

**CENTERS FOR MEDICARE AND MEDICAID SERVICES  
HEARING OFFICER DECISION**

<b>IN THE MATTER OF:</b>	*	
<b>Centene Venture Company Michigan</b>	*	<b>DOCKET NOS. MA-PD 2020-15</b>
<b>Centene Venture Company Tennessee</b>		<b>MA-PD 2020-16</b>
<b>Centene Venture Company Kansas</b>	*	<b>MA-PD 2020-17</b>
<b>Sunflower State Health Plan, Inc.</b>		<b>MA-PD 2020-18</b>
<b>Centene Venture Company Indiana, Inc.</b>	*	<b>MA-PD 2020-19</b>
<b>Centene Venture Company Alabama</b>		<b>MA-PD 2020-20</b>
<b>Health Plan, Inc.</b>	*	<b>MA-PD 2020-21</b>
<b>Centene Venture Company Indiana, Inc.</b>	*	
		<b>Contract Year 2021</b>
<b>Denial of Medicare Advantage</b>	*	
<b>Prescription Drug Initial Application</b>		<b>Contract Nos. H0482, H2853, H6830,</b>
	*	<b>H9387, H1774, H4343, H7925</b>
	*	

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## **I. JURISDICTION**

This appeal is provided pursuant to 42 C.F.R. §§ 422.660<sup>1</sup> and 423.650. The Centers for Medicare and Medicaid Services (CMS) Hearing Officer designated to hear this case is the undersigned, Brenda D. Thew.

## **II. ISSUE**

Whether CMS properly denied the initial application submitted by each of the seven Appellants<sup>2</sup> (Appellants or Centene), all of whom share Centene Corporation as a common parent organization, to offer Medicare Advantage – Prescription Drug (MA-PD) plans for contract year (CY) 2021.

## **III. DECISION SUMMARY**

The Hearing Officer finds that Centene was operating under a misperception and was unintentionally misled by CMS when Centene submitted its application. Therefore, the Hearing Officer finds that Centene has met its burden of proving, by a preponderance of the evidence, that CMS' denial of each of its MA-PD applications was inconsistent with a fair interpretation of the controlling authorities. Accordingly, the Hearing Officer reverses CMS' denial of Centene's MA-PD application for each of the seven Appellants.

## **IV. PROGRAM BACKGROUND**

The Medicare Advantage (MA or Part C) program offers Medicare beneficiaries the option of receiving health care benefits through a privately-operated coordinated care delivery system.<sup>3</sup> The Social Security Act (the Act) authorizes the Secretary of the United States Department of Health & Human Services (the Secretary) to contract with entities seeking to offer MA and Medicare outpatient prescription drug (Part D) benefits to their plan enrollees.<sup>4</sup> Through regulation, the

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<sup>1</sup> 42 C.F.R. § 423.500 (Part D) states that, for purposes of that subpart, MA organizations offering Part D plans must follow the requirements for part 422 (Part C) for MA organizations, except in cases where additional requirements are mandated. Likewise, 42 C.F.R. § 422.500 (Part C) states that MA organizations offering prescription drug plans must follow the requirements of part 423 (Part D) specifically related to the prescription drug benefit.

<sup>2</sup> The seven entities appealing their MA-PD contract denials in this matter are Centene Venture Company Michigan (Contract No. H0482), Centene Venture Company Tennessee (Contract No. H2853), Centene Venture Company Kansas (Contract No. H6830), Sunflower State Health Plan, Inc. (Contract No. H9387), Centene Venture Company Indiana, Inc. (Contract No. H1774), Centene Venture Company Alabama Health Plan Inc. (Contract No. H4343) and Centene Venture Company Indiana, Inc. (Contract No. H7925). All seven have Centene Corporation as a common parent organization. Appellants' Hearing Brief at 2 (June 12, 2020); CMS' Reply Brief at 3 n.2 (June 19, 2020). At the request of the Appellants, and with no objection from CMS, the Hearing Officer has consolidated the appeals. *Id.* Since the seven application denials under appeal were prepared by the same parent entity and present identical issues, this decision will refer to a single application with the understanding that it applies to all seven applications unless stated otherwise. In addition, Centene's Exhibits A and E contain seven separate contracts, one for each of the seven Appellants. The Hearing Officer will cite to the pages or sections appearing in the first contract (Centene Venture Company Michigan, Contract No. H0428) in both of those exhibits, unless otherwise noted.

<sup>3</sup> See 42 U.S.C. §§ 1395w-21 *et seq.*; see also 42 C.F.R. § 422.4(a)(1) (“[a] coordinated care plan is a plan that includes a network of providers that are under contract or arrangement with the organization to deliver the benefit package approved by CMS.”).

<sup>4</sup> 42 U.S.C. § 1395w-27; see also § 1395w-112.

Secretary has delegated this contracting authority to CMS, which has established the general provisions for entities seeking to qualify as MA-PD plans.<sup>5</sup> An organization may not offer MA or Part D benefits unless it has entered into a contract with CMS.<sup>6</sup> An MA organization offering coordinated care plans (including Health Maintenance Organizations) must offer Part D benefits in the same service area.<sup>7</sup> Entities seeking to offer a new MA product must demonstrate, through the submission of an application developed by CMS, that they meet the qualifications.<sup>8</sup> CMS provides guidance by way of annual Solicitations with regard to the form and manner in which an organization must submit its MA-PD application. CMS conducts a review of all submitted MA applications and issues determinations consistent with 42 C.F.R. § 422.502(c).

In order to meet the requirement that they offer a Part D plan, MA organizations must also satisfy the Part D application requirements to demonstrate their qualification as a Part D sponsor. Organizations intending to offer Part D benefits must complete a certified application in the form and manner required by CMS.<sup>9</sup> Applicants must demonstrate that they meet all Part D program requirements to qualify as an MA-PD sponsor in their proposed service area. Furthermore, in order to ensure their compliance with the terms and conditions of its contract with CMS, an organization must enter into a contract with all first tier, downstream, and related entities who will perform Part D related functions on their behalf.<sup>10</sup>

CMS conducts a review of all submitted Part D applications and issues determinations consistent with 42 C.F.R. § 423.503(c). These determinations are based solely on information contained in the applications.<sup>11</sup> After an organization timely submits its initial application, CMS affords applicants two opportunities to correct any deficiencies. Following the initial review, CMS issues an email notice to an applicant informing it of a courtesy opportunity to submit curing materials (courtesy notice).<sup>12</sup> Following a second round of review, CMS issues a Notice of Intent to Deny (NOID), pursuant to 42 C.F.R. § 423.503(c)(2), affording the applicant ten days to provide curing materials. If CMS does not receive a revised application or a revised application still does not demonstrate that the applicant is qualified to act as a Part D sponsor, CMS denies the application pursuant to 42 C.F.R. § 423.503(c)(2)(iii).<sup>13</sup> If CMS denies an MA-PD application, the applicant has a right to a hearing before a CMS Hearing Officer in accordance with 42 C.F.R. §§ 422.660(a) and 423.650(a). At the hearing, the applicant has the burden of proving by a preponderance of the evidence that CMS' determination was inconsistent with the MA-PD regulatory requirements.<sup>14</sup>

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<sup>5</sup> 42 C.F.R. §§ 422.400, 422.501, 422.503(b).

<sup>6</sup> 42 U.S.C. § 1395w-27(a); *see also* § 1395w-112(b)(1).

<sup>7</sup> 42 C.F.R. § 422.4(c)(1).

<sup>8</sup> 42 C.F.R. § 422.501.

<sup>9</sup> 42 C.F.R. § 423.502(c)(1).

<sup>10</sup> 42 C.F.R. § 423.505(i).

<sup>11</sup> 42 C.F.R. § 423.503(a)(1).

<sup>12</sup> CMS' Response Brief at 2-3 and CMS' Exhibit 1, § 2.4.1.3.

<sup>13</sup> *Id.*

<sup>14</sup> 42 C.F.R. §§ 422.660(b), 423.650(b).

## V. STATEMENT OF THE CASE AND PROCEDURAL HISTORY

On January 8, 2020, CMS posted the final Solicitation for applications for MA-PD 2021 contracts (Solicitation)<sup>15</sup> on its website.<sup>16</sup> MA-PD 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 12, 2020.<sup>17</sup>

The Solicitation required Part D contract applicants to provide responses to a series of attestations related to Part D requirements as well as documentation demonstrating their ability to meet program requirements. CMS provided specific instructions with regard to the first tier, downstream and related entities.<sup>18</sup> Particularly relevant here, Section 3.1.1.C of the Solicitation required 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.”<sup>19</sup> Section 3.1.1.E of the Solicitation required applicants to upload copies of executed contracts with their Part D subcontractors, and that each executed contract must “[d]escribe the payment or other consideration the first tier, downstream, or related entity will receive for performance under the contract.”<sup>20</sup> Additionally, on January 8, 2020, CMS presented a virtual training session wherein a CMS representative reviewed the “requirements for the contracting section of the application.”<sup>21</sup> With regard to the payment terms in the subcontracts, the representative stated that, “[a]s always, you are permitted to redact pricing details.”<sup>22</sup> Finally, Section 3.1.1.F of the Solicitation required applicants to upload a “crosswalk” for each contract submitted. The crosswalk is a list of the requirements set forth in Section 3.1.1.E for which applicants are to identify the corresponding citations to the location of the contract provision, which satisfies each requirement.<sup>23</sup>

On February 12, 2020, the Appellants submitted both MA and Part D applications for coordinated care plan contracts with a Part D addendum for their respective contracts.<sup>24</sup> Along with their initial applications, the Appellants provided contracts with Envolve Pharmacy Solutions, Inc. (Envolve), under which Envolve would perform certain Part D functions on behalf of Centene.<sup>25</sup> The contracts included terms governing the method and timing of payments, recoupments, penalties, and other miscellaneous terms related to payment,<sup>26</sup> as well as a provision which stated Centene

<sup>15</sup> CMS' Exhibit 1. The document is titled Solicitation for Applications for Medicare Prescription Drug Plan 2020 Contracts, but is applicable to the 2021 contract year.

<sup>16</sup> See [https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/RxContracting\\_ApplicationGuidance.html](https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/RxContracting_ApplicationGuidance.html); CMS' Reply Brief at 2.

<sup>17</sup> See CMS' Reply Brief at 2; see also CMS' Exhibit 1, §§ 1.3, 2.4.

<sup>18</sup> CMS' Exhibit 1, §§ 3.1.1.A-F.

<sup>19</sup> *Id.* at § 3.1.1.C.

<sup>20</sup> *Id.* at § 3.1.1.E.5.

<sup>21</sup> Appellants' Exhibit K at 6.

<sup>22</sup> *Id.* at 7.

<sup>23</sup> See CMS' Exhibit 1 at Appendix X.

<sup>24</sup> See CMS' Reply Brief at 3.

<sup>25</sup> *Id.*; Appellants' Hearing Brief at 3 and Exhibit A.

<sup>26</sup> Appellants' Exhibit A at §§ 5.1 – 5.8.

would pay Envolve certain fees specified in an exhibit to the contract (Pricing Exhibit).<sup>27</sup> The Pricing Exhibit consisted of a chart on which, among other things, dispensing fees, rebates and discounts could be shown for brand name and generic drugs but the chart itself was blank,<sup>28</sup> i.e., no specific numerical values or prices were shown.<sup>29</sup> The crosswalk submitted with Centene's initial application contained no additional language regarding specific prices, but rather merely cited to the related contract pages, sections, and/or exhibits.<sup>30</sup>

On March 16, 2020, CMS issued a courtesy notice of deficiencies associated with the Appellants' Part D application.<sup>31</sup> The courtesy notice identified a number of contracting deficiencies and listed two individuals as the "Point of Contact for Questions" for this group of deficiencies. Particularly relevant to this appeal, the courtesy notice included the following language:

CMS has completed its review of your pending 2021 Part D application. This notification is only in relation to your Part D application for contract [numbers H0482, H1774, H2853, H4343, H6830, H7925 and H9387].

....

This review of your Part D application under [H0482, H1774, H2853, H4343, H6830, H7925 and H9387] identified certain deficiencies which are listed below.

....

**- The contract your organization submitted for key Part D functions does not contain finalized payment or consideration terms. The contract referenced is between Envolve Pharmacy Solutions, Inc. and [APPLICANT ENTITY]. Compensation section does not include specific payment terms. No indication that these were agreed to and omitted. May cure by adding**

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<sup>27</sup> *Id.* at § 5.1 ("As compensation for the Services provided by Envolve under this Agreement, Health Plan [or MCO] will pay the fees specified in **Exhibit A** (the '**Fees**')."). *See also* § 5.2 ("Health Plan will pay Envolve for all Covered Pharmacy Services based upon the rates set forth in **Exhibits A and A-1** of this Agreement.").

<sup>28</sup> Appellants' Exhibit A contains the Pricing Exhibit for all seven Appellants. Six of the Pricing Exhibits are identical. The Pricing Exhibit for Contract No. H6830, however, does not contain a chart. Appellants' Exhibit A at 373. This minor difference does not impact the outcome of this decision.

<sup>29</sup> *Id.* at 50-52. Of the two exhibits referenced in the contract, the parties focus on Exhibit A, titled "Compensation – Medicare." As submitted with Centene's initial application, this exhibit was a blank chart. The record also contains Exhibit A-1 titled "Specialty Drug Network Price List – Medicare." *Id.* at 52. Rather than presenting any definitive monetary prices, this exhibit states "The price list is available upon request." *Id.* Appellants' Exhibit A does not contain consecutive pagination. As Exhibit A contains 563 pages, the Hearing Officer will cite to the Portable Document Format (PDF) page number(s) to identify specific page references.

<sup>30</sup> *Id.* at 79.

<sup>31</sup> Appellants' Exhibit B. *See also* Appellants' Hearing Brief at 3; CMS' Reply Brief at 3.

**specifics or indicating (in crosswalk of contract) agreement and intentional omission.**

....

CMS is providing your organization with an opportunity to correct the above noted deficiencies. For those issue areas that require an upload of a document in CMS' Health Plan Management System (HPMS) please note, you are required to resubmit ALL of the documents for that particular section. Refer to the ReadMe file (included in the Part D templates) for the list of required documents for each section.<sup>32</sup>

On March 24, 2020, Centene responded to the courtesy notice explaining that "the contract . . . and contract crosswalk [are] being updated to address the deficiencies" and that "[a] final updated contract and contract crosswalk [were] not available at the time of our deficiency response submission."<sup>33</sup>

On April 13, 2020, CMS issued a formal NOID.<sup>34</sup> Relevant to this appeal, the NOID included the following language:

CMS identified the following deficiencies in your application:

....

**- The contract your organization submitted for key Part D functions does not contain finalized payment or consideration terms. The contract referenced is between Envolve Pharmacy Solutions, Inc. and [APPLICANT ENTITY]. Compensation section does not include specific payment terms. No indication that these were agreed to and omitted. May cure by adding specifics or indicating (in crosswalk of contract) agreement and intentional omission.**<sup>35</sup>

The same two CMS employees were also listed as points of contact and their email addresses were provided in the NOID.

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<sup>32</sup> *Id.* (emphasis added).

<sup>33</sup> Appellants' Hearing Brief at 3 and Exhibit C.

<sup>34</sup> Appellants' Exhibit D. *See also* Appellants' Hearing Brief at 3; CMS' Reply Brief at 3.

<sup>35</sup> *Id.* (emphasis added).

In response to the NOID, on April 23, 2020, Centene submitted an updated contract and crosswalk.<sup>36</sup> The updated contract still did not contain any specific prices, but Centene added to both the Pricing Exhibit and crosswalks the following statement:

Drug pricing and fees to be determined prior to the January 1, 2021 implementation, upon completion of a pricing and fees review in Q4 2020.<sup>37</sup>

For the convenience of the reader, the Hearing Officer will refer to this language as Centene’s “price determination language.”

On May 20, 2020, after the NOID was issued and the cure period had expired, CMS issued the denial notice to Centene detailing a single contracting deficiency.<sup>38</sup> The denial notice included the following language:

CMS denied your application based on the following deficiencies:

Part D Deficiencies:

Contracting

**- The contract your organization submitted for key Part D functions does not contain finalized payment or consideration terms. The contract referenced is between Envolve Pharmacy Solutions, Inc. and [APPLICANT ENTITY]. Compensation section does not include specific payment terms. No indication that these were agreed to and omitted. May cure by adding specifics or indicating (in crosswalk of contract) agreement and intentional omission.**<sup>39</sup>

On June 3, 2020, Centene filed seven hearing requests with the CMS Office of Hearings appealing the May 20, 2020 Denial Notices. On June 5, 2020, the CMS Office of Hearings acknowledged receipt of Centene’s hearing requests and set briefing and witness list deadlines for the parties. On June 12, 2020, Centene submitted its Initial Brief. On June 19, 2020, CMS submitted its Responsive Brief. On June 24, 2020, Centene submitted its Reply Brief and Motion for Summary Judgment. On July 1, 2020, CMS submitted its Memorandum in Opposition of Centene’s Motion for Summary Judgment and in Support of Its Own Counter-Motion for Summary Judgment. Based on these filings, the Hearing Officer notified the parties that this matter would be conducted as a hearing on the record without a live hearing or testimony. Centene was represented by Christine

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<sup>36</sup> Appellants’ Hearing Brief at 4 and Exhibit E.

<sup>37</sup> Appellants’ Hearing Brief at 4 and Exhibit E at 48, 76, 125, 153, 202, 230, 400, 414, 463, 491, 540, 568, 617, 645. *See also* CMS’ Reply Brief at 3.

<sup>38</sup> Appellants’ Exhibit F. *See also* Appellants’ Hearing Brief at 4; CMS’ Reply Brief at 3.

<sup>39</sup> Appellants’ Hearing Brief at 4 and Exhibit F (emphasis added).

Clements and Erica Kraus of Sheppard Mullin. CMS was represented by Scott Nelson of the Medicare Drug Benefit and C&D Data Group/Center for Medicare.

## **VI. DISCUSSION, ANALYSIS AND CONCLUSIONS OF LAW**

### **A. Motion for Summary Judgment and Counter-Motion for Summary Judgment**

Both parties have moved for summary judgment in this matter, although CMS maintains that some material facts are in dispute.<sup>40</sup> The regulations at 42 C.F.R. § 422.684(b) and 42 C.F.R. § 423.662(b) grant the Hearing Officer the authority to rule on such a motion. A motion for summary judgment is appropriate when there is no genuine dispute as to any material fact.<sup>41</sup> Indeed, in promulgating these regulations, the Secretary explained that “[w]here no factual dispute exists, the hearing officer may make a decision on the papers, without the need for a hearing.”<sup>42</sup> Material facts are those that might affect the outcome of the suit under the governing law.<sup>43</sup> In evaluating a motion for summary judgment, “[t]he pertinent inquiry is whether there are any genuine factual issues that properly can be resolved only by a finder of fact because they may reasonably be resolved in favor of either party.”<sup>44</sup> The facts that CMS claims are in dispute are questions of legal interpretation,<sup>45</sup> which the Hearing Officer is able to resolve without the need for testimony or a hearing. Though it disputes certain points made by Centene, CMS, in moving for summary judgment on its own, clearly believes any facts that may be in dispute are immaterial. As such, the Hearing Officer finds that deciding this matter on the papers submitted is appropriate.

Therefore, the Hearing Officer must consider whether Centene has met its burden of proving by a preponderance of the evidence that CMS’ decision to deny Centene’s application was incorrect.<sup>46</sup>

### **B. Contextual Background**

At the outset, the Hearing Officer observes that throughout the application process, Centene was operating under a misperception that was unintentionally created by CMS. This led to CMS’ deficiencies notices, while seemingly clear on their face, being misinterpreted by Centene. The Hearing Officer concludes, however, that Centene’s understanding of the requirements and interpretation of the notices were reasonable under the totality of the circumstances and that Centene was inadvertently misdirected by CMS. The Hearing Officer finds that the undisputed facts show that Centene’s response to the notices was both reasonable and responsive and that the parties failed to have a meeting of the minds. Therefore, as explained more fully below, Hearing

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<sup>40</sup> Applicants’ Reply Brief and Motion for Summary Judgment (June 24, 2020); CMS’ Memorandum in Opposition to Applicants’ Motion for Summary Judgment and in Support of Counter-Motion for Summary Judgment at 2 (July 1, 2020) (CMS’ Motion for Summary Judgment).

<sup>41</sup> See FED. R. CIV. P. 56(a).

<sup>42</sup> 72 Fed. Reg. 68700, 68714 (Dec. 5, 2007).

<sup>43</sup> *Variety Stores, Inc. v. Wal-Mart Stores, Inc.*, 888 F.3d 651, 659 (4th Cir. 2018).

<sup>44</sup> *Id.* (internal quotations and citations omitted).

<sup>45</sup> CMS disputes whether or not it “clarif[ied] that it sought specific pricing, instead directing Appellants to revise their crosswalks.” CMS’ Motion for Summary Judgment at 2. The underlying facts, namely the content of the deficiency notices and Centene’s responsive submission, are not in dispute. The controversy centers on the significance of those undisputed facts as they relate to the controlling authorities.

<sup>46</sup> See 42 C.F.R. §§ 422.660(b), 423.650(b).

Officer concludes that Centene has met its burden of proving, by a preponderance of the evidence, that CMS' denial of its MA-PD application was not consistent with a fair interpretation of the controlling authorities.

While the instant appeal stems from Centene's CY 2021 contract application denials, the events surrounding Centene's CY 2020 contract applications must be considered in order to provide context to the parties' interactions and interpretations of communications. The parties do not dispute that Centene received approval<sup>47</sup> of four MA-PD contract applications that contained "price determination language" that is nearly identical to the language that it added to its CY 2021 applications.<sup>48</sup> Specifically, Centene's CY 2020 contracts with Envolve contained payment terms virtually identical<sup>49</sup> to its 2021 contracts, including a provision stating that Envolve would be paid the "fees specified in" an exhibit that, like the CY 2021 Pricing Exhibit, did not contain any monetary values. Centene's 2020 contract applications were ultimately<sup>50</sup> approved with the following "price determination language" appearing on the similar Pricing Exhibit:

Drug pricing and fees to be determined prior to implementation.<sup>51</sup>

It is critical to note—and the parties do not dispute—that Centene first learned that CMS' approval of its 2020 contract applications (which contained the "price determination language") was in error **after CMS denied Centene's CY 2021 contract application.**<sup>52</sup> CMS does not explain exactly when it became aware that it had mistakenly approved Centene's CY 2020 contracting approach, nor does the record reflect any indication that Centene could have discerned that CMS made an error in CY 2020 prior to submitting its CY 2021 contract application.

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<sup>47</sup> Centene refers to CMS' response to its 2020 application as "conditional approval." Appellants' Hearing Brief at 4. CMS does not dispute, however, that it approved Centene's applications for the four contracts containing the language at issue.

<sup>48</sup> Appellants' Hearing Brief at 4.

<sup>49</sup> Appellants' Exhibit E contains Centene's updated Pricing Exhibit for all seven appellants. Six of the Pricing Exhibits are identical and contain the "price determination language" displayed in red font. The Pricing Exhibit for Contract No. H9387, however, contains specific information in the chart (including, *e.g.*, dispensing and administrative fees) but lacks the "price determination language." Nonetheless, Centene's application for Contract No. H9387 was denied by CMS.

<sup>50</sup> Appellants' Exhibit J at 26. As Appellants' Exhibit J does not contain consecutive pagination, the Hearing Officer will cite to the PDF page number(s) to identify specific page references.

<sup>51</sup> Exhibit J at 44. In contrast to the CY 2021 application, the crosswalk in Centene's 2020 Envolve contract contained no "price determination language," but only referenced pages or sections where payment terms could be found in the contract. *Id.* at 68.

<sup>52</sup> Appellants' Hearing Brief at 6 and Exhibit M. On May 20 and 26, 2020, following denial of its contract applications, Centene emailed a CMS point of contact seeking clarification of the basis for the denial. In its May 26 email, Centene stated, "Our understanding has always been that final payment or consideration terms can be determined during the 4<sup>th</sup> Quarter prior to the effective date." CMS' emailed response stated, "[w]e missed this deficiency in last years' applications . . . . When we saw this term in the contracts during the first round of review this year, we cited them as deficient in the [courtesy] . . . notices." Appellants' Exhibit M. The Hearing Officer notes that Centene did not include the "price determination language" in its initial application or in response to the courtesy notice, thus it could not have known until after CMS reviewed its response to the NOID that the language was unacceptable.

CMS, however, insists that the CY 2020 MA-PD contract application cycle, and any actions it took in that cycle, are irrelevant to the CY 2021 cycle. It protests the administrative burden it would suffer if it were required to re-review a plan's submissions for an indefinite number of previous contract cycles to ensure consistency in its evaluation of applications.<sup>53</sup> In fact, CMS predicts that such a look-back could give preferential treatment to "experienced" applicants if they received previous approvals in error.<sup>54</sup>

The Hearing Officer agrees that, if the Agency makes a mistake, it is not bound to repeat that mistake. The Hearing Officer also agrees that an expanded review reaching into the past would require CMS to review materials beyond those contained in the application itself, which is prohibited by the applicable regulations.<sup>55</sup> Nonetheless, CMS must be cognizant that it "sets the stage" for its interpretation of Solicitation requirements and review of applications with each contract cycle. Understandably, entities that interact regularly with a federal agency develop an understanding and perception of what the decision makers find acceptable. Experienced applicants, over time, become familiar with CMS' requirements, expectations and approach as they participate in consecutive contract cycles. While applicants must be responsive to clear Agency instructions, the Hearing Officer notes that MA-PD applicants cannot be expected to accurately read the mind of an individual Agency reviewer. In hindsight, in this particular situation, CMS' expectations, as conveyed in the deficiency notices, reasonably could have been interpreted in various ways.

Further, as Centene points out, during a training session held prior to the submission of CY 2021 applications, a CMS representative stated, "**As always**, you are permitted to redact pricing details."<sup>56</sup> The Hearing Officer notes that the training session transcript contains numerous references to "previous" or "prior" years.<sup>57</sup> The Hearing Officer, therefore, finds that it is reasonable for applicants to anticipate a level of continuity in the way CMS analyzes specific, approved language that remains constant from year to year.<sup>58</sup>

### C. Analysis

There is no dispute that the CY 2021 Solicitation required applicants to submit executed contracts with their Part D subcontractors and that each contract must "describe" the payment or consideration that the first tier, downstream and related entities would receive.<sup>59</sup> Centene's initial application included its contract with Envolve that contained a section entitled, "Compensation, Billing and Payment."<sup>60</sup> While CMS accurately characterizes this section as presenting the terms for payment processing, the section also provides that Envolve will be paid the "fees specified" in

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<sup>53</sup> CMS' Motion for Summary Judgment at 2-3.

<sup>54</sup> *Id.* at 3.

<sup>55</sup> See 42 C.F.R. §§ 422.502(a)(1), 423.503(a)(1).

<sup>56</sup> Appellants' Exhibit K at 8 (emphasis added).

<sup>57</sup> See, e.g., *id.* at 4-8, 12, 14, 21.

<sup>58</sup> The Hearing Officer notes that CMS advised participants during the training that the information discussed would not modify or supersede any regulations, manual provisions or other written guidance issued by CMS. Appellants' Exhibit K at 1. The training did, however, highlight a theme of continuity in CMS' approach.

<sup>59</sup> CMS' Exhibit 1 at § 3.1.1.E.5.

<sup>60</sup> Appellants' Exhibit A at 20.

the Pricing Exhibit. As submitted with the initial application, the Pricing Exhibit was merely a blank chart.<sup>61</sup> In addition, the crosswalk simply looped the reader back to applicable parts of the contract but contained no prices or other substantive information.

Centene's initial application for CY 2021, therefore, did not contain the "price determination language" that was approved in CY 2020.<sup>62</sup> At the first stage of review, CMS provided Centene with a courtesy notice that warned that its contract with Envolve did not contain terms for finalized or specific payment and offered that Centene "[m]ay cure by adding specifics or indicating (in crosswalk of contract) agreement and intentional omission."<sup>63</sup>

In response to the courtesy notice, Centene did not make an effort to cure or to contact CMS for guidance.<sup>64</sup> Instead, it alerted CMS that its contract and crosswalk were being updated to address the deficiencies but that the updated contract and crosswalk were not yet available.<sup>65</sup> It was, therefore, not surprising when CMS issued its NOID identifying exactly the same deficiency with regard to the Envolve contract. Specifically, both the courtesy notice and the NOID stated that Centene's contract with Envolve:

[D]oes not contain finalized payment or consideration terms. . . . Compensation section does not include specific payment terms. No indication that these were agreed to and omitted. May cure by adding specifics or indicating (in crosswalk of contract) agreement and intentional omission.<sup>66</sup>

In response to the NOID, again without contacting CMS, Centene uploaded its updated contract with Envolve, apparently electing to use the second option to cure and modeling its approach on its approved CY 2020 contracts. The updated version, with one minor exception,<sup>67</sup> continued to contain a blank chart in the Pricing Exhibit, but that exhibit and the crosswalk both now displayed "price determination language" similar to that which accepted by CMS in CY 2020:

Drug pricing and fees to be determined prior to the January 1, 2021 implementation, upon completion of a pricing and fee review in Q4 2020.<sup>68</sup>

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<sup>61</sup> *Id.* at 50.

<sup>62</sup> *See id.* at 50, 79.

<sup>63</sup> Appellants' Exhibit B.

<sup>64</sup> Centene explained that, based on the courtesy notice, it needed to correct multiple deficiencies in its contracts. Appellants' Hearing Brief at 5-6. It chose to focus on those deficiencies, rather than uploading another round of incomplete contracts. *Id.* In response to the courtesy notice, Centene could have submitted updated, although incomplete, contracts with the "price determination language," however the Hearing Officer finds that Centene's business decision (to defer a complete response) was reasonable in light of the circumstances. Based on its experience in the CY 2020 application cycle, Centene reasonably believed that its "price determination language" would be acceptable to CMS.

<sup>65</sup> Appellants' Exhibit C.

<sup>66</sup> Appellants' Exhibits B and D.

<sup>67</sup> *See supra* note 48.

<sup>68</sup> Appellants' Hearing Brief at 4 and Exhibit E at 48, 76. *See also* CMS' Reply Brief at 3.

CMS, however, rejected the attempted cure and denied the application.

CMS maintains that the Solicitation requirements and both deficiency notices were clear: Centene was to provide, or intentionally omit, “specific payment terms.”<sup>69</sup> It argues Centene’s application was missing a material element of the contract—an agreement on price. CMS claims there is no distinction between “price” and “payment” thus Centene should have known it was required to agree on a definitive “amount of money” that it would pay Envoke.<sup>70</sup> CMS objects to Centene’s “price determination language” on the grounds that such arrangement is arguably unenforceable and creates litigation risk.<sup>71</sup> Further, CMS sees a clear distinction between “redaction” and “intentional omission” of agreed upon prices. It asserts that an agreement on payment the terms must precede redaction or an indication that the specifics have been omitted from a contract application.

The Hearing Officer finds that CMS’ interpretation of the language in the Solicitation and deficiency notices was understandable and reasonable. The Hearing Officer also finds, however, that in the context of Centene’s experience during the CY 2020 application cycle, its reading of the Solicitation and the cure options, and its use of the “price determination language,” was equally reasonable and logical. Albeit unintentionally, CMS created the impression that Centene’s “price determination language” was acceptable in a Part D application based on its actions in the CY 2020 cycle. While the Hearing Officer also agrees that redaction and omission are two separate concepts, CMS appears to use the terms as equally acceptable alternatives. CMS’ training session instructed that redaction was “always” acceptable, thus, it was reasonable to conclude that a specific price, once agreed upon, could be presented in a contract application, then deliberately obscured. Similar to its situation in CY 2020, however, Centene did not have specific prices to present in its initial CY 2021 application or during the cure period. The Hearing Officer finds that, in light of its experience during the CY 2020 contract cycle, it was reasonable for Centene to interpret the cure option to “intentionally omit” as permitting the use of “price determination language” that has been accepted in CY 2020. While CMS asserts any reasonable reliance that Centene had based on its experience in the CY 2020 cycle became unreasonable upon receipt of the deficiency notices,<sup>72</sup> the Hearing Officer disagrees. When receiving both of the identical deficiency notices, Centene remained under the impression that its “price determination language” would be acceptable based on its experience in CY 2020.<sup>73</sup>

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<sup>69</sup> CMS’ Motion for Summary Judgment at 2.

<sup>70</sup> *See id.*

<sup>71</sup> CMS’ Responsive Brief at 4.

<sup>72</sup> *Id.* at 5.

<sup>73</sup> As explained earlier, similar “price determination language” had been accepted by CMS in CY 2020 and, since Centene had not included such language in its initial CY 2021 application or in its response to the courtesy notice, CMS did not have the opportunity to review it during the cure periods. Accordingly, the language had not yet been rejected by CMS.

Comparing the fact patterns in *In re Gateway Health Plan of Ohio, Inc.*<sup>74</sup> and *In re Universal Care Inc.*<sup>75</sup> to its situation, Centene argues that it, like the applicants there, was materially prejudiced and misdirected by communications from CMS.<sup>76</sup> CMS asserts, however, that those cases do not require reversing an application denial whenever an applicant is confused by CMS' instruction.<sup>77</sup> CMS points out that the applicants in both *Gateway* and *Universal*, unlike Centene, took advantage of CMS' offer to provide clarifying instruction. CMS argues that the applicants in both cases were granted relief only after making a good faith effort to understand CMS' instruction and CMS had the opportunity to provide additional guidance.

The Hearing Officer notes, however, that the applicants in both *In re Universal Care Inc.* and *In re Gateway Health Plan of Ohio, Inc.* had reason to question CMS' feedback and thus both contacted CMS during the cure period. In both cases, the applicants had already submitted what they believed to be exactly the documentation CMS subsequently flagged as missing. Here, Centene knew it had not included specific prices or its previously accepted "price determination language" with its initial application. Centene knew it had not redacted prices or made any representation about omission of an agreement and prices. Centene even acknowledged in its response to the courtesy notice that it was still updating its contract and crosswalk. CMS could reasonably interpret Centene's response to mean that specific prices would be contained in the application in the final cure period and, seeing no change in the application, understandably issued the identical deficiency language in the NOID. In reading the NOID, Centene continued to have no reason to question its comprehension of the notice. The language CMS used to identify the deficiency, read in light of Centene's experience in CY 2020, reasonably led Centene to expect that its "price determination language" would be acceptable to CMS. In fact, Centene supplied even more information in its CY 2021 "price determination language" (*i.e.*, Centene informed CMS that it and Envolve would complete a review of pricing and fees in the fourth quarter of 2020 in connection with determining their prices and fees) than it did for CY 2020. The Hearing Officer finds that Centene, unlike the applicants in *Gateway* and *Universal*, had no reason to suspect that it did not understand the notices and thus no reason to seek clarification from CMS.

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<sup>74</sup> *In re Gateway Health Plan of Ohio, Inc.*, Docket No. 2013 MA-PD 6 (Aug. 9, 2013). (In a courtesy notice, CMS notified the applicant that a contract had not been uploaded, but inadvertently did not identify the contract. The applicant reasonably assumed which contract CMS intended to identify and provided more information. CMS then issued a NOID, stating for the first time that a different contract was missing. The applicant reached out to CMS for assistance and asked if adding a specific addendum to the contract would cure the deficiency. CMS responded yes, but even with the addendum, CMS subsequently denied the application. The Hearing Officers found that "the parties engaged in what each apparently thought was a clear exchange . . . [but] parties ultimately did not fully understand each other." *Id.* at 13.)

<sup>75</sup> *In re Universal Care Inc.*, Docket No. 2017-4 MA/PD (July 24, 2017). (The applicant inadvertently submitted an unexecuted document but CMS stated, in both a NOID and a teleconference, that the document was not filed. When the applicant re-submitted all documents, it accidentally omitted one document that had been previously filed. The Hearing Officers found that the applicant complied with CMS' requirements, even reaching out for assistance, but that CMS' feedback misdirected the applicant's efforts to cure.)

<sup>76</sup> Appellants' Hearing Brief at 7; Appellants' Reply Brief and Motion for Summary Judgment at 2.

<sup>77</sup> CMS' Responsive Brief at 6.

## VII. RULING

It is apparent that CMS reasonably expected Centene to add specific monetary prices to its contract **or** to provide concrete confirmation of an existing agreement on those prices along with a succinct indication that Centene deliberately chose to withhold the specific prices. It is equally apparent that, when it responded to the NOID, Centene was reasonably operating under the misperception that its “price determination language” would satisfy CMS’ written request based on Centene’s experience in the CY 2020 contract cycle, coupled with CMS’ message to the industry that inferred overarching continuity in the application review process. As a result, the Hearing Officer concludes that the parties did not reach a meeting of the minds. Therefore, considering the totality of the circumstances, the Hearing Officer finds that Centene was inadvertently misdirected by CMS’ prior acceptance of contracts containing similar “price determination language.” Centene reasonably misinterpreted the deficiency notices, which, in hindsight, were ambiguous from Centene’s perspective. The language suggested, to Centene, that CMS expected a simple amendment to the contract in order to cure the deficiency.<sup>78</sup>

Accordingly, the Hearing Officer finds that Centene has met its burden of proving, by a preponderance of the evidence, that CMS’ denial of its MA-PD application was inconsistent with a fair interpretation of the controlling authorities. Hence, the Hearing Officer reverses CMS’ denial of Centene’s MA-PD applications submitted by Centene Venture Company Michigan (Contract No. H0482), Centene Venture Company Tennessee (Contract No. H2853), Centene Venture Company Kansas (Contract No. H6830), Sunflower State Health Plan, Inc. (Contract No. H9387), Centene Venture Company Indiana, Inc. (Contract No. H1774), Centene Venture Company Alabama Health Plan, Inc. (Contract No. H4343), and Centene Venture Company Indiana, Inc. (Contract No. H7925) for the CY 2021 application cycle.

*Brenda D. Thew*

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Brenda D. Thew, Esq.  
CMS Hearing Officer

Date: August 26, 2020

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<sup>78</sup> The Hearing Officer notes that Centene states it has complied with “CMS’ request, as . . . articulated in response to [Centene’s] inquiry after the Contract Determination[], by including specific pricing terms in its Envolv . . . contract.” Appellant’ Hearing Brief at 9. The Hearing Officer is unable to consider additional information beyond that reviewed by CMS, but it does not appear that Centene has submitted the updated materials into the hearing record.