

# **CENTERS FOR MEDICARE & MEDICAID SERVICES HEARING OFFICER DECISION**

**IN THE MATTER OF:**

\*

\*

**Exemplar Health Insurance Company, Inc.**

\*

**Contract Year 2022**

\*

**Hearing Officer Docket No. H-21-0006**

**Contract No. S3546**

\*

\*

**Denial of Medicare Part D Application**

\*

## **TABLE OF CONTENTS**

<b>I.</b>	<b>FILINGS .....</b>	<b>1</b>
<b>II.</b>	<b>ISSUE .....</b>	<b>1</b>
<b>III.</b>	<b>SUMMARY OF DECISION .....</b>	<b>1</b>
<b>IV.</b>	<b>LEGAL AUTHORITY .....</b>	<b>1</b>
<b>A.</b>	<b>GENERAL APPLICATION AND ADMINISTRATIVE REVIEW PROCESS .....</b>	<b>1</b>
<b>B.</b>	<b>LICENSURE REQUIREMENTS FOR NEW PDP APPLICANTS .....</b>	<b>3</b>
<b>V.</b>	<b>STATEMENT OF FACTS .....</b>	<b>7</b>
<b>VI.</b>	<b>TABLE 2: SUMMARY OF STATE LICENSURE APPLICATION DOCUMENTATION ..</b>	<b>8</b>
<b>VII.</b>	<b>DISCUSSION, FINDINGS OF FACT AND CONCLUSIONS OF LAW .....</b>	<b>10</b>
<b>VIII.</b>	<b>ORDER .....</b>	<b>14</b>

## **I. FILINGS**

This decision is being issued in response to the following:

- (a) Exemplar Health Insurance Company, Inc. (“Exemplar”) Hearing Request dated May 27, 2021;
- (b) Exemplar’s Initial Brief dated June 7, 2021;
- (c) Centers for Medicare & Medicaid Services’ (“CMS”) Reply Brief dated June 14, 2019; and
- (d) Exemplar’s Reply Brief dated June 17, 2021.

## **II. ISSUE**

Whether CMS’ decision to deny Exemplar’s Part D application to operate a new Prescription Drug Plan (“PDP”) product was inconsistent with regulatory requirements.

## **III. SUMMARY OF DECISION**

Exemplar has not established by a preponderance of the evidence that CMS’ denial of its application was inconsistent with the controlling authority. Exemplar has not obtained state licensure in seven of the nine states in which it intended to operate. Although Exemplar ultimately filed Regional Plan Waiver applications for those states, the waiver applications did not qualify for CMS approval by the time CMS issued its final application determinations. While Exemplar provided alternative approaches to overcome some of the deficiencies in its waiver applications for CMS to consider, the Hearing Officer does not have authority to order CMS to do so.

## **IV. LEGAL AUTHORITY**

### **A. GENERAL APPLICATION AND ADMINISTRATIVE REVIEW 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, 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 through a standalone PDP contract 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)(1)(2).

CMS posted the final Solicitation for Applications for Medicare Prescription Drug Plan 2022 Contracts (“Solicitation”) on its website on December 30, 2020.<sup>1</sup> The Solicitation required Part D contract applicants to provide responses to a series of attestations related to Part D requirements

---

<sup>1</sup> Available at [https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/RxContracting\\_ApplicationGuidance.html](https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/RxContracting_ApplicationGuidance.html).

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. Organizations were to submit their applications through the Health Plan Management System (“HPMS”), CMS’ electronic system of record for the administration of the MA and Part D programs. The applications were due to CMS by February 17, 2021.

Part D plans must complete the certified application in the “form and manner required by CMS,” and provide appropriate documentation regarding State licensure (or Federal waiver). 42 C.F.R. § 423.502(c) provides:

(c)(1) In order to obtain a determination on whether it meets the requirements to become a Part D plan sponsor, an entity, or an individual authorized to act for the entity (the applicant) must fully complete all parts of a certified application in the form and manner required by CMS, including the following:

(i) Documentation of appropriate State licensure or State certification that the entity is able to offer health insurance or health benefits coverage that meets State- specified standards as specified in subpart I of this part; or

(ii) A Federal waiver as specified in subpart I of this part.

(2) The authorized individual must describe thoroughly how the entity is qualified to meet the all requirements described in this part.

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 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 notice of deficiencies, and provides a “courtesy cure period” to the applicant. Solicitation at § 2.4.1.3, CMS Exhibit C-1 at 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).

**B. LICENSURE REQUIREMENTS FOR NEW PDP APPLICANTS**

The service area for a PDP sponsor consists of one or more PDP regions as established in accordance with the regulation. 42 C.F.R. § 423.112. CMS has established 34 PDP regions, including several multistate regions, pursuant to the regulation. Prescription Drug Benefit Manual, Chapter 5, § 40 and Appendix 2.<sup>2</sup> Relative to this case, the multistate regions include Region 25 (Iowa, Minnesota, Montana, Nebraska, North Dakota, South Dakota and Wyoming) and Region 31 (Idaho and Utah). A PDP sponsor must provide coverage in all the regions in its service area in their entirety. *Id.* at § 40. A PDP sponsor cannot provide coverage in just one state of a multistate region.

The Part D regulations require PDP sponsors to be “organized and licensed under State law as a risk bearing entity eligible to offer health insurance or health benefits coverage in each State in which it offers a prescription drug plan,” except where a regional plan waiver has been granted pursuant to 42 C.F.R. §§ 423.410 or 423.415. 42 C.F.R. § 423.401(a)(1). The statutory authority for the regional plan waiver for PDPs is located at SSA § 1860D-12(c)(1)(B), which reads:

(B) Application of regional plan waiver rule.—In addition to the waiver available under subparagraph (A), the provisions of section 1858(d) shall apply to PDP sponsors under this part **in a manner similar to the manner in which such provisions apply to MA organizations under part C**, except that no application shall be required under paragraph (1)(B) of such section in the case of a State that does not provide a licensing process for such a sponsor. (Emphasis added.)

Section 1858(d) states:

(d) ORGANIZATIONAL AND FINANCIAL REQUIREMENTS.—

(1) IN GENERAL.—In the case of an MA organization that is offering an MA regional plan in an MA region and—

(A) meets the requirements of section 1855(a)(1) with respect to at least one such State in such region; and

(B) with respect to each other State in such region in which it does not meet requirements, **it demonstrates to the**

---

<sup>2</sup> Prescription Drug Benefit Manual, CMS Pub. 100-18, Chapter 5, *available at* [https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/Downloads/MemoPDBManualChapter5\\_093011.pdf](https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/Downloads/MemoPDBManualChapter5_093011.pdf).

**satisfaction of the Secretary that it has filed the necessary application to meet such requirements,** the Secretary may waive such requirement with respect to each State described in subparagraph (B) for such period of time as the Secretary determines appropriate for the timely processing of such an application by the State (and, if such application is denied, through the end of such plan year as the Secretary determines appropriate to provide for a transition). (Emphasis added.)

In terms of the implementing regulations, an organization can receive a waiver under 42 C.F.R. § 423.410(b) or (c) (a “Single State Waiver”) in any of the following circumstances:

(b)(1) *Failure to act on licensure application on a timely basis.* The State failed to complete action on the licensing application within 90 days of the date that the State received a substantially complete application.

(2) Denial of application based on discriminatory treatment. The State denied the license application on either of the following bases—

(i) The State imposed material requirements, procedures, or standards (other than solvency requirements) not generally applied by the State to other entities engaged in a substantially similar business; or

(ii) The State required, as a condition of licensure, that the organization offer any product or plan other than a prescription drug plan.

(3) *Denial of application based on application of solvency requirements.* The State denied the licensure application, in whole or in part, on the basis of the PDP sponsor's failure to meet solvency requirements and

(i) The solvency requirements are different from the solvency standards CMS establishes in accordance with § 423.420; or

(ii) CMS determines that the State imposed, as a condition of licensing, any documentation or information requirements relating to solvency that are different from the standards CMS establishes in accordance with § 423.420.

(4) *Grounds other than those required by Federal Law.* The application by a State of any grounds other than those required under Federal law.

(c) *Waiver when licensing process not in effect.* The grounds for approval specified in paragraph (b)(1) of this section are deemed met if CMS determines that the State does not have a licensing process in effect for PDP sponsors.

....

(e) *Waiver requirements.* The following rules apply to waiver applications or waivers granted under this section.

(1) *Treatment of waiver.* The waiver applies only to that State, is effective for 36 months, and cannot be renewed.

Moreover, 42 C.F.R. § 423.415 provides that entities who wish to offer a PDP in more than one state in a region may receive temporary waivers. The sections states:

(a) *General Rule.* Subject to paragraphs (b) and (c) of this section, if an applicant seeking to become a PDP sponsor wishes to operate in more than one state in a region, and is licensed as a risk bearing entity in at least one State in the region, then the applicant may receive a temporary regional plan waiver for the States which it is not licensed.

(b) *Filing of application.* The applicant *must demonstrate to the satisfaction* of CMS that it filed the necessary licensure applications *with each State* in the region to which it does not already have State licensure, except that no application is necessary if CMS determines that the State does not have a licensing process or potential PDP sponsors.

(c) *Processing of application for temporary waiver.* The Secretary determines the time period appropriate for the timely processing of the application for temporary waiver.

(d) *Time limit for temporary waiver.* The temporary waiver expires at the end of time period that the Secretary determines is appropriate for timely processing of the application by the State or States, but in no case is a waiver extended beyond the end of the calendar year.

The regulations generally addressing the Part D application process likewise require that PDPs demonstrate that they are compliant with licensure requirements or have obtained a waiver. The regulation at 42 C.F.R. § 423.502 states:

(c)(1) In order to obtain a determination on whether it meets the requirements to become a Part D plan sponsor, an entity, or an individual authorized to act for the entity (the applicant), must fully

complete all parts of a certified application in the form and manner required by CMS, including the following:

- (i) Documentation of appropriate State licensure or State certification that the entity is able to offer health insurance or health benefits coverage that meets State-specified standards as specified in subpart I of this part; or
- (ii) A Federal waiver as specified in subpart I of this part.

Because organizations are required to demonstrate State licensure or that they have a Federal waiver to obtain a favorable application decision, CMS collects applications for the Federal Waiver of State Licensure (both Single State Waivers and Regional Plan Waivers) as part of the application process for new Part D sponsors.

The Solicitation includes the following chart which contains attestations and instructions for applicants wishing to operate new PDP contracts.

Table 1: Licensure Attestations for New PDP Applicants

Attest 'Yes,' 'No,' or "Does Not Apply" to the Following Licensure Requirements.	Yes	No	NA
<p>Applicant is licensed under State law as a risk-bearing entity eligible to offer health insurance or health benefits coverage in each State in which the Applicant proposes to offer Part D drug benefits.</p> <ul style="list-style-type: none"> <li>If the answer to this attestation is "YES," then upload in HPMS the documentation (e.g., licensing certificate or letter), from each state licensing authority of your organization's status as an entity entitled to bear risk.</li> <li>If the answer to this attestation is "NO" see Attestation #2 and complete the Federal Waiver of State Licensure application found in Appendix VII for every state in your proposed service area in which you are not licensed.</li> </ul>			
<p>If the applicant is not State licensed as a risk-bearing entity eligible to offer health insurance or health benefits coverage in each State in which the applicant proposes to offer Part D benefits, is the applicant licensed as a risk-bearing entity in at least one State?</p> <ul style="list-style-type: none"> <li>If the answer to this attestation is "YES," then upload in HPMS the documentation (e.g., licensing certificate or letter), from each state licensing authority of your organization's status as an entity entitled to bear risk.</li> <li>If the answer to this attestation is "NO," the applicant must submit via HPMS the Appendix entitled Financial Solvency Documentation.</li> </ul>			

Solicitation at § 3.1.2.B, CMS Exhibit C-1 at 4. As instructed, organizations that attest “no” to the first attestation are required to complete the Federal Waiver of State Licensure. Organizations that are not also licensed in at least one state must provide the required Financial Solvency Documentation.

Federal Waiver of State Licensure requires the applicant to indicate whether it intended to apply for a Single State Waiver or Regional Plan Waiver. Applicants for Regional Plan Waivers must verify the state(s) in the region for which it has licenses and provide the following documentation for the licensure applications filed with unlicensed states:

- Copy of the dated cover sheet to the application(s) for unlicensed states;
- State confirmation of the receipt and completeness of each application;
- State requests for additional information; and
- All pertinent correspondence with the state(s) relating to the status of the application.

See Exemplar Exhibit P-2 at P-0015. The waiver application also requests other information, including contact information for State officials.

The applications for Federal Waiver of State Licensure are processed by CMS during the same timeframe as the annual PDP application process. See CMS Exhibit C-2 at 2, ¶ 11. Applications are denied for applicants that fail to demonstrate that they have obtained state licensure or qualify for a waiver. 42 C.F.R. §§ 423.502(c) and 423.503(c)(2)(iii).

## **V. STATEMENT OF FACTS**

On February 17, 2021, Exemplar submitted an application for a new PDP contract operating in Regions 25 and 31. As part of the application, Exemplar attested that it was licensed under State law as a risk-bearing entity eligible to offer health insurance or health benefits coverage in each State in which it proposed to offer Part D drug benefits. CMS Exhibit C-6. Exemplar did not provide any of the required documentation of State licensure, although it did upload Articles of Incorporation that had been filed with the State of Montana five days previously, on February 12, 2021. CMS Exhibit C-3. Exemplar did not inform CMS whether it had applied for licensure in any of the states in its proposed service area. Nor did Exemplar indicate that it intended to apply for a Federal Waiver of State Licensure.

On March 23, 2021, CMS issued a courtesy notice of deficiencies to Exemplar identifying several deficiencies, including that it “failed to submit evidence of State licensure for one or more states in [its] proposed service area. Specifically, IA, MN, MT, NE, ND, SD, WY, ID, and UT.” CMS Exhibit C-4. CMS provided Exemplar until March 31, 2021 to submit curing materials.



Exemplar uploaded various curing materials on March 30, 2021. At that time, it uploaded its Certificate of Authority to offer insurance in the State of Montana that had been granted on March 8, 2021. CMS Exhibit C-5. Montana is one of the states in Region 25. No other licensure documentation was uploaded. Exemplar continued to attest that it actually had State licenses in all the States in its proposed service area. Again, Exemplar did not inform CMS whether it had applied for licensure in any of the remaining states in their proposed service area or whether it intended to apply for a Federal Waiver of State Licensure.

On April 19, 2021, CMS issued a NOID to Exemplar based on its continued failure to provide documentation of licensure in the eight other states in its proposed service area. Exemplar Exhibit P-1. CMS provided Exemplar ten days to respond to the NOID with curing materials. Responses to the NOID were due April 29, 2021.

Exemplar submitted additional materials via HPMS on April 29, 2021 and continued to attest that it had licenses in all the states in its proposed service area. Exemplar provided a Certificate of Authority to offer insurance in Utah, a state in Region 31, which had been granted two days previously on April 27, 2021. CMS Exhibit C-7. Despite their attestation continuing to indicate that it did not need and was not requesting any waivers, Exemplar also uploaded two Regional Plan Waiver applications — one for Region 25 and one for Region 31. Exemplar Exhibit P-2.

Exemplar requested a Regional Plan Waiver for six States in Region 25 (Iowa, Minnesota, Nebraska, North Dakota, South Dakota, and Wyoming), listing Montana as the only Region 25 State in which it was currently licensed. Exemplar requested a Regional Plan Waiver for the remaining State in Region 31 (Idaho), listing Utah as the only Region 31 State in which it was currently licensed.

Exemplar submitted evidence that it had applied for licensure on March 22, 2021, in the seven States for which it purported to be requesting waivers. CMS found that Exemplar did not provide the required State confirmation of receipt and completeness of the applications for all seven States. CMS prepared the following summary of the documentation provided.

**VI. TABLE 2: SUMMARY OF STATE LICENSURE APPLICATION DOCUMENTATION**

State	Date of Application Cover Sheet	Documentation of State: Confirmation of Receipt	Documentation of State: Confirmation of Completion	State Decision
Iowa	03/22/2021 Exhibit 8 at 11	None	None	None
Minnesota	03/22/2021 Exhibit 8 at 14	None	None	None
Nebraska	03/22/2021 Exhibit 8 at 17	None	None	None

State	Date of Application Cover Sheet	Documentation of State: Confirmation of Receipt	Documentation of State: Confirmation of Completion	State Decision
North Dakota	03/22/2021 Exhibit 8 at 20	None	None	None
South Dakota	03/22/2021 Exhibit 8 at 23	04/05/2021 Exhibit 8 at 26	NA	04/12/2021 Denial Exhibit 8 at 28
Wyoming	03/22/2021 Exhibit 8 at 30	NA	NA	03/25/2021 Denial Exhibit 8 at 32
Idaho	03/22/2021 Exhibit 9 at 13	04/23/2021 Exhibit 9 at 15	None	NA

CMS Reply Brief at 8.

Regarding the South Dakota and Wyoming denials noted above, such States refused to accept and review licensure applications from Exemplar because they did not meet seasoning requirements (i.e., the applicant had not been in operation for the minimum period of time required by State law). In South Dakota, the State declined to accept the application because Exemplar “doesn’t meet South Dakota’s seasoning requirement of two continuous calendar years of operating experience.” Exemplar Exhibit P-2 at P-0035. Similarly, Wyoming declined to accept the application because Exemplar “does not meet the requirement for the report of examination that Wyoming requires pursuant to W.S. 26-3-112(a)(vi). Also, [Exemplar] does not meet Wyoming’s seasoning requirement under W.S. § 26-3-105.” *Id.* at P-0039. The seasoning requirement under Wyoming law is also two years. W.S. § 26-3-105(a). While Exemplar claims in its waiver application for Region 25 to be working with these States to obtain waivers, it presented no documentation from the States that they would consider such requests. Exemplar Exhibit P-2 at P-0029 and P-0036.

CMS issued a denial of Exemplar’s application on May 27, 2021. Exemplar Exhibit P-3. The basis for the denial was stated as follows:

Your organization failed to submit evidence of State licensure for one or more states in your proposed service area. Specifically IA, MN, NE, ND, SD, WY and ID.

In its Reply Brief, CMS summarizes that the application was denied because Exemplar “did not have licensure or an approved waiver of licensure for every state in its proposed service area. This denial was also notification that the Regional Plan Waiver applications submitted as part of the PDP application had been denied.” CMS Reply Brief at 8. Exemplar indicates that it did not understand the basis for this decision because CMS had failed to address Exemplar’s Regional Plan Waiver applications in its response. Exemplar Initial Brief at 3. Immediately after receiving

the denial, on May 27, 2021, Exemplar had an email exchange with CMS to pursue this inquiry. The initial email from Exemplar to CMS read:

Exemplar received the denial for S3546, included below, and want[s] to confirm if you are still reviewing the waiver or understand the status for our apps for region 25 and 31.

Exemplar Exhibit P-4 at P-0060. In response to this email, CMS initially replied:

The waiver was not granted.

*Id.* Later that day, CMS elaborated on the basis for the denial as follows:

Just to provide you more information, your application attested “yes” to the attestation that it was “licensed under State law . . . in each State in which the applicant proposes to offer Part D drug benefits,” despite the fact that your organization was not licensed in all the states. Your organization did not submit an application for the federal waiver of state licensure until April 29, when it responded to the Notice of Intent to Deny, which was after the application due date. Your organization did not qualify for the waiver because it had not applied for licenses in 7 of the 9 states covered by the 2 PDP regions in its proposed service area by February 17, 2021, when the applications were due. To receive a waiver of state licensure, “the applicant must demonstrate that it submitted a substantially complete licensure application in each State in the region for which it does not already have State licensure” by the application due date.

*Id.*

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

In exercising its authority, 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, 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.

The regulations are clear that an applicant must document that it has a State license, State certification or a Federal waiver to meet CMS’ standards. *See* 42 C.F.R. § 423.502(c)(1)(i), (ii). Exemplar failed to meet the application requirements when it submitted its initial application. Moreover, Exemplar failed to timely cure the deficiencies by April 29, 2021 — the deadline established in the NOID.

In its Initial Brief, Exemplar indicated that based upon its understanding of CMS’ post-denial e-mail communication (*supra*, p.10; Exemplar Exhibit P-4 at P-0060), Exemplar believed that

CMS based its decision strictly on an allegedly non-existent “requirement” that the applicant submit its Regional Plan Waiver requests (and State licensure applications) by the February 17, 2021 application deadline. Exemplar Initial Brief at 4. In its Reply Brief, CMS clarified, however, that the scope of the communication was intended to help Exemplar with future applications by providing CMS’ assessment of the root cause, which led to this particular application denial. CMS articulates:

CMS attempted to provide more clarity to Exemplar on why the application was denied after Exemplar asked about the waiver applications, in part so they might be better prepared for future applications. CMS cited the late submission of the waiver application and the applications for state licensure because these were Exemplar’s most significant missteps, but the email did not and was not intended to list all the deficiencies in the waiver application. In fact, CMS had reviewed the waiver application and determined that it was not approvable for several reasons.

CMS expects waiver applications to be submitted at the time the application is due because it expects applicants to truthfully attest “no” to the first licensure attestation (see Table 1) and follow the instructions in the attestation to submit a waiver application. Accordingly, no applicant has ever to our knowledge submitted a waiver application after the initial application submission. Exhibit C-2, Item 7. The late submission cut the time CMS usually has to review waiver applications down from three months to three weeks and ultimately deprived Exemplar of the opportunity to cure deficiencies. Waiting until March 22, 2021 to apply for state licensure also made it difficult for Exemplar to obtain the required documentation from the states, because even relatively short delays in states sending confirmations of receipt and completeness of applications would mean that copies could not be sent to CMS before the final deadline for uploading curing materials. Therefore, CMS believes that the late licensure and waiver applications are the root cause of Exemplar’s failure to submit approvable waiver applications.

However, the lateness of the licensure and waiver applications would not have resulted in the PDP application’s denial if the waiver application had been complete and otherwise approvable. CMS reviewed the waiver application and determined it was not. CMS determined that the applications lacked much of the required documentation and that Exemplar did not have active licensure applications in South Dakota and Wyoming as of April 29. CMS therefore denied Exemplar’s application.

CMS did not provide a comprehensive list of the reasons the waiver application was not approved in the email sent after issuing the denial because at that point, Exemplar was not able to cure the deficiencies. Exemplar was not in any way prejudiced by the lack of a detailed explanation. By waiting to submit the waiver application until after it received the NOID, Exemplar forfeited the opportunity it would otherwise have had to fix deficiencies. Unlike Centene in the case cited in Exemplar's brief, Exemplar did not misunderstand a NOID and therefore lose a meaningful opportunity to respond.

#### CMS Reply Brief at 8-9.

In its subsequent briefing, Exemplar did not defend its failure to provide an accurate initial certification. Moreover, the Hearing Officer notes that Exemplar did not change its attestation at any time throughout the cure period. Accordingly, the Hearing Officer finds that Exemplar's own failure to provide an accurate attestation (with corresponding documentation) in the initial application resulted in it losing an opportunity to take advantage of CMS' application review and cure process to attempt to provide a final package of application materials that may be satisfactory to CMS.

Nevertheless, despite its failures, Exemplar still argues that its submission substantively met the applicable Regional Plan Waiver documentation requirements for Iowa, Minnesota, Nebraska, North Dakota and Idaho. Exemplar indicates that according to its reading of 42 C.F.R. § 423.415(b) (and in accordance with the overarching section 1860D-12 (c)(1)(B) of the Social Security Act), the regulation merely requires that a licensure application is filed when seeking a Regional Plan Waiver, and that CMS is adding an additional requirement relating to the applicant receiving an affirmative communication from the State confirming receipt and completeness of the application. Exemplar Reply Brief at 3-5.

CMS also provides sound reasoning regarding why it expects applicants to present ample information and documentation when filing a Regional Plan Waiver request. CMS requires that information and documentation because it is used to determine whether an applicant filed valid and complete licensure applications; whether the States are actively considering those applications; and whether the States are considering waivers of any requirements, such as seasoning, that barred consideration of the licensure applications. CMS Reply Brief at 11; CMS Exhibit C-2 at 1-2, ¶¶ 10, 13. CMS was unable to do any of this based on the materials it received. Therefore, CMS properly denied Exemplar's Regional Plan Waiver requests for Regions 25 and 31. *See* CMS Reply Brief at 8; *see also* Exemplar Exhibits P-3 and P-4.

The Hearing Officer notes that the controlling authority also expressly provides a level of discretion for CMS in reviewing waivers: "*The applicant must demonstrate to the satisfaction of CMS that it filed the necessary licensure application with each State in the region for which it does not already have State licensure . . .*" 42 C.F.R. § 423.415(b); *see also* SSA § 1860D-12(c)(1)(B).

Under 42 C.F.R. § 423.415(b), an applicant must demonstrate it met the waiver requirements for *each* state. Based upon the limited and incomplete information CMS received (*see supra*, p. 9, Table 2) by the cure deadline for Iowa, Minnesota, Nebraska, North Dakota and Idaho, the Hearing Officer finds that CMS’ decision to deny the application in its entirety on May 27, 2021 was proper.

Moreover, CMS provides a reasoned argument for electing to not enter a contract with Exemplar on the basis that Exemplar was ineligible to obtain a license in Wyoming and South Dakota for two years. CMS articulates

To obtain a Regional Plan Waiver, an organization must have a licensure application in the state for which it is seeking a waiver or the State must not have a licensing process for potential PDP sponsors. 42 CFR § 423.415(b). Regional Plan Waivers are meant to give organizations time to become licensed, not to override state licensure decisions, as reflected in the maximum one year length of the waiver allowed by § 423.415(d). Therefore, CMS denies Regional Plan Waiver applications when the state has denied the organization’s licensure application.

....

To offer plans starting January 1, 2023, Exemplar would therefore have to be licensed as a risk bearing entity in all states in its service area pursuant to § 423.401. But South Dakota’s and Wyoming’s “seasoning” requirements mean that Exemplar could not qualify for licenses in those states until March 8, 2023 at the earliest . . . .

If CMS approved Exemplar’s application with a Regional Plan Waiver for South Dakota and Wyoming and, as the information in the application indicates, the PDP sponsor could not obtain licensure for those states effective January 1, 2023, CMS would have to terminate the contract or Exemplar would have to drop Region 25 at the end of 2022 because the sponsor could not continue to enroll Medicare beneficiaries in 2023. Such terminations are disruptive to beneficiaries and CMS does not enter into contracts that it is reasonably certain will result in such disruptions. CMS therefore would not approve, and in this case did not approve, a waiver application under these circumstances.

CMS Reply Brief at 11-12.

Exemplar argues that CMS is authorized by 42 C.F.R. § 423.415(b) to allow Exemplar to be offered in South Dakota and Wyoming despite the States not accepting its application due to seasoning requirements. Exemplar Reply Brief at 6. To support its claim, as an analogy, Exemplar presents a comment and response which concerns preemption authority in situations where a State

only allowed non-profit organizations to apply under its State HMO licensure law. Exemplar Reply Brief at 6-7 (citing 70 Fed. Reg. 4194, 4318 (Jan. 28, 2005)). The Hearing Officer finds that such authority is neither on point or directly controlling. Moreover, Exemplar provides alternative approaches for CMS to consider, including CMS allowing Exemplar to transition from a Regional Plan Waiver to a Single State Waiver, or providing a novation to the contract at the end of 2022 to an affiliate. Without reaching the legality of such proposals, the Hearing Officer finds that it does not have authority to order CMS to consider these alternatives.

The Hearing Officer must decide if CMS' determinations were consistent with the regulatory requirements of 42 C.F.R. §§ 423.650 and 423.664. The Hearing Officer finds that Exemplar failed to timely meet CMS' application requirements, thus CMS' denials were an appropriate exercise of its delegated authority. Exemplar did not meet its burden of proving, by a preponderance of the evidence, that CMS' determinations were inconsistent with the controlling authority.

### **VIII. ORDER**

CMS properly denied Exemplar's Part D application.

---

Benjamin R. Cohen, Esq.  
CMS Hearing Officer

Date: August 18, 2021