

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

IN THE MATTER OF:

MedStar Family Choice, Inc.	*	
	*	
Denial of Service Area Expansion Application	*	DOCKET NO.
Medicare Advantage/Prescription Drug Plan Organization	*	2013 MA/PD APP. 8
Contract Year 2014, Contract No. H9915	*	
	*	
Denial of Specialized Medicare Advantage Plan	*	DOCKET NO.
For Special Needs Individuals	*	2013 MA/PD APP. 11
Medicare Advantage/Prescription Drug Plan Organization	*	
Contract Year 2014, Contract No. H9915	*	
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**ORDER GRANTING SUMMARY JUDGMENT**

**I. JURISDICTION**

This appeal is provided pursuant to 42 C.F.R. §§ 422.660 and 423.650. The Centers for Medicare and Medicaid Services (CMS) Hearing Officer designated by the CMS Administrator to hear this case is the undersigned, Brenda D. Thew. By agreement of the parties, the two appeals captioned above are being adjudicated simultaneously.

**II. ISSUE**

Whether CMS' denial of the following applications for Contract Year (CY) 2014 on the grounds that the applicant lacked 14 months performance history was consistent with 42 C.F.R. §§ 422.501, 422.502, 423.502 and 423.503:

- (a) Service Area Expansion (SAE) application submitted by MedStar Family Choice, Inc. (MedStar) to offer Medicare Advantage/Medicare Advantage Prescription Drug (MA-PD) plans in Baltimore City and Baltimore County, Maryland. (Hearing Officer Docket No. APP8), and
- (b) Initial application submitted by MedStar to offer a Specialized Medicare Advantage Plan for Special Needs Individuals (SNP) in the District of Columbia, and Baltimore City and Baltimore County, Maryland for Contract Year 2014. (Hearing Officer Docket No. APP11)

### **III. 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>1</sup> The Medicare Modernization Act of 2003 made changes to MA and allowed beneficiaries to elect a voluntary outpatient prescription drug benefit within a Part C plan.<sup>2</sup> Plans offering both the Part C and Part D benefits are known as Medicare Advantage-Prescription Drug (MA-PD) plans. Organizations that are approved to offer MA-PD benefits are required to maintain a provider network that ensures “adequate access to covered services” for its plan enrollees in each operative service area. This network must include a variety of providers, including primary care physicians, specialists, and hospitals<sup>3</sup> and must offer an outpatient prescription drug benefit in the service areas in which they offer a Part C benefit.<sup>4</sup>

Additionally, the Medicare Modernization Act of 2003 created MA coordinated care plans (CCPs) that were specifically tailored for beneficiaries with special health care needs. These Specialized MA Plans for Special Needs Individuals (SNPs) are designed to serve populations including institutionalized beneficiaries, beneficiaries eligible for both Medicare and Medicaid services (dual eligibles), and individuals suffering from severe chronic conditions.<sup>5</sup> Like MA-PD providers, MA organizations offering CCPs, including SNPs, must offer Part D benefits in the same service areas.<sup>6</sup>

The Secretary of the United States Department of Health & Human Services (the Secretary) is authorized to contract with entities seeking to offer MA and MA-PD benefits.<sup>7</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>8</sup>

#### **A. APPLICATION PROCESS – REGULATORY AUTHORITY**

Potential MA-PD organizations submit applications to CMS, in which the applicant organization must document that it has a provider network in place that meets CMS requirements.<sup>9</sup> These applications must be completed “in the form and manner required by CMS.”<sup>10</sup> Presently, CMS

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<sup>1</sup> See 42 U.S.C. § 1395w-21 *et seq.*

<sup>2</sup> See, generally, Medicare Modernization Act of 2003, Public Law 108-173, Sec. 231 (codified at 42 U.S.C. § 1395w-28(b)(6)).

<sup>3</sup> 42 C.F.R. § 422.112(a)(1).

<sup>4</sup> 42 C.F.R. § 422.4(c)(1). See also, generally, 42 U.S.C. § 1395w-112 (Medicare Part D).

<sup>5</sup> The regulatory definition that encompasses Medicare Advantage SNPs is found at 42 C.F.R. § 422.4 and reads, in part, as follows:

*Specialized MA Plans for Special Needs Individuals* means an MA coordinated care plan that exclusively enrolls special needs individuals . . . and that provides [prescription drug] benefits . . . to all enrollees; and which has been designated by CMS as meeting the requirements of an MA SNP as determined on a case-by-case basis . . .

<sup>6</sup> 42 C.F.R. § 422.4(c)(1).

<sup>7</sup> 42 U.S.C. § 1395w-27.

<sup>8</sup> 42 C.F.R. §§ 422.400 *et seq.*, 422.503(b) *et seq.*

<sup>9</sup> 42 C.F.R. § 422.501(c)(2).

<sup>10</sup> 42 C.F.R. § 422.501(c)(1) and 423.502(c)(1).

requires the electronic submission of MA-PD applications in two parts, a Part C application and a Part D application, via the Health Plan Management System (HPMS) program.<sup>11</sup> After receiving a MA-PD application, CMS makes a determination as to whether the applicant organization meets all of the relevant program requirements.<sup>12</sup> The pertinent regulation provides:

(a) *Basis of Evaluation and Determination.*

(1) With the exception of evaluations conducted under paragraph (b) of this section, CMS evaluates an application for an MA contract or for a Specialized MA Plan for Special Needs Individuals solely on the basis of information contained in the application itself and any additional information that CMS obtains through other means such as on-site visits.

(2) After evaluating all relevant information, CMS determines whether the applicant's application meets all the requirements described in this part.<sup>13</sup>

As part of its assessment of a plan's qualifications, CMS considers the applicant's performance under a current or prior contract during the 14 months preceding the submission of the pending application and may deny an application based on the entity's failure to comply with a Part C requirement during this period. CMS may rely on this basis even if the applicant demonstrates through its submitted application that it otherwise meets all of the requirements for qualification as a Part C contractor. Specifically, the regulation states:

(b) *Use of information from a current or prior contract.*

(1) Except as provided in paragraphs (b)(2) through (b)(4) of this section, if an MA organization fails during the 14 months preceding the deadline established by CMS for the submission of contract qualification applications to comply with the requirements of the Part C program under any current or prior contract with CMS under title XVIII of the Act or fails to complete a corrective action plan during the 14 months preceding the deadline established by CMS for the submission of contract qualification applications, CMS may deny an application based on the applicant's failure to comply with the requirements of the Part C program under any current or prior contract with CMS even if the applicant currently meets all of the requirements of this part.

(2) In the absence of 14 months of performance history, CMS may deny an application based on a lack of information available to determine an applicant's capacity to comply with the requirements of the MA program.<sup>14</sup>

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<sup>11</sup> See generally, CMS Brief APP11 at 2-3.

<sup>12</sup> 42 C.F.R. § 422.502(a). The analogous provision for Part D appears at 42 C.F.R. § 422.503(a). Throughout this Order, references to regulations governing Part C should be read to include the analogous regulations for Part D, unless otherwise noted.

<sup>13</sup> 42 C.F.R. § 422.502(b).

<sup>14</sup> 42 C.F.R. § 422.502(b).

After initial applications are submitted, CMS affords applicants an additional “courtesy” review and a period in which the applicant may cure its deficiencies.<sup>15</sup>

If CMS approves the application, it gives written notice to the applicant that it qualifies as an MA-PD plan.<sup>16</sup> If the applicant fails to correct all of the deficiencies, CMS issues the applicant a “Notice of Intent to Deny” (NOID) pursuant to 42 C.F.R. § 422.502(c)(2). The NOID serves as written notice

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Prior to 2010, CMS considered an applicant’s past performance in a previous contract when determining whether to approve an application for a new or expanded contract. In 2010, CMS published regulations clarifying that it would consider an applicant’s performance during the 14 months preceding the date by which organizations must submit their contract qualification applications. Explaining why it chose 14 months as the criteria, CMS stated that “Fourteen months covers the time period from the start of the previous contract year through the time that applications are received for the next contract year.” 75 Fed. Reg. 19678, 9684 (April 15, 2010).

In 2011, CMS’ past performance review was further refined when it added additional language to § 422.502(b) and § 432.503(b) establishing the authority to deny an application based on a lack of information available to determine an applicant’s potential future performance. CMS reasoned that existing regulations established that organizations with current or prior contracts with CMS were subject to denial if they failed during the preceding 14 months to comply with the requirements of the Part C or Part D programs.

...In the absence of 14 months of performance, however, this leaves a gap whereby CMS must either assume full compliance and exempt the entity from the past performance review, or deny additional applications from such entities until the applicant has accumulated 14 months’ experience, during which it complied fully with the requirements of the Part C and/or Part D program.

Our interest in protecting Medicare beneficiaries and limiting program participants to the best performing organizations possible strongly suggest that we take the latter approach. Our justification for proposed this change was two-fold. First, we would ensure that new entrants to the Part C or Part D program could fully manage their current contracts and books of business before further expanding. Second, this change would require that entities rightfully focus their attention on launching their new Medicare contracts in a compliant and responsible manner rather than focusing attention almost immediately on further expansions.

76 Fed. Reg. 21432, 21524 (April 15, 2011).

<sup>15</sup> The 2014 Solicitation for Applications for Medicare Prescription Drug Plan 2014 Contracts indicates:

For those applications with valid submissions, CMS will notify your organization via email of any deficiencies and afford a courtesy opportunity to amend the application.... Applicants failing to cure deficiencies following the courtesy cure period will be issued a Notice of Intent to Deny the application. Applicants receiving notices of intent to deny have 10 days to remedy their applications. The end of the 10-day period is the last opportunity an applicant has to provide CMS with clarifications or correction. CMS will only review the last submission provided during this cure period. Application materials will not be accepted after this 10-day time period.

<http://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/Downloads/2014-Part-D-Application.pdf> at 12 (last visited July 29, 2013).

<sup>16</sup> 42 C.F.R. § 422.502(c)(1).

that the application will be denied if, within 10 days of receiving the NOID, the applicant fails to revise its application to remedy any defects CMS identified.<sup>17</sup>

If, after the 10-day cure period, 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 and/or 423.650. The regulations provide that at a hearing, the applicant has the burden of proving by a preponderance of the evidence that CMS' determination was inconsistent with the requirements of §§ 422.501 and 422.502 for Part C and/or §§ 422.502 and 423.503 for Part D.

In addition, the regulations governing the hearing process provide that either party may ask the Hearing Officer to rule on a motion for summary judgment.<sup>18</sup>

## **B. APPLICATION PROCESS – SUB-REGULATORY AUTHORITY**

On November 16, 2012, CMS released through HPMS a draft of its 2014 Application Cycle Past Performance Review Methodology (Performance Review Methodology). CMS accepted and considered comments from interested organizations. On January 10, 2013, CMS posted on its website the final Solicitation for Applications for Medicare Prescription Drug Plan 2014 Contracts. On the same day, notice of this posting was provided through HPMS to potential applicants. CMS offered training regarding completion of these applications and interested organizations were afforded the opportunity to submit questions which were answered during a conference call.

On January 17, 2013, CMS issued the Performance Review Methodology in final form through HPMS.<sup>19</sup> The introductory paragraph to the Methodology reads:

This methodology below describes in detail the approach CMS uses to evaluate the performance of all Medicare C and D contractors, evaluations that may also identify organizations with performance so impaired that CMS would prohibit the organization from further expanding its Medicare operations.<sup>20</sup>

The Performance Review Methodology also addresses the impact that the 14 month performance requirement will have on applicants during the 2014 application cycle:

In April 2011, CMS published new regulations stating that in the absence of 14 months' performance history we may deny an application based on a lack of information available to determine an applicant's capacity to comply with the requirements of the Part C or Part D programs. (§

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<sup>17</sup> 42 C.F.R. § 422.502(c)(2).

<sup>18</sup> 42 C.F.R. §§ 422.684 and 423.662. *See also* Medicare Program, Revisions to the Medicare Advantage and Part D Prescription Drug Contract Determinations, Appeals and Intermediate Sanctions Processes, 72 Fed. Reg. 68700, 68714 (December 5, 2007) (Preamble to final rule stating, "In ruling on such a [Summary Judgment] motion, we propose that the hearing officer would be bound by the CMS regulations and general instructions. Where no factual dispute exists, the hearing officer may make a decision on the papers, without the need for a hearing.").

<sup>19</sup> CMS 2014 Application Cycle Past Performance Review Methodology Final (Methodology), *available at* <http://cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/Downloads/2014-Application-Cycle-PastPerformance-Methodology-Final.pdf> (last visited July 29, 2013).

<sup>20</sup> *Id.* at 5.

422.502(b)(2) and § 423.503(b)(2)) Therefore, *during the 2014 Application Cycle, organizations that commence their Part C and/or Part D operations in 2013 will not be permitted to expand their service areas or product types until they have accumulated at least 14 months of performance experience, which can then be evaluated under this methodology.*<sup>21</sup>

The language in this instruction is consistent with that contained in the Performance Review Methodology for the 2013 Application Cycle which provided, in pertinent part,

...beginning with the 2013 Application Cycle, organizations that commence their Part C and/or Part D operations in 2012 will not be permitted to expand their service areas or product types until they have accumulated at least 14 months performance experience...<sup>22</sup>

Additional sub-regulatory guidance elaborates on the requirements that must be met for MA plans seeking to offer SNPs. In the Medicare Managed Care Manual, CMS notes three categories of SNP plans: Chronic Condition SNPs (C-SNPs), Dual-Eligible SNPs (D-SNPs), and Institutional SNPs (I-SNPs).<sup>23</sup> Each type of SNP requires different efforts from the sponsor organization.

For example, in addition to specifying the fifteen chronic condition types that fall under the purview of a C-SNP plan, CMS notes that these determinations are subject to later review:

The list of SNP-specific chronic conditions is not intended for purposes other than clarifying eligibility for the C-SNP CCP benefit package. CMS will periodically re-evaluate the fifteen chronic conditions as it gathers evidence on the effectiveness of care coordination *through the SNP product*, and as health care research demonstrates advancements in chronic condition management.<sup>24</sup>

The Managed Care Manual also distinguishes between SNP offerings and other MA options. In the context of C-SNPs, CMS notes:

A C-SNP cannot be structured around multiple common co-morbid conditions that are not clinically linked in their treatment because this arrangement, by its very nature leads to *a general market product rather than a product tailored for a particular population.*<sup>25</sup>

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<sup>21</sup> *Id.* (emphasis added).

<sup>22</sup> MedStar Initial Brief APP8 Exhibit E.

<sup>23</sup> See generally Medicare Managed Care Manual, Chapter 16-B: Special Needs Plans, Rev. 98, Issued May 20, 2011 (the Managed Care Manual), available at <http://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/mc86c16b.pdf> (last visited July 26, 2013).

<sup>24</sup> Managed Care Manual § 20.1 (emphasis added).

<sup>25</sup> *Id.* at § 40.6.2 (emphasis added).

Furthermore, CMS has distinct expectations for SNP sponsors with regard to the plan's Model of Care (MOC) and Plan Benefit Package (PBP):

CMS expects MA organizations offering SNPs to begin with a well-developed MOC, structure their service delivery system to support this model, and design their PBP to address the specialized needs of the targeted beneficiaries. In addition, *SNP-specific PBPs should incorporate some or all benefits that exceed the basic required Medicare A and B benefits offered by other MA products available in the same service area.*<sup>26</sup>

Likewise, the 2014 Medicare Advantage Application notes that:

- The MA program is comprised of a variety of product types, including:
  - Coordinated Care Plans (CCPs)
    - Health Management Organizations (HMOs) with or without a Point of Service (POS) benefit.
    - Local Preferred Provider Organizations (LPPOs)
    - Regional Preferred Provider Organizations (RPPOs)
    - Special Needs Plans (SNPs)
  - Private Fee-for-Service (PFFS) plans
  - Medical Savings Account (MSA) plans
  - Employer Group Waiver Plans (EGWPs)<sup>27</sup>

Later in the application, organizations are required to “select the type of MA product [they] will provide”.<sup>28</sup>

The deadline for submitting final applications for CY 2014 MA-PD contracts to CMS was February 21, 2014.<sup>29</sup>

#### **IV. FACTUAL AND PROCEDURAL BACKGROUND**

MedStar is currently an MA-PD sponsor operating in the District of Columbia under Contract No. H9915. MedStar's contract became effective January 1, 2013. Prior to this date, MedStar has not had any contracts with CMS to offer any MA or MA-PD plans.<sup>30</sup>

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<sup>26</sup> *Id.* at § 80.2 (emphasis added).

<sup>27</sup> MedStar Reply APP11 Exhibit B at § 1.2.

<sup>28</sup> *Id.* at § 2.8.

<sup>29</sup> CMS Brief APP8 at 3.

<sup>30</sup> MedStar Initial Brief APP8 at 1; CMS Brief APP8 at 4.

In November 2012, MedStar submitted a Notice of Intent to Apply for a SAE for CY 2014 under its Part C and D contract. CMS then contacted MedStar to inform the organization that its application would be denied because it lacked 14 months past performance history with the Part C or Part D programs as required by regulation and CMS' 2014 Performance Review Methodology. At MedStar's request, CMS met with the organization on January 8, 2013 and reiterated that its application would be denied.<sup>31</sup>

On February 20, 2013,<sup>32</sup> MedStar submitted a SAE application seeking to expand its Contract H9915 by offering MA-PD plans in two counties in Maryland. On the same day, MedStar also submitted an initial application to offer a Dual Eligible SNP (D-SNP) in the District of Columbia (the existing service area of Contract H9915), and in the two counties in Maryland that are the subject of its SAE application.<sup>33</sup> CMS responded to the SAE and D-SNP applications through separate communications.

#### **A. MEDSTAR'S SAE APPLICATION**

On March 13, 2013, CMS sent MedStar a Deficiency Notice describing several deficiencies in its Part C SAE application. The notice provided instructions and a deadline for MedStar to make changes in its application to correct the deficiencies.<sup>34</sup> On March 28, 2013, CMS sent MedStar a Deficiency Notice regarding its Part D SAE application. That notice stated that CMS had completed its review of the 2014 Part D application and that:

--Your organization attested that its existing contract with CMS was not in effect prior to January 1, 2012. Your organization is therefore not eligible to apply for a new contract or serve area expansion for 2014.<sup>35</sup>

Both notices concluded with the statement, "the outcome of the past performance analysis is not included in this round of application reviews. Any past performance-related difficulties will be provided to applicants at the end of April."<sup>36</sup>

On April 2, 2013, MedStar reached out to CMS via email and asked, "If a plan receives a deficiency focused on past performance...[i]s there an opportunity to provide more background information in order to attempt to cure the deficiency?" CMS responded, noting that in HPMS, MedStar's contract reflected an effective date of January 1, 2013. CMS inquired whether the information was incorrect. MedStar confirmed that the information in HPMS was correct but offered to provide background information about the company for CMS' consideration. CMS responded, "At this time, CMS is not accepting additional information regarding the 14-month experience requirement for the purposes of qualifying to expand your existing contract."<sup>37</sup>

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<sup>31</sup> CMS Brief APP8 at 4; CMS Brief APP11 at 4.

<sup>32</sup> CMS asserts that the SAE application was submitted February 21, 2013. There is no dispute regarding the timeliness of the application.

<sup>33</sup> MedStar Initial Brief APP8 at 1; MedStar Initial Brief APP11 at 1-2; CMS Brief APP8 at 4. CMS Brief APP11 at 4.

<sup>34</sup> MedStar Initial Brief APP8 Exhibit B.

<sup>35</sup> *Id.*

<sup>36</sup> *Id.*

<sup>37</sup> MedStar Initial Brief APP8 Exhibit D. The email exchange occurred between MedStar's Director of Medicare Compliance and CMS' Deputy Division Director of the Division of Benefit Purchasing and Monitoring .



On April 26, 2013, CMS sent MedStar two separate NOIDs for its Part C and Part D SAE applications. Both NOIDs stated that CMS intended to deny the application because MedStar lacked the required 14 months of past performance history. Specifically, the NOID stated:

Neither your organization, nor your organization's parent, has an existing contract with CMS that was in effect as of January 1, 2013 [sic]. Consequently, your organization is not eligible to apply for a new contract or contract expansion for 2014.<sup>38</sup>

The NOID for the Part C SAE application identified a few additional deficiencies including, among other things, lack of evidence of state licensure and missing copies of its contracts with four providers. The NOID for the Part D SAE application was based only on the lack of 14 months performance history. Both NOIDs provided the applicant with an opportunity to cure any deficiency other than those related to past performance. MedStar asserts that it successfully addressed all the other deficiencies.<sup>39</sup>

On May 31, 2013, CMS issued a final Denial Notice for MedStar's SAE application in two counties in Maryland for both Part C and Part D. The final notice stated that the sole basis for the denial was that:

Neither your organization, nor your organization's parent, has an existing contract with CMS that was in effect as of January 1, 2012. Consequently, your organization is not eligible to apply for a new contract or contract expansion for 2014. This deficiency applies to both the MA and Part D applications.<sup>40</sup>

## **B. MEDSTAR'S D-SNP Application**

On March 13, 2013, CMS sent MedStar an application status notice, in the form of an email, regarding its D-SNP application. The notice congratulated MedStar, stating that CMS had found no deficiencies in its D-SNP application.<sup>41</sup> On May 31, 2013, MedStar received an email from CMS granting conditional approval of its SNP Application. The notice listed additional approvals that were required in for MedStar to contract with CMS as a SNP sponsor.<sup>42</sup> The notice also stated,

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<sup>38</sup> MedStar Initial Brief Exhibit A. The NOID should have stated "in effect as of January 1, 2012." MedStar noted its awareness of the typographical error. The NOID for MedStar's Part D application reflected the accurate date of "January 1, 2012."

<sup>39</sup> *Id.*; MedStar Initial Brief APP8 at 2.

<sup>40</sup> MedStar Initial Brief APP8 Exhibit C.

<sup>41</sup> MedStar Initial Brief APP11 Exhibit A; CMS Brief APP11 Exhibit D.

<sup>42</sup> The notice stated, "In order to contract with CMS as a SNP sponsor, your bid, including your formulary, must also be approved as required by 42 CFR 423 Subpart F. Additionally, your organization must complete all other pre-implementation activities including system and data testing... You are also required to submit and receive CMS approval of your MIPPA compliant State Medicaid Agency Contract (required) and marketing materials..." MedStar Initial Brief APP11 Exhibit B; CMS Brief APP11 Exhibit G.

...CMS expects to send SNP contracts to applicants receiving final approval and notices of intent to deny/denial letters (should any be necessary) in late summer, 2013.

...If there are any changes to the information you have supplied during the application process, or we determine that any of the information upon which we based the approval is inaccurate, this approval may be withdrawn and a letter of intent to deny and/or denial notice may be issued.<sup>43</sup>

MedStar proceeded to invest resources in developing its bid for its SNP plan.<sup>44</sup>

On June 24, 2013, the Director of CMS' Medicare Drug & Health Plan Contract Administration Group telephoned a MedStar executive to inform MedStar that its SNP application would be denied. On the same day, MedStar received official notice of denial, in the form of a letter from CMS, of its D-SNP application. The letter identified one deficiency as the basis for the denial:

Neither your organization, nor your organization's parent, has an existing contract with CMS that was in effect prior to January 1, 2013. Consequently, your organization is not eligible to apply for a new contract, contract expansion or new Special Needs Plan for 2014.<sup>45</sup>

## V. CONTENTIONS

### A. APPLICANT'S CONTENTIONS

With respect to both its SAE and D-SNP applications, MedStar contends that CMS' denial is inconsistent with applicable regulations. MedStar argues that CMS must first apply the general standard set forth at § 422.502(a)(1) in its review of applications. That is, CMS is to conduct an individualized evaluation of each application solely on the basis of the information in the application and any additional information obtained through other means such as on-site visits. MedStar acknowledges that this is a general rule, modified by the phrase "with the exception of evaluations conducted under paragraph (b);" i.e., evaluations of an applicant's past performance in the program. It asserts, however, that based on the plain language of the regulation, MedStar was entitled to have its application evaluated based on the available information relating to the applicant's compliance capacity, rather than being denied solely on the absence of 14 months of performance history. It emphasizes that §422.502(a)(2) states that CMS conducts "evaluations" under paragraph (b) thus the provisions, read as a whole, requires that all actions CMS takes under paragraph (b) consist of "evaluations" of "all relevant information." MedStar posits that CMS could have drafted §§ 422.502(b)(2) and 423.503(b)(2) to mandate denial of all applicants with less than 14 months performance history, but failed to do so. Instead, the regulations, MedStar asserts, unambiguously provide CMS with discretion in evaluating past performance in

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<sup>43</sup>*Id.*

<sup>44</sup> MedStar Initial Brief APP11 at 2; MedStar Reply Brief APP11 at 5.

<sup>45</sup> MedStar Initial Brief APP11 Exhibit C.

that they state that “CMS *may* deny an application based on a lack of information available to determine an applicant’s capacity to comply with the requirement of the MA program.”<sup>46</sup>

Furthermore, MedStar does not believe that the introductory clause in § 422.502(b)(1), “except as provided in subparagraphs (b)(2) through (b)(4) of this section,” completely exempts application denials under (b)(2) from the overall requiring in section (a) that CMS conduct evaluations of applications on all relevant information.<sup>47</sup>

MedStar argues that CMS’ Performance Review Methodology memoranda, which states that CMS will deny all applicants with less than 14 months experience, ignores the discretionary aspect of the regulation and thus changes the meaning of the unambiguous regulation. MedStar points out that when there is no ambiguity in the meaning of a regulation, an agency is not entitled to deference in its interpretation of the regulation citing *Christensen v. Harris Cnty.*, 529 U.S. 576, 588 (2000).<sup>48</sup> Following this line of argument, MedStar contends that CMS’ denial of all SAE applications from sponsors with less than 14 months experience changes the meaning of the regulation. Therefore, MedStar argues, applicants were denied fair notice and the opportunity to comment, as required by the Administrative Procedures Act (APA).<sup>49</sup>

Regarding its SAE application, MedStar claims that it relied to its detriment on the plain language of §§ 422.502(b) and 422.503(b) which it understood entitled it to an evaluation of whether its application contained sufficient information to gauge its qualifications. It claims that it could and likely would have applied for a broader service area in the first instance had it know it would absolutely be prohibited from seeking a serve area expansion in year two of its program participation. With respect to its D-SNP application, MedStar asserts that it has “expended significant financial resources in the development to its SNP for 2014” based on the May 31, 2013, conditional approval notice thus the “late stage” denial (on June 24, 2013) was fundamentally unfair.<sup>50</sup>

Focusing on its D-SNP application, MedStar contends a SNP is not an expanded product type as contemplated by CMS’ Performance Review Methodology.<sup>51</sup> MedStar argues that, since it already offers a CCP in the Washington, D.C. service area, the offering of an additional CCP, in this case a D-SNP option, should not be considered a product expansion. In support, MedStar points to the 2014 MA Application, in which an organization is asked to identify “the type of MA product it will provide.”<sup>52</sup> The Plan notes that this application chart allows plans to identify their application as a coordinated care plan submission. MedStar, however, points to the absence of a SNP designation, “Significantly, the chart makes no reference to SNPs as a separate product type.”<sup>53</sup> If the SNP is not seen as an expanded product type, MedStar reasons that the 14 months experience requirement is inapplicable.

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<sup>46</sup> MedStar Initial Brief APP8 at 5-7. Emphasis added.

<sup>47</sup> MedStar Reply APP8 at 3.

<sup>48</sup> MedStar Initial Brief APP8 at 7.

<sup>49</sup> MedStar Initial Brief APP8 at 9.

<sup>50</sup> MedStar Initial Brief APP11 at 7; MedStar Reply APP11 at 7.

<sup>51</sup> MedStar Reply APP11 at 2. *See also* MedStar Reply Exhibit A.

<sup>52</sup> MedStar Reply APP11 Exhibit B at § 2.8.

<sup>53</sup> MedStar Reply APP11 at 3.

Additionally, regarding its D-SNP application, MedStar contends that CMS violated § 422.502(c)(2)(i) and its own policy and guidance when it issued an official denial notice without first providing a NOID.<sup>54</sup> Furthermore, MedStar argues that the only alleged deficiency (that MedStar lacked 14 months performance history) was known to CMS throughout the entire application process.<sup>55</sup> Pointing to preamble language supporting the rationale for notices that an application will be denied, MedStar emphasizes that

“[I]n order for applicants to have a consistent understanding of the expectations on which we base our contract approval and denials....*Organizations that fail to completely and accurately apply receive a courtesy e-mail explaining the deficiency and are given an opportunity to cure. Organizations that are still deficient after the initial opportunity to cure receive a notice of intent to deny and are given another opportunity to cure.*” 75 Fed.Reg. 19677, 19683 (April 15, 2010). (Emphasis added.)<sup>56</sup>

Moreover, MedStar complains that the subsequent final denial issued June 24, 2013, was not based on factors enumerated in the conditional approval. Therefore, MedStar suggests, the denial (based solely on lack of 14 months performance history) was inconsistent with the elements of the official conditional approval notice.<sup>57</sup>

With respect to the “late stage” denial of its D-SNP application, MedStar claims it was subjected to fundamental unfairness and a denial of due process. It asserts that at no point during the many communications it had with CMS dating from the submission of its SNP application until the phone call and official denial it received on June 24, 2013, had it been informed by CMS that its D-SNP application would be subject to the 14 month rule in 42 C.F.R. § 422.502(b)(2).<sup>58</sup>

MedStar opposes CMS’ Motion for Summary Judgment.<sup>59</sup> The Plan believes that there are genuine disputes of material fact, and that summary judgment is therefore inappropriate for these cases. In particular, MedStar contends that the record suggests that CMS has previously approved SAE or SNP applications submitted by other organizations having less than 14 months performance history. The Plan argues that, “[I]f there are other instances in which CMS has chosen to grant similarly situated applications, but CMS denied the MedStar service area expansion, it would be a material fact that would need to be developed through the hearing process.”<sup>60</sup> MedStar believes there is a question of fact regarding the basis upon which CMS may

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<sup>54</sup>In its initial brief filed June 20, 2013, MedStar asserted that the May 31, 2013, conditional approval it received on its D-SNP application should compel approval of its SAE application. In that CMS retracted the conditional approval and officially denied the SNP application on June 24, 2013, after MedStar’s brief was submitted, this argument will not be addressed.

<sup>55</sup> MedStar Initial Brief APP11 at 4-6.

<sup>56</sup> MedStar Initial Brief APP11 at 5-6.

<sup>57</sup> MedStar Initial Brief App11 at 6-7; MedStar Reply APP11 at 4.

<sup>58</sup> MedStar Reply APP11 at 5.

<sup>59</sup> MedStar Reply APP8 at 5-6; MedStar Reply APP11 at 5-6.

<sup>60</sup> MedStar Reply APP8 at 5.

have approved applications to conduct demonstration projects submitted by organizations that appear to have less than 14 months performance history. The Plan argues that the possible approval of such demonstration projects “is material to this matter and should be heard by the Hearing Officer.”<sup>61</sup>

## B. CMS CONTENTIONS

CMS contends that it is not obligated to review the Medicare contract performance of all applicants before making a determination that a specific applicant has failed to comply with the requirements of its contract. CMS believes that the introductory clause in § 422.502(b)(1), “Except as provided in subparagraphs (b)(2) through (b)(4) of this section,” carves out for special treatment those situations where evaluation of the applicant’s Medicare contract performance is not required in order to deny the application.<sup>62</sup>

CMS reasons that the subparagraphs at § 422.502(b)(2)-(4) describe conditions that, when present, make the compliance analysis required pursuant to § 422.502(b)(1) redundant. For example, if CMS has recently terminated an organization’s Medicare contract, no further evaluation of an applicant’s performance history is necessary for CMS to deny an application. Similarly, CMS argues, § 422.502(b)(2) triggers the ability for CMS to exercise its denial authority when a specific condition (the absence of 14 months performance history) is met. CMS believes that MedStar is incorrectly interpreting the subsections of § 422.502 leading it to believe that subparagraph (b)(2) is to be read separately from subparagraph (b)(1) when, in CMS’ view, paragraph (b) in total provides for four different types of evaluations. It asserts that once it afforded MedStar its own individual evaluation and determined that the length of MedStar’s history as a Medicare contractor was less than 14 months, its determination to deny was proper.<sup>63</sup>

CMS agrees with MedStar that (2)(b) is unambiguous. On the other hand, CMS disagrees that the words “may deny” in § 422.502(b)(2) prevent it from using its authority to deny all applications from applicants who have less than 14 months performance history. In fact, CMS finds no relevance to any distinction between “may,” “will,” or “shall” because its denial of the MedStar application is the result of CMS’ interpretation of its own regulations. It relies on *Auer v. Robbins*, 519 U.S. 452, 461 (1997) for the principle that an agency’s interpretation of its own

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<sup>61</sup> *Id.* Through a July 23, 2013, e-mail to CMS and the Hearing Officer, MedStar reiterated its request that the following purported factual disputes be considered, “as a part of the deliberations on the motions”:

- The basis for CMS approving two demos that appear to involve applicants with less than 14 months performance history, as discussed in the email exchange submitted by CMS as exhibit 5 to CMS’s reply brief for Docket No. 2013 MA/PD App. 8.
- Whether the SNP applications (other than H9915) mentioned in the email exchange also received an approval letter in May, and if so, whether they subsequently received notices of denial and the dates of such denials.
- Whether, since 42 CFR 422.502(b)(2) and 423.503(b)(2) took effect, CMS approved any other SAE or application for a SNP or other entity with less than 14 months of performance history.
- Whether CMS has in the past issued an official denial notice based on the same facts known at the time of conditional approval.

<sup>62</sup> CMS Brief APP8 at 6.

<sup>63</sup> CMS Brief APP8 at 5-6.

regulations are controlling unless they are “plainly erroneous or inconsistent with the regulation.”<sup>64</sup>

CMS traces the history of its decision to adopt § 422.502(b)(2) and the problem CMS was addressing with that regulation. CMS reiterates the rationale in the preamble to that regulation in which it explained that it wanted to ensure adequate time for a new entity in the MA/MA-PD program to demonstrate its ability to comply with program requirements before it expanded. Practically speaking, CMS explains, a new entity in the MA program would have merely 2 months in operation before the subsequent contract year application cycle. CMS believed it was in the best interest of Medicare beneficiaries to limit program participation to those who had demonstrated 14 months of compliance rather than assuming future compliance from new entities with minimal time in the program.<sup>65</sup>

With regard to MedStar’s SAE application, CMS asserts that it was unreasonable for MedStar to rely on its reading of the regulation and not seek a larger service area in its initial application for a calendar year 2013 MA contract. CMS rejects the idea that MedStar was justified in looking only to the regulation language, on the rationale that MedStar had itself declared the provision to be unambiguous, rather than reviewing other public documents. Among other things, CMS points to language in the 2013 Performance Review Methodology issued prior to MedStar’s February 2012 initial application submission which stated “...beginning with the 2013 Application Cycle, organizations that commence their Part C and/or Part D operation in 2012 will not be permitted to expand their service areas or product types until they have accumulated at least 14 months of performance experience...”<sup>66</sup> In addition, CMS offers confirmation that MedStar was aware of its length of tenure in the Medicare program based on MedStar’s attestation, as part of its 2013 application, that it had not held a Medicare contract that had been in effect since January 1, 2011.<sup>67</sup>

CMS contends that it is not precluded from officially denying MedStar’s SNP application because it initially issued a conditional approval. CMS admits that the conditional approval notice was sent in error.<sup>68</sup> It offers evidence of CMS’ intention, as shown in an email communication in mid-April 2013, to issue NOIDs to a number of organizations that were new Medicare contractors in 2013, including MedStar.<sup>69</sup>

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<sup>64</sup> CMS Brief APP8 at 7.

<sup>65</sup> CMS Brief APP8 at 7-8.

<sup>66</sup> CMS Brief APP8 at 8-9.

<sup>67</sup> CMS Brief APP8 at 9 referencing MedStar’s Initial Brief APP8 Exhibit 4.

<sup>68</sup> In addition, CMS indicates that it discussed the 14 month requirement with MedStar at the outset of the 2014 contract application process:

After receiving the Notice of Intent to Apply, CMS contacted MedStar to advise the organization that such an application would be denied because the Applicant lacked 14 months’ past performance history with the Part C or Part D program, as provided for in 42 C.F.R. § 422.502(b)(2) and the 2014 Past Performance Methodology. In response to a request from the Applicant, CMS met with MedStar on January 8, 2013, and reiterated that the agency would deny its application for this reason.

CMS Brief APP 11 at 4.

<sup>69</sup> CMS Brief APP11 Exhibit H.

Furthermore, with respect to the mistakenly issued conditional approval notice, CMS refers to language in the notice that asserts “If your MA service area has not been approved due to unresolved deficiencies, your new SNP or SNP SAE application cannot be approved.”<sup>70</sup> CMS states that MedStar knew its SAE application for two Maryland counties had been denied thus should have known its SNP in those areas could not be approved.<sup>71</sup> For this reason, in CMS’ view, MedStar knew when it received the May 31, 2013, conditional approval notice that it was not qualified to operate a SNP.

CMS has moved for Summary Judgment on both appeals in this matter. The agency contends that there is no genuine dispute of material fact and the record demonstrates the appropriateness of its actions. CMS claims that it is undisputed that MedStar did not have 14 months of program experience that are required for approval of a service area or product expansion. Therefore, CMS asserts that its determinations were correct as a matter of law.

## VI. DECISION

### A. Motion for Summary Judgment

During a hearing to review a contract determination under Part 422 or 423, an applicant is required to prove, by a preponderance of the evidence, that CMS’ denial of an application was inconsistent with applicable regulatory requirements.<sup>72</sup> In addition, pursuant to 42 C.F.R. §§ 422.668 and 423.664, the CMS Hearing Officer must comply with the provisions of title XVIII and related provision of the Social Security Act, regulations issued by the Secretary and general instructions issued by CMS in implementing the Act.

In accordance with Rule 56(a) of the Federal Rules of Civil Procedure, summary judgment shall be granted if the movant shows that there is no genuine dispute as to any material fact and movant is entitled to judgment as a matter of law.

A motion for summary judgment is appropriate when there are no *material* facts in dispute.<sup>73</sup> A material fact is one that has an effect of establishing or refuting an essential element under

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<sup>70</sup> CMS Brief APP11 at 6 and Exhibit G.

<sup>71</sup> *Id.* The Hearing Officer notes that MedStar also argued that its SNP application should have been approved for the District of Columbia because it already held a MD-PD contract in that service area. This argument was made subsequent to CMS’ brief was filed and thus was not addressed by CMS.

<sup>72</sup> 42 C.F.R. §§ 422.660 and 423.650.

<sup>73</sup> Upon being informed that the Hearing Officer anticipated ruling on the pending motions for summary judgment, MedStar first identified four facts it claims are in dispute. The parties were then advised, via email, that:

The Hearing Officer does not have the authority to compel CMS to answer the questions raised by MedStar Family Choice (MedStar) in the below correspondence. The Part C and Part D appeal regulations note that the Plan bears the burden of proof at hearing. Furthermore, the appeal regulations establish that the Plan presents its arguments and evidence before CMS responds. Notably, these regulations do not include a discovery mechanism. See 42 C.F.R. § 422 Subpart N.

To date, CMS has not indicated that it intends to call any witnesses that could testify as to the substance of MedStar’s inquiries concerning these demonstration projects and SNP applications. If CMS elects to respond to MedStar’s questions in writing, such response

consideration.<sup>74</sup> The Supreme Court has noted that, “Only disputes over facts that might affect the outcome of the suit under governing law will properly preclude the entry of summary judgment. Factual disputes that are irrelevant or unnecessary will not be counted.” *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 248 (1986). At the summary judgment stage, facts must be viewed in the light most favorable to the nonmoving party only if there is a “genuine” dispute as to those facts. *Scott v. Harris*, 550 U.S. 372, 380 (2007)(citing FED.R.CIV.P. 56(c)). Moreover, the mere existence of *some* alleged factual dispute between the parties will not defeat an otherwise properly supported motion for summary judgment; the requirement is that there be no *genuine* issue of *material* fact.” *Anderson*, 477 U.S. at 247–248 (1986) (emphasis in original).

MedStar’s applications were denied on the grounds that it lacked 14 months performance history as required by CMS instructions and regulations. The material fact, therefore, is whether MedStar has a performance history in the MA-PD program that exceeds 14 months. There is no dispute regarding the length of MedStar’s tenure as Medicare Contractor operating an MA-PD plan. Indeed, MedStar confirmed to CMS and in the record here that it has been operating only since January 1, 2013, less than the requisite 14 months.<sup>75</sup>

On July 26, 2013, CMS declined to respond to MedStar’s questions.<sup>76</sup> The record does not reflect whether plans with less than 14 months performance history were approved for SAEs, new SNP applications or to conduct demonstrations; whether CMS incorrectly issued other conditional approval notices followed by official denials; or what information may have been known to CMS if it blundered in its responses to other applicants. Answers to those questions, however, would not change the Hearing Officer’s analysis: the material fact in this appeal is whether MedStar’s performance history exceeds 14 months.

## **B. CMS DETERMINATION IS CONSISTENT WITH REGULATIONS**

The Hearing Officer agrees with the parties that the regulations at 42 C.F.R. §§ 422.502(b)(2) and 423.503(2)(b) are unambiguous. Each regulation gives CMS the discretion to approve or deny an application from an MA organization that has less than 14 months performance history. Having discretion, however, does not mean an agency must perform an analysis of each individual factor in each individual situation before making the decision to approve or deny.

Here, CMS has established criteria, which it began implementing in 2013, under which entities that began their contracts in the previous year would “not be permitted to expand their service areas or product types until they have accumulated at least 14 months performance experience.” CMS’ rationale for exercising its authority in this way is clearly spelled out in the legislative history underlying §§ 422.502(b)(2) and 423.503(b)(2). CMS requires a new MA-PD plan sponsor to demonstrate 14 months compliance with program requirements in order to protect

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will be placed within the administrative record. In the event CMS wishes not to volunteer this information, the Hearing Officer’s review will be confined to those materials that have been entered into the record.

<sup>74</sup> *Black’s Law Dictionary* 977 (6<sup>th</sup> ed. 1990).

<sup>75</sup> MedStar Initial Brief APP8 at 8-9; CMS Brief APP8 at 4.

<sup>76</sup> See *supra* n.61.



Medicare beneficiaries and afford them access to the best performing organizations. It considered the alternative approach—accepting on faith that an organization with as little as two months presence in the MA program could continue to comply with all program requirements—but declined to adopt it. It chose instead to require 14 months performance history. The criteria is consistent with the regulatory language, CMS’ rationale for the regulatory language, and is an appropriate exercise of CMS’ discretion.

CMS’ instructions in the Performance Review Methodology do not constitute a change in the regulation so as to implicate APA requirements. Rather, CMS’ instructions give notice regarding how CMS will wield the authority it is granted under the regulation. Furthermore, MedStar’s concern that applicants could have been denied notice and the opportunity to comment on the purported change is unfounded. CMS released draft versions of its 2013 and 2014 Past Performance Review Methodology memoranda for comment. MedStar and any other interested entity had the opportunity to comment.

MedStar sees a strict order of precedence coded within the regulations that, in its view, requires CMS to analyze information in each application in a certain order, rather than uniformly denying all applicants with a certain performance history. The Hearing Officer disagrees. The regulations direct CMS to consider past performance, information in the application and information CMS obtains through means such as site visits. The regulations recognize that the material CMS considers when evaluating past performance (under any provision in § 422.502(b)) is different from the information contained in the application itself. The introductory clauses at issue<sup>77</sup> do not require CMS to first review the application and make a determination on its face.

Indeed, several of the past performance scenarios that CMS considers under § 422.502(b) could be ultimately determinative in CMS’ evaluation of an application. For example, under § 422.502(b)(3), CMS may deny an application solely on the basis that the applicant organization had been terminated from the program in the previous 38 months. In such a situation, the plan is not able to remedy the problem and no further evaluation is necessary. This concept is rooted in the need for efficiency in administering the Medicare program. If at any point during the review process CMS determines that an applicant has a deficiency that cannot be cured, efficient administration of the program dictates that the evaluation must be concluded and a determination made. CMS followed that process here. MedStar, however, would have CMS continue its evaluation even after it had denied an application under one of those scenarios. The evaluation process that MedStar advocates would be onerous and unproductive. Recognizing that MedStar could not roll back the date of its entry into the Medicare program, CMS was well within its authority to deny MedStar’s applications.

Despite MedStar’s short history as an MA-PD sponsor, it asserts that it could offer additional information<sup>78</sup> to demonstrate that it could comply, or continue to comply, with program regulations as it operates in additional service areas and/or offers a SNP. There is no regulatory requirement, nor does MedStar point to one, that would require CMS to consider additional

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<sup>77</sup>“...with the exception of evaluations conducted under paragraph (b)...” in § 422.502(a)(1) and “...except as provided in paragraphs (b)(2) through (b)(4)...” in § 422.502(b)(1).

<sup>78</sup> See MedStar Initial Brief APP8 Exhibit F.

information. Instead, § 422.502(a)(1) is clear that applications are evaluated solely on the information contained therein.

### **C. CMS FAILED TO FOLLOW ITS OWN NOTIFICATION PROCEDURES**

It is evident that CMS failed to follow its own notification procedures regarding MedStar's SNP application. From the outset, CMS's communications regarding MedStar's SAE and D-SNP applications were inconsistent. When MedStar indicated its intention to submit an application in November 2012, CMS warned that it was not eligible to apply for SAE because it lacked 14 month's performance history. CMS subsequently met with MedStar to reiterate that message.<sup>79</sup> As predicted, CMS issued a NOID MedStar's SAE application affirmatively stating that that MedStar was not eligible to apply for a contract because it lacked the requisite performance history. Incongruously, however, on the very same day, CMS congratulated MedStar by email that its SNP application was found to have no deficiencies. Clearly, CMS should have issued a NOID in response to the SNP application. Instead, it mistakenly issued a conditional approval on May 31, 2013.

The conditional approval listed various elements of the SNP application that were still pending approval. The notice also stated that "A SNP can only be offered in an MA-Approved service area." In mid June 2013, CMS withdrew the conditional approval and issued a final denial notice. The denial, however, was based on MedStar's relatively short performance history rather than any of the conditions in the notice.

While it is preferable for an agency to follow its own procedures, in this instance, CMS ultimately issued the correct response to MedStar's D-SNP application. The language in the conditional approval notice does not limit CMS' ability to deny the application on other proper grounds. CMS' final determination was proper because it was based on an accurate measure of the duration of MedStar's performance history. CMS' failure to comply with its own procedures in this case does not override the threshold requirement that organizations must have a minimum of 14 months performance history to be eligible to submit applications to expand their service areas and/or offer new product types.

Moreover, MedStar was not prejudiced by the circuitous route CMS followed to issue its final determination. The Hearing Officer recognizes that CMS' failure to issue a courtesy email or a NOID theoretically deprived MedStar of the opportunity to cure deficiencies identified in its D-SNP application during the application process. The deficiency that served as the basis of the denial, however, was not curable. MedStar could not create 14 months of performance history when it had operated a contract for less time.

In that the regulations are unambiguous and CMS' is acting within its authority to decline to expand the service area for any plan with less than 14 months performance history, CMS' denial of MedStar's SAE application, requesting an expansion into two counties in Maryland, was correct. Since MedStar did not have an approved MA-PD plan in Maryland, CMS' denial of MedStar's D-SNP application for two counties in Maryland was correct.

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<sup>79</sup> CMS Brief APP11 at 4. The informal communication appears to be separate from the courtesy email notice described in the 2013 Application Instructions.

#### **D. A SNP IS A DISTINCT PRODUCT TYPE**

MedStar's application to provide a D-SNP offering in the District of Columbia is similarly flawed. While the fact that MedStar currently operates as a MA organization in the District of Columbia distinguishes this application from the previously-noted SAE submittal, the D-SNP application is also hindered by the Plan's inability to demonstrate 14 months of performance history.

The 2014 Methodology clearly states that the 14 month performance requirement applies to plans that seek "to expand their service areas or product types." However, MedStar contends that its prior history as a MA organization is irrelevant in this context, as a D-SNP is not a new "product type" as contemplated in the regulations and Methodology. In support, MedStar relies on portions of the 2014 MA Application that treat a CCP as a product type, but do not distinguish between types of CCPs. MedStar contends that since it offers a CCP within the District of Columbia, the offering of another subcategory of CCP, in this case a D-SNP, cannot be considered a product expansion.

MedStar's reliance on this isolated provision of the MA Application is misplaced. The statutory, regulatory and sub-regulatory framework that governs the MA program establishes that SNPs are a distinct product type. Therefore, MedStar's application to offer such a product is subject to the 14 month performance requirement that governs product type expansions. As statutorily enacted, all SNP plans fall under the broad categorization of CCP packages. The 2014 MA Application provision cited by the Plan reflects this fact. However, the regulations that establish CMS' contract review process distinguish between standard applications for MA contracts and those applications seeking approval "for a Specialized MA Plan for Special Needs Individuals."

The Medicare Managed Care Manual further differentiates between SNP plans and other MA CCPs. First, the Manual requires SNPs to be "a product tailored for a specific population." Furthermore, SNP plans are expected to offer "some or all benefits that exceed the basic required Medicare A and B benefits offered by other MA products available in the same service area." CMS clearly evaluates SNPs differently than it does other MA offerings, and even other CCP offerings, within a given service area. SNPs are expected to be narrowly-tailored to address the specific needs of a distinct beneficiary community, and the plan is expected to offer a benefit package to that population that exceeds other available options. The Managed Care Manual containing this language was updated and disseminated in May 2011. MedStar was, or should have been, aware that CMS considers SNPs to be a distinct product type.

MedStar's attempt to offer a D-SNP plan constituted an application for product expansion that is subject to the 14 month performance demonstration requirement. MedStar acknowledges that it cannot meet this requirement. CMS' denial of the D-SNP application was therefore an appropriate exercise of its contracting authority.

## E. RELIANCE AND FUNDAMENTAL FAIRNESS

MedStar's claim of detrimental reliance is without merit. In apparent hindsight, MedStar asserts that it did not apply for a larger service area in 2013 based on its understanding of §§ 422.502(b) and 423.503(b). CMS provided notice in the instructions for submitting applications for Calendar Year 2013 contracts that it was beginning a policy with the 2013 Application Cycle under which organizations would not be permitted to expand their service areas or product types until they had 14 months performance history. This approach is consistent with CMS' authority under Parts 422 and 423. It was not reasonable for MedStar to rely on its own narrow reading of two provisions to the exclusion of other publically available guidance. MedStar does not claim to be unaware of the 2013 instructions and, indeed appears to have followed them appropriately in that its application to establish an MA-PD in the 2013 Application Cycle was approved.

Similarly, it was not reasonable for MedStar to "expend significant financial resources" related to its SNP application. As discussed *supra*, MedStar knew or should have known that its applications could not be approved because it lacked the requisite 14 months performance history.<sup>80</sup> Moreover, CMS has been clear that it does not compensate organizations for the costs of preparing and submitting applications.<sup>81</sup> Even if MedStar suffered fundamental unfairness as a result of CMS' conflicting communications and its reliance on the conditional approval had been reasonable, the Hearing Officer has no authority to grant any relief on this basis.

## VII. CONCLUSION

The Hearing Officer finds that CMS acted within its authority in denying application H9915. CMS' Motion for Summary Judgment is granted.



Brenda D. Thew  
CMS Hearing Officer

July 31, 2013

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<sup>80</sup> § 422.501 et seq.

<sup>81</sup> *Supra* n. 15