

# CENTERS FOR MEDICARE & MEDICAID SERVICES

## HEARING OFFICER DECISION

**IN THE MATTER OF:**

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**Leon Health Plans, Inc.**

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**Contract Year 2022**

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**Contract No. H4286**

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**Hearing Officer Docket No. H-21-0015**

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**Denial of Initial Applications to Offer**

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**Medicare Advantage/Medicare Advantage-**

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**Prescription Drug Plans**

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## **I. FILINGS**

This Decision is being issued in response to the following:

- (a) Leon Health Plans, Inc. (“Leon”) Hearing Request dated June 10, 2021;
- (b) Leon’s Initial Hearing Brief (“Leon Initial Brief”) dated June 22, 2021;
- (c) Centers for Medicare & Medicaid Services’ (“CMS”) Brief in Reply to Applicant’s Brief (“CMS Reply Brief”) dated July 6, 2021;
- (d) Leon’s Reply to CMS Hearing Brief (“Leon Reply Brief”) dated July 9, 2021; and
- (e) July 16, 2021 Hearing Transcript.

## **II. ISSUE**

Whether the Applicant has shown by a preponderance of the evidence that CMS’ determination was inconsistent with the requirements of 42 C.F.R. §§ 423.502 and 423.503.<sup>1</sup>

## **III. SUMMARY OF DECISION**

The Hearing Officer finds that CMS’ communications (Part D Deficiency Notice, NOID and subsequent email correspondence) regarding the alleged deficiency were ambiguous and unintentionally misleading. While CMS may have expected very specific regulatory language or citations be added to the originally submitted contract by way of a formally executed amendment, Leon ultimately followed the express direction provided by CMS. The Hearing Officer finds that Leon was unintentionally deprived of a full and fair opportunity to cure the cited deficiency to CMS’ satisfaction in accordance with 42 C.F.R. §§ 423.502(c) and 423.503.

## **IV. APPLICATION AND REVIEW PROCESS (GENERALLY)**

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, or Part D, benefits to their plan enrollees. Social Security Act §§ 1857 and 1860D-12. An organization may not offer MA or Part D benefits unless it has entered into a contract with CMS. *Id.* at §§ 1857(a) and 1860D-12(b)(1). CMS has the regulatory authority to set the form and manner for the submission of applications for qualification as a Part D plan sponsor. *See* 42 C.F.R. §§ 423.502(c) and 423.504(b)(1). Pursuant to § 423.502(c)(1), organizations intending to offer Part D benefits must complete a certified application in the “form and manner” required by CMS.<sup>2</sup> Applicants must also “describe thoroughly how the entity is

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<sup>1</sup> The parties agreed to the statement of the issue. Transcript of Proceedings (“Tr.”) at 4.

<sup>2</sup> 42 C.F.R. §§ 423.500-520 specifically governs the Application Procedures and Contracts with Part D plan sponsors. 42 C.F.R. § 423.500 specifies, however, that “[f]or purposes of this subpart, Medicare Advantage (MA) [Part C] organizations offering Part D plans follow the requirements of part 422 of this chapter for MA organizations, except in cases where the requirements for the qualified prescription drug coverage involve additional requirements.”

qualified to meet” the regulatory requirements. 42 C.F.R. § 423.502(c)(2). Applications are submitted through the Health Plan Management System (“HPMS”).

CMS conducts a review of all submitted Part D applications pursuant to § 423.503 and issues determinations consistent with § 423.503(c). When evaluating applications, “CMS evaluates an application for a MA contract . . . solely on the basis of information contained in the application itself and any additional information that CMS obtains through other means such as on site visits.” 42 C.F.R. § 423.503(a)(1). CMS reviews the application to determine whether it meets all of the necessary requirements. 42 C.F.R. § 423.503(a)(2). CMS then notifies the applicant of any deficiencies by emailing a courtesy Part D Deficiency Notice and specifying a date by which the deficiencies are to be cured. This is an applicant’s first opportunity to amend its application.

If an applicant fails to remedy all of the deficiencies in its application by the specified date, or if CMS determines that the plan is not able to meet the requirements to become a Part D sponsor in the requested service area, then CMS issues a Notice of Intent to Deny (“NOID”). 42 C.F.R. § 423.503(c)(2)(i). The NOID contains a summary of the basis for CMS’ preliminary finding. An applicant that receives a NOID is provided ten days from the date of notice to respond, in writing, to CMS’ preliminary findings and to revise its application remedying any defects that CMS has identified. 42 C.F.R. § 423.503(c)(2)(ii). The formal NOID process is outlined at 42 C.F.R. § 423.503(c)(2)(i)–(iii), which states:

(i) If CMS finds that the applicant does not appear to contract as a Part D sponsor, it gives the applicant notice of intent to deny the application and a summary of the basis for this preliminary finding.

(ii) Within 10 days from the intent to deny, the applicant must respond in writing to the issues or other matters that were the basis for CMS’ preliminary finding and must 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 or has not provided CMS enough information to allow CMS to evaluate the application, CMS will deny the application.

In the final rule regarding the MA prescription drug (“PD”) applications procedure and how it will assist plans in their understanding of deficiency notices, CMS stated:

All application communications include contact information for CMS subject matter specialists. We are always willing to work with applicants to ensure a complete understanding of program and contracting requirements. 75 Fed. Reg. 19678, 19683 (Apr. 15, 2010).

To this end, in its Part D Deficiency Notice and NOID, CMS provides a specific point of contact for the listed deficiencies. Leon Exhibits P-4 and P-8.

If an applicant fails to submit a revised application within ten days from the date of the NOID issuance, or CMS believes that a revised application fails to meet the necessary requirements to contract as a Part D plan sponsor in the requested service area, CMS denies the application. 42 C.F.R. § 423.503(c)(2)(ii)–(iii). If, after review, CMS denies the application, written notice of the determination and the basis for the determination is given to the applicant. 42 C.F.R. § 423.503(c)(3).

If CMS denies a Part D application, the applicant is entitled to a hearing before a CMS Hearing Officer and may request a hearing within fifteen calendar days after the receipt of the denial. 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).<sup>3</sup> 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 Social Security Act] and related provisions of the Act, the regulations issued by the Secretary, and general instructions issued by CMS in implementing the Act.”

## V. AUTHORITY RELATING TO CONTRACT EXECUTION AND DOWNSTREAM ENTITIES

The Part D regulations at 42 C.F.R. § 423.505(i) provide that sponsors may contract with other entities to perform Part D related functions on the sponsor’s behalf. The regulation also mandates that contracts contain mandatory terms as well as terms “CMS may find necessary and appropriate in order to implement requirements in this part.” 42 C.F.R. §§ 423.505(i)(3), (5) and 423.505(j).

The final Solicitation was posted on CMS’ website on December 30, 2020.<sup>4</sup> The Solicitation requires entities seeking to contract as a Part D plan sponsor to submit applications through the HPMS. The HPMS-generated application requires that the applicant prove, through attestations and supporting documentation, that it meets certain requirements. With regard to an applicant delegating the performance of certain Part D functions, applicants may utilize “first tier, downstream, or related entities.” See Solicitation at § 3.1.1.C-E, Leon Exhibit P-5 at P-001705-09. Section 3.1.1.C of the Solicitation (Leon Exhibit P-5 at P-001705) provides that contracts must be in place for delegated functions.

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) as “first tier entities.” These entities may in turn contract with other

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<sup>3</sup> In addition, either party may ask the Hearing Officer to rule on a Motion for Summary Judgment. 42 C.F.R. § 423.662(b).

<sup>4</sup> <https://www.cms.gov/files/document/2022-part-d-application.pdf>.

entities, defined as “downstream entities,” for the performance of the delegated function.

....

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.

Applicants must identify 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. (Emphasis added.)

....

**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 and whether the first tier, downstream and related entities are off-shore.

The chart (referenced above) within the Solicitation of Part D functions requires an applicant to identify the entity that will perform any of the following (Leon Exhibit P-5 at P-001706-07):

A pharmacy benefit program that performs adjudication and processing of pharmacy claims at the point of sale.

A pharmacy benefit program that performs negotiation with prescription drug manufacturers and others for rebates, discounts, or other price concessions on prescription drugs.

A pharmacy benefit program that performs administration and tracking of enrollees drug benefits in real time, including TrOOP balance processing.

A pharmacy benefit program that performs coordination with other drug benefit programs, including, for example, Medicaid, state pharmaceutical assistance programs, or other insurance.

A pharmacy benefit program that develops and maintains a pharmacy network.

A pharmacy benefit program that operates an enrollee grievance and appeals process.

A pharmacy benefit program that performs customer service functionality, that includes serving seniors and persons with a disability.

A pharmacy benefit program that performs technical assistance service functionality.

A pharmacy benefit program that maintains a pharmaceutical and therapeutic committee.

A pharmacy benefit program that performs enrollment processing.

Data Validation Contractor

Data Validation Pre-Assessment Consultant

Additionally, the Solicitation at § 3.1.1.E (Leon Exhibit P-5 at P-001707-09) addresses the requirement that executed contracts provide certain terms. The Solicitation states:

E. [U]pload 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. As noted above, this requirement applies even if an entity contacting 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:

....

7. Be signed by a representative of each party with legal authority to bind the entity.

9. *Contain language obligating* the first tier, downstream, or related entity to abide by State and Federal privacy and security requirements, including the confidentiality and security provisions stated in the regulations for this program at 42 CFR §423.136. (Emphasis added.)

....

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

With regard to the element 9 requirement to abide by privacy and security requirements stated above, the full text of 42 C.F.R. § 423.136 provides:

For any medical records or other health and enrollment information it maintains with respect to enrollees, a PDP sponsor must establish procedures to do the following—

Abide by all Federal and State laws regarding confidentiality and disclosure of medical records, or other health and enrollment information. The PDP sponsor must safeguard the privacy or any information that identifies a particular enrollee and have procedures that specify-

(a) For what purposes the information is used within the organization; and

(1) To whom and for what purposes it discloses the information outside the organization.

## **VI. PROCEDURAL HISTORY AND STATEMENT OF FACTS**

On February 17, 2021, Leon submitted an application for an MA/MA-PD Health Maintenance Organization plan in Florida under contract number H4286. As part of its Part D application, Leon provided a Management Agreement between Leon Management International, Inc. (“LMI”) and the entity listed on Schedule A of the contract, LHP Administrative Services, Inc. (“LHP”).<sup>5</sup> Leon Exhibit P-1 at P-000616, P-000636.

The crosswalk submitted with this subcontract did not include a citation to a location in the contract where the language *allegedly* required in Element 9 of the Solicitation could be found. *Id.* at P-000637. On March 23, 2021, CMS issued a Part D Deficiency Notice associated with Leon’s application, which provided the following alleged deficiency:

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 and State privacy and security requirements, including the confidentiality and security provisions stated in the Medicare Part D regulations at 42 CFR § 423.136. The contract referenced is between LHP Administrative Services Inc and Leon Management International, Inc.

Leon Exhibit P-4 at P-001677.

CMS provided Leon until March 31, 2021 to submit curing materials. *Id.* at P-001679. Leon explains that while it believed the LHP-LMI Management Agreement was not for Part D functions,

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<sup>5</sup> A reference to the applicant was added in the amended Management Agreement submitted on March 30, 2021. Leon Exhibit P-6 at P-002402.

it nevertheless uploaded various curing materials on March 30, 2021, including an Amended and Restated Management Agreement between LMI and LHP and an updated corresponding crosswalk. Leon Exhibit P-6 at P-002378-2411, P-002412-13.

The Amended and Restated Management Agreement stated that:

LMI and each of the Clients have entered into this Agreement in order to provide for LMI's and the Clients' respective contractual responsibilities with respect to, among other things, an arrangement whereby LMI would provide the Clients with relief from administrative obligations to process and pay Staff their regularly scheduled wages or salaries, and to afford Staff the ability to participate in LMI-sponsored employee benefit plans as adopted by Clients as participating employers in such plans, including the ability to continue to conveniently contribute to the 401(k) or other employee retirement plans. In addition, the parties desire to hereby contract for LMI to provide to one or more of the Clients, on an as needed basis, substantial managerial, administrative, finance, executive, human resources, MIS and other functions, all as more particularly provided below (the "Management Services"), which Management Services will be provided by certain executive, management, administrative, finance, human resources, MIS and other employees of LMI or of an Affiliate of LMI (and which employees for all purposes shall be deemed to be employees of LMI or of the applicable Affiliate of LMI, but not of Clients, and are hereinafter referred to as the "LMI Employees").

*Id.* at P-002378.<sup>6</sup>

The crosswalk included a reference which paraphrased a large part of 42 C.F.R. § 423.136, as follows:

**5. CONFIDENTIALITY AND ENROLLEE RECORD REQUIREMENTS.**

Downstream Entity shall comply with all confidentiality and enrollee record accuracy requirements, including: (1) abiding by all federal and State laws regarding the confidentiality and disclosure

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<sup>6</sup> CMS argues that "while the Management Services are ostensibly described in Schedule A to the agreement, Schedule A does not appear to list the services to be provided by LMI and, indeed, indicates that 'LMI hereby delegates to [LHP] the Services (such Services to be referred to as "*Delegated Services*")', despite LHP being identified as the 'Client.'" CMS Brief at 6 (citing Leon Exhibit P-10 at P-004037-38). At the hearing, Leon clarified that "LMI doesn't have a direct relationship here with Leon and doesn't sponsor a plan, so it doesn't have any Part D functions to delegate." Tr. at 26. Regarding the purpose of the provision itself, Leon's counsel represented its "best understanding is that it is essentially an artifact and that these contracts are similar to others that the company regularly enters into. Again, I think it comes back to the point of what LMI has to delegate. It doesn't have any Part D functions to delegate so if it was to delegate something, it would be something else." *Id.* at 27.

of medical records or other health and enrollment information; (2) ensuring that medical information is released only in accordance with applicable Federal or State law, or pursuant to court orders or subpoena; (3) maintaining the records and information in an accurate and timely manner; and (4) ensuring timely access by Covered Persons to the records and information that pertains to them.

Leon Exhibit P-6 at P-002404.

Nevertheless, CMS issued a NOID on April 19, 2021, using the same language cited above in the March 23, 2021 Part D Deficiency Notice.<sup>7</sup> The NOID specifically noted points of contact for Leon to reach out to with questions. Leon Exhibit P-8 at P-003455-57.

Leon emailed CMS the same day it received the NOID, asking how it should remedy the alleged deficiency in the Amended and Restated Management Agreement between LHP and LMI.<sup>8</sup> On April 20, 2021, CMS instructed Leon to “[p]lease include the additional language.” Leon Exhibit 9 at P-003459. In response, on April 26, 2021, Leon submitted a revised version of the Amended and Restated Management Agreement between LHP and LMI, which included the following new language at Exhibit B, § 9:

Without limiting the generality of the foregoing, First Tier Entity, Downstream, and any Related Entity shall abide by all applicable Federal and State privacy and security requirements, including the

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<sup>7</sup> In its Reply Brief, CMS included additional background regarding its expectations as it deemed the crosswalk language insufficient and proceeded to issue the NOID. CMS explained that “[i]n the absence of a citation to §423.136, CMS requires that the contract include the specific requirements in the regulation, including the requirements at § 423.136(a)(1) and (2) that the organization have procedures that specify the purpose that the protected information is used within the organization and to whom and for what purposes it discloses the information outside the organization.” CMS Brief at 4.

<sup>8</sup> Leon Exhibit P-9 at P-003460. The email stated:

I am working with Leon Health Plan on the MA-PD application. I have copied the Compliance Officer on this email. We are requesting clarification related to a deficiency to ensure we can meet expectations.

....

[T]here is also this provision, referenced elsewhere in the crosswalk:  
Exhibit B, Section 9 “COMPLIANCE WITH FEDERAL AND STATE LAWS. First Tier Entity, Downstream Entity, and any Downstream or Related Entity shall comply with all applicable laws including Medicare laws, regulations and CMS and/or State instructions.”

Our question is as follows: If we reference the additional provision in the crosswalk, does this satisfy the requirement, or do we need to specifically add the language “including the confidentiality and security provisions stated in the Medicare Part D regulations at 42 CFR § 423.136.”?

confidentiality and security provisions stated in the Medicare Part D regulations at 42 CFR § 423.136.

Leon Exhibit P-10 at P-004046.

CMS issued a final Application Denial on May 27, 2021. Leon Exhibit P-3 at P-001672-74. Once again, the Application Denial utilized the same denial language from CMS' March 23, 2021 Part D Deficiency Notice and the April 19, 2021 NOID.

Leon promptly emailed CMS, requested an opportunity to discuss the application, and noted that “the exact language required by CMS was inserted into the agreement verbatim.” Leon Exhibit P-11 at P-005096.

According to Leon, on May 28, 2021, CMS informed Leon by telephone that “the denial was issued because it was not clear that the parties to the contract . . . had agreed to the language that was inserted on the [April 26, 2021] submission[.]” Leon Exhibit P-15 at P-005121 and P-005123 (Hernandez Declaration and Exhibit). Leon told CMS that the revised Amended and Restated LHP-LMI Management Agreement was valid without the need to formally re-execute the document, and both parties to the agreement had been fully aware of and in agreement to the terms of the new language in the revised document. *Id.*; *see also* Leon Exhibit P-11 at P-005093-5100.<sup>9</sup>

In any event, during the May 28, 2021 call, CMS instructed Leon to submit a separate, executed amendment to the Amended and Restated LHP-LMI Management Agreement. Leon Exhibit P-15 at P-005120-23; *see also* Leon Exhibit P-11 at P-005093-5100. Leon submitted Amendment No. 1 to the Amended and Restated Management Agreement the same day. Leon Exhibit P-12 at P-005102-13. Leon then emailed CMS on June 4, 2021, to request an update on the application. Leon Exhibit P-13 at P-005116. CMS responded on the same date, stating that “[u]nfortunately, we will not be able to accept the material as curing the deficiencies in the application.” *See id.* at P-005115. Leon next emailed CMS on June 7, 2021, asking: “Is CMS’s conclusion that the language in Amendment No.1 to Amended and Restated Management Agreement does not cure the identified deficiency or is CMS unable to provide the rationale for the denial?” Leon Exhibit P-14 at P-005118. CMS responded that “[t]he issue is that we do not ordinarily allow post-application period cures outside the appeals process.” *Id.*

At end, CMS recognized that while the final April 26, 2021 submission added the new 42 C.F.R. § 423.136 citation reference, it was not re-executed and accordingly “there still was no contract incorporating these terms and demonstrating capability to comply with § 423.505, as required by § 423.504(b)(1).” CMS Brief at 5.<sup>10</sup> Accordingly, on appeal CMS cites additional terms relating

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<sup>9</sup> This representation by Leon was based on the fact that all of the members of the respective Boards of Managers of LMI and LHP—who also constitute the most senior corporate officers of both LMI and LHP—had authorized and directed that the LMI-LHP Amended and Restated Management Agreement be revised by adding the CMS-requested language and further authorized and directed that the executed signature pages to the original Amended and Restated Management Agreement be attached to the revised document. Leon Exhibit P-16 at P-005125-28 (Junco Declaration). Mr. Junco, General Counsel of both LMI and LHP, added the language electronically that day and attached the executed signature pages. *See id.*

<sup>10</sup> *See also* Tr. at 36 (“CMS simply determined that the contract had not been amended to include 423.136 language and therefore the contract did not include it.”).

to amendments within the Amended and Restated Management Agreement. The terms of Section 13 state, in relevant part:

13.1 **Assignment/Amendment.** . . . [N]one of the terms and provisions of this Agreement may be modified or amended except by an instrument in writing executed by each party.

. . . .

13.3 **Entire Agreement.** This document and any addenda or exhibits attached hereto constitute the entire agreement between the parties with regard to the subject matter herein. No prior oral or written agreement, practice, or course of dealing between the parties relating to the subject matter herein (including, without limitation, the Original Management Agreement) shall supersede the Agreement.

Leon Exhibit P-10 at P-004034; CMS Brief at 6.

## **VII. DISCUSSION, FINDINGS OF FACT AND CONCLUSION OF LAW**

Leon has shown by a preponderance of the evidence that CMS' determination was inconsistent with the requirements of 42 C.F.R. §§ 423.502 and 423.503.

CMS' current concern is that "when Leon submitted its final curing materials on April 26, 2021, the additional language to fulfill the Element 9 requirement was inserted at the end of . . . the contract, and there was no update to the execution date . . ." CMS Brief at 5. CMS notes that "nothing was included in the application materials to indicate that this was an agreed upon change to the contract." *Id.* at 4. CMS emphasizes that it issues contracts solely on the basis of the information in the application itself and accordingly, the Hearing Officer may not consider any materials beyond those originally evaluated by CMS as part of its review. *Id.* at 7. Moreover, CMS argues that its underlying position is supported by regulation. CMS explains

Inherent in the use of the term "contract" at § 423.505(i) and other locations within the Part D regulations is the requirement that the definition of a contract is met in each document provided; that is, offer, acceptance, and consideration are required to form a binding agreement. For the purposes of the application process, CMS believes it is critical for the sponsor to demonstrate, through its contacts, that it has reached a mutual and definitive understanding with its delegated entity of the expectations as laid out in the Part D Solicitation.

CMS Brief at 5 (citing Leon Exhibit P-5 at P-001707-09).

From the onset, the communications within the March 23, 2021 Part D Deficiency Notice and the April 19, 2021 NOID were not congruent with the level of specificity expected from Leon by the CMS review team. In review, the official notices to Leon indicated:

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 and State privacy and security requirements, including the confidentiality and security provisions stated in the Medicare Part D regulations at 42 CFR § 423.136. The contract referenced is between LHP Administrative Services, Inc and Leon Management International, Inc.

Leon Exhibit P-4 at P-001677.

However, as noted above, in its Reply Brief CMS provides expanded detail regarding why it believes Leon's submission prior to the NOID was deficient. CMS explains:

In the absence of a citation to §423.136, CMS requires that the contract include the specific requirements in the regulation, including the requirements at § 423.136(a)(1) and (2) that the organization have procedures that specify the purpose that the protected information is used within the organization and to whom and for what purposes it discloses the information outside the organization.

CMS Brief at 4.

The crosswalk did not expressly contain the text specific to subsections (1) and (2) which CMS is now clarifying, through the appeal process, would have been deemed acceptable in the absence of a citation. The Hearing Officer notes, however, that beyond not communicating the fuller explanation that CMS now provides, the March 23, 2021 Part D Deficiency Notice and the April 19, 2021 NOID simply reference the broader regulatory citation 42 C.F.R. § 423.136. In fact, CMS did not specify the cite to section (a) or subsections (1) and (2) or, accordingly, relay an expectation that the text itself from the subsections be included.

After receiving the NOID on April 19, 2021, Leon asked CMS how it should remedy the alleged deficiency and on April 20, 2021, CMS simply instructed Leon to “[p]lease include the additional language.” Leon Exhibit P-9 at P-003459. In response, on April 26, 2021, Leon submitted amended materials within the previously signed documents, which included the exact language (i.e., the confidentiality and security provisions stated in the Medicare Part D regulations at 42 C.F.R. § 423.136) that CMS requested. Leon Exhibit P-10 at P-004046. The Hearing Officer notes that CMS never expressly requested that Leon provide a formal, newly executed amendment to the contract.

The Hearing Officer finds that Leon has met its burden in proving, by a preponderance of the evidence, that CMS' denial of its application was inconsistent with a fair interpretation of the

controlling authority. The Hearing Officer notes that CMS' original Part D Deficiency Notice and NOID both contained a level of ambiguity and were unintentionally misleading. There is no evidence that Leon did not avail itself to valuable opportunities throughout the application and review process to submit materials that were responsive to the deficiency notices. Moreover, while CMS might have assumed that its April 20, 2021 email implied that the amended contract materials would need to be resigned to be acceptable, Leon ultimately followed the direction provided by CMS. The Hearing Officer also finds that based on Leon's understanding of Florida law (which CMS did not contest), it reasonably believed that a formally executed amendment was unnecessary for the additional language to be binding. The Hearing Officer speculates that if the deficiency notices had not been ambiguous, Leon would have revised the contract in the specific way that CMS expected it to be amended.<sup>11</sup> Accordingly, the Hearing Officer finds that Leon was unintentionally deprived of a full and fair opportunity to cure the contract in accordance with 42 C.F.R. §§ 423.502(c) and 423.503.<sup>12</sup>

Given the finding that Leon was unintentionally misled during its opportunity to cure its application, the Hearing Officer will not reach the arguments related to whether CMS justifiably believed that the contract at issue specifically relates to the delegation of Part D functions.<sup>13</sup>

### **VIII. ORDER**

CMS' May 27, 2021 determination is reversed.

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Benjamin R. Cohen, Esq.  
CMS Hearing Officer

Date: August 25, 2021

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<sup>11</sup> See Tr. at 21 (“[A]fter the application denial issue and Leon learned that CMS wanted that type of documentation, Leon provided it the same day.”).

<sup>12</sup> CMS points to the Amended and Restated Management Agreement (Sections 13.1 and 13.3) in support of its position that “for Leon to have effectively amended the agreement, it needed to have an instrument in writing executed by each party.” Tr. at 39. However, CMS' interpretation of these provisions is immaterial given that Leon was unintentionally deprived of a full and fair opportunity to cure the deficiency at issue in accordance with 42 C.F.R. §§ 423.502(c) and 423.503.

<sup>13</sup> See Tr. at 34 (noting that the agreement specifies that managed care activities would be delegated, which typically includes enrollment functions, coordination of benefits and customer services); Leon Exhibit P-6 at P-002397. See also *supra* note 6.