CENTERS FOR MEDICARE AND MEDICAID SERVICES
HEARING OFFICER DECISION

IN THE MATTER OF:

Boston Medical Center Health Plan, Inc.	*	
	*	
Denial of Service Area Expansion Application (SAE)	*	DOCKET NO.
(Part C and Part D)	*	2016 MA/PD APP. 4
	*	
Contract Year 2017, Contract No. H9585	*	

ORDER GRANTING SUMMARY JUDGMENT

I. JURISDICTION

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.[1] The Medicare Prescription Drug, Improvement, and Modernization Act of 2003 made changes to the MA program and allowed beneficiaries to elect a voluntary outpatient prescription drug benefit within a Part C plan.[2] 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 plan enrollees in each operative service area.[3] Each organization's network must include a variety of providers, including primary care physicians, specialists, and hospitals,[4] and must offer an outpatient prescription drug benefit in the service areas in which it offers a Part C benefit.[5]

The Secretary of the United States Department of Health and Human Services ("the Secretary") is authorized to contract with entities seeking to offer MA and MA-PD benefits.[6] Through regulation, the Secretary has delegated this contracting authority to the Centers for Medicare and Medicaid Services (CMS), which has established the general provisions for entities seeking to qualify as MA-PD plans.[7]

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[1] *See* 42 U.S.C. § 1395w-21 *et seq.*
[2] *See, generally,* Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Public Law 108-173, Sec. 231 (codified at 42 U.S.C. § 1395w-28(b)(6)).
[3] 42 C.F.R. § 422.112(a).
[4] 42 C.F.R. § 422.112(a)(1).
[5] 42 C.F.R. § 422.4(c)(1). *See also, generally,* 42 U.S.C. § 1395w-112 (Medicare Part D).
[6] 42 U.S.C. § 1395w-27.
[7] 42 C.F.R. §§ 422.400 *et seq.*, 422.503(b) *et seq.*, 42 C.F.R. § 422.502(a). The analogous provision for Part C and Part D appear at 42 C.F.R. Parts 422 and 423 respectively. Throughout this Order, unless otherwise indicated, references to regulations governing Part C should be read to include the analogous regulations for Part D.

If CMS denies a MA-PD application, the applicant organization is entitled to a hearing before a CMS Hearing Officer.[8] The regulations at 42 C.F.R. §§ 422.660(b)(1) and 423.650(b)(1) dictate that "the applicant has the burden of proving by a preponderance of the evidence that CMS' determination was inconsistent with the requirements of [42 C.F.R. §§ 422.501-502 and 423.502-503]."[9] The regulations governing the hearing process provide that either party may ask the Hearing Officer to rule on a motion for summary judgment.[10] In exercising his or her authority, the CMS Hearing Officer must comply with the provisions of Title XVIII and related provisions of the Social Security Act, regulations issued by the Secretary, and general instructions issued by CMS in implementing the Act.[11]

II. ISSUE

The issue is whether Boston Medical Center Health Plan, Inc. ("BMCHP" or "Plan") has proven by a preponderance of the evidence that CMS' denial of its service area expansion ("SAE") applications for Contract Year 2017 on the grounds that the applicant lacked the requisite performance history was inconsistent with regulatory requirements.

III. FINDINGS

The Hearing Officer grants CMS' Motion for Summary Judgment. The parties agree there is no dispute of material facts and that BMCHP does not have 14 months of performance history in the MA program. BMCHP has not established by a preponderance of the evidence that CMS' denial was inconsistent with controlling authority.

IV. FACTUAL AND PROCEDURAL BACKGROUND

A. BMCHP

BMCHP is an MA organization authorized to offer MA and MA-PD plans in Suffolk County, Massachusetts under a contract with CMS (#H9585). BMCHP commenced offering services to Medicare eligible members effective January 1, 2016. It also offers a Dual-Eligible Special Needs Plan ("D-SNP") and each of its enrollees there is also enrolled in the State's Senior Care Option ("SCO") program offered by the Massachusetts Executive Office of Health and Human Services for Medicaid members age 65 and older. In order to serve SCO members, BMCHP must have one contract with the Commonwealth of Massachusetts ("Commonwealth or State") to offer benefits to SCO members and a separate contract with CMS to offer benefits to MA SNP members residing in the same geographic service area. The Commonwealth's Medicaid Director

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[8] 42 C.F.R. § 422.660.

[9] The regulations at 42 C.F.R. §§ 422.501-502 and 423.502-503 establish the contract application requirements and review procedures.

[10] 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 (Dec. 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.").

[11] 42 C.F.R. § 422.688.

submitted a letter in support of BMCHP's application noting, among other things, that BMCHP has "19 years of successful experience as a Medicaid managed care organization covering a similar population."[12]

B. Application History

i. Initial Application

On February 16, 2016, BMCHP submitted MA and MA-PD applications for service area expansion, as well as a proposal/application to offer a D-SNP for an additional county (Hampden County) in Massachusetts. BMCHP attested that the MA and MA-PD plans it currently offered had not been operational since January 1, 2015, or earlier; thus, it had less than 14 months experience with the program.[13] With its initial application, BMCHP requested that CMS exercise its discretion under 42 C.F.R. § 422.502(b)(2) to permit BMCHP to expand its D-SNP service area to include Hampden County. BMCHP further provided a summary of the Plan's performance history and justifications to support granting the application, despite BMCHP's acknowledged lack of 14 months of experience with the program.[14]

ii. Deficiency Notices and Response

On March 9, 2016, CMS issued an MA deficiency notice and a SNP deficiency notice. The notices outlined areas of deficiency based on CMS review, including that BMCHP did not have at least 14 months of performance history with the MA program as of the application due date. In the deficiency notices, CMS asserted that BMCHP was not eligible to apply for a new MA product or SAE at this time. On March 21, 2016, BMCHP received a Part D deficiency notice which outlined, as the only area of deficiency, that BMCHP's existing contract was not in continuous effect prior to January 1, 2015. In the deficiency notice, CMS further asserted that BMCHP was not eligible to apply for a new contract or SAE for 2017. While BMCHP acted to cure identified MA network deficiencies, it did not, at this stage, submit additional information to cure the MA, SNP and Part D deficiencies that were based on the lack of 14 months of performance history.[15]

iii. Notices of Intent to Deny and Response

On April 18, 2016, BMCHP received Notices of Intent to Deny ("NOID") for its MA and MA-PD applications, as well as its SNP application/proposal. The NOIDs reiterated that BMCHP was ineligible for a SAE in connection with its MA and SNP applications during the 2017 application cycle because it did not have 14 months of performance history with the MA program as of the application due date. The MA-PD notice reiterated

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[12] Memorandum in Support of Boston Medical Center Health Plan Inc.'s Appeal of CMS' Denials of Its Service Area Expansion Applications (#H9585) filed June 27, 2016 ("BMCHP Brief") at 3.
[13] *See* CMS Brief in Reply to Applicant's Brief in the Matter of the Denial of Part C and Part D Applications Submitted by Boston Medical Center Health Plan, Inc. Docket No. – 2017MA/PD App. 4 ("CMS Brief"), Ex. 2.
[14] BMCHP Brief at 6.
[15] *Id.*

CMS' position that BMCHP was ineligible to apply for a new contract or SAE for 2017. On April 27, 2016, BMCHP responded to the NOID, requesting that CMS exercise it discretion to grant BMCHP's application because of BMCHP's strong performance history and the benefit BMCHP's plan would have to a unique dually eligible population to be served by the SCO and MA programs. BMCHP pointed to the support of the State's Medicaid Director and the potential advancement of significant public policy goals.[16]

iv. Denial Notices

On May 26, 2016, CMS denied BMCHP's MA, Part D and SNP applications, identifying the only basis for denial as the lack of 14 months of performance under its current Medicare contracts.[17] BMCHP's application otherwise demonstrated that it met all other MA, Part D, and SNP application requirements.[18]

v. Appeal

On June 8, 2016, BMCHP timely filed its appeal, pursuant to 42 C.F.R. §§ 422.660(a)(1), 422.662, 423.6650(a)(1) and 423.651, to challenge CMS' denial of its MA and MA-PD SAE applications and its application/proposal to offer a D-SNP, all of which relate to a single county in Massachusetts (Hampden County). On June 27, 2016, BMCHP filed a Memorandum in Support of Boston Medical Center Health Plan Inc.'s Appeal of CMS' Denials of Its Service Area Expansion Applications ("BMCHP Brief"). On July 1, 2016, CMS filed its Brief in Reply to Applicant's Brief in the Matter of the Denial of Part C and Part D Applications Submitted by Boston Medical Center Health Plan, Inc. Docket No. – 2017MA/PD App. 4 ("CMS Brief") which included a Motion for Summary Judgment. On July 8, 2016, BMCHP filed a Reply Memorandum in Further Support of its Appeal of CMS's Denial of its Service Area Expansion Applications ("BMCHP Reply").

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[16] *Id.* at 6-7.

[17] With respect to the MA and SNP applications, the sole basis articulated for the denials was that BMCHP had attested in its application that it did not have at least 14 months of performance history with the MA program as of the application due date and; therefore, BMCHP, according to CMS, was ineligible to apply for a new MA product or service area expansion this application cycle. With respect to the Part D application, the sole deficiency cited was BMCHP's attestation that its existing contract with CMS was not continuous effect prior to January 1, 2015, which meant that BMCHP, according to CMS, was not eligible to apply for a new contract or SAE for 2017. Despite the different wording, the sole basis for CMS' rejection of the application in each instance was effectively that BMCHP was ineligible for application approval because it did not have did not have 14 months of MA/Part D performance history.

[18] CMS Brief at 7; BMCHP Brief at 7.

V. LEGAL AUTHORITIES

A. Regulatory Text

The controlling regulation at 42 C.F.R. § 422.502[19] states, in pertinent part:

> (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.
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> (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.

B. Preamble

Prior to 2010, the regulations provided that CMS consider an applicant's past performance in a "previous year's contract"[20] or prior contract[21] when determining whether to approve an application for a new or expanded contract. In 2009, CMS published a Proposed Rule which introduced the 14-month look-back provision introduced in Section A above.[22] The proposed rule stated:

> We also propose to clarify that the period that will be examined for past performance problems be limited to those identified by us during the 14 months *prior to the date* by which organizations must submit contract qualification applications to CMS.[23]

The corresponding final rule at 75 Fed. Reg. 19,678, 19,685 (Apr. 15, 2010) added:

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[19] 42 CFR Part 422 covers Medicare Advantage (Part C) organization. See also 42 CFR 423.503 for parallel language for Prescription Drug Plans (Part D) organizations.
[20] 42 C.F.R. § 423.503(b).
[21] 42 C.F.R. § 422.502(b).
[22] The 14 month look-back provision was originally codified in a modified 42 C.F.R. § 422.502(b) and has been recodified to the current 42 C.F.R. § 422.502(b)(1) pursuant to the final rule at 76 Fed. Reg. 21,432, 21,524 (Apr. 15, 2011).
[23] 74 Fed. Reg. 54,634, 54,642 (Oct. 22, 2009) (emphasis added).

> The purpose of the past performance review is to determine whether the sponsor has demonstrated, over a 14-month period, whether it has operated its Part C or D contract in a manner that suggests that it is generally meeting and capable of meeting program requirements and that new Medicare business would not jeopardize that status.
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> . . . We believe that the 14 month look-back provides an adequate amount of time for us to review an MA organization's or Part D sponsor's performance and the choice of 14 months as the look-back period was not arbitrary. As we noted previously, and in the proposed rule, 14 months covers the period spanning the start of the contract year to the time we receive applications for the following contact year. To shorten that time period to, say, 12 months would leave a gap in our past performance review. Similarly, limiting the period to the 14-month timeframe gives sponsors and organizations the opportunity and incentive to promptly establish a positive compliance track record so that the next CMS past performance review will find them eligible for additional Part C or Part D business.

In 2011, CMS' past performance review was further refined when it added additional language at §§ 422.502(b)(2) and 422.503(b)(2) addressing situations in which applicants do not have 14 months of performance history. In the Final Rule at 76 Fed. Reg. 21,432–21,524 (emphasis added),[24] CMS explained

> In the absence of 14 months of performance . . . 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 suggests that *we take the latter approach.* Our justification for proposing 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.

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[24] *See also* corresponding Proposed Rule at 75 Fed. Reg. 71,190, 71241 (Nov. 22, 2010) which states: "At this time, we are proposing to further refine our intended approach to using past performance in making application determinations. Specifically, we are concerned about entities submitting applications to us where the entity has operated its contract(s) with us for less than 14 months at the time it submits a new application or service area expansion request. Practically speaking, an entity contracting with us for the first time would merely have 2 months experience before applications would be due for the following contract year. Two months is an inadequate amount of time for the entity to demonstrate its ability to comply with all Part C and/or Part D requirements."

C. Agency Materials

CMS explains that it published the first Past Performance Methodology in December 2010 for use during the CY 2012 Application Cycle. CMS issued the 2017 Application Cycle Past Performance Methodology ("the Methodology") on December 24, 2015, through the Health Plan Management System (HPMS), the electronic system of records that CMS maintains for the administration of the Part C and Part D programs.[25] CMS explains that it routinely provides program guidance through HPMS, and there is no substantive difference between HPMS-issued guidance and guidance included in the Medicare Managed Care and Prescription Drug Manuals. Since CMS had proposed no substantive changes to the methodology from the document issued the previous year, CMS explained that it did not solicit public comments to a draft version of the 2017 Methodology. CMS last requested public comments on a draft Methodology on December 23, 2014, which was applied during the 2016 application review cycle.

In the Methodology, CMS announced that the 14 month period of past performance review for the 2017 application cycle would be January 1, 2015 through February 29, 2016. CMS also reminded organizations that it had the regulatory authority to deny applications from organizations with less than 14 months Part C and Part D performance history and that during the 2017 application review cycle, "organizations that commence their Part C and Part D operations in 2016 will not be permitted to expand their service areas or product types until they have accumulated at least 14 months of performance experience." CMS also announced in the same passage that it would not apply the provision to organizations that have operated for less than 14 months but are related to an entity that has the requisite Part C and Part D experience. 2016.[26]

VI. PARTIES' CONTENTIONS

A. CMS' Contentions

CMS states that it is entitled to summary judgment as there is no genuine issue of material fact and the undisputed facts warrant judgment for the moving party (CMS). It is undisputed that BMCHP, at the time it submitted its SAE application in February 2016, had operated its current MA-PD contract for less than 14 months preceding the submission deadline. CMS contends that, as it applied its reasonable interpretation of the regulatory authority, BMCHP cannot prove by a preponderance of the evidence that CMS' denial of its application was inconsistent with the requirements governing the Parts C and D application processes. Moreover, CMS' policy and justification for declining to use its discretion to approve BMCHP is sound. Also, the relevant facts in this case are indistinguishable for those presented in *MedStar Family Choice, Inc.* ("*MedStar*"), 2013 MA/PD App. 8 & App. 9 (July 31, 2013) [27](as both applicants had less than 14 months MA experience and were unrelated to experienced entities) in which the Hearing Officer upheld CMS' determination.

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[25] CMS Brief Ex. 1.

[26] CMS Brief Ex. 1 at 3.

[27] *MedStar Family Choice, Inc.*, 2013 MA/PD App. 8 & App. 9 (July 31, 2013), *available at* https://www.cms.gov/Regulations-and-Guidance/Review-Boards/Medicare-Advantage-Prescription-Drug-Plan-Decisions/List-of-MA-PD-Decisions.html.

CMS articulates that the presence of the word "may" in the text of § 422.502(b)(2) indicates that CMS has discretion to approve or deny an application under that authority, but CMS has elected to exercise its discretion to, in effect, make blanket denials of all SAE applicants without the required experience and has provided instruction to that effect in the Methodology. CMS notes that the Hearing Officer has held previously that the Methodology as it relates to § 422.502(b)(2) is valid. In *MedStar*, the Hearing Officer wrote that, "Each regulation [§§ 422.502(b)(2) and 423.503(b)(2)] 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 situation before making the decision to approve or deny." The decision also stated that, "The criteria is consistent with the regulatory language, CMS' rationale for the regulatory language, and is an appropriate exercise of CMS' discretion." The Hearing Officer also noted that "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."[28]

CMS argues that the regulation establishing its authority to categorically deny all SAE applicants that have held a Medicare contract for less than 14 months is clear, when read in the proper context. CMS denied BMCHP's SAE application on the basis of its authority at § 422.502(b)(2) which provides that, "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." CMS contends that this provision states clearly both the application denial authority and the rationale for the exercise of that authority. The operative portion of the provision states that CMS need only identify the presence of the condition (i.e., "In the absence of 14 months of performance history. . .") that triggers its use of the denial authority (". . . CMS may deny an application . . .") and concludes by providing the reader with the rationale for the authority (". . . based on a lack of information available to determine an applicant's capacity to comply with the requirements of the MA program."). Therefore, CMS need only find that an applicant did not have Medicare contract experience covering the entire period between January 1, 2015, and February 29, 2016. No further analysis was required of CMS.

CMS notes that BMCHP relies on a different reading of § 422.502(b)(2) to create an obligation on CMS to conduct a review of an applicant's past performance that is outside the scope of the information reviewed in the Methodology. CMS states, however, that there is nothing in the plain language of § 422.502(b)(2), the accompanying preamble, or other guidance that supports BMCHP's reading. As noted above, on its face, the phrase, "based on a lack of information available to determine an applicant's capacity to comply with the requirements of the MA program" simply identifies the rationale for the authority CMS may use to deny an application based exclusively on an SAE applicant's lack of 14 months experience operating an MA contract.

Also, CMS states that § 422.502(b)(2) must be read in context with § 422.502(b)(1). The regulations at § 422.502(b)(1) establish that CMS has the authority to deny an application based

[28] CMS Brief at 9 *citing MedStar* at 17.

on the failure to comply with requirements of its contract, and that the exclusive universe of relevant information that CMS will consider is the organization's performance during the 14 months preceding the deadline. According to CMS, § 422.502(b)(2) continues that CMS has reasonably concluded that SAE applicants with less than 14 months of MA operations in effect have an incomplete performance data set upon which CMS can make a reliable determination. CMS argues that it would be unreasonable to read § 422.502(b)(2) as creating an obligation on the part of CMS to examine an applicant's non-Part C performance when § 422.502(b)(1) so clearly establishes Part C performance as the exclusive and relevant record upon which CMS will make a determination.

CMS contends that treating the requirement in § 422.502(b)(1) as though unrelated to that stated in § 422.502(b)(2)--because the former requires CMS to evaluate an applicant's "compliance" while the latter speaks to an applicant's "capacity to comply"--leads BMCHP to essentially make a distinction without a difference. A determination that an organization is compliant with a set of program requirements is, in effect, a determination that it has the capacity to comply. Thus, when applying § 422.502(b)(1), CMS is obligated to make a determination concerning the applicant's capacity to comply with Part C requirements only when the applicant has MA experience that fills the 14-month review period. When the applicant can present only two months of Part C experience, CMS is incapable of making a reliable determination about its capacity to comply and therefore, by the language of § 422.502(b)(2), CMS may simply deny the application.

Further, CMS states that the preamble through which CMS adopted § 422.502(b)(2) makes it clear that CMS intended that § 422.502(b)(2) be read in conjunction with § 422.502(b)(1). In the preamble discussion accompanying CMS' proposal of § 422.502(b)(2), CMS stated, "At this time, we are proposing to refine our intended approach to using past performance in making application determinations."[29] CMS also quotes a second CMS Hearing Officer decision which stated, "CMS adopted 42 C.F.R. § 422.502(b)(2) to enhance § 422.502(b)(1) in order to specifically address how it would treat those organizations whose Medicare contract performance was of a duration of less than the 14 months preceding the application deadline." *In the Matter of Harvard Pilgrim Health Care, Inc.*, 2014 MA/PD App. 6 (H1660) & App. 7 (H6750) (July 17, 2014).[30]

By contrast, CMS asserts that the preamble discussions provide no support for BMCHP's reading of the regulatory language. CMS described the issue that prompted it to propose §422.502(b)(2) in the preamble accompanying the notice of final rulemaking: CMS stated that it adopted § 422.502(b)(2) after recognizing that, for MA organizations with less than 14 months of Part C performance, there was 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

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[29] 75 Fed. Reg. at 71241.

[30] *In the Matter of Harvard Pilgrim Health Care, Inc.*, 2014 MA/PD App. 6 (H1660) & App. 7 (H6750) at 9 (July 17, 2014), *available at* https://www.cms.gov/Regulations-and-Guidance/Review-Boards/Medicare-Advantage-Prescription-Drug-Plan-Decisions/List-of-MA-PD-Decisions.html