DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
7500 Security Boulevard, Mail Stop C3-01-20
Baltimore, Maryland 21244-1850
Telephone 410-786-3176 Facsimile 410-786-0043

Office of the Attorney Advisor

CENTERS FOR MEDICARE & MEDICAID SERVICES

VIA ELECTRONIC MAIL AND FIRST CLASS MAIL

SEP - 8 2014

Mr. Ankur J. Goel
McDermott Will & Emery
The McDermott Building
500 North Capitol Street, NW
Washington, DC 20001

Re: Harvard Pilgrim Health Care, Inc., Docket Nos. 2014 MA/PD App. 6 and App. 7

Dear Mr. Goel:

Enclosed is a copy of the Administrator's decision in the above case affirming the decision of the Hearing Officer. This constitutes the final administrative decision of the Secretary of the Health and Human Services

Sincerely yours,

Jacqueline R. Vaughn
Attorney Advisor

Enclosure

CENTERS FOR MEDICARE AND MEDICAID SERVICES

Decision of the Administrator

In the Matter of:	**Claim for:**
Harvard Pilgrim Health Care Inc.	**Medicare Advantage Prescription Drug Plan** **Period Beginning: 2015** **Review of:** **Docket Nos. 2014 MA/ PD App.6 (H1660) & App. 7 (H6750)** **Dated: July 17, 2014**

This case is before the Administrator, Centers for Medicare & Medicaid Services (CMS), for review of the CMS Hearing Officer's decision. Harvard Pilgrim Health Care, Inc. (HPHC, the Plan or Applicant) timely requested administrative review under 42 C.F.R. §§422.692(a) and 423.666(a). The Administrator initiated review under 42 C.F.R. §§422.692(d) and 423.666(d). CMS' Centers for Medicare submitted comments stating that the CMS Hearing Officer's decision should be affirmed. The Plan resubmitted its prior comments, requesting that the Administrator review and reverse the CMS Hearing Officer's decision. Accordingly, this case is now before the Administrator for final administrative review.

Issue

The issue involves whether the Plan demonstrated that CMS' denials of the service area expansion applications for Contract year (CY) 2015 on the grounds that the Applicant lacked the requisite 14 months performance history was inconsistent with the regulations.

CMS Hearing Officer's Decision

The CMS Hearing Officer concluded that the Plan cannot provide by a preponderance of the evidence that the CMS denials were inconsistent with the requirements governing Part C and Part D application process. The CMS Hearing Officer upheld the denials finding that the 14 month look back period refers to the 14

months immediately preceding the application. Further, nothing in the regulation envisioned consideration of routine, post-contract activities (e.g., reconciliations or claims adjudications) to count towards the 14 month look-back period. Further, there is nothing in the preamble which indicates that CMS intended to create a completely new performance timeframe other than the 14 months preceding the application deadline. The Guidance and Instructions specifically refers to the 14 months preceding the application and states that the "14 month performance period that will be assessed for the 2015 Application Review Cycle is January 1. 2013 through February 28, 2014." Therefore, the CMS Hearing Officer determined that the Plan had not established that CMS' denials of the SAE applications were inconsistent with the regulation.

Comments

The Plan submitted comments requesting that the Administrator reverse the CMS denial and that the Administrator use her discretion to allow the applications approval based on the several following reasons. Harvard Pilgrim Health Care, Inc. (HPHC) is the oldest non-profit health maintenance organization in New England founded in affiliation with Harvard Medical School and has been an exemplary partner with CMS. The Plan lacked the 14 months of performance data immediately preceding the application period, but it had participated for decades in Medicare managed care initiatives and had non-renewed only as late as 2010 due to statutory changes in the program. At first opportunity, it began to prepare to reenter the market submitting its notice of intent in 2013 for the 2014 contract year. Only 13 months had elapsed from when the Plan had ended its performance obligations (reconciliations, etc.) and began performing under its current 2014 contract. The Plan argued that these activities assured that the Plan remained knowledgeable of CMS requirements in order to begin operations in 2013 for the 2014 contract year. The Plan argued that the 14 months of immediately preceding performance data is at most a discretionary requirement and that discretion is to be exercised when there is a "lack of information to determine the applicant's ability to apply." Here, CMS need not and should not exercise its discretion to deny the application. The Plan has an extensive compliance history with CMS, under Part C and Part D and, thus, it is not a new entrant just commencing operations, unlike those just beginning their contracts for the first time in 2014. In additional, a denial of the SAE applications deprives Medicare beneficiaries, including those in two counties[1] where there is

[1] The Plan stated that H6750 proposed to expand to Cheshire and Sullivan counties in New Hampshire, which otherwise remains without access to any coordinated care plan options and, in both applications, denials would impair beneficiaries in seven counties in MA, NH ME from being able to compare plans that have exemplary consumer satisfaction and quality.

currently no coordinated care plan option, access to high quality plan and limits beneficiary choice. The denials also fail to achieve the stated purpose behind 42 CFR 422.502(b)(2) to protect Medicare beneficiaries and limit choice to the best performing plans.[2]

CMS' Center for Medicare submitted comments objecting to the Plan's argument, that the time it spend in wrapping up its contract that ended in 2010 (August 2012) was equivalent to actually having a contract with CMS.[3] (CM clarified that the Plan had not had a contract with CMS since 2010 at which point it was no longer participating in the Medicare program. Any data submission or reporting that occurred after 12/31/2010 in relation to the former contract is not considered participating in the Medicare program, nor relevant to an analysis of the Plan's past performance.

Discussion

The entire record furnished by the Hearing Officer has been examined, including all correspondence, position papers, exhibits, and subsequent submissions.

Sections 1857 and 1860D of the Social Security Act authorizes CMS to enter into contracts with entities seeking to offer Medicare Advantage (MA/Part C) benefits and Medicare outpatient prescription drug (Part D) to plan enrollees. Under the regulations at 42 C.F.R. §§422.500 and 423.500 *et seq.*, CMS has respectively established the general provisions for entities seeking to qualify as Medicare Advantage (MA) organizations under Part C, and/or Prescription Drug Plans (PDP) under Part D.[4] The regulation at 42 C.F.R. §422.4(c)(1) requires that MA organizations offering coordinated care plans (CCPs) must offer Part D benefits in

---

[2] Letters were written in support of the Plan's application from: Susan M Collins; Angus S King, Jr.; Anne M. Kuster; Edward J. Markey, Elizabeth Warren; John F Tierney, Michaels E Capuano, Stephen F. Lynch, William Keating and Katherine Clark; Michael H. Michaud and Chillie Pingree; Jeanne Shaheen and Kelly Agotte. In addition, a letter was sent to CMS from James Weinstein, CEO, Dartmouth-Hitchcock Health Systems.

[3] This Plan's argument, pointing out the time period it continued to "perform" its contract obligations after the contract had ended, was not new, but raised, in addition to the Plan's request for Administrator review, also in its hearing briefs and recognized and addressed by the CMS Hearing Officer decision.

[4] CMS has revised and/or clarified some of the regulatory text governing the Part C and Part D programs. See, e.g., Proposed Rule, 74 Fed. Reg. 54634 (Oct. 22, 2009) and final Rule, 75 Fed. Reg. 19678 (April 15, 2010); 77 Fed. Reg. 22072, April 12, 2012 (final rule with comment period.)

the same service areas. Organizations seeking to expand the service area of a current contract through a service area expansion (SAE) application must demonstrate that they meet the necessary qualifications to be approved. Consequently, such plans must meet applicant requirements under Part C and Part D.

Pursuant to 42 C.F.R. §§422.501 and 423.502, organizations seeking to qualify as an MA-PD plan have their applications reviewed by CMS to determine whether they meet the application requirements to enter into such a contract. The regulation concerning the Part C application requirements at 42 C.F.R. §422.501[5] states, in relevant part:

> (c) Completion of an application.
>
> > (1) In order to obtain a determination on whether it meets the requirement to become an MA organization and is qualified to provide a particular type of MA plan, an entity, or an individual authorized to act for the entity (the applicant) must complete a certified application in the form and manner required by CMS, including the following:
> > i. Documentation of appropriate State licensure or State certification that the entity is able to offer health insurance or health benefits coverage that meets State-specified standards applicable to MA plans, and is authorized by the State to accept prepaid capitation for providing, arranging, or paying for the comprehensive health care services to be offered under the MA contract.
> > ii. For regional plans, documentation of application for State licensure in any State in the region that the organization is not already licensed.
> > (2) The authorized individual must thoroughly describe how the entity and MA plan meet, or will meet, the requirements described in this part.

Similarly, under the regulations at 42 CFR 422.501(c)(2), 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. Under the regulations at 42 CFR 522.501(c)(1) these applications also must be "completed in the form and manner required by CMS." The Part D regulatory

---

[5] See similar language for Part D at 42 C.F.R. §423.504(b)(2). The Part D application provisions are consistent with the Part C application provision.

application requirements track those set forth under the Part C regulatory application requirements, as appropriate.

CMS established an online application process for both Part C and Part D plans referred to as the Health Plan Management System (HPMS). All new applicants and applicants' requesting a Service Area Expansion (SAE) are to be submitted through the HPMS by the strict deadlines established by CMS. CMS provided training and technical assistance to plans in completing their application. Plan applications were evaluated solely on the materials that were submitted into the HPMS system within the CMS established windows and deadlines. After the applicant files its initial application, CMS reviews the application and notifies the applicant of any existing deficiencies. The applicant is then given the opportunity to correct the deficiencies.

The regulations at 42 C.F.R. §422.502 specify the evaluation and determination procedures for applications to be determined qualified to act as an MA organization, and states in pertinent part:

> (a) Basis for evaluation and determination.
>
> (1) With the exception of evaluations conducted under paragraph.(b) CMS evaluates an entities application for an MA contract.... solely on the basis of information contained in the application itself and any additional information that CMS obtains through on-site visits.
> (2) After evaluating all relevant information, CMS determines whether the application meets all the requirements in this part.[6]

Specifically, the regulation at 42 CFR 422.502(b) for Part C[7] referenced at paragraph (a)(1) states:

---

[6] The preamble to 75 Fed. Reg. 19678, 19683 (April 15, 2010), states that "we specifically proposed to make explicit that we will approve only those applications that demonstrate that they meet all (not substantially all) Part C and Part D requirements." CMS also states that expecting applications to meet "all" standards is practical and explains that "applicants receive enough information to successfully apply and are given two opportunities with instructions to cure deficiencies."

[7] The corresponding provision for the Part D applications at 423.503(b) provides: "b) Use of information from a current or prior contract. (1) Except as provided in paragraphs (b)(2), (3), and (4) of this section, if a Part D plan sponsor fails during the 14 months preceding the deadline established by CMS for the submission of contract qualification applications (or in the case of a fallback entity, the previous 3-year contract) to comply with the requirements of the Part D program under any current or prior contract with CMS under title XVIII of the Act or fails to complete a

> regulations provide that organizations with current or prior contracts with CMS are subject to CMS denial of any new applications for additional or expanded Part C or D contracts if they fail during the preceding 14 months to comply with the requirements of the Part C or D programs, even if their applications otherwise demonstrate that they meet all of the Part C or D sponsor qualifications. 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 programs.
>
> 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.
>
> Therefore, we proposed modifying §422.502(b) and §423.503(b) by adding additional language at §422.502(b)(2) and §423.503(b)(2) 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 program, respectively[8]

With respect to the need for 14 months of performance history immediately preceding the application deadline, Plans were advised of this proposed change as

---

[8] 76 Fed. Reg. 21432, 21524 (April 15, 2011) ("Centers for Medicare & Medicaid Services 42 CFR Parts 417, 422, and 423 Medicare Program; Changes to the Medicare Advantage and the Medicare Prescription Drug Benefit Programs for Contract Year 2012 and Other Changes") (final rule); see also 75 Fed. Reg. 71190 (November 22, 2010)("Centers for Medicare & Medicaid Services 42 CFR Parts 417, 422, and 423 Medicare Program; Proposed Changes to the Medicare Advantage and the Medicare Prescription Drug Benefit Programs for Contract Year 2012 and Other Proposed Changes")(proposed rule).

early as the November 2010 *Federal Register*. A further discussion of the clarification was set forth in the April 2011 *Federal Register*. This was also followed up with instructions and guidance to Applicants.[9] In the same year of the clarification published in the *Federal Register*, CMS issued the "Performance Review Methodology for the 2013 Application Cycle" on December 2, 2011, which stated that:

> 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. (§422.502(b)(2) and §423.503(b)(2)) *Therefore, 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 of performance experience, which can then be evaluated under this methodology.*
>
> Importantly, these provisions only pertain to applying entities that currently operate Part C or Part D contract(s) but have done so for less than 14 months, and further, are unrelated (by virtue of being subsidiaries of the same parent) to any other contracting entity with at least 14 months' experience. So long as a contracting entity or another subsidiary of its parent organization has operated one or more Medicare contracts for the requisite period of time, applications for new contracts or service area expansions submitted by a current contracting entity will not be subject to denial for having less than 14 months experience. (Emphasis added.)

At the time that the Plan first applied to reenter the Program, a Guidance issued January 17, 2013, set forth the "2014 Application Cycle Past Performance Review Methodology Final"[10] and directly addressed further comments on this issue, stating that:

---

[9] See, e.g., December 2, 2011 Memorandum and Attachment "Performance Review Methodology for the 2013 Application Cycle" http://www.cms.gov/Medicare/Health-Plans/HealthPlansGenInfo/Downloads/32_PastPerformanceMethodology.pdf

[10] http://cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/Downloads/2014-Application-Cycle-PastPerformance-Methodology-Final.pdf

> Treatment of Organizations with less than 14 Months Performance History. The methodology document mentions the regulatory provision that gives CMS the authority to deny applications from entities with less than 14 months experience at the time an application is submitted (§422.502(b)(2) and §423.503(b)(2)). One organization that began its Medicare operations in January 2013 submitted comments that CMS should change its policy. CMS' position has not changed. The policy, published by CMS as a final rule in April 2011, was in place when organizations initially applied in February 2012 to operate in 2013, and plans had access to this regulation and should have considered this provision at the outset. Numerous organizations have told us they were aware of the provision and have made decisions accordingly. One organization starting Medicare operations in 2013 praised CMS' policy saying that it ensures plans newly entering the Medicare market will focus on the right things (i.e., taking care of beneficiaries) during their first year, instead of focusing on immediate expansion. *In the preamble discussion accompanying the publication of this regulatory provision, CMS provided no indication that we would consider exceptions to this policy.* However, sponsors have the opportunity to challenge CMS' application of this policy in their particular case by pursuing the regular administrative hearing process the Part C and D regulations afford all denied applicants (Subpart N of 42 C.F.R. Parts 422 and 423). (Emphasis added.)

Finally, for the Plan's applications under review, a Guidance requesting comments was issued November 15, 2013, setting forth the "2015 Application Cycle Past Performance Review Methodology Update-Request for Comments" and a final "2015 Application Cycle Past Performance Review Methodology Update" was issued January 15, 2014"[11]. The Guidance again explained the use of the performance review methodology for all plans, stating that:

> Each year, the Centers for Medicare & Medicaid Services (CMS) conducts a comprehensive review of the past performance of Medicare Advantage Organizations (MAO), Medicare Prescription Drug Plan (PDP) Sponsors, and Cost Plans. The review methodology is a tool that CMS uses to evaluate the performance of all Medicare contractors; these evaluations may also identify organizations with performance so impaired that CMS would prohibit the organization from further

[11] http://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/Downloads/2015ApplicationCyclePastPerformanceMethodologyFinal_01-15-14.pdf

> expanding its Medicare operations. Specifically, pursuant to 42 C.F.R. § 422.502(b) and § 423.503(b), CMS may deny an organization's application either to offer Medicare benefits under a new contract or in an expanded service area during the subsequent contract year if a review of an organization's past performance finds that the organization has been out of compliance with any requirement.

CMS also again specifically addressed the use of the performance review methodology in the application process, stating that:

> CMS clarified in its April 15, 2010 final Part C and D regulations that we limit our performance review each year to the 14-month period leading up to the annual application submission deadline. (As a practical matter, we count the entire calendar month in which applications are due as the 14th month.) The specific 14-month performance period that will be assessed for the 2015 Application Review Cycle is January 1, 2013 through February 28, 2014.
>
> For an instance of non-compliance to be considered in the review, the non-compliance or poor performance must have either occurred or been identified during the 14 month period. Thus, we may include in our analysis non-compliance that occurred in prior years but did not come to light or was not addressed until sometime during the review period. Likewise, if the problem occurred during the 14-month period but it was not identified until, for instance, the month following the end of the review period but before we finalize our results, we include the matter in our assessment.
>
> 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. (§ 422.502(b)(2) and § 423.503(b)(2)) *Therefore, during the 2015 Application Cycle, organizations that commence their Part C and/or Part D operations in 2014 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*
>
> Importantly, these provisions only pertain to applying entities that currently operate Part C or Part D contract(s) but have done so for less than 14 months, and further, are unrelated (by virtue of being

> subsidiaries of the same parent) to any other contracting entity with at least 14 months' experience. So long as a contracting entity or another subsidiary of its parent organization has operated one or more Medicare contracts for the requisite period of time, applications for new contracts or service area expansions submitted by a current contracting entity will not be subject to denial for having less than 14 months experience.

After initial applications are submitted, CMS affords applicants an additional "courtesy" review and a period in which the applicant may cure its deficiencies. If CMS approves the application, it gives written notice to the applicant that it qualifies as an MA-PD plan. However, if an applicant fails to correct all of the deficiencies, CMS will issue the applicant a Notice of Intent to Deny under the regulations at 42 C.F.R. §422.502(c)(2).[12] 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 CFR 422.660 and/or 423.650. The regulations provide that at a hearing, the applicant has the burden of providing 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 the Part D program.

In this case, the Plan submitted its applications for the SAEs in February 2014. The Plan 2014 MA/PD App 6 (H1660) and App 7(H6750) involved service area expansion (SAE) requests for the two respective coordinated care plans.[13] The Applicant's SAEs proposed to expand to seven counties in Massachusetts, Maine and New Hampshire. Pursuant to the SAE application, a plan must attest that the MA plans currently offered by the Applicant, Applicant's parent organization or subsidiary of the Applicant's parent organization have been operational since January 1, 2013 or earlier. In this case the Plan answered "No." for both SAE applications that neither the Applicant, Applicant's parent organization, nor the subsidiary of the Applicant's parent organization has been operational since January 1, 2013, or earlier.

In March 18, 2014 and April 1, 2014, CMS sent the Plan separate Deficiency Notices, respectively, for its Part C and Part D SAE applications citing the Plan's failure to have at least 14 months of performance history with the Part C and Part D programs as of the application date. The subsequent Notices of Intent to Deny were issued April 28, 2014 for both applications stating that the Applicant had attested

---

[12] See similar language for Part D at 42 C.F.R. §423.503(c)(2).

[13] The Contract H1660 covers the counties of Suffolk, Norfolk, Bristol and Worchester, MA and York and Cumberland in Maine. The Contract H6750 covers the counties of Rockingham, Hillsborough and Merrimack in New Hampshire.

that the organization did not have the necessary 14 months of performance data immediately preceding the applicant date and therefore was not eligible to apply for new products or a SAE at this time.[14] Finally on May 28, 2014, CMS sent the Plan the final Denial Notices of its Part C and Part D SAE applications H1660 and H6750. CMS denied the requests, finding that the Applicant was not eligible for the SAEs at this time as the Plan did not have the necessary 14 months of performance data immediately preceding the applicant date required at that time to expand, as attested on the applications.

After a review of the record and applicable law and policy, the Administrator finds that the CMS Hearing Officer properly upheld CMS' denials of the Plan's SAE applications for Part C and Part D on the grounds that neither the Plan, nor its parent organization, had the required 14 months performance data immediately preceding the application deadline as required by CMS instructions and regulations. The record shows that it is undisputed that neither the Plan, nor the parent organization, had an existing contract with CMS that was in effect as of January 1, 2013. Further, CMS provided sufficient and repeated notices in the *Federal Register* (through notice and comment rulemaking) and in Memorandum Guidance for Applicants prior to the Plan's initial MA/PD applications to reenter the program of this rule that CMS had adopted the authority to deny an application with less than 14 months of performance data and the important reasons for such a policy.[15] All organizations in such a situation would only have two months of data upon which to evaluate an entity's performance, which CMS found to be inherently inadequate. In establishing its authority to deny applications for this reason, CMS notably did not set forth exception criteria, under which all such applicants, that are otherwise equally presenting only two months of data from immediately preceding the deadline, could meaningfully and similarly demonstrate they were able to comply with the Part C and Part D requirements for the existing contract prior to allowing for expansion.

The Plan is requesting an exception not only to the 14 months of data but also to the CMS performance methodology when it requests that CMS rely on alternative means to qualify its past performance. CMS has developed a specific performance

---

[14] The Part D Notice erroneously referred to the Plan's failure to comply with the current or prior year contract, but correctly pointed out that it could not be cured.

[15] While the Plan suggests that CMS has the discretion to use alternative methods or data to evaluate a plan's ability to expand its Medicare operations, even *assuming arguendo* such discretionary authority exist to replace the requisite 14 months of performance data, the Plan knowingly risked that CMS might not use such discretion in the later year application when it failed to include such areas and types in its initial application, nor did the Plan offer a rigorous analysis of the performance data it proposes should be used as an alternative.

methodology, which has been subject to comments, under which all plans are evaluated. Just as the regulation has not created an exception process for the 14 months of performance data analyzed under the CMS performance methodology, the regulation or Guidance does not provide for the consideration of older performance data under prior contracts or routine, post-contract activities (e.g., reconciliations or claims adjudications) as alternative data to be used to evaluate a plan's performance.

CMS rationally balanced, *inter alia*, the need to protect Medicare beneficiaries and allow the most able of performing organizations to serve them (as demonstrated by their actual performance under the MA/PD contract), over any advantage to providing more immediate additional choice to those same beneficiaries. CMS has also established consistent performance standards applied to the same period of data for all plans to ensure a meaningful consistent performance methodology. Finally, the Plan was given sufficient notice of such a policy with respect to the 14 months of performance to plan accordingly when making its initial application. In sum, the Administrator finds that the CMS denials of the Plan's SAE applications were consistent with the facts and law and that the CMS Hearing Officer affirmation was proper.

Decision

The Administrator affirms the decision of the CMS Hearing Officer in accordance with the foregoing opinion.

THIS CONSTITUTES THE FINAL ADMINISTRATIVE DECISION OF THE SECRETARY OF HEALTH AND HUMAN SERVICES

Date: 9/4/14

Marilyn Tavenner
Administrator
Centers for Medicare & Medicaid Services