CENTERS FOR MEDICARE AND MEDICAID SERVICES

Hearing Officer Decision

In the Matter of:

WellCare Health Plans of New Jersey, Inc.	*	Docket No.: 2014 MA/PD App. 10
	*	(SAE Parts C and D)
	*	Docket No.: 2014 MA/PD App. 11
	*	(SNP)
Contract Year 2015, Contract No. H0913	*	

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 Officers designated by the CMS Administrator to hear this case are the undersigned, Benjamin R. Cohen and Brenda D. Thew.

Issue

Whether CMS' denial of WellCare Health Plans of New Jersey, Inc.'s (WellCare) applications for service area expansion (SAEs) of its Part C and D operations, as well as its applications to add special need plan (SNP) offerings to its contracts, was consistent with the requirements of 42 C.F.R. §§ 422.501 and 422.502 and/or 423.502 and 423.503.

Statutory and Regulatory 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.[1] The Medicare Prescription Drug, Improvement, and Modernization Act of 2003 made changes to MA 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

[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)(1).
[4] *Id.*

must offer an outpatient prescription drug benefit (Part D) in the service areas in which it offers a Part C benefit.[5]

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.[6] 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.[7] CMS reviews applications from those entities to determine whether they meet the application requirements to enter into an MA-PD contract.[8]

If CMS denies a MA-PD application, the applicant organization is entitled to a hearing before a CMS Hearing Officer.[9] The regulation at 42 C.F.R. § 422.660(b)(1) dictates 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]."[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]

Application Process and Past Performance Evaluation

CMS has the regulatory authority to set the form and manner for the submission of applications by entities seeking to qualify as a MA organization offering a MA or MA-PD plan.[12] Specifically, CMS requires that applications be submitted through the Health Plan Management System (HPMS) and in accordance with instructions and guidelines that CMS may issue. Entities seeking to offer a new MA product or a SNP[13] must demonstrate that they meet regulatory qualifications. Those qualifications include appropriate State licensure, sufficient administrative capability to oversee the plan offerings, the capacity to enroll and dis-enroll beneficiaries, demonstrating that they hold contracts with a sufficient number and variety of medical service providers to ensure that all covered Medicare services will be available and accessible to their enrollees, and maintaining a minimum enrollment of beneficiaries.[14] Those organizations seeking to expand the service area of a current contract (through a SAE application) must demonstrate that they have the licensure and contracted provider network required to offer Medicare benefits consistent with Part C requirements in the new service area.[15]

---

[5] 42 C.F.R. § 422.4(c)(1). *See generally* 42 U.S.C. § 1395w-112 (Medicare Part D).
[6] 42 U.S.C. § 1395w-27.
[7] 42 C.F.R. Part 422 Subparts I – N. The analogous provisions 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.
[8] *See* 42 C.F.R. §§ 422.501, 423.502.
[9] 42 C.F.R. § 422.660.
[10] The regulations at 42 C.F.R. §§ 422.501-502 and 423.502-503 establish the contract application requirements and review procedures.
[11] 42 C.F.R. § 422.688.
[12] 42 C.F.R. § 422.501(b)-(c).
[13] A special needs plan is officially referred to as a "Specialized MA Plan for Special Needs Individuals." 42 C.F.R. § 422.4.
[14] 42 C.F.R. §§ 422.501, 422.503.
[15] CMS Reply at 2.

In addition, as noted above, applicants must demonstrate that they meet all Part D program requirements to qualify as an MA-PD sponsor in their proposed service area.[16] Current MA-PD organizations seeking to expand the service area in which they provide benefits must complete two SAE applications—a coordinated care plan SAE application addressing MA (Part C) requirements, and a Part D SAE application addressing prescription drug benefit plan requirements.[17]

After receiving a MA-PD application, CMS makes a determination as to whether the applicant organization meets all of the relevant program requirements. This determination is based solely on information contained in the application or obtained by CMS through methods such as onsite visits.[18]

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. CMS may deny an application based on the applicant's failure to comply with a Part C or Part D 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 contractor.[19]

The text of the controlling regulation at 42 C.F.R. § 422.502[20] reads, in pertinent part:

> *(b) Use of information from a current or prior contract.*
>
> (1) …if an MA organization fails during the 14 months preceding the deadline established by CMS for the submission of contract qualification

[16] 42 C.F.R. § 422.500(a) and Part 423.
[17] CMS Reply at 2.
[18] 42 C.F.R. § 422.502(a).
[19] 42 C.F.R. §§ 422.502(b), 423.503(b).
[20] *See* analogous provision for Part D at 42 C.F.R. §423.503(b).

In the Preamble to the 2010 Proposed Rule, CMS further explained the controlling (modified) regulation.

> As described in § 422.502(b) and § 423.503(b), we may deny an application based on the applicant's failure to comply with the terms of a prior contract with CMS even if the applicant currently meets all of the application requirements. However, we propose to modify § 422.502(b) and § 423.503(b) to state that we will review past performance across all of the contracts held by the applicant.

74 Fed.Reg. 54,634, 54,641 (Oct. 22, 2009).

The Hearing Officers further note that in the Preamble to the 2010 Final Rule, CMS also stated:

> Our denial of an application based on an applicant's past contract performance is a reflection of our belief that an organization demonstrating significant operational difficulties should focus on improving its existing operations before expanding into new types of plan offerings or additional service areas.

75 Fed.Reg. 19,678, 19,685-86 (Apr. 15, 2010).

> 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.

The regulation at 42 C.F.R. §§422.504(m)(1)[21] states:

> (1) CMS may determine that an MA organization is out of compliance with a Part C requirement when the organization fails to meet performance standards articulated in the Part C statutes, regulations, or guidance.

Subregulatory Instructions

On January 15, 2014, CMS released its 2015 Application Cycle Past Performance Review Methodology Update (2015 Methodology)[22] which outlined the framework of its past performance review methodology:

> 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.
>
> ***Review Period***
> 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 2012 Application Review Cycle is January 1, 2010 through February 28, 2011.[23]
>
> * * *
>
> ***Performance Categories and Negative Performance Points***
> For the 2015 Application Cycle, we have established 11 distinct performance categories. We carefully analyze the performance of all contracts in each performance category and assign "negative points" to

[21] *See* analogous provision for Part D at 423.505(n)(1)
[22] Applicant Exhibit 6.
[23] *Id*. at 6.

> contracts with poor performance in that category. The number of potential negative points corresponds to the risk to the program and our beneficiaries from deficient performance in that particular area.
>
> The 11 performance categories that are included in the review for the 2015 application cycle include:
>
> 1. **Compliance Letters** (i.e., Notices of Non-Compliance, Warning Letters, and Corrective Action Plans (CAPs))
>
> * * *
>
> **3. Multiple Ad Hoc Corrective Action Plans (CAPs)** (i.e., findings of egregious violations that were discovered outside of the audit process, such as through beneficiary complaints)
>
> 4. **Ad Hoc CAPs with Beneficiary Impact** (i.e., CAPs where the compliance violation hindered health (e.g. denial of healthcare services or prescription drugs) or financial condition (e.g. charging of incorrect premiums or cost sharing) [24]

In explaining how it applies its criteria for issuing these compliance notices (NONCs, Warning Letters and CAPs), CMS stated:

> CMS may issue a range of compliance notices to document contracting organizations' non-compliance with Medicare program requirements. CMS determines the nature of each instance of non-compliance by identifying and weighing a range of factors, including the duration of the conduct, the significance of the applicable program requirement and whether the organization reported the conduct to CMS. Because instances of non-compliance usually involve a unique set of facts, our process for determining the severity of compliance notices is based more on the fair application of a broad set of principles to those facts rather than a set methodology. [25]

The 2015 Methodology contains the additional description for multiple ad hoc CAPs as follows:

> Using the dataset developed for the Compliance Letter category, we identify all contracts that received more than one ad hoc compliance CAP during the performance period (or shortly after the performance period to the extent that the non-compliance occurred during the performance period). Ad hoc compliance CAPs are relatively rare and are typically issued only when other forms of intervention have failed to correct a problem and/or the problem was especially egregious. Receiving more

[24] *Id.* at 7.
[25] *Id.* at 4. Emphasis added.

> than one such CAP during a performance period is a powerful indication of ongoing performance problems. All contracts meeting the criteria in this category receive 1 negative performance point.[26]

Likewise, the 2015 Methodology contains the additional description regarding ad hoc CAPs with beneficiary impact as follows:

> Ad hoc compliance CAPs can be issued for numerous reasons. Some CAPs are related, directly or indirectly, to a beneficiary's experience with the services and protections the contracting organization is required to provide, while others are not. An example of a CAP we previously issued that does not present a significant threat to beneficiaries (and therefore, no beneficiary impact as defined here) concerns late reporting of financial information to CMS. The non-compliance in this instance involves largely administrative aspects of the Medicare program that, while crucial to the overall administration of the Medicare program, do not relate to beneficiaries' day-to-day use of the Medicare benefit. In contrast, an example of a CAP where there is beneficiary impact concerns proper administration of the organization's beneficiary call center. Other CAP topics that are associated with beneficiary impact and are therefore counted under this category include: 4RX data submissions to CMS, enrollment and disenrollment processing, application of correct low income subsidy (LIS) status for plan members, volume of member complaints logged into CMS' Complaints Tracking Module (CTM), failure to provide appropriate Part D drugs, failure to apply safety edits when processing claims, processing of member appeals and grievances, marketing abuses, overall failure to appropriately administer the Part D benefit, execution of benefit coverage determinations, and formulary administration.
>
> We extract from HPMS each individual CAP issued during the performance period (or shortly thereafter for conduct that occurred during the performance period) and assess it to determine whether the non-compliance stated in the CAP request should be characterized as conduct that had a beneficiary impact. Because organizations that have experienced such problems represent more of a performance risk, all contracts meeting the criteria in this category receive 1 negative performance point *for each issued CAP* that had beneficiary impact.[27]

In calculating scores under the 2015 Methodology, CMS states the following:

> ***Summary of Negative Point Values and Calculation of Contract-Level Scores***

[26] *Id.* at 10.

[27] *Id.* at 10-11. Emphasis added. *See* Exhibit 6 at 11 n. 6 ("CAPS indicate in the body of the letter if the issue was related to beneficiary experience (i.e. will be considered to have beneficiary impact for this purpose)."

The results of the analyses described above are then compiled in separate Part C and Part D tracking spreadsheets. A contract is assigned the designated number of negative performance points in each category where it is deemed deficient according to the results of the analysis. Otherwise, the contract receives a score of 0 for the particular category. We sum the results across the performance categories to calculate a total negative performance score. Higher scores indicate evidence of performance problems across multiple and varied and/or high risk dimensions. Table 3 on the following page summarizes the negative performance points associated with each performance area.

Summarizing Results at the Contracting Organization (Legal Entity) Level

While the analyses described above are conducted at the contract level, it is necessary to summarize the results at the legal entity level. Frequently a contracting organization (i.e., a licensed, risk-bearing legal entity) holds multiple contracts with CMS. In turn, some parent organizations own numerous legal entities, each of which hold one or more CMS contracts. We summarize the contract-level performance results at the contracting organization level by assigning to a contracting organization the highest point value assessed for each performance area among all of the contracts held by that organization.

…Contracting organizations with high negative performance scores (according to the cut-offs described below) are checked to see if they are applying for an initial contract or a service area expansion. Such applications are denied.

Additionally, we identify applying contracting organizations with no prior contracting history with CMS (i.e., a legal entity brand new to the Medicare program). We determine whether that entity is held by a parent of other Part C or D contracting organizations. In these instances, it is reasonable in the absence of any actual contract performance by the subsidiary applicant, to impute to the applicant the performance of its sibling organizations as part of CMS' application evaluation.

Negative Performance Point Thresholds

In determining those organizations that have significant performance problems, we established a contracting organization threshold of 4 negative performance points for Part C and 5 negative performance points for Part D. The difference is due to a larger number of applicable categories where points may be accumulated by Part D sponsors (e.g., formulary or LIS specific categories). It is sufficient to reach the

> designated threshold for either the Part C or Part D analysis to be considered an overall poor performer.
>
> These cut-offs were established to identify organizations that were outliers in at least one serious performance category (e.g. a current sanction) or in multiple performance categories. While even 1 negative performance point indicates a contract's "outlier" status in an important performance area, we established 4 or 5 points as the minimum total score for identifying those organizations with performance problems significant enough for us to take definitive action, such as denying expansion applications. This allows us to concentrate on those organizations that are either performance outliers in multiple categories or otherwise represent a high risk to the program. That said, we reserve the flexibility to increase the threshold values as necessary to account for shifts in the underlying performance categories and their associated point values to ensure that the analysis continues to identify true outliers. [28]

Medicare Plan Finder Tool

Medicare's open enrollment period runs from October 15 through December 7 each year with new coverage beginning on January 1 of the following year. The Medicare Plan Finder web tool, https://www.medicare.gov/find-a-plan/questions/home.aspx, helps consumers search for and compare Medicare health and drug plans in a beneficiary's area. Consumers can use the web tool to obtain information about coverage and benefits available from various plans; costs for premiums, copayments, deductibles and/or coinsurance; and costs not covered by insurance. In addition, beneficiaries can obtain a personalized cost estimate for their prescription drugs under several Medicare plans by entering their zip code, their prescription drugs and dosages for each, and the pharmacies they prefer to use.[29]

In its Reply Brief, CMS provided further information regarding its Medicare Plan Finder tool, stating:

> CMS first developed the Medicare Prescription Drug Plan Finder (now called the Medicare Plan Finder – MPF) in the fall of 2005 for beneficiaries to evaluate their Part D plan options during the program's first open enrollment period for Part D. The MPF provides beneficiaries with a searchable database through which they can enter the locations where they may have outpatient prescriptions filled (for many beneficiaries, this may be a location other than their primary residence as they may regularly visit family in another state or spend winter months in warmer climates, referred to as "snowbirds") and the medications that they regularly take. The search results will show a beneficiary the drug prices he can expect to pay at the pharmacies located in the desired areas under different Part D plans. The MPF is populated by data provided by all Part

[28] *Id.* at 16-18.
[29] CMS Reply Brief at 4-5. *See also* CMS Exhibit D.

D sponsors according to instructions provided by CMS. Exhibit A. The MPF remains on display throughout the year, and Part D sponsors must regularly update their plan information every two weeks according to a CMS-published schedule. Exhibit B. Generally, sponsors must submit their drug pricing information two weeks prior to the date on which the information is posted for public view on the MPF. The drug pricing information includes a full representation of the sponsor's contracted pharmacy network. Exhibit A, p. 12. During those two weeks, CMS reviews the submitted data, using an outlier methodology to identify submissions that may be inaccurate. Exhibit C. CMS contacts organizations whose submissions are flagged during the quality review for confirmation that their data is correct. If a sponsor cannot confirm the accuracy of its data or does not respond to CMS' inquiry, CMS suppresses that sponsor's plan information from display on the MPF, pending a corrected data submission. Exhibit A, p. 7. Suppression means that a plan's pricing information (including pharmacy network) is removed from the website and the enrollment button beneficiaries normally may use to elect a plan directly is disabled. Exhibit D, last question, p. 2.; Applicant's Exhibit 11, p. 12.

All beneficiaries may elect MA and Part D plans during the annual election period (AEP), which runs from October 15 through December 7 each year. §422.62(a)(2)(iii), §423.38(b). For most beneficiaries, this is the only opportunity during the year when they may elect a new MA or Part D plan. (Some categories of beneficiaries may make elections at other times, including individuals that become Medicare-eligible in mid-year and those that qualify for special help based on low income.) [30]

STATEMENT OF FACTS

Timeline of Relevant Events—MPF Display and Corrective Action Plan[31]

On November 12, 2013, CMS was contacted by a pharmacist/manager at Mills Cashway Pharmacy ("Mills Cashway") in St. Martin Parish, Louisiana.[32] The pharmacist stated that his pharmacy had a contract to participate in WellCare's Part D network, but that it was not displayed as such on Medicare.gov (which contains the MPF) or on WellCare's own website or published marketing materials.[33] On November 18, 2013, CMS contacted Third Party Station, a pharmacy services administrative organization (PSAO), which was authorized to make pharmacy contracting arrangements on behalf of a number of pharmacies, including Mills Cashway.[34] Third Party Station confirmed for CMS, on the same day, that 16 of its client pharmacies, including Mills Cashway, had executed network participation agreements with

[30] CMS Reply Brief at 4-5.
[31] Timeline derived from CMS Brief 5 -6.
[32] CMS Exhibit E1.
[33] *Id*.
[34] CMS Exhibit E2.

WellCare but had complained to Third Party Station that their locations were not listed in WellCare's Part D public materials.[35] Based on that information, CMS began its own analysis of the accuracy of WellCare's MPF network by comparing WellCare's MPF pharmacy network to the list of Part D contracted pharmacies WellCare provided to the CMS Atlanta Regional Office (RO) on November 21, 2013.[36] CMS also asked WellCare, on November 21, 2013, for confirmation that Mills Cashway was a participant in WellCare's Part D network. WellCare provided confirmation on the same day.[37] Based on that information and CMS's verification that Mills Cashway was not listed in WellCare's MPF pharmacy network, on November 22, 2013, CMS immediately suppressed WellCare's information from display on the MPF.[38]

During the same time frame but on a separate track, the CMS Atlanta RO had been communicating with WellCare about issues related to its pharmacy benefit manager (PBM), including its MPF pharmacy listing. In response to an RO inquiry, WellCare stated on November 22, 2013, that approximately 1300-1500 pharmacies had been omitted from its MPF submission but that the updated file it had submitted on November 12, 2013, for display on November 25, 2013, was correct.[39] Relying on that assurance, CMS ended WellCare's MPF suppression on November 25, 2013.[40]

On November 26, 2013, CMS asked WellCare for the exact number of pharmacies that had been omitted from the MPF.[41] WellCare stated in reply the same day that its PBM subcontractor, Catamaran, knew about the inaccuracies in the displays of WellCare's Part D pharmacy network on October 18, 2013, but did not inform WellCare of the issue until November 7, 2013.[42] In the same message, WellCare stated that 1,245 pharmacies had been omitted in error from WellCare's MPF network listing. Having conducted its own analysis of WellCare's pharmacy network data, CMS believed that the number of omitted pharmacies was higher than the 1,245 identified by WellCare and asked, on December 10, 2013, whether WellCare had conducted any further analysis of its network.[43] WellCare replied that same day, stating that it would conduct an audit of its MPF pharmacy file on December 13, 2013.[44] On January 15, 2014, CMS inquired about the results of the audit. WellCare replied the next day stating that the audit revealed that in fact 3,380 pharmacies[45] had been left out of its MPF submissions and that this information had been disclosed to the RO on January 3, 2014.[46] On January 22, 2014, CMS requested a further update. WellCare replied on the same day stating that it found no additional problems beyond what the internal WellCare audit had found, and that its January 21, 2014 MPF submission was accurate.[47]

---

[35] *Id.*
[36] CMS Exhibit E3.
[37] CMS Exhibit E4.
[38] CMS Exhibit E5.
[39] CMS Exhibit E6.
[40] CMS Reply Brief at 6.
[41] CMS Exhibit E7.
[42] *Id*. at 3.
[43] CMS Exhibit E8.
[44] *Id.* at 4.
[45] Specifically, WellCare reported "1,888 pharmacies missing from plan finder . . . and 1,492 pharmacies that were not loaded into the new Catamaran platform (RxClaim)." CMS Exhibit E8 at 2.
[46] CMS Exhibit E8.
[47] *Id.*

On February 27, 2014 CMS issued to WellCare a Request for Corrective Action Plan (CAP), based on Part D non-compliance that had beneficiary impact, which stated:

> The Centers for Medicare & Medicaid Services (CMS) is issuing this request for the development and implementation of a corrective action plan (CAP) to WellCare Health Plans, Inc., which operates through its subsidiaries the Medicare Advantage-Prescription Drug (MA-PD) and Medicare Prescription Drug Plan (PDP) Sponsor contracts listed above, in response to its failure to comply with Part D requirements concerning the representation of its contracted pharmacy network in reports to CMS for use in populating the Medicare Plan Finder (MPF). WellCare's pharmacy network errors also prevented its plan members from receiving point-of-sale coverage for Part D drugs at certain network pharmacies.
>
> Part D sponsors must provide CMS with information necessary to facilitate a process for current and prospective beneficiaries to exercise choice in obtaining prescription drug coverage. 42 C.F.R. §§ 423.48 and 423.505(f)(2). Pursuant to that authority, CMS collects pharmacy network and drug pricing information from Part D sponsors to maintain the Medicare Plan Finder (MPF), a searchable website where beneficiaries can find information about a PDP's network pharmacies in their area and the prices they can expect to pay for Part D drugs under sponsors' plans. CMS routinely provides instructions to Part D sponsors on the process for submitting their pharmacy network and drug pricing information, including the "2014 Drug Pricing Guidelines and Calendar" released on April 26, 2013. According to these instructions, sponsors were required to begin submitting their CY 2014 network and pricing information on September 9, 2013, to allow the MPF to display information beneficiaries needed to select a Part D plan during the annual election period (AEP) that began on October 1, 2013. On page 12 of the instructions, CMS noted that sponsors' submissions were to include a full representation of their contracted Part D networks. CMS also advised sponsors on page 7 that we would review all MPF submissions and would suppress from display information about plans whose data submission was incorrect. We adopted this policy to prevent beneficiaries from relying on incorrect information in making their plan election for the upcoming benefit year.
>
> In November 2013, some pharmacies contacted CMS with their concern that they had signed contracts to participate in WellCare's Part D network but were not listed as WellCare pharmacies on the MPF. When CMS brought this complaint to WellCare's attention, it acknowledged in a November 26, 2013, message that its pharmacy benefit manager, Catamaran, first received complaints from pharmacies omitted from WellCare's MPF display on October 18, 2013. Catamaran determined that approximately 1,200 WellCare pharmacies had been omitted from its data

submission for the CY 2014 plan year. Catamaran did not alert WellCare until November 7, 2013, to the fact that its CY 2014 MPF submissions to that point had failed to include approximately three percent of the WellCare Part D pharmacy network until November 7, 2013. WellCare never reported the matter to CMS, allowing pharmacy network information it knew (through its delegated entity, Catamaran, the performance of which WellCare is accountable according to 42 C.F.R. §423.505(i)(1)) to be incorrect at least as early as October 18, 2013, to remain displayed on the MPF during the AEP. Also, in a later communication to CMS on January 22, 2014, WellCare stated that an audit it conducted in December 2013 identified 1,888 discrepancies between its actual contracted pharmacy network and the information it provided for the MPF. In the same message, WellCare stated that its MPF submission discrepancies continued after January 1, 2014, as its December 2013 audit methodology failed to account for 1,492 of its network pharmacies.

As noted above, CMS has instructed all Part D sponsors that their information will be suppressed from display on the MPF upon a determination that the submitted information is incorrect. WellCare avoided this consequence during the AEP, when beneficiaries most rely on the information displayed on the MPF, by failing to disclose to CMS the information it had concerning its inaccurate MPF submissions.

The confusion surrounding WellCare's pharmacy network had beneficiary impact beyond the provision of incorrect information to beneficiaries. In response to an inquiry from CMS based on beneficiary complaints we had received, WellCare also reported in February 2014 that it rejected approximately 950 Part D claims between January 1 and January 9, 2014, when its claim processing system failed to recognize certain contracted pharmacies as members of the WellCare network and denied claims for Part D drugs submitted by WellCare plan members. In these instances, WellCare failed to comply with the requirement stated at 42 C.F.R. § 423.505(b)(17) that it provide Part D benefits by means of a point-of-service (POS) system to adjudicate drug claims in a timely and efficient manner.

Consistent with CMS' authority at 42 C.F.R. §§ 423.507(b)(3) and 423.509(c), we request that your organization develop and implement a CAP designed to ensure that your organization will develop and implement a plan for coming into and maintaining compliance with Part D requirements concerning the accurate reporting of MPF data, the production of pharmacy directories, the payment of claims at point of sale for network pharmacies, and the effective oversight of delegated entities. CMS will continue to monitor your organization's performance and will

consider the CAP closed when it is demonstrated that your organization has come into compliance with the identified program requirements.

We appreciate your organization's prompt attention to this matter. Should your organization fail to come into compliance in a timely manner, CMS may consider taking enforcement actions in the form of intermediate sanctions (e.g., the suspension of marketing and enrollment activities) or civil money penalties pursuant to our authority under 42 C.F.R. 423, Subpart O or the issuance of a contract termination notice pursuant to 42 C.F.R. 423, Subpart K.

Please be aware that this CAP request will be included in the record of your organization's part Medicare contract performance, which CMS will consider as part of your review of any application for new or expanded Medicare contracts your organization may submit. For past performance analysis purposes, **this is considered a Part D issue with beneficiary impact.** In issuing this CAP request, CMS considered that WellCare failed to self-disclose this matter.[48]

Procedural History - SAE and SNP Applications and Basis for Denial [49]

In November 2013, WellCare submitted a Notice of Intent to Apply for a SAE and SNP for contract year 2015 under its MA-PD contract Number H0913. In February 2014, WellCare submitted two SAE applications (each SAE application included an one each for MA, Part D, and SNP), seeking approval to expand its MA-PD services into Bergen, Somerset, and Union counties, and an initial SNP application to offer a SNP product in Bergen, Essex, Hudson, Middlesex, Passaic, Somerset, and Union counties.[50]

On April 14, 2014, CMS provided to WellCare Health Plans, Inc., the parent organization to WellCare, the result of its analysis of the past Medicare contract performance of all the parent organization's subsidiaries using the 2015 Methodology.[51] Among other things, CMS stated that WellCare was a past performance outlier and therefore CMS would not approve its pending SAE and SNP applications. CMS posted details of the scoring methodology on HPMS, including the information that WellCare received five negative performance points based on its Part D-related performance.[52] CMS assigned WellCare two points for the number and type of compliance notices it received, one point for receiving multiple ad hoc CAPs, and two points for each of the two CAPs for non-compliance that had beneficiary impact. The five points placed it at the threshold CMS established in the 2015 Methodology for identifying Part D sponsors as compliance outliers. [53]

[48] Applicant Exhibit 7. Emphasis added.
[49] Procedural History derived from CMS Reply Brief at 4. *See also* Applicant Exhibit 25.
[50] CMS Reply Brief at 4.
[51] Applicant Exhibit 5A.
[52] Applicant Exhibit 5B.
[53] Derived from CMS Reply Brief at 4.

On April 28, 2014, CMS issued notices of intent to deny all of WellCare's SAE applications based on WellCare's failure to comply with a current or previous year's contract.[54] On May 28, 2014, CMS issued two denial notices (one addressing the MA and Part D applications, the other addressing the SNP application) to WellCare.[55] WellCare filed a timely appeal of CMS' denial of its applications.

Contentions

Introduction

The Hearing Officers note there does not appear to be a dispute as to the historical events or material facts in this case. In general, WellCare has appealed because CMS denied WellCare's applications on the grounds that WellCare failed to comply with the Part D provisions of its Medicare contracts during the 14 months prior to the submission of the 2015 Part C and D SAE and SNP Applications. Fundamentally, WellCare is contesting CMS' decision (1) to issue the February 27, 2014 CAP and (2) that the CAP itself, if appropriately issued, was properly characterized as addressing a Part D non-compliance issue that had beneficiary impact. As a direct result of the February CAP with beneficiary impact, CMS assigned WellCare two of its five total negative past performance points which, under the 2015 Methodology, required CMS to deny WellCare's SAE and SNP applications**.** Specifically, CMS assigned WellCare a point for in the Multiple Ad Hoc CAPS category and a point in the Ad Hoc CAPS with Beneficiary Impact category.[56]

WellCare's Contentions

WellCare contends that CMS must follow its own rules and practices consistently in similar situations. It argues that in issuing a CAP with beneficiary impact to WellCare, CMS has treated WellCare differently and more harshly than other plans that have had similar performance issues or even higher error rates in MPF data submissions.[57] Outlining the criteria for issuing a compliance letter, WellCare points out that CMS uses three graduated levels of letters (NONCs, warning letters and CAPs) but issued the most severe option to WellCare.[58]

WellCare notes that the CAP cited two violations—inaccurate MPF data and point of sale (POS) denials—but that CMS is not pursuing POS denials as an issue.[59] WellCare maintains that the remaining MPF violation alone does not meets the criteria for a CAP because the inaccurate MPF data issue was not a persistent or continuing problem where other forms of intervention

---

[54] Applicant Exhibit 3A-C.
[55] Applicant Exhibit 4A-B.
[56] WellCare received a separate negative performance point within the Ad Hoc CAP with Beneficiary Impact category and two points in the Compliance Letters category. The three points were unrelated to the subject February 2013 CAP and WellCare does not contest the issuance of such points (Tr.13). Additionally, the February 2014 Ad Hoc CAP at issue, combined with another CAP which is not contested, triggered the issuance of the disputed Multiple Ad Hoc CAPs point.
[57] Applicant Opening Brief 5-9, Tr. 353-356
[58] Applicant Opening Brief at 7.
[59] *See* Tr. at 731.

have failed nor was it an especially egregious problem.[60] Instead, WellCare argues that the MPF issue was caused by a one-time software platform migration project which was fixed.[61]

WellCare contends that the MPF violation is not consistent with the types of issues for which CMS has issued CAPs.[62] It presents evidence of 158 MPF violations addressed by CMS, 156 of which received a compliance letter lower than a CAP. WellCare asserts that CMS issued only two CAPs for MPF violations–one to its plan and one in a much more serious situation.[63] WellCare noted that CMS produced one compliance letter[64] which addressed a situation at least as serious as WellCare, but CMS did not issue a CAP with beneficiary impact.[65] In short, WellCare acknowledges that while every situation is unique, there is no meaningful distinction between its transgression and any other plan that had a data error (which likewise may have caused beneficiary "confusion") yet received a less severe warning.[66]

Arguing that even if it were appropriate to issue a CAP, WellCare contends that CMS should not have classified the CAP as one with beneficiary impact. WellCare presented an analysis demonstrating that only a single beneficiary who was a customer of an erroneously omitted pharmacy may have actually disenrolled as a result of the MPF issue.[67] WellCare emphasized that beneficiaries generally use the MPF as a shopping tool to compare plans during enrollment time as opposed to checking the costs of drugs after enrollment. It explained that the MPF tool, in reality, is never 100% accurate because the data it contains is not "real-time data."[68] WellCare calculated that there is a lag of approximately 14-27 days between the time a plan submits updated MPF pharmacy/pricing data and the time CMS makes that information available on the MPF.[69]

Moreover, a WellCare executive testified that if a beneficiary had a question regarding the pharmacies in the plan he/she had selected, rather than consulting the MPF, the beneficiary would more likely call the plan's customer service line, contact the pharmacy or review the plan's printed directory.[70] WellCare further explained that if a beneficiary's pharmacy was erroneously omitted from the MPF, the MPF would reflect a higher default pricing for the

---

[60] Applicant Opening Brief at 8, Applicant Exhibit 6.
[61] Tr. 347-348.
[62] Applicant Opening Brief at 9-10, Tr. 8-11. *See* WellCare's demonstrative exhibit at 40D in which WellCare outlines the standard as it understands CMS' policies.
[63] The parties note that CMS also issued a CAP for MPF issues to RxAmerica, LLC. CMS explained that it issued the CAP after determining that the prices listed on the MPF for RxAmerica for some medications were incorrect and differed from the prices RxAmerica plan members were actually charged at network pharmacies. Ultimately, CMS referred the matter to the Department of Justice which led to a settlement for deceptive pricing charges. Applicant Opening Brief at 9, CMS Reply Brief at 11.
[64] CMS Exhibit I.
[65] Tr. 356-358.
[66] Tr. 360-362. WellCare also argued that CMS did not consistently apply its policy on failure to self-disclose issues. WellCare analyzed CAPs CMS issued since January 2012 and concluded that the WellCare CAP was the only instance in which CMS specifically considered failure to self-disclose to be an aggravating factor. Applicant Opening Brief at 12. A WellCare executive testified that it was difficult to determine what level of self-reporting CMS expected of a plan. Tr. 110-113.
[67] Tr. 292-299, 363-364.
[68] Applicant Reply Brief at 5.
[69] Tr. 253-255.
[70] Tr. 245.

beneficiary's prescription drugs than would be available from a plan pharmacy. Therefore, WellCare argues, enrolled beneficiaries who shopped at the pharmacies that were erroneously omitted from the MPF were not damaged because they would ultimately pay less than the higher default drug price shown on the MPF.[71]

WellCare claims that CMS' response to the MPF issue demonstrates that CMS did not consider the problem to be significant. Tracing the events that transpired starting at the time CMS was notified of the issue by one of the omitted pharmacies, WellCare argues that CMS could have suppressed WellCare's information on the MPF during the open enrollment period.[72]

CMS Contentions

CMS believes that the CAP issuance was appropriate and that the MPF issue was correctly characterized as conduct that had beneficiary impact; therefore, CMS properly assigned both the Multiple Ad Hoc CAPS and Ad Hoc CAPS with Beneficiary Impact negative past performance points at issue. CMS believes that WellCare's non-compliance was significant because its erroneous data could have caused beneficiaries to pick the wrong plan and/or impact them financially, during the annual election period.[73] CMS states that its past performance methodology provides that CAPs are for persistent problems or very serious concerns that require in-depth and continued monitoring.[74] CMS emphasized that the inaccurate MPF submissions continued over a period of four very critical months and required frequent follow-up from CMS.[75]

CMS comments that the MPF issues alone are enough to support the issuance of a CAP with beneficiary impact and explains that the POS failure issue referenced in the CAP was background.[76]

CMS contends that besides duration of the non-compliance, factors such as criticality, urgency of the requirement and the number of opportunities that a plan has to take a corrective action is relevant when CMS decides whether a CAP should be issued. CMS argues that during the period in question, WellCare had the opportunity to take corrective action every two weeks and made nine submissions, but none of them was completely correct.[77]

CMS also alleges that WellCare's failure to self-report is particularly egregious because the organization (or its agents) knew about the non-compliance, but it failed to report it to CMS at a time when it knew that the consequences of self-reporting would be suppression.[78]

To address WellCare's assertion that it was treated differently than 156 of 158 organizations that did not receive CAPS for MPF issues, CMS provided insight into the process that led to the

[71] Tr. 145-146, 306-309.
[72] WellCare explains that it learned for the first time during preparations for the hearing that CMS in fact suppressed its information for the period November 22-25, 2014. Tr. at 89-90, CMS Exhibit E-5.
[73] Tr. 387-388, 403-405.
[74] Tr. 387-388, 403-405.
[75] Tr. 366.
[76] Tr. 368, 372.
[77] Tr. 385-388.
[78] Tr. 391-393.

issuance of those lower level compliance notices. Generally, for the 625 MA-PD contracts it oversees, CMS conducts data-driven quality assurance checks in which it sets a threshold of a ten percent accuracy rate.[79] That is, if a quality assurance check shows that a plan's information is inaccurate or inconsistent ten percent of the time, CMS sends compliance notices (as opposed to CAPs) and the plan is suppressed.[80] CMS explained that because WellCare's non-compliance level was not high enough to be caught within this ten percent filter, WellCare's information was not automatically suppressed on MPF.[81] CMS recognized that if WellCare's level of non-compliance had been over the ten percent threshold, there ultimately may never have been a CAP warranting beneficiary impact which led to a negative performance point.[82] Regarding WellCare's suggestion that CMS could have elected to suppress for non-compliance earlier (even though WellCare did not reach the ten percent threshold) and thus avoided issuance of the CAP, CMS explains that it chose not to do so because WellCare represented to CMS that it was repairing the issue. Moreover, CMS explained that, at such time, it was foreseeable a plan could complain if it were suppressed despite not hitting the ten percent threshold.[83] CMS contends that WellCare's suggestion that CMS had a duty to suppress WellCare's information so WellCare would not be placed in a position where a beneficiary impact CAP was ultimately issued is not supportable.[84]

Decision

The Hearing Officers find that CMS' denial of WellCare's applications for service area expansion (SAEs) of its Part C and D operations, as well as its applications to add special need plan (SNP) offerings to its contracts, was consistent with the requirements of 42 C.F.R. §§ 422.501 and 422.502 and/or 423.502 and 423.503 and CMS' subregulatory guidance.

The Hearing Officers note that in the February 27, 2014 CAP, CMS identified WellCare's failure to comply with Part D requirements in two respects. Specifically, the CAP referenced inaccuracies in WellCare's MPF submissions to CMS and POS failures that allegedly caused the denial of some WellCare members' Part D drug claims. At the hearing, CMS clarified that the non-compliance that formed the basis for the CAP was the MPF issue and that the POS allegations were provided as background. In return, WellCare argues that as CMS is no longer pursing the POS failure allegation, the MPF issue, standing alone, is insufficient to support a CAP with beneficiary impact. The Hearing Officers observe that the CAP itself does not expressly state whether it was issued on two separate, independent bases or a combination of the POS and MPF issues. The Hearing Officers find, however, that the detailed circumstances surrounding the MPF independently support the issuance of a CAP with beneficiary impact.

The Hearing Officers note that despite the existence of descriptive agency guidance, the determination as to the appropriate level of a compliance notice is not an exact science; rather it inherently requires and necessitates a level of judgment and discretion. Accordingly, CMS formally notified existing MA-PD plans that it may issue one of a range of compliance notices,

[79] Tr. 374.
[80] Tr. 374, 417-421.
[81] CMS explains that under suppression, the basic information regarding the plan is listed, but beneficiaries or potential beneficiaries are unable to find detailed drug related information or enroll. Tr. 438-439.
[82] Tr. 418-422.
[83] Tr. 422-428.
[84] CMS Reply Brief at 11-12.

after identifying and weighing a variety of factors, including the "significance of the applicable program requirement."[85] Further, CMS was clear that each instance of non-compliance involves a "unique set of facts."[86] In the 2015 Methodology, CMS described the nature of an instance of non-compliance that would be sufficient to support a CAP as continuing and/or severe, systemic, persistent, very serious, and/or needing in-depth and continued monitoring by CMS.[87] CMS also explained that CAPs generally are "typically issued only when other forms of intervention have failed to correct a problem and/or the problem was particularly egregious."[88] CMS characterized the nature of non-compliance that results in beneficiary impact as "related, directly or indirectly to a beneficiary's experience with the services and protections the contracting organization is required to provide,"[89] and/or presenting a "threat to beneficiaries' health … or financial condition."[90] CMS provided examples of CAP topics that are associated with beneficiary impact including enrollment and disenrollment processing, call center administration and marketing abuses.[91] The MA-PD functions in these examples impact a Medicare beneficiary's experience, regardless of whether the beneficiary ultimately enrolls in the specific MA-PD plan at issue.

At the hearing, both parties discussed the "significance" of the MPF issue, as CMS references such term in the 2015 Methodology[92] in addressing a CAP with beneficiary impact. The Hearing Officers recognize that the adjective, "significant," may properly be used to describe various degrees of statistical correlation in a continuum ranging from beyond mere chance to measurably large.[93] Contextually, CMS' 2015 Methodology does not place the threshold for a beneficiary impact CAP at the very highest end of the continuum as it references concepts such as the "indirect" "experience" of beneficiaries. Moreover, several of the examples that CMS listed to describe a CAP with beneficiary impact (i.e., marketing, enrollment and call center problems) are akin to WellCare's MPF problems in that they involve a Medicare beneficiary (or a potential plan-enrollee) who is interfacing with the MA organization or its publicly available information.

The Hearing Officers find that it was not unreasonable for CMS to determine that the MPF issue was persistent, continuing and serious. CMS' Central Office received a complaint directly from a pharmacy that had been omitted in error from WellCare's network and thus did not appear on the MPF. CMS quickly learned that other pharmacies that executed network participant agreements were not listed in WellCare's public materials. Moreover, CMS' Regional Office had been communicating with WellCare regarding MPF issues over several critical months. CMS monitored and followed-up regarding WellCare's on-going problems throughout the months leading up to the issuance of the CAP. CMS received multiple assurances from WellCare confirming the accuracy of the MPF data, followed by discoveries, by CMS or WellCare, that the data remained incorrect for thousands of pharmacies.

---

[85] Applicant Exhibit 6 at 4.
[86] *Id.*
[87] *Id.* at 8.
[88] *Id.* at 10.
[89] *Id.* Emphasis added.
[90] *Id.* at 7.
[91] *Id.* at 10.
[92] *See supra*, notes 25, 27, underscored text from 2015 Methodology.
[93] *See Significant definition,* Miriam-Webster.com, http://www.merriam-webster.com/dictionary/significant (last visited Aug. 13, 2014.

The record and testimony reflect that other plans with inaccurate MPF submissions were suppressed by CMS and subsequently received NONCs and warning letters rather than CAPs while WellCare was not suppressed but received the most severe compliance notice. The Hearing Officers recognize the possibility that if the incorrect data submission had initially created a sufficiently large error rate to reach the ten percent filter in CMS' quality assurance checks, WellCare may have been automatically suppressed and not have reached the point of receiving a CAP with beneficiary impact or the additional negative performance points.

The Hearing Officers, however, find that CMS acted within its discretion and in accordance with the 2015 Methodology in issuing the CAP with beneficiary impact to WellCare. The non-compliance continued over a period of four critical months, Well Care's assurances regarding the accuracy of its data were not reliable, continuous monitoring from CMS was required, and the listings for thousands of pharmacies were impacted. Therefore, the Hearing Officers find it was proper for CMS to assess the two negative performance points associated with the February 27, 2014 CAP under the process established in the 2015 Methodology. Accordingly, the Applicant has not proven by a preponderance of the evidence that CMS' denial of its applications was inconsistent with the requirements of 42 C.F.R. Parts 422 and 423 and CMS' sub-regulatory guidance.

Benjamin R. Cohen, Esq.
CMS Hearing Officer

Brenda D. Thew, Esq.
CMS Hearing Officer

August 15, 2014