deficiencies on April, 19, 2021. (Exhibit P-5.) In response, on April 29, 2021, eternalHealth submitted materials that included a new subcontractor relationship chart and five new subcontracts. The documentation reflected that eternalHealth had submitted a primary change to its delegated entity structure. The Applicant had changed its PBM to OptumRx and submitted documentation of its first-tier contract with that entity and OptumRx pharmacy contract templates. The Applicant also submitted a set of downstream entity contracts that did not name OptumRx as a party. Rather, the contracts were between United Healthcare Services (UHS) and four downstream entities: MRIoA, TeleTech Healthcare Solutions, R.R. Donnelley and Sons, West Notifications, and MCMC.

On May 10, 2021, eternalHealth notified CMS that it had not received a separate application number in response to the Notice of Intent to Apply it had submitted in November 2020 for the local preferred provider organization (LPPO) for which it intended to seek a contract year (CY) 2022 contract in the same service area. CMS advised eternalHealth that the failure to assign an application number for its LPPO application was a clerical oversight. CMS assigned the number H2694 to the LPPO application, including the Part D portion of the application after eternalHealth confirmed that it had intended to submit the same information for its LPPO Part D application as it did for its H1208 Part D application. CMS consequently applied the review history of H1208 to contract H2694. (Exhibit P-9.)

CMS issued the Part D denial notices for both H1208 and H2694 on May 27, 2021, based on four areas of the applications' deficiencies. The deficiencies were related to the documents submitted for the first time during the last cure period following the issuance of the NOID. (Exhibit P-10.) CMS determined that the new documents provided on April 29, 2021, failed to demonstrate a contractual relationship between OptumRx and UHS. CMS also found that the contract between eternalHealth and OptumRx did not have an effective date prior to January 1, 2022, which was

necessary because OptumRx had agreed to provide services that required performance prior to the start of the 2022 benefit year. Finally, CMS found that eternalHealth failed to provide the Pharmacy Provider Agreement referenced in the pharmacy contract templates it submitted and particularly the Pharmacy Manual, and its downstream entity contracts failed to identify eternalHealth specifically as the Part D entity for which they would be performing delegated functions.

CMS Hearing Officer Decision

The CMS Hearing Officer upheld CMS' determinations for Contract Nos. H1280 and H2694, stating that in its final opportunity to cure its application, Applicant filed a new relationship chart identifying OptumRx as its first tier PBM, with OptumRx contracting with several downstream entities. However, the corresponding downstream contracts are structured so that UHS (an affiliate of OptumRx) enters into those contracts "on behalf of itself and its affiliates," yet UHS was not identified on the relationship chart.

Additionally, the effective date of the contract between Applicant and OptumRx, which can be fairly read to include marketing and enrollment services, was January 1, 2022. Contracts relating to the performance of delegated Part D functions necessary to support an applicant's pre-benefit year operations enrollment-related services must have an effective date no later than October 15, 2021. Based on these findings, the CMS Hearing Officer affirmed CMS' denial of the applications to offer new Medicare Advantage Prescription Drug products under Contract Nos. H1280 and H2694.

Since the Hearing Officer upheld CMS' determination based on Sub-Issues 1 and 2, the Hearing Officer found it unnecessary to reach a substantive decision regarding the parties' arguments relating to Sub-Issues 3 and 4.

Applicant's Request for Review

The Applicant first challenged the substantive validity of the deficiency findings. Regarding Deficiency 1, the Applicant argues that the affiliate relationship between UHS and OptumRx created a legally binding obligation to downstream entities to furnish services to OptumRx and therefore the application fulfilled CMS' requirements. As to Deficiency 2, the Applicant argued that OptumRx was not providing services or products to be used in preparation for the next year's contract and, therefore, the January 1, 2022 contract effective date was appropriate. Further, as to Deficiency 3 and 4, the Applicant stated it was not on notice as to Deficiency 3 in its initial filing with a different PBM and was therefore prejudiced by this notice failure. As to Deficiency 4, the Applicant applied a reasonable reading of the requirements.

However, in the alternative, the Applicant argued it submitted documentation demonstrating that it has since cured the deficiencies and requests that the agency consider these submissions. The Applicant stated that it offers a uniquely Member centric-affordable Medicare Advantage option, unique linguistic and cultural competency, a commitment to female leadership and diversity which will benefit Medicare beneficiaries, and deep local community investment and much-needed market competition. In a supplementary filing, the Applicant confirmed that

eternalHealth was ready to serve Medicare beneficiaries in Massachusetts should the Administrator allow for the opportunity to cure its Part D applications for contract year 2022.

CMS submitted comments stating that the CMS Hearing Officer properly upheld CMS' denial of eternalHealth's 2022 Part D applications based on the Applicant's failure to comply with the Part D application requirements. However, CMS stated it was aware that the Applicant has made policy arguments for granting approval that the Hearing Officer could not consider as part of his decision. CMS requested that, if the Administrator determines that approval is appropriate for policy reasons, such as expanded access to culturally and linguistically competent coverage for Medicare beneficiaries, the Administrator's written opinion make clear that the application and appeals process was conducted consistent with Part D requirements.

Discussion

Sections 1857 and 1860D-12 of the Social Security Act authorizes CMS to enter into contracts with entities seeking to offer Medicare Advantage (MA) (Part C) benefits and Medicare outpatient prescription drug (Part D) benefits to their plan enrollees. Pursuant to §§ 1857(a) and 1860D-12(b)(1) an organization may not offer Part D benefits unless it has entered into a contract with CMS.

Under 42 C.F.R. § 423.502(c), organizations intending to offer Part D benefits must complete a certified application in the form and manner required by CMS and demonstrate that they meet all Part D program requirements to qualify as a Part D sponsor in their proposed service area for the product. CMS posted the final "Solicitation for Applications for Medicare Prescription Drug Plan 2022 Contracts" (Solicitation) on its website on December 30, 2020. The Solicitation required Part D contract applicants to provide responses to a series of attestations related to Part D requirements as well as documentation demonstrating their ability to meet program requirements. The documentation included licensure information, contracts with subcontractors such as Pharmacy Benefit Managers (PBMs), contract templates for network pharmacies, a statement of corporate organization and organizational compliance plans. CMS provides the Health Plan Management System (HPMS) as the means for organizations to submit their applications for the MA-PD programs. The applications were due to CMS by February 17, 2021.

CMS conducts a review of all submitted Part D applications pursuant to 42 C.F.R. §423.503 and issues determinations consistent with § 423.503(c). Organizations that offer Part D benefits through a Prescription Drug Plan (PDP) are referred to as Part D sponsor. 42 C.F.R. §423.4. Once qualified as a Part D sponsor, PDP sponsors execute a PDP contract with CMS. Under current regulations and procedures, after receiving an application, CMS reviews the application for any issues. CMS then notifies the applicant of any deficiencies by electronically sending a Part D Deficiency Notice, and provides a "courtesy cure period" to the applicant. This is an applicant's first opportunity to amend its application. If an applicant fails to cure its deficiencies, CMS will issue a Notice of Intent to Deny (NOID). 42 C.F.R. §423.503(c)(2). The NOID affords an applicant a second opportunity to cure its application. After a NOID is issued, an applicant has a final ten-day period to cure any deficiencies in order to meet CMS' requirements. If the applicant fails to do so, CMS will deny the application. 42 C.F.R. § 423.503(c)(2)(ii)–(iii).

If CMS denies the application, an applicant receives written notice of the determination and the basis for the determination. 42 C.F.R. §423.503(c)(3). Subsequently, applicants may request a hearing before a CMS Hearing Officer. 42 C.F.R. §§ 423.503(c)(3)(iii) and 423.650. Furthermore, the applicant has the burden of proving by a preponderance of the evidence that CMS' determination was inconsistent with the controlling requirements of 42 C.F.R. § 423.502 (application requirements) and §423.503 (evaluation and determination procedures). 42 C.F.R. §423.650(b)(1). The CMS Hearing Officer decision is subject to Administrator review under 42 C.F.R. §423.666.

In this case, the Administrator finds that the record supports CMS' findings that the application had the foregoing deficiencies and was consequently properly denied. The CMS Hearing Officer properly found that the Applicant failed to demonstrate by a preponderance of the evidence that CMS' determinations for Contract Nos. H1280 and H2694 were inconsistent with the requirements of 42 C.F.R. §423.503.

Deficiency 1 — Failure to Demonstrate A Contractual Relationship Between OptumRx and UHS.

On the last day of the submission period to cure the Applications, eternalHealth submitted documentation indicating that it changed the PBM to OptumRx and also filed a new relationship chart that identified OptumRx as its first-tier entity that contracted with several downstream entities. However, the downstream contracts were structured so that UHS (not OptumRx) was the party to the contracts "on behalf of itself and its Affiliates" and the downstream entity "will provide certain services to [UHS] and its Affiliates." OptumRx is an affiliate of UHS, but OptumRx is not referenced in the contract(s), while UHS does not appear on the relationship chart. On its face, a review of these documents would not confirm the legal and binding contractual/affiliate relationship between UHS and OptumRx and, hence, its legal obligations in accordance with the CMS requirements to the Applicant.

The Hearing Officer properly upheld CMS' position that the Applicant's submissions were not acceptable because they did not clearly demonstrate the legal chain of delegation to its identified first tier and downstream entities. While the downstream contracts might, as the Applicant contended, constitute a legally binding obligation between the entities, the documents do not on their face show such a relationship and CMS' determination that they do not satisfy the controlling authority criteria is within CMS' discretion under 42 C.F.R. § 423.501. The Administrator agrees that the application failed to clearly demonstrate the regulatory required contractual links and delegation chains between entities, as also required by solicitation instructions and required relationship chart. The Applicant failed to demonstrate by a preponderance of the evidence that CMS' determinations for Contract Nos. H1280 and H2694 were inconsistent with the requirements of 42 C.F.R. §423.503 as to Deficiency 1.

Deficiency 2 — OptumRx Contract Effective Date Deficiency

The Applicant's PBM contract with OptumRx was for three years with an effective date of January 1, 2022. The Administrator finds that the record reasonably supports CMS' conclusion that the services which OptumRx agreed to perform included the delegated Part D functions

necessary to support eternalHealth's pre-benefit year operations enrollment-related services, etc., and, therefore, should have been effective no later than October 15, 2021.

The Hearing Officer properly upheld CMS' denial as OptumRX was required to perform pre-benefit year services and the Applicant would need to have the details of OptumRx's Part D pharmacy network finalized no later than October 15, 2021. Accordingly, the Administrator agrees, with the Hearing Officer upholding the CMS deficiency finding that the January 1, 2022 effective date in the contract between Applicant and OptumRx did not meet the requirements set forth in the controlling authority. The Applicant failed to demonstrate by a preponderance of the evidence that CMS' determinations for Contract Nos. H1280 and H2694 were inconsistent with the requirements of 42 C.F.R. § 423.503 as to Deficiency 2.

Deficiency 3 — Failure to Provide Pharmacy Provider Agreement and

Deficiency 4 — Failure to Reference eternalHealth In Downstream Contracts

For Deficiency 3 and 4, the Applicant argued that it was prejudiced by CMS' initial application review on the basis that CMS did not flag the same type of alleged deficiencies during its first two rounds of review of the application materials, when the Applicant had an arrangement with a different PBM. However, CMS properly pointed out that the Applicant submitted a new PBM on the deadline date, and beyond any further curing time period, thereby, mooting any alleged prior notice issues with the initial PBM contract. The CMS Hearing Officer declined to reach a decision on these two deficiencies because of the Application's failures under Deficiency 1 and 2. However, CMS' denial on these deficiencies can be supported. The Applicant submitted a new PBM and related documentation pursuant to the NOID and, therefore, any prior deficiencies notice was not applicable and the CMS' deficiency findings were accurate on the last submissions. The Applicant failed to demonstrate by a preponderance of the evidence that CMS' determinations were inconsistent with the requirements of 42 C.F.R. § 423.503 with respect to Deficiencies 3 and 4.

In sum, after a review of the record, the applicable law, CMS policy, and the parties' arguments, the Administrator finds that the CMS denials and the CMS Hearing Officer affirmation were proper and correct and in conformity with the Part D regulations and application guidelines. The Applicant failed to demonstrate by a preponderance of the evidence that CMS' determinations were inconsistent with the requirements of 42 C.F.R. § 423.503.

However, pursuant to the Administrator's discretionary contractual authority, and for policy reasons provided by the Applicant, the Administrator modifies the CMS denials and the CMS Hearing Officer decision to allow the Applicant the opportunity to demonstrate that it meets the relevant Part D regulatory and guidance application requirements in light of the policy considerations presented in this case. The Administrator further holds that, in allowing the Applicant the opportunity to correct the deficiencies in the application process at this time, the Applicant must promptly submit the documentation required by CMS within the timeframes that CMS specifies pursuant to this decision. CMS will review the documentation for whether the documentation cures the cited Applications' deficiencies.[3] The CMS determination on the

[3] For example, in Applicant's alternative arguments, the Applicant points to the following exhibits to demonstrate it has cured any deficiencies. *See e.g.*, P-15, "Amendments to Downstream Contracts between UHS and TTEC, RRD,

whether the submitted documentation cures the Applications' deficiencies, in conformity with requirements of the Part D Program, will be incorporated as the final decision of the agency on Contract Nos. H1280 and H2694.

Nothing in the decision guarantees that eternalHealth, Inc. will be permitted to enroll Medicare beneficiaries under Contract Nos. H1280 and H2694 for the CY 2022 contract year. The plans will have to meet all other contractual milestones required by CMS.

MRIoA, Intrado Interactive Services Corporation (f/k/a West Notifications, Inc.), and MCMC," pp 794 – 809; P-16, "OptumRx Pharmacy Provider Manual," pp 810-975; P-17, "Amendment to OptumRx Prescription Drug Benefit Administration Agreement and Joinder Agreement by and between eternalHealth, Inc., OptumRx and UHS," pp 976 – 981; P-18, "May 27, 2021 "OptumRx Letter." pp 982 – 983.

DECISION

The Administrator modifies the decision of the Hearing Officer in accordance with the foregoing opinion.

THIS CONSTITUTES THE FINAL ADMINISTRATIVE DECISION OF THE SECRETARY OF HEALTH AND HUMAN SERVICES

Date: September 24, 2021

Jonathan Blum
Principal Deputy Administrator
Center for Medicare & Medicaid Services