

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

<b>IN THE MATTER OF:</b>	*	
<b>Meridian Health Plan of Michigan, Inc.</b>	*	
<b>Denial of Medicare Advantage Prescription Drug Initial Application</b>	*	<b>DOCKET NO. MA-PD 2020-09</b>
	*	
<b>Contract Year 2021</b>		
<b>Contract No. H4237</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 Meridian Health Plan of Michigan, Inc. (Meridian) to offer a Medicare Advantage – Prescription Drug (MA-PD) plan for contract year (CY) 2021.

## **III. DECISION**

The Hearing Officer concludes that Meridian has not met its burden of proving that CMS' denial of its MA-PD application was inconsistent with the regulatory requirements. Meridian did not submit with its application, as required by CMS, an executed contract containing all necessary flow down clauses with one of the first tier, downstream or related entities which it listed as performing Part D functions on its behalf or a chart illustrating the relationships with its first tier, downstream or related entities. Accordingly, the Hearing Officer affirms CMS' denial of Meridian's MA-PD application.

## **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>2</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>3</sup> Through regulation, the Secretary has delegated this contracting authority to CMS, which has established the general provisions for entities seeking to qualify as MA-PD plans.<sup>4</sup> An organization may not offer MA or Part D benefits unless it has entered into a contract with CMS.<sup>5</sup> An MA organization offering coordinated care plans (including Health Maintenance Organizations) must offer Part D benefits in the same service area.<sup>6</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>7</sup> CMS

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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> 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>3</sup> 42 U.S.C. § 1395w-27; see also § 1395w-112.

<sup>4</sup> 42 C.F.R. §§ 422.400, 422.501, 422.503(b).

<sup>5</sup> 42 U.S.C. § 1395w-27(a); see also § 1395w-112(b)(1).

<sup>6</sup> 42 C.F.R. § 422.4(c)(1).

<sup>7</sup> 42 C.F.R. § 422.501.

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.<sup>8</sup> 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>

## **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> Organizations were to submit their applications through the Health Plan Management System (HPMS), CMS' electronic system of record for the

<sup>8</sup> 42 C.F.R. §§ 422.500(a), 423.500. 42 C.F.R. § 423.500 notes 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.

<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 to Request Made on Behalf of Meridian Health Plan of Michigan for Hearing Officer Review of CMS' Denial of the Organization's CY 2021 Medicare Part D Contract Application (H4237) at 2 (June 16, 2020) (CMS' Reply Brief) 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).

<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.

administration of the MA and Part D programs. Organizations were to submit the applications under Contract identification (ID) numbers that HPMS assigned to each entity that provided a notice of intent to apply after October 2019. 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> This section also instructed applicants to identify, in a template chart set forth in Section 3.1.1.C, which entity was performing which Part D function.<sup>20</sup> In addition, Section 3.1.1.D of the Solicitation required applicants to “[p]repare and upload into HPMS a chart showing the relationship between the applicant and each first tier, downstream, and related entity identified in section 3.1.1 C. This chart must include the names of all entities in the contracting chain between the applicant and the entity performing the identified function.”<sup>21</sup> For clarity, the Hearing Officer will refer to the chart required by Section 3.1.1.C as the “Function Chart” and the chart required by Section 3.1.1.D as the “Relationship Chart.”

On February 12, 2020, Meridian submitted both MA and Part D applications for a coordinated care plan contract under contract number H4237.<sup>22</sup> With this initial application, Meridian listed Comprehensive Health Management, Inc. (CHMI) as an entity that would provide enrollment processing services (a Part D function).<sup>23</sup> Meridian explains its relationship to CHMI, which is one of the first tier, downstream or related entities that it listed as performing Part D functions on its behalf, as follows. Meridian historically received administrative services from Meridian Management Company, LLC, f/k/a Caidan Management Company, LLC (MMC). WellCare Health Plans, Inc. (WellCare), which acquired Meridian in September, 2018, historically received administrative services from CHMI. When WellCare acquired Meridian, MMC and CHMI entered into a “Bridge Agreement” in which CHMI now performs some administrative services and provides access to certain vendor contracts so that MMC can still provide administrative services to Meridian.<sup>24</sup> There is no direct agreement between Meridian and CHMI; MMC had an agreement with CHMI. MMC was still providing its administrative services to Meridian, but now relied on support from CHMI to do so.<sup>25</sup> When Meridian submitted its initial application, Meridian listed CHMI as an entity that would provide enrollment processing services and also uploaded an administrative services contract with Meridian and MMC covering enrollment services, but it

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<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> The only other information collected in this template chart, which is a three-column table, is whether the entity is off-shore.

<sup>21</sup> CMS’ Exhibit 1, § 3.1.1.D.

<sup>22</sup> See CMS’ Reply Brief at 4.

<sup>23</sup> CMS’ Exhibit 2.

<sup>24</sup> Meridian’s Initial Brief at 2 (June 9, 2020).

<sup>25</sup> *Id.* at 3.

admittedly did not describe the intervening relationship between MMC and CHMI.<sup>26</sup>

On March 16, 2020, CMS issued a courtesy notice of deficiencies associated with Meridian's Part D application.<sup>27</sup> The courtesy notice identified four contracting deficiencies, and listed two individuals as the "Point of Contact for Questions" for this group of deficiencies. Relevant to this appeal,<sup>28</sup> 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 number H4237.

....

This review of your Part D application under H4237 identified certain deficiencies which are listed below.

....

**-Your organization did not upload an executed contract with one of the first tier, downstream or related entities that is performing a Part D function on your behalf. The first tier, downstream or related entity referenced is Comprehensive Health Management, Inc.**

....

**-Your organization did not provide a chart showing the relationship between your organization and each first tier, downstream, and related entity identified in section 3.1.1 C of the application.**

....

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

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<sup>26</sup> *Id.* While Meridian initially represented that the agreement between Meridian and MMC was uploaded in response to the courtesy notice (Meridian's Initial Brief at 3), it later acknowledged that, as CMS described, it was uploaded with its initial application. See Meridian's Reply Brief at 2 (June 22, 2020); CMS' Reply Brief at 4; Transcript of Proceedings ("Tr.") at 55. The difference in timing is immaterial to the Hearing Officer's decision.

<sup>27</sup> Meridian's Exhibit A.

<sup>28</sup> Two other contracting deficiencies, which are not relevant to this appeal, were noted: "The contract your organization submitted is not for a term of at least the one-year contract period for which this application was submitted. The contract referenced is between TPUSA, Inc. and Comprehensive Health Management, Inc.. [*sic*] Contract must run through at least December 31 of the benefit year (2021)" and "[y]our organization failed to upload evidence of incorporation." *Id.*

(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>29</sup>

On March 24, 2020, Meridian submitted documents to CMS in response to the courtesy notice including a 347 page organizational chart.<sup>30</sup> Meridian also submitted a document titled Note to Reviewer,<sup>31</sup> which provided a brief description of what was done to cure each deficiency. The relevant deficiencies and replies were addressed with the following language:

**Deficiency:** Your organization did not upload an executed contract with one of the first tier, downstream or related entities that is performing a Part D function on your behalf. The first tier, downstream or related entity referenced is Comprehensive Health Management, Inc.

**Response:** Meridian Health Plan of Michigan Inc. is working to update the Comprehensive Health Management contract. This will be ready during the NOID deficiency upload.<sup>32</sup>

....

**Deficiency:** Your organization did not provide a chart showing the relationship between your organization and each first tier, downstream, and related entity identified in section 3.1.1 C of the application.

**Response:** Please see the H4237\_MI\_Part D Administrative Relationships PFD in the Part D contracting zip file.<sup>33</sup>

On April 13, 2020, CMS issued a formal Notice of Intent to Deny (NOID).<sup>34</sup> Relevant to this appeal,<sup>35</sup> the NOID included the following language:

CMS identified the following deficiencies in your application:

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<sup>29</sup> Meridian's Exhibit A (emphasis added).

<sup>30</sup> Meridian's Initial Brief at 2-3 and Meridian's Exhibit I; CMS' Reply Brief at 7.

<sup>31</sup> CMS' Reply Brief at 6; CMS' Exhibit 8; Tr. at 33.

<sup>32</sup> The witness for Meridian testified that this response was a copy and pasting error, since it is identical to the response to the deficiency listed immediately prior. Tr. at 33-35. As previously noted, the other deficiency is not relevant to this appeal. *See supra* note 28.

<sup>33</sup> CMS' Exhibit 8.

<sup>34</sup> Meridian's Exhibit B. *See also* Meridian's Initial Brief at 2; CMS' Reply Brief at 4.

<sup>35</sup> One other contracting deficiency, which is not relevant to this appeal, was noted: "The contract your organization submitted is not for a term of at least the one-year contract period for which this application was submitted. The contract referenced is between TPUSA, Inc. and Comprehensive Health Management, Inc.. [sic] Contract must run through at least December 31 of the benefit year (2021)." Meridian's Exhibit B.

....

**-Your organization did not upload an executed contract with one of the first tier, downstream or related entities that is performing a Part D function on your behalf. The first tier, downstream or related entity referenced is Comprehensive Health Management, Inc.**

....

**-Your organization did not provide a chart showing the relationship between your organization and each first tier, downstream, and related entity identified in section 3.1.1 C of the application. The 3.1.1 C chart is intended as a guide for what to enter in the HPMS Part D data (see instructions under 3.1.1 C). Per 3.1.1 D please upload a chart showing the relationship between the applicant and each first tier, downstream, and related entity identified in section 3.1.1.C.<sup>36</sup>**

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

In response to the NOID, on April 22, 2020, Meridian submitted additional documentation in an attempt to cure these deficiencies.<sup>37</sup> Included in these documents was a Bridge Agreement that describes the intervening relationship between CHMI and MMC, as well as an additional chart and explanations in a Note to Reviewer document<sup>38</sup> related to the relationships between Meridian, MMC, and CHMI.<sup>39</sup> CMS determined that the Bridge Agreement did not include all of the required flow down clauses, and that Meridian did not include the contracting relationship chart requested in both the courtesy notice and NOID.<sup>40</sup>

On May 20, 2020, after the NOID was issued and the cure period had expired, CMS issued the denial notice to Meridian detailing a number of related contracting deficiencies.<sup>41</sup> The denial notice included the following language:

CMS denied your application based on the following deficiencies:

Part D Deficiencies:

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<sup>36</sup> *Id.* (emphasis added).

<sup>37</sup> Meridian's Initial Brief at 2; CMS' Reply Brief at 4.

<sup>38</sup> Meridian's Exhibit L; Tr. at 41-43.

<sup>39</sup> Meridian's Initial Brief at 3.

<sup>40</sup> CMS' Reply Brief at 4. Meridian does not dispute that the contract at the time of submission did not have the required flow down terms. Meridian's Initial Brief at 3-4; Meridian's Reply Brief at 3; Tr. at 49-50.

<sup>41</sup> Meridian's Exhibit C.

## Contracting

- The contract your organization submitted for key Part D functions does not contain language obligating the first tier, downstream or related entity to abide by all applicable Federal laws and regulations, as well as CMS instructions. The contract referenced is between Comprehensive Health Management, Inc. and Caidan Management Company, LLC.
- The contract your organization submitted for key Part D functions does not contain language that you have the authority to revoke the contract in the event that you or CMS determine that the first tier, downstream or related entity is not performing satisfactorily. The contract referenced is between Comprehensive Health Management, Inc. and Caidan Management Company, LLC.
- The contract your organization submitted for key Part D functions does not contain language clearly indicating that the first tier, downstream or related entity has agreed to participate in your Medicare Prescription Drug Benefit program. The contract referenced is between Comprehensive Health Management, Inc. and Caidan Management Company, LLC.
- The contract your organization submitted for key Part D functions does not contain language sufficient to ensure that the first tier, downstream or related entity will make its books or records related to Part D operations available for Federal inspection. The contract referenced is between Comprehensive Health Management, Inc. and Caidan Management Company, LLC.
- 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 Comprehensive Health Management, Inc. and Caidan Management Company, LLC.
- The contract your organization submitted for key Part D functions does not describe the functions, including the reporting requirements to be performed by the subcontractor. The contract referenced is between Comprehensive Health Management, Inc. and Caidan Management Company, LLC.
- The contract your organization submitted for key Part D functions does not contain language sufficient to ensure that the first tier,



downstream or related entity will hold beneficiaries harmless for fees that are your organization's responsibility. The contract referenced is between Comprehensive Health Management, Inc. and Caidan Management Company, LLC.

- The contract your organization submitted for key Part D functions does not contain flow-down clauses requiring the activities of the first tier, downstream or related entity to be consistent with your organization's contractual obligations as a Part D sponsor. The contract referenced is between Comprehensive Health Management, Inc. and Caidan Management Company, LLC.

- The contract your organization submitted for key Part D functions does not contain language stating that your organization will monitor the first tier, downstream or related entity's performance on an ongoing basis. The contract referenced is between Comprehensive Health Management, Inc. and Caidan Management Company, LLC.

- Your organization did not provide a chart showing the relationship between your organization and each first tier, downstream, and related entity identified in section 3.1.1 C of the application. The 3.1.1 C chart is intended as a guide for what to enter in the HPMS Part D data (see instructions under 3.1.1 C). Per 3.1.1 D please upload a chart showing the relationship between the applicant and each first tier, downstream, and related entity identified in section 3.1.1 C.<sup>42</sup>

On June 1, 2020, Meridian filed a hearing request with the CMS Office of Hearings appealing the May 20, 2020 Denial Notice. On June 2, 2020, the CMS Office of Hearings acknowledged receipt of Meridian's hearing request and set briefing and witness list deadlines for the parties. On June 9, 2020, Meridian submitted its Initial Brief. On June 16, 2020, CMS submitted its Responsive Brief. On June 22, 2020, Meridian submitted its Reply Brief. On June 24, 2020, both parties submitted their witness lists. The Hearing Officer conducted a hearing via live videoconference on June 30, 2020. Meridian was represented by Christine 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. Meridian submitted a Post-Hearing Brief on July 7, 2020.

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<sup>42</sup> *Id.* See also Meridian's Initial Brief at 2; CMS' Reply Brief at 4.

## VI. MERIDIAN'S POSITION

Meridian requests that the Hearing Officer overturn the May 20, 2020 contract determination made by CMS. Meridian maintains that CMS was not clear in communicating what deficiencies were present in their application and, as such, it did not have an opportunity to address the deficiencies during the prescribed cure periods. It argues that all of the deficiencies have been cured following the May 20 contract determination, and the Hearing Officer should accept that as a basis to overturn CMS' decision. To provide additional support for this request, Meridian cites several decisions of the Administrator<sup>43</sup> in which a deficient application was allowed to be cured, in the Administrator's discretion, because there were "compelling public policy arguments with respect to the beneficiary related value of the Plan's services provided to vulnerable Medicare populations."<sup>44</sup>

When Meridian submitted its initial application, it listed CHMI as an entity that would provide enrollment services in the chart it submitted pursuant to Section 3.1.1.C of the Solicitation,<sup>45</sup> but admittedly did not describe the intervening relationship between itself and CHMI.<sup>46</sup> Meridian believes CMS could and should have inferred the relationships that existed between Meridian and CHMI based on other contracts that were submitted.<sup>47</sup> Based on its reading of the CMS Application ReadMe File<sup>48</sup> and Section 3.1.1.C of the Solicitation together, Meridian believed the chart it submitted to meet the requirements of Section 3.1.1.C was also sufficient to satisfy Section 3.1.1.D's instructions to "[p]repare and upload into HPMS a chart showing the relationship between the applicant and each first tier, downstream, and related entity identified in section 3.1.1 C."<sup>49</sup>

After receiving the courtesy notice, which stated that there was no executed contract with CHMI, Meridian believed that CMS had overlooked an agreement already uploaded, and while Meridian had uploaded an agreement between Meridian and MMC in the initial application, it had not uploaded the Bridge Agreement that describes the intervening relationship between MMC and CHMI.<sup>50</sup> Nor did it upload the MMC – CHMI Bridge Agreement in response to the courtesy notice.<sup>51</sup> Meridian argues that the language in the courtesy notice was not specific enough for it to understand what was missing from its application.<sup>52</sup> With regard to the deficiency related to a chart showing the relationships, Meridian uploaded its 347 page document identified as an organizational chart.<sup>53</sup> At the hearing, the witness for Meridian explained that page 14 of this chart

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<sup>43</sup> *In re Cmty. Care Alliance of Ill.* (Docket No. 2013-MA/PD-App-07) (Aug. 4, 2013 Adm'r Dec.) at 7; *In re Blue Cross Blue Shield of Mich.* (Docket No. 2013-C/D-App-05) (Aug. 12, 2013 Adm'r Dec.) at 10; *In re American Health Alliance, Inc.* (Docket No. 2010-C/D-App-1) (July 9, 2010 Adm'r Dec.) at 9.

<sup>44</sup> Meridian's Initial Brief at 4-5.

<sup>45</sup> CMS' Exhibit 2.

<sup>46</sup> Meridian's Initial Brief at 3; Tr. at 55.

<sup>47</sup> Meridian's Reply Brief at 2; *see also* Tr. at 68-70.

<sup>48</sup> Meridian's Exhibit H.

<sup>49</sup> *Id.*; CMS' Exhibit 1, §§ 3.1.1.C-D.

<sup>50</sup> Meridian's Reply Brief at 2-3; CMS' Reply Brief at 4; Tr. at 31-32, 55.

<sup>51</sup> Tr. at 67 (noting that the Bridge Agreement was uploaded after the NOID).

<sup>52</sup> Meridian's Reply Brief at 2; Tr. at 31-33.

<sup>53</sup> CMS' Reply Brief at 7; Meridian's Initial Brief at 3 and Meridian's Exhibit I.

shows an ownership link between WellCare Management Group and CHMI, and that page 19 of the chart shows an ownership link between MMC and WellCare Management Group.<sup>54</sup>

Following the NOID, which again cited the failure of Meridian to upload an executed contract with CHMI,<sup>55</sup> Meridian uploaded the Bridge Agreement that describes the intervening relationship between MMC and CHMI, as well as a new chart<sup>56</sup> and explanation of the relationships between Meridian, MMC, and CHMI.<sup>57</sup> In the denial notice, CMS no longer cited the lack of an executed contract, but listed new deficiencies because the Bridge Agreement did not contain all of the necessary flow down clauses. Meridian believes it was effectively precluded from curing this deficiency because once it was identified, there were no additional opportunities to cure. Meridian argues that the reason it was identified at this late stage was due to CMS' vague deficiency notices.<sup>58</sup>

Meridian also notes that the Bridge Agreement has been amended to include all of the required flow down terms, thus curing the deficiencies noted in May 20, 2020 denial notice, and requests the Hearing Officer overturn that denial. Citing *In re Gateway Health Plan of Ohio, Inc.*<sup>59</sup> and *In re Universal Care, Inc.*<sup>60</sup>, Meridian argues that the language in the deficiencies did not point directly to the gaps in its application, which it claims materially prejudiced its ability to cure the application by misdirecting its efforts to do so, thus warranting a reversal of CMS' denial by the Hearing Officer.<sup>61</sup>

## **VII. CMS' POSITION**

CMS argues that the Hearing Officer's review is limited to a review of the record upon which CMS made its application denial determination. As such, CMS insists that the Hearing Officer cannot consider any curing materials submitted or created following the application denial, also noting that the decisions of the Administrator cited by Meridian are governed by a different standard than these proceedings.<sup>62</sup> CMS believes its denial was proper because it evaluated Meridian's subcontracting arrangements based on its responses to Sections 3.1.1.C, D, and E of the Solicitation, and that it did not objectively meet the criteria for approval. Since Meridian listed CHMI as the entity to which it would delegate enrollment processing services, CMS expected to see an executed contract between Meridian and CHMI with the appropriate flow down terms. While other contracts involving CHMI or Meridian and other entities had been submitted, none delegated enrollment processing services to CHMI or were between Meridian and CHMI.<sup>63</sup> If a Relationship Chart had been submitted as required by Section 3.1.1.D of the Solicitation, CMS states it may have been able to understand the ultimate delegation and relationship amongst the

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<sup>54</sup> Tr. at 37-38.

<sup>55</sup> Meridian's Initial Brief at 3 and Meridian's Exhibit B.

<sup>56</sup> Meridian's Initial Brief at 3.

<sup>57</sup> *Id.* See also Tr. at 67.

<sup>58</sup> Meridian's Initial Brief at 3.

<sup>59</sup> Docket Number 2013 MA-PD 6 (Aug. 9, 2013) (Gateway).

<sup>60</sup> Docket Number 2017-4 MA/PD (July 24, 2017) (Universal).

<sup>61</sup> Meridian's Initial Brief at 4-6; see generally Meridian's Reply Brief.

<sup>62</sup> CMS' Reply Brief at 4-5.

<sup>63</sup> *Id.* at 5.

parties, but with the possibility of other parties or unknown contractual relationships, CMS declined to speculate.<sup>64</sup> Indeed, following the courtesy notice, Meridian indicated it was working to update the CHMI contract.<sup>65</sup>

Further, CMS argues that the 347 page organizational chart Meridian submitted after the courtesy notice was not responsive to the stated deficiency nor was it accompanied by any direction or instruction as to the functions being delegated to any particular entities.<sup>66</sup> CMS disputes that either its deficiency notice or the Solicitation were unclear with regard to what was expected for this chart. Indeed, following the NOID, which provided additional language and guidance in the deficiency compared to the courtesy notice, Meridian uploaded a concise chart that illustrated certain contractual links to delegated entities.<sup>67</sup> This chart, however, still showed Meridian having a direct link with CHMI, and was inaccurate and deficient.<sup>68</sup>

CMS acknowledges that, following the NOID and Meridian's submission of the Bridge Agreement, the reason for denial changed from a failure to provide an executed contract to a failure to provide a contract with the correct flow down clauses. CMS argues that the contracts must be between certain parties and contain certain terms, and that proof of such contracts must be submitted within certain time periods. These requirements are set forth in the applicable regulations at 42 C.F.R. 423 Part K, and neither CMS nor the Hearing Officer can approve a deficient application after the cure periods have lapsed.<sup>69</sup> CMS concludes its arguments by noting that CMS staff were listed on both the courtesy notice and NOID as available to assist Meridian, but Meridian did not contact CMS for clarification or help.<sup>70</sup>

CMS maintains that it reviewed Meridian's Part D application and reached a decision to deny the application in a manner fully in accordance with the applicable statutes, regulations and guidance. It asserts that Meridian has not met its burden of proving by a preponderance of the evidence that CMS' decision to deny Meridian's application was incorrect. CMS requests that the Hearing Officer deny Meridian's request for relief.<sup>71</sup>

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

As explained below, the Hearing Officer concludes that Meridian has not met its burden of proving that CMS' determination was inconsistent with the MA-PD regulatory requirements. Meridian was provided with two written notices, both of which were adequate, and an opportunity to communicate with CMS so that Meridian could have timely rectified the deficiencies at issue.

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<sup>64</sup> *Id.* at 5-7. *See also* Tr. at 82-84, 105-07 (noting that making incorrect inferences can further complicate the application process).

<sup>65</sup> CMS' Exhibit 8.

<sup>66</sup> CMS' Reply Brief at 7.

<sup>67</sup> *Id.*; Meridian's Exhibit K; Tr. at 46-47.

<sup>68</sup> *Id.* An updated chart was submitted after Meridian's MA-PD application was denied. *See* Meridian's Exhibit N.

<sup>69</sup> CMS' Reply Brief at 4-6.

<sup>70</sup> *Id.* at 7-8.

<sup>71</sup> *Id.* at 8.

Initially, the Hearing Officer notes that Meridian's reliance on *Gateway* and *Universal* is misplaced. In both those cases, CMS provided, albeit inadvertently, erroneous and incomplete information in the courtesy notice, the NOID, and subsequent communications with the applicant. These errors were found to have affirmatively misled and prejudiced the applicant. Here, the feedback provided by CMS in the courtesy notice and NOID, in light of the situation as a whole, was sufficiently clear in explaining the deficiencies in Meridian's application based on the instructions in the Solicitation.

With respect to the contracting deficiency, the courtesy notice was accurate and specific in relation to what the Solicitation required: Meridian's application did not contain an executed contract with CHMI. The Hearing Officer understands Meridian's reasoning for not questioning the notice. Meridian explained that it believed CMS had overlooked the contract, because it had previously uploaded three contracts involving CHMI and "other entities identified in Section 3.1.1.C"<sup>72</sup> and had also submitted an agreement between Meridian and MMC.<sup>73</sup> Meridian acknowledges that the reason for submitting a contract between itself and MMC would have been unclear to CMS, since no contract was submitted explaining the intervening relationship between MMC and CHMI.<sup>74</sup> The Hearing Officer also notes that Meridian alerted the reviewer that it was "working to update the" CHMI contract which it would upload when it responded to the NOID. While testimony at the hearing revealed that the statement to the reviewer was "a human error" due to copying and pasting from other, unrelated MA-PD applications,<sup>75</sup> it did not indicate any confusion or misunderstanding on Meridian's part.

Meridian asserts that it was misled by CMS' failure to be more precise in the notices, especially since CMS admitted it could have inferred the relationship between Meridian and CHMI,<sup>76</sup> as further evidenced by the fact that the reviewer expressly noted the application was missing a contractual link between the two entities.<sup>77</sup> Meridian's efforts to shift the burden to CMS to decipher its contracting arrangements and/or affirmatively reach out to Meridian to clarify is unsustainable. The Hearing Officer agrees that CMS should not make inferences in reviewing applications and, based on Meridian's inadvertent "copy-and-paste error,"<sup>78</sup> had no reason to suspect confusion.<sup>79</sup> The Hearing Officer finds that pursuant to 42 C.F.R. § 423.503(a)(1), CMS must evaluate an entity's application solely on the basis of the information contained in the application itself.

While Meridian has explained why it did not avail itself of its first opportunity to cure the contracting deficiency, based on the documents and responses submitted, it is not surprising that

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<sup>72</sup> Meridian's Reply Brief at 2; Tr. at 31-32.

<sup>73</sup> See *supra* note 26.

<sup>74</sup> Tr. at 56-57; see also Meridian's Reply Brief at 2.

<sup>75</sup> Tr. at 34.

<sup>76</sup> *Id.* at 94-95; CMS' Reply Brief at 5. See also Meridian's Post-Hearing Brief at 3-4.

<sup>77</sup> CMS' Exhibit 7.

<sup>78</sup> CMS' Exhibit 8; Tr. at 34, 57.

<sup>79</sup> Tr. at 82-84, 105-07 (noting the potential consequences of CMS drawing incorrect inferences). CMS explained that, while CMS could have inferred that Meridian had established a contractual link between MMC and CHMI, it was also possible that Meridian intended to use yet another downstream entity to contract separately with both MMC and CHMI to complete the contractual links to each of its downstream entities. CMS' Reply Brief at 5-6.

the NOID continued to identify the same contract deficiency regarding the contract with CHMI. Meridian does not dispute that, unfortunately, the contract it submitted after the NOID, which was its final opportunity to cure, was also deficient as CMS determined and stated in the contract denial.<sup>80</sup>

Likewise, with respect to the instructions and feedback regarding the Relationship Chart, the Hearing Officer finds that CMS' communications were clear. The Hearing Officer recognizes that Meridian believed the Function Chart it uploaded in its initial application in response to instructions in 3.1.1.C was itself sufficient to also satisfy the Relationship Chart requested in 3.1.1.D.<sup>81</sup> After receiving the courtesy notice, Meridian uploaded the 347 page organizational chart which it also believed was sufficient to satisfy the Relationship Chart requirement.<sup>82</sup> In fact, CMS' use of the term "chart" in both instructions is not optimal. Section 3.1.1.C, however, includes a template three-column table along with instructions to insert certain information on the "chart below."<sup>83</sup> In contrast, Section 3.1.1.D. directs applicants to "[p]repare . . . a chart showing the relationship between the applicant and . . . [certain entities] **identified in section 3.1.1 C.**"<sup>84</sup> Clearly, the two Solicitation sections refer to different documents and request the applicant to illustrate two different things: (1) which downstream or related entities will perform which Part D function(s), and (2) the relationship between the applicant and each listed entity. Further, as noted below, although the Read Me file does not reference the Relationship Chart, Section 3.1.1.D itself states, "[p]repare and upload into HPMS a chart . . . ." While Meridian argues that the 347 page organizational chart it uploaded following the courtesy notice met the requirements of the Relationship Chart,<sup>85</sup> the Hearing Officer finds that CMS was reasonable in concluding that the submission was not clear in "showing the relationship" between Meridian and CHMI as required by the Solicitation. The directions at 3.1.1.D of the Solicitation required Meridian to submit "a chart showing the relationship" between the entities, but what Meridian submitted was a *series* of several hundred charts showing the relationships between different entities within Meridian's corporate framework. Although Meridian now points to two non-sequential pages within the 347 page document that could elucidate the business relationships at issue, Meridian also admits that the submission was not clear in its attempt to identify all of Meridian's first tier, downstream or related entities.<sup>86</sup>

In addition, CMS' courtesy notice and NOID regarding the Relationship Chart were consistent with the instructions in Sections 3.1.1.C and 3.1.1.D. Furthermore, compared to the courtesy notice, the NOID provided additional guidance that expressly differentiated between the instructions for the two sections.<sup>87</sup> As a result of this additional guidance, Meridian uploaded a

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<sup>80</sup> Meridian's Initial Brief at 2; Meridian's Reply Brief at 3; CMS' Reply Brief at 4; Tr. at 55.

<sup>81</sup> Meridian's Initial Brief at 3.

<sup>82</sup> *Id.*

<sup>83</sup> CMS' Exhibit 1, § 3.1.1.C.

<sup>84</sup> *Id.* § 3.1.1.D (emphasis added).

<sup>85</sup> Tr. at 37-38.

<sup>86</sup> *Id.* at 56-67, 63-65.

<sup>87</sup> "The 3.1.1 C chart is intended as a guide for what to enter in the HPMS Part D data (see instructions under 3.1.1 C). Per 3.1.1 D please upload a chart showing the relationship between the applicant and each first tier, downstream, and related entity identified in section 3.1.1 C." Meridian's Exhibit B.

concise chart that illustrated certain contractual links to delegated entities.<sup>88</sup> The chart, however, still showed Meridian having a direct link with CHMI, and was inaccurate and deficient.<sup>89</sup> While Meridian thinks it was disadvantaged by not receiving the more robust explanation of the Relationship Chart deficiency in the courtesy notice, the Hearing Officer finds that both notices were clear.

The Hearing Officer recognizes that Meridian was perplexed when CMS apparently approved applications from Meridian affiliates even though they had not submitted Relationship Charts.<sup>90</sup> The record, however, does not contain every detail of materials submitted for each Meridian affiliate so the Hearing Officer is unable to fully evaluate this argument. If anything, this purported discrepancy should have led Meridian to question how its application was different from those CMS had approved. Nonetheless, the Hearing Officer finds that CMS must review each application “solely on the basis of information contained in the application itself . . . .”<sup>91</sup>

Further, the Hearing Officer agrees that the Read Me file, as Meridian points out, does not specifically include a reference to or naming convention for the Relationship Chart required by Section 3.1.1.D.<sup>92</sup> CMS characterizes the Read Me file as “technical instruction for Part-D application upload” to be used as a “guide to operating” the HPMS online application process with instructions on how and where to upload files.<sup>93</sup> The Read Me file does, as Meridian asserts, state that applicants should refer to it to “determine which Part D supporting files are required.”<sup>94</sup> Although CMS acknowledged that the Read Me file did not identify or provide a naming convention for the Relationship Chart,<sup>95</sup> the Hearing Officer agrees with CMS that, when read as a whole, the Read Me file is intended to provide technical instruction for navigating the HPMS system, not to provide an exhaustive list of substantive requirements for MA-PD applications, which are set forth in the Solicitation. Indeed, the Solicitation makes no mention of the Read Me file, and applicants are only directed to the Read Me file within the document titled “Part D Application Upload **Technical** Instructions.”<sup>96</sup>

While the lack of instruction in the Read Me file regarding the Relationship Chart may have contributed to Meridian’s misunderstanding of the Solicitation’s instructions, the deficient Relationship Chart was not the only basis for CMS’ denial of Meridian’s application. Assuming, *arguendo*, that the missing Relationship Chart had been insufficient on its own to support a denial of Meridian’s application,<sup>97</sup> the Hearing Officer notes that, ultimately, CMS also denied Meridian’s application because it failed to submit a contract with all of the required flow down

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<sup>88</sup> CMS’ Reply Brief at 7; Meridian’s Exhibit K; Tr. at 46-47.

<sup>89</sup> *Id.* An updated chart was submitted after Meridian’s MA-PD application was denied. See Meridian’s Exhibit N.

<sup>90</sup> Tr. at 38-39, 44-45, 64-65.

<sup>91</sup> 42 C.F.R. § 423.503(a)(1).

<sup>92</sup> Meridian’s Initial Brief at 3, 6; Meridian’s Reply Brief at 4; Meridian’s Post-Hearing Brief at 2; Tr. at 22-23. See also Meridian’s Exhibit H.

<sup>93</sup> Tr. at 98.

<sup>94</sup> Meridian’s Reply Brief at 3.

<sup>95</sup> Meridian’s Post-Hearing Brief at 2; Tr. at 98-102.

<sup>96</sup> Meridian’s Exhibit O (emphasis added).

<sup>97</sup> Meridian’s Post-Hearing Brief at 2-3; Tr. at 79.

clauses. Indeed, Meridian does not contest that the contract it provided for CMS' review was deficient in this regard.<sup>98</sup>

It appears that Meridian has included in its filing before the Hearing Officer a properly executed contract with CHMI with the flow down terms CMS requires. Further, Meridian has submitted a revised Relationship Chart that seems to conform to CMS' requirements. While Meridian cites precedent in which the CMS Administrator overturned appropriate contract denials on the basis of public policy,<sup>99</sup> the Hearing Officer does not possess the same broad scope of discretionary authority as the CMS Administrator; rather the Hearing Officer must decide if CMS' determination was consistent with regulatory and programmatic requirements and does not extend to review of materials beyond that which was considered by CMS during its review.<sup>100</sup>

Therefore, the Hearing Officer finds that Meridian has not established by a preponderance of the evidence that CMS' denial of its MA-PD application was inconsistent with 42 C.F.R. §§ 422.501 and 422.502 (Part C) and §§ 423.502 and 423.503 (Part D). Meridian did not submit with its application, as required by CMS, an executed contract with one of the first tier, downstream or related entities which it listed as performing a Part D function on its behalf, or a chart illustrating the relationship with its first tier, downstream or related entities. Accordingly, the Hearing Officer affirms CMS' denial of Meridian's MA-PD application.

*Brenda D. Thew*

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Brenda D. Thew, Esq.  
CMS Hearing Officer

Date: August 7, 2020

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<sup>98</sup> Meridian's Initial Brief at 3-4; Meridian's Reply Brief at 3; Tr. at 55.

<sup>99</sup> See *supra* note 45.

<sup>100</sup> See 42 C.F.R. §§ 422.660, 422.688, 423.650, 423.664.