DEPARTMENT OF HEALTH & HUMAN SERVICES

Centers for Medicare & Medicaid Services
Office of Hearings
7500 Security Boulevard
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August 19, 2024

VIA ELECTRONIC DELIVERY

Tracy Purcell
Chief Operating Officer
BlueCross BlueShield of Tennessee
1 Cameron Hill Circle
Chattanooga, TN 37402

Arianne Spaccarelli
Health Insurance Specialist
MAPD Appeals Team
7500 Security Boulevard
Baltimore, MD 21244

RE: Hearing Officer Decision
Hearing Officer Docket Number: H-24-00022
Medicare Advantage/Prescription Drug Plan Contract Denial
Shared Health Insurance Company, Contract Number: H2096

Dear Ms. Purcell and Ms. Spaccarelli:

A copy of the Hearing Officer's Decision and Order for the above-referenced appeal is attached.

The Hearing Officer's Decision and Order may be appealed to the Administrator of the Centers for Medicare & Medicaid Services. The parties may request review by the Administrator within 15 calendar days of receiving this decision. *See* 42 C.F.R. § 422.692; 42 C.F.R. § 423.666. Requests for review should be sent via email to Jacqueline R. Vaughn, Director, Office of the Attorney Advisor, at Jacqueline.Vaughn@cms.hhs.gov, with a copy to Arlene O. Gassmann, Paralegal Specialist, at Arlene.Gassmann@cms.hhs.gov.

Sincerely,

Office of Hearings

DEPARTMENT OF HEALTH AND HUMAN SERVICES
CENTERS FOR MEDICARE & MEDICAID SERVICES

SHARED HEALTH INSURANCE COMPANY	*	
Contract No. H2096	*	**CMS Hearing Officer Case No.: H-24-00022**
Petitioner	*	
v.	*	**Denial of Initial Application to Provide a Medicare Advantage /Medicare Advantage – Prescription Drug Plan**
CENTERS FOR MEDICARE & MEDICAID SERVICES,	*	
Respondent	*	

HEARING OFFICER DECISION

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I. FILINGS

a) May 30, 2024 Hearing Request regarding the Centers for Medicare & Medicaid Services' ("CMS'") Initial Application Denial, filed by Shared Health Insurance Company;[1]
b) June 7, 2024 Shared Health Insurance Company's Brief ("Plan Brief") and Plan Exhibits P-1 through P-16;
c) June 14, 2024 CMS' Brief in Reply to Applicant's Brief and Motion for Summary Judgment Supporting CMS' Denial of Shared Health Insurance Company's Initial Application for a Medicare Advantage Prescription Drug Plan ("MA-PD") Contract (H2096) for Contract Year 2025 and Exhibits C-1 through C-5;
d) June 14, 2024 CMS' Corrected Brief in Reply to Applicant's Brief ("CMS' Corrected Brief") and Motion for Summary Judgment ("Motion for Summary Judgement") Supporting CMS' Denial of Shared Health Insurance Company's Initial Application for a Medicare Advantage Prescription Drug Plan ("MA-PD") Contract (H2096) for Contract Year 2025 and Exhibits C-1 through C-5;
e) June 21, 2024 Shared Health Insurance Company's Reply Brief ("Plan Reply Brief") and Exhibits;
f) July 16, 2024 Shared Health Insurance Company's Hearing Exhibits 1 and 1A;
g) July 17, 2024 CMS' Hearing Exhibits C-1 through C-3.

II. JURISDICTION

This appeal is provided pursuant to 42 C.F.R. §§ 422.660 and 423.650. The CMS Hearing Officers designated to hear this case are the undersigned, Amanda S. Costabile and Benjamin R. Cohen.

III. ISSUE

Whether CMS' denial of Shared Health Insurance Company's initial application for an MA/MA-PD contract (Contract No. H2096) based on Shared Health Insurance Company's failure to meet CMS' contracting requirements was inconsistent with regulatory requirements.

IV. DECISION SUMMARY

The Hearing Officers find that Shared Health Insurance Company was unintentionally deprived of a full and fair opportunity to cure the cited deficiency to CMS' satisfaction. Also, Shared Health Insurance Company (hereinafter, "SHIC") has proven by a preponderance of the evidence, considering CMS regulations, subregulatory guidance, and case-specific email directives, that it met CMS' requirements based on a reasonable and contextual interpretation of those collective references, instructions and communications. Accordingly, the Hearing Officers hereby overturn CMS' May 31, 2024 denial of SHIC's initial application for contract number H2096.

[1] Within the hearing and throughout the briefs, Shared Health Insurance Company is also sometimes referred to as the "Applicant" or "applicant."

V. AUTHORITIES, APPLICATION REVIEW PROCESS AND SUBREGULATORY GUIDANCE

A. Application Review

Under Title XVIII of the Social Security Act ("the Act") (codified at 42 U.S.C. §§ 1395-1395lll), CMS is authorized to enter into contracts with entities seeking to offer Medicare Part C and Part D benefits to their plan enrollees. 42 U.S.C §§ 1395w-27, 1395w-112. CMS requires an entity seeking to contract as an MA organization to submit an application through the Health Plan Management System ("HPMS").[2] *See* "Part C-Medicare Advantage and 1876 Cost Plan Expansion Application" at https://www.cms.gov/files/document/cy-2025-medicare-advantage-part-c-application.pdf (last visited June 25, 2024). The "Part C-Medicare Advantage and 1876 Cost Plan Expansion Application" is specifically "[f]or all new applicants and existing Medicare Advantage organizations seeking to expand a service area[.]" *Id*. at 1.

The regulation at 42 C.F.R. § 422.501 sets forth the application requirements for entities that seek a contract as an MA organization offering an MA plan and additional application requirements for MA organizations seeking to offer a Specialized MA plan for Special Needs Individuals. Among other requirements, applicants must provide documentation of appropriate state licensure, demonstrate that they are licensed under state law as a risk-bearing entity eligible to offer health insurance or health benefits, and submit a properly executed CMS State Certification Form. *See also* 42 C.F.R. § 422.400; "Part C-Medicare Advantage and 1876 Cost Plan Expansion Application" at https://www.cms.gov/files/document/cy-2025-medicare-advantage-part-c-application.pdf (last visited June 25, 2024).

MA organizations offering prescription drug plans must meet the requirements under Part 422 as well as follow the requirements of Part 423. 42 C.F.R. § 422.500. The regulation at 42 C.F.R. § 423.502 sets forth the pertinent application requirements, including that the applicant must fully complete all parts of a certified application in the form and manner required by CMS. 42 C.F.R. § 423.502(c)(1). MA organizations offering qualified prescription drug coverage are known as MA-PD plans. 42 C.F.R. § 423.4.

CMS posted the final Solicitation for Applications for Medicare Advantage and Medicare Prescription Drug Plan 2025 Contracts ("Part D Application") on January 9, 2024, at https://www.cms.gov/medicare/coverage/prescription-drug-coverage-contracting/application-guidance. The Part D Application requires Part D applicants to provide responses to a series of attestations related to Part D requirements and document their ability to meet the Part D program requirements. Among other document requirements, applicants must provide 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.

[2] HPMS is the primary information collection vehicle within which MA organizations will communicate with CMS during the application process, bid submission process, ongoing operations of the MA program, reporting and oversight activities. https://www.cms.gov/files/document/cy-2025-medicare-advantage-part-c-application.pdf at 6.

CMS evaluates an entity's application solely on the basis of information contained in the application itself and any additional information that CMS obtains through on-site visits and any essential operations test. 42 C.F.R. § 423.503(a)(1). After reviewing whether the application meets all requirements, CMS issues, if necessary, a Deficiency Notice in which CMS notifies an applicant of deficiencies within the application and allows a specific time within which the applicant may cure the deficiencies. *See* CMS Corrected Brief at 2. If the applicant fails to cure the deficiencies cited within the Deficiency Notice or if the applicant is otherwise unable to meet the pertinent regulatory requirements, CMS issues the applicant a Notice of Intent to Deny ("NOID") that summarizes the basis of the preliminary finding. 42 C.F.R. § 423.503(c)(2)(i). Pursuant to 42 C.F.R. § 423.503(c)(2)(ii), the applicant will have ten days from the NOID to respond in writing to correct deficiencies in the application.

If, in response to the NOID, the applicant either fails to submit a revised application within ten days from the date of the NOID, or if after timely submission of a revised application, CMS still finds that the applicant does not appear qualified or has not provided CMS enough information to allow CMS to evaluate the application, CMS will deny the application. 42 C.F.R. § 423.503(c)(2)(iii). For an application denial, CMS provides the applicant with written notice of the determination and the basis for the determination. 42 C.F.R. § 423.503(c)(3).

A contract applicant that has been determined to be unqualified to enter into a contract with CMS under Part D of Title XVIII of the Act in accordance with 42 C.F.R. §§ 423.502 and 503, is entitled to a hearing before a CMS Hearing Officer. 42 C.F.R. § 423.503(c)(3)(iii). The applicant has the burden of proving by a preponderance of the evidence that CMS' determination was inconsistent with the requirements of 42 C.F.R. §§ 423.502 (application requirements) and 423.503 (evaluation and determination procedures). 42 C.F.R. § 423.650(b)(1). In addition, either party may ask the Hearing Officer to rule on a Motion for Summary Judgment. 42 C.F.R. § 423.662(b). The authority of the Hearing Officer is found at 42 C.F.R. § 423.664, which specifies that "[i]n exercising his or her authority, the hearing officer must comply with the provisions of title XVIII [of the Act] and related provisions of the Act, the regulations issued by the Secretary, and general instructions issued by CMS in implementing the Act."[3]

B. Contracting Requirements

Within subpart K of the Part D regulations, CMS describes its application procedures and contracts with Part D plan sponsors. Under 42 C.F.R. § 423.500, CMS specifically describes that the "subpart sets forth the application procedures and contracts with Part D plans: application

[3] Within the preamble to the 2010 Final Rule, the Secretary provided additional clarification regarding the hearing process:

> [T]he applicant would not be permitted to submit additional revised application material to the Hearing Officer for review should the applicant elect to appeal the denial of its application. Allowing for such a submission and review of such information as part of the hearing would, in effect, extend the deadline for submitting an approvable application.

75 Fed. Reg. 19678, 19683 (Apr. 15, 2010).

procedures and requirements; contract terms; procedures for termination of contracts; [and] reporting by Part D plans."

Under 42 C.F.R. § 423.505, CMS sets forth the contract provisions that must be specified in contracts between Part D plan sponsors and CMS. Pertinent to the instant appeal, 42 C.F.R. § 423.505(i) discusses a Part D plan sponsor's relationship with any first tier, downstream or related entity, specifically listing the provisions that "[e]ach and every contract governing Part D sponsors and first tier, downstream, and related entities[] must contain[.]" 42 C.F.R. § 423.505(i)(3). Part D plan sponsors that delegate certain activities or responsibilities to first tier, downstream or related entities must also include the specific requirements and provisions listed under 42 C.F.R. § 423.505(i)(4)-(6) within their contracts.

Within the Part D application itself, CMS states that

> [a] Part D sponsor may meet program requirements by delegating the performance of certain required functions to entities with which it contracts directly, referred to in the Part D regulations (§ 423.501)[4] as "first tier entities." These entities may in turn contract with other entities, defined as "downstream entities," for the performance of the delegated function. A related entity is an entity that is a parent, subsidiary, or subsidiary of the parent of the Part D Sponsor. A related entity may be either a first tier or downstream entity.

CMS Exhibit C-1 at pdf page 9.

Within the same section of 3.1.1.C, CMS also advises that

> "[w]here 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.

[4] Under 42 C.F.R. § 423.501, CMS provides the following regulatory definitions:

> • *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.
>
> • *Downstream entity* means any party that enters into a written agreement, 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.
>
> • *Related entity* means any entity that is related to the [Part D plan] sponsor by common ownership or control and, among other things, performs some of the Part D plan sponsor's management functions under contract or delegation.

> . . .
>
> 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. Where an applicant is a subsidiary to a parent organization and that organization purports to contract with other entities on the applicant's behalf, the applicant must consider the parent organization a first tier entity and provide a contract between itself and its parent that meets Part D requirements. CMS will not consider any other types of materials, including articles of incorporation, organizational charts, or lists of board members or senior executives, which the applicant might believe demonstrate that the parent is authorized to contract on the applicant's behalf.

Id. (emphasis omitted).

Under Section 3.1.1.E, the Part D Application provides additional instruction as follows:

> [U]pload 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 Sections 3.1.1C . . . and with any first tier, downstream, or related entity that contracts with any of the identified entities on the applicant's behalf. As noted above, this requirement applies even if an entity contracting on the applicant's behalf is the applicant's parent organization or a subsidiary of the applicant's parent organization. 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 in the contract.

Id. at pdf page 11 (emphasis omitted).

The remainder of Section 3.1.1.E lists out an additional nineteen specific contract requirements that, "[u]nless otherwise indicated, each and every contract must" address. *Id*. at pdf pages 11-13. More specifically, CMS states that "[e]ach complete contract must meet all of the above requirements when read on its own." *Id*. at 13.

VI. PROCEDURAL HISTORY AND STATEMENT OF FACTS

On February 14, 2024, SHIC submitted a contract "application for a local coordinated care plan . . . to offer MA and Part D plans in Texas under contract number H2096." CMS' Corrected Brief at 4. Specifically, SHIC states that it "intends to sponsor MA-PD plans, including a Medicare Advantage Dual-Eligible Special Needs Plan ('D-SNP')" in three Texas counties. Plan Brief at 1.

CMS states that SHIC's "application stated that [CVS] and [BCBST] would be performing several key Part D functions and [SHI][5] would be performing customer service functions on SHIC's behalf." CMS' Corrected Brief at 4. SHIC notes that it "is a wholly owned subsidiary of [BCBST][.]" Plan Brief at 1.

On March 19, 2024, CMS issued SHIC a Part D Deficiency Notice within which CMS cited several deficiencies in SHIC's Part D application. CMS' Corrected Brief at 4. The Deficiency Notice listed the following contracting deficiencies (in pertinent part):[6]

- 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 [BCBST].
- 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 [SHI].
- The executed agreement submitted is between a first tier, downstream or related entity and an organization other than the Applicant. Applicant did not submit an agreement to establish the relationship between the applicant and the organization identified on the first tier, downstream or related contract. The contract referenced is between [CVS] and [BCBST].
- The contract your organization submitted to perform key part D functions does not include a reference to your organization. The contract referenced is between [CVS] and [BCBST].

Plan Exhibit P-4 at 1-2.

On March 21, 2024, SHIC emailed CMS using one of the "Contracting" "Point of Contact for Questions" email addresses provided in the March 19, 2024 Deficiency Notice. Plan Exhibit P-5 at 4. Within SHIC's email message, SHIC provides the following "brief explanation" (in pertinent part) to "resolve the deficiencies identified in the Contracting . . . sections." *Id.* at 2.

> [SHIC] is a wholly owned subsidiary of Southern Diversified Business Services, Inc. which is a wholly owned subsidiary of [BCBST]. It is a Texas for-profit corporation incorporated on February 14, 2024. Additionally, our [Pharmacy Benefits Management ("PBM")] contract with CVS is through our parent company, [BCBST]. [SHIC] is a party to the contract through this affiliation.

Id. at 2-3.

On March 22, 2024, CMS responded by email to SHIC's message. Within the email, CMS stated

[5] "SHIC" and "SHI" are separate organizations.

[6] The additional deficiencies listed within the Deficiency Notice are not pertinent to the instant appeal. *See* CMS' Corrected Brief at 4.

> [SHIC] needs to be referenced by name when benefitting from services under a contract to which it is not a party. It is not a party to the PBM contract, and it is not included in the Exhibit A list of affiliates with access to the PBM services. Because [SHIC] is not a party to the contract, it must establish what is referred to in the Part D application as a chain of delegation. To do so, an agreement is needed with [BCBST]. A contract with Shared Health, Inc. is also requested because it appears as a subcontractor performing a Part D function in HPMS.

Id. at 1

On March 26, 2024, SHIC provided curing materials in response to the Deficiency Notice. Plan Brief at 7. SHIC states that, in response to CMS' explanation, it submitted (among other curing materials not pertinent to the instant appeal) "the PBM Agreement, with an updated Schedule A (BlueCross Affiliates) that listed [SHIC] and noted [SHIC] is a party to the PBM agreement[.]" *Id*. at 6-7.

On April 16, 2024, CMS issued SHIC a NOID in which CMS cited numerous deficiencies (listed in pertinent part):

- 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 [BCBST].
- 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 [SHI].
- The executed agreement submitted is between a first tier, downstream or related entity and an organization other than the Applicant. Applicant did not submit an agreement to establish the relationship between the applicant and the organization identified on the first tier, downstream or related contract. The contract referenced is between [CVS] and [BCBST].

Plan Exhibit P-3 at 2.

On April 17, 2024, SHIC emailed CMS, in accordance with the email addresses listed on the NOID, to "inquire about the Contracting deficiencies" listed in the NOID. Plan Exhibit P-8 at 4. As SHIC explains in its brief,

> [a]t the same time, Shared Health Georgia, Inc. ("SHG") was communicating via email with CMS regarding its application for contract H7974,[7] which also received a [NOID] for the same contract deficiencies noted in the NOID for H2096. In this correspondence, [CMS] explained, relevant also to H2096:

[7] For reasons unrelated to the issues here, SHG withdrew its application after initially appealing it.

. . .

> Still needed [are]: . . .
>
> A contract between the applicant and [BCBST] because (1) BCBST is performing a Part D function, and (2) it is needed to complete what is referred to in the application as the chain of delegation (because BCBST is contracting with CVS). This would also cure one deficiency in the contract between CVS and BCBST. . . .
>
> A contract between the applicant and [SHI] as they are performing a Part D function.

Plan Brief at 8-9; Plan Exhibit P-9 (email dated April 17, 2024 from CMS to SHG).

On April 19, 2024, SHG followed up with CMS regarding its remaining contracting deficiencies. Plan Exhibit P-9 at 1. Within its email message, SHG asks

> [w]ould the attached Administrative Services Agreement address the three remaining Part D deficiencies listed [in the NOID (quoted *supra*)]? The agreement addresses the relationship between [SHI] and [SHG], as well as the relationship between [SHG] and [BCBST].
>
> . . .
>
> We received the same deficiencies for our other plan H2096. Our plan is to have a similar agreement executed to address those deficiencies.

Id.

On the same date, CMS responded, stating

> [i]t is the contract requested between the applicant and [SHI] but would not cure the request for an agreement with [BCBST] because they are contracting with the PBM. If you submit the contract between the applicant and Shared Health and the contract between Shared Health and [BCBST], those will establish what is referred to in the application as the chain of delegation.

Id.

In response to the NOID, on April 25, 2024, SHIC submitted the following agreements: "(1) Administrative Services Agreement between [SHI] and [SHIC], dated February 14, 2024, and (2) Administrative Services Agreement, by and between [SHI], [BCBST] and Volunteer State Health Plan, Inc. ("VSHP"), dated February 1, 2014." Plan Brief at 9; CMS' Corrected Brief at 4.

On May 15, 2024, CMS issued a Denial Notice to SHIC. CMS Corrected Brief at 4. CMS issued an updated Denial Notice on May 31, 2024, in which CMS cited the following application deficiencies for contracting:

- The executed agreement submitted is between a first tier, downstream or related entity and an organization other than the Applicant. Applicant did not submit an agreement to establish the relationship between the applicant and the organization identified on the first tier, downstream or related contract. The contract referenced is between [CVS] and [BCBST].[8]
- 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 [BCBST].
- The contract your organization submitted for key Part D functions does not contain flow-down clauses requiring the activities of the first tier, downstream or related entity to be consistent with your organization's contractual obligations as a Part D sponsor. The contract referenced is between [SHI] and [BCBST] and [VSHP].[9]
- The contract your organization submitted for key Part D functions does not contain language clearly indicating that the first tier, downstream or related entity has agreed to participate in your Medicare Prescription Drug program. The contract referenced is between [SHI] and [BCBST] and [VSHP].
- The contract your organization submitted for key Part D functions does not contain language obligating the first tier, downstream or related entity to abide by all applicable Federal laws and regulations, as well as CMS instructions. The contract referenced is between [SHI] and [BCBST] and [VSHP].
- The contract your organization submitted for key Part D functions does describe the functions, including the reporting requirements to be performed by the subcontractor. The contract referenced is between [SHI] and [BCBST] and [VSHP].
- The contract your organization submitted for key Part D functions does not contain language sufficient to ensure that the first tier, downstream or related entity will make its books or records related to Part D operations available for Federal inspection. The contract referenced is between [SHI] and [BCBST] and [VSHP].
- The contract your organization submitted for key Part D functions does not contain language that you have the authority to revoke the contract in the event that you or CMS determine that the first tier, downstream or related

[8] Within the hearing, CMS states that, with respect to the CVS contract, although SHIC's Denial Notice listed the CVS contract as a deficiency, "[t]o be clear, we do not consider that to be a deficiency anymore, and that's why we didn't argue that in our brief." Transcript ("Tr.") at 22.

[9] During the hearing, CMS clarified that VSHP "has no relationship to this application whatsoever[,]" thus their inclusion on the deficient contract listed in the Denial Notice is not part of the instant appeal. Tr. at 25-26.

entity is not performing satisfactorily. The contract referenced is between [SHI] and [BCBST] and [VSHP].

- The contract your organization submitted for key Part D functions does not contain language sufficient to ensure that the first tier, downstream or related entity will hold beneficiaries harmless for fees that are your organization's responsibility. The contract referenced is between [SHI] and [BCBST] and [VSHP].
- The contract your organization submitted for key Part D functions does not include a reference to your organization. The contract referenced is between [SHI] and [BCBST] and [VSHP].
- 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 between [SHI] and [BCBST] and [VSHP].

Plan Exhibit P-1 at 1-2.

On May 30, 2024, SHIC timely requested a hearing. SHIC filed its initial brief on June 7, 2024; CMS filed its responsive Corrected Brief on June 14, 2024; and SHIC filed a Reply Brief on June 21, 2024. The Hearing Officers postponed the June 26, 2024 hearing to consider CMS' Motion for Summary Judgment. After denying CMS' Motion for Summary Judgment on July 9, 2024, the Hearing Officers rescheduled the hearing for July 15, 2024. During the hearing, the Hearing Officers admitted four additional exhibits as Hearing Exhibits 1-4; Hearing Exhibits 1 and 1A were submitted as Plan Hearing Exhibit P-1[10] and Hearing Exhibits 2, 3 and 4 were submitted as CMS Hearing Exhibits C-1 through C-3. The Hearing Officers confirmed, during the hearing, that neither party objected to the admission of these additional exhibits.

VII. PARTIES' CONTENTIONS

A. SHIC's Contentions

SHIC argues that it "believes that it met the requirements for its Application based on its reasonable interpretation of CMS's guidance at the time of submission and that it was materially prejudiced during the application process by CMS's unclear guidance." Plan Reply Brief at 1.
SHIC states that throughout the application process, and "based on its communication with CMS, SHIC believed the application deficiencies to be specific to the CVS Contract . . . and expected CMS's review of the corrected CVS Contract to cure all deficiencies." *Id*. at 2. SHIC asserts that had CMS "more clearly explained that the deficiencies extended beyond the CVS Contract, then SHIC would have submitted the intercompany documents earlier and had the opportunity to cure the noted deficiencies during the application period." *Id*. SHIC also states that it did not understand the deficiencies noted in the Denial Letter until CMS provided details in its June 14,

[10] Within the pre-hearing conference immediately prior to the hearing, the Plan requested to submit an additional exhibit consisting of a contract. During the hearing, CMS did not object to the admission of this exhibit. Tr. at 6. Although the Plan provided additional explanation of its exhibit during the hearing, the Hearing Officers will not consider this additional contract in the instant appeal as it was not submitted prior to the application deadline. *See* Tr. at 118-19; note 3 *supra*.

2024 Corrected Brief that indicated that the deficiency was related to something other than the CVS Contract. *Id*. at 1, 5.

SHIC argues that CMS' post-Deficiency Notice March 22, 2024 email "primarily focuse[d] on the PBM services" and did not specifically state that BCBST was "listed as a subcontractor performing a Part D function[,]" thus SHIC asserts that it was "reasonable for the [SHIC] team to have believed that the CVS contract was what was needed to cure this request related to the contract with [BCBST]." Plan Reply Brief at 3; Tr. at 114. In response, SHIC "uploaded a CVS contract with an updated Schedule A that clearly establishes SHIC as a party to the CVS contract." Plan Reply Brief at 3-4.

SHIC states that it "was confused when similar deficiencies were noted in the April 16, 2024 [NOID][,]" and immediately reached out to CMS.[11] *Id*. SHIC asserts that after receiving the NOID, it attempted to request a telephone call with CMS[,]" but, as CMS was not available to meet by phone, SHIC "relied on its reasonable interpretation of email communication with CMS." *Id*. at 2, 4. SHIC states that it, once again, reasonably read the post-NOID email messages from CMS "to be specific to the CVS contract." *Id*. at 4. SHIC opines that

> even though SHIC believed that CMS had information sufficient to resolve the deficiencies by closely reviewing the CVS Contract, SHIC submitted the updated CVS Contract as well as the requested intercompany documents to CMS.

Id. at 5.

B. CMS' Response

In its Response Brief, CMS argues that

> SHIC failed to demonstrate that it complied with the requirements to contract as a Part D sponsor because a contract it submitted both to support the delegation of functions to a downstream entity and the provision of key Part D functions did not include the terms required by the regulation. In addition to identifying BCBST as contracting with CVS on its behalf, SHIC identified them as performing key Part D functions on its behalf. [*sic*] While SHIC indicated that some of these functions would also be performed by CVS, SHI, or SHIC itself, BCBST was listed as the only organization operating the enrollee appeals and grievance process and enrollment processing. Exhibit C-2. The importance of these functions makes it particularly important that the contract delegating these functions to BCBST comply with all CMS requirements—failure to properly process enrollments or administer appeals can result in a beneficiary failing to receive lifesaving drugs.

CMS' Corrected Brief at 5.

[11] SHIC's witness testified that "we're also a little bit confused because the same deficiencies were noted in the deficiency notice and the [NOID]. It was obvious we weren't hitting the mark, but we were unsure of how to resolve these deficiencies." Tr. at 40.

During the hearing, CMS clarified that the basis of CMS' denial of SHIC's application was that SHIC "failed to submit a contract with [BCBST] that complied with CMS requirements as outlined in section 3.1.1E of the application and 42 CFR section 423.505(i)." Tr. at 103. Specifically, CMS points to "page 30 of the actual application" (Tr. at 110) that requires that

> each and every contract must . . . 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.[12]

Id. at 111; CMS Exhibit C-1 at pdf pages 11-12 (emphasis omitted).

CMS goes on to explain that the BCBST contract that was submitted "did not reference the functions that the applicant itself indicated would be performed, such as appeals and grievances, and it neither included the applicant as a party nor mentioned the applicant at all." Tr. at 104. CMS asserts that "in order for the contract to meet requirements, it must first be the contract that actually governs their services[,] [a]nd in failing to list [SHIC], it's unclear that that contract covers the services that [BCBST] would be performing on [SHIC's] behalf." *Id*. at 108-09. CMS argues that "the application deficiency notice, [NOID], email communications, and denial notice all clearly indicated that the applicant was required to submit a contract with [BCBST] that complied with Part D requirements." *Id*. at 104.

VIII. DISCUSSION AND ANALYSIS

The Hearing Officers note that at the hearing it became apparent that there were multiple pathways to cure the final submission (e.g., contracts between two entities, contracts between more than two entities, etc.), and also note that throughout the application process, the parties discussed numerous entities involved in the instant Part D application—SHIC, SHI, BCBST, CVS, VSHP—and a parallel process involving SHG and the same organizations. In the instant case, the parties presented multiple controlling regulatory subsections as well as guidance within the application itself, which contained highly technical textual differences.

The Hearing Officers find that CMS' communications (Part D Deficiency Notice, NOID, and email correspondence) when read together, contained ambiguities and were unintentionally misleading, especially the last email from CMS on April 19, 2024, at 4:16 PM,[13] in which CMS

[12] CMS asserts that the sentence "[i]f 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" requires applicants to be included **within the contract** as an entity benefitting from the contract. Tr. at 111. However, the Hearing Officers note that the instruction does **not** explicitly state such a directive (as opposed to, for example, being **identified** in the First Tier, Downstream, and Related Entity Relationship Chart within Section 3.1.1.D of the Part D Application).

[13] To recap, CMS' email reads as follows (in response to SHIC's question whether the Administrative Services Agreement that was attached to SHIC's email would "address the three remaining Part D deficiencies listed[:]

> It is the contract requested between the applicant and Shared Health, Inc. but would not cure the request for an agreement with [BCBST] because they are contracting with the PBM. If you submit

did not clearly distinguish which Shared Health organization—SHIC or SHI—was referenced when stating SHIC should submit a contract between "Shared Health and BlueCross BlueShield of Tennessee, Inc."[14] Plan Exhibit P-9 at 1. CMS claims that, by its final submission, SHIC should have understood that CMS expected it to submit a contract between itself and its parent organization, BCBST, that also contained various flow-down clauses and a reference that BCBST was performing certain Part D functions on SHIC's behalf.[15] Instead, SHIC believed it was responsive and compliant with CMS' directive in submitting an Administrative Services Agreement between SHI and BCBST.[16] At the hearing, CMS indicated that an Administrative Services Agreement between SHI and BCBST could have cured the application if it included SHIC as a party to the agreement, indicated what Part D functions that BCBST was performing on SHIC's behalf, and included certain flow-down clauses.

The Hearing Officers conclude that SHIC, in its final submission, reasonably relied upon CMS' email communications to provide what was ultimately needed to ensure that its application satisfied CMS' requirements in total. SHIC has demonstrated that it met CMS' requirements based on a reasonable and contextual interpretation considering both CMS' guidance and its fact-specific directives, together. Accordingly, the Hearing Officers hereby overturn CMS' May 31, 2024 denial of SHIC's initial application for contract number H2096.

> the contract between the applicant and Shared Health and the contract between Shared Health and [BCBST], those will establish what is referred to in the application as the chain of delegation.

Plan Exhibit P-9 at 1.

[14] During the hearing, SHIC's witness testified that, with respect to the April 19, 2024 email (quoted in note 16, *supra*), she

> wasn't really sure what it meant, to be honest with you, because in other places, the responses reference [SHIC]. In some places they refer to [SHI]. And in this response, I assume [SHI] [b]ecause that's what the first sentence implied.

Tr. at 44.

[15] *See* note 12, *supra*.

[16] In addition to a contract between SHIC and SHI that CMS states met CMS requirements. Tr. at 23-24.

IX. ORDER

The Hearing Officers hereby reverse CMS' May 31, 2024 denial of application H2096.

Amanda S. Costabile -S
Digitally signed by Amanda S. Costabile -S
Date: 2024.08.19 15:03:26 -04'00'

Amanda S. Costabile, Esq.
CMS Hearing Officer

Benjamin Cohen -S
Digitally signed by Benjamin Cohen -S
Date: 2024.08.19 15:00:58 -04'00'

Benjamin R. Cohen, Esq.
CMS Hearing Officer

Date: August 19, 2024