CENTERS FOR MEDICARE AND MEDICAID SERVICES
Hearing Officer Decision

In the Matter of

Universal Health Insurance Company, Inc.	*	
	*	Docket Nos. 2010 C/D App 11
Denial of Initial Applications, H8098 and H8319	*	and 12
	*	

Jurisdiction

This appeal is provided pursuant to 42 C.F.R. §422.660. The Centers for Medicare and Medicaid Services (CMS) Hearing Officer designated by the CMS Administrator to hear this case is the undersigned, Paul Lichtenstein.

Issue

Whether CMS' denials of the Applicant's MA-PD initial applications for calendar year 2011 were consistent with the requirements of 42 C.F.R. §§422.501 and 422.502.

Procedural Authority

The Social Security Act (SSA or the Act) authorizes CMS to enter into contracts with entities seeking to offer Medicare Advantage (MA) benefits (Part C) and Medicare outpatient prescription benefits (Part D) to Medicare beneficiaries. SSA §§1857 and 1860D-12. Pursuant to 42 C.F.R. §§422.500 and 423.500 et seq.,[1] CMS has established the general provisions for entities seeking to qualify as Medicare Advantage-Prescription Drug (MA-PD) plans. The types of MA plans are delineated at 42 C.F.R. §422.4. The types include Coordinated Care Plans (CCPs) that include a network of providers that are under contract with the organization to deliver services, 42 C.F.R. §422.4(a)(1). CCPs may include health maintenance organizations, provider sponsored organizations and regional and local preferred provider organizations (PPOs). Private Fee-for-Service (PFFS) plans may also participate as MA plans.

[1] CMS has recently revised and/or clarified some, but not all of the regulatory text governing the Part C and Part D programs. *See* Proposed Rule, 74 Fed. Reg. 54634 (October 22, 2009) and Final Rule, 75 Fed. Reg. 19678 (April 15, 2010). The Final Rule states in part that "This final rule makes revisions to the regulations governing the Medicare Advantage (MA) program (Part C) and prescription drug benefit program (Part D) based on our continued experience in the administration of the Part C and D programs. The revisions strengthen various program participation and exit requirements; strengthen beneficiary protections; ensure that plan offerings to beneficiaries include meaningful differences; improve plan payment rules and processes; improve data collection for oversight and quality assessment, implement new policies and clarify existing program policy." The Rule is effective June 7, 2010 and applies from contract year 2011 (the year at issue) forward.

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. *See* 42 C.F.R. §§422.501 and 423.502.

The current regulation concerning the Part C application requirements at 42 C.F.R. §422.501 states, in relevant part:

> (c) Completion of an application.
>
> > (1) In order to obtain a determination on whether it meets the requirements to become an MA organization and is qualified to provide a particular type of MA plan, an individual authorized to act for the entity (the applicant) must fully complete all parts of a certified application, **in the form and manner required by CMS**, . . .
> >
> > (2) The authorized individual must thoroughly describe how the entity and MA plan is qualified to meet, or will meet, **all the requirements** described in this part.

(Emphasis added).

CMS has established an online application process for both Part C and Part D plans called the Health Plan Management System (HPMS). All new applications and requests to expand service areas had to be submitted through the HPMS by deadlines established by CMS. CMS provided training and technical assistance to plans in completing their applications and plan applications were evaluated solely on the materials they submitted into the HPMS by the deadline established by CMS.

The regulation at 42 C.F.R. §422.502 specifies the evaluation and determination procedures for applications to be determined qualified to act as a Part C sponsor. It states, in relevant part:

> (a) Basis for evaluation and determination.
> (1) With the exception of evaluations conducted under paragraph (b) [Use of information from a current or prior contract], CMS evaluates an application for a 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 applicant meets **all the requirements** described in this part. (Emphasis added).[2]

[2] In the preamble to the recent regulatory revision at 75 Fed. Reg. 19678, 19683 (April 15, 2010), CMS indicated 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 applicants 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."

After an applicant files its initial application, CMS reviews the application, notifies the applicant of deficiencies and gives the applicant an opportunity to correct the deficiencies.

If the applicant fails to correct all of the deficiencies, CMS issues the applicant a Notice of Intent to Deny under the regulation at 42 C.F.R. §422.502(c)(2). The regulations at 42 C.F.R. §422.502 states, in relevant part:

> (c) Notice of Determination. * * *
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> (1) Approval of Application. * * *
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> (2) Intent to Deny.
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> (i) If CMS finds that the applicant does not appear be able to meet the requirements for an MA organization and/or has not provided enough information to evaluate the application, it gives the applicant notice of intent to deny the application and a summary of the basis for this preliminary finding.
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> (ii) Within 10 days of the date of the notice, the applicant must respond in writing to the issues or other matters that were the basis for CMS' preliminary finding and may revise its application to remedy any defects CMS identified.
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> (iii) If CMS does not receive a revised application within 10 days from the date of the notice, or if after timely submission of a revised application, CMS still finds the applicant does not appear qualified to contract as an MA organization or has not provided enough information to allow CMS to evaluate the application, CMS will deny the application.[3]

If CMS denies an MA-PD applicant, the applicant has a right to a hearing before a CMS Hearing Officer under 42 C.F.R. §422.660(b). The current Part C regulation at §422.660(b)(i), states, at hearing, the applicant has the burden of proving by a preponderance of the evidence that CMS' determination was inconsistent with the requirements of §§422.501 and 422.502.

Substantive Authority

Statutory and Regulatory Background:

[3] The preamble to the final regulation at 75 Fed. Reg. 19678, 19683 (April 15, 2010) states that "[w]e also proposed to clarify our authority to decline to consider application materials submitted after the expiration of the 10-day period following our issuance of a notice of intent to deny an organization's contract qualification application. . . . Further, we noted that consistent with the revisions to § 422.650(b)(2) and § 423.660(b)(2) [sic §422.660(b)(2) and §423.650(b)(2)], which are discussed elsewhere in this final rule, the applicant would not be permitted to submit additional revised application material to the Hearing Officer for review should the applicant elect to appeal the denial of its application."

The Medicare Improvements for Patients and Providers Act of 2008 (MIPPA), Pub. L. 108-7, modified the statutory provider access standards for some geographic areas served by PFFS plans. Prior to MIPPA, PFFS plans were permitted to meet standards for access to services by establishing a certain level of payment rate for providers that equaled or exceeded the rate under original Medicare or through written contracts with providers.

MIPPA modified these standards by specifying that, in certain counties, PFFS plans would be required to meet the access standards "only through entering into written contracts" with providers "and not, in whole or in part, through the establishment of payment rates . . . ." Pub. L. No. 110-275, § 162 (2008).

On September 18, 2008, CMS amended the access requirements applicable to PFFS plans to reflect the requirements of MIPPA.[4] 42 C.F.R. §422.114(a)(2)(ii). CMS also provided guidance to Medicare Advantage Organizations in a September 15, 2008 memorandum entitled, Guidance for Regulations in CMS 4131-F and CMS 4138-IFC[5] and later, in its January 19, 2010 Memorandum entitled, Transition of Private Fee-for Service Contractors to Network-Based Access Requirements.[6] In its guidance CMS advised PFFS plans that do not meet the network access requirements will be non-renewed at the end of the 2010

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[4] 73 Fed. Reg. 54226, 542330 (September 18, 2008). The preamble states in relevant part, "Specifically, for plan year 2011 and subsequent plan years, MIPPA requires that non-employer/union MA PFFS plans (employer/union sponsored PFFS plans are addressed in a separate provision of MIPPA) that are operating in a network area (as defined in section 1852(d)(5)(B) of the Act) must meet the access standards described in section 1852(d)(4). As noted above, in order to meet the access standards in section 1852(d)(4), PFFS plans must have contracts with a sufficient number and range of providers to meet the access and availability standards described in section 1852(d)(1) of the Act. These PFFS plans may no longer meet the access standards by paying not less than the original Medicare payment rate and having providers deemed to be contracted, as provided under Sec. 422.216(f). Section 162(a)(1) of MIPPA is reflected in regulations at 42 CFR 422.114(a)(3).

. . . .

An existing PFFS plan may have some counties in its current service area that meet the definition of a network area and other counties that do not. In order to operationalize section 162(a)(1) of MIPPA, CMS will not permit a PFFS plan to operate a mixed model where some counties in the plan's service area are considered network areas and other counties that are non-network areas. Beginning in plan year 2011, an MA organization offering a PFFS plan will be required to create separate plans within its existing service areas where it is offering PFFS plans based on whether the counties located in those service areas are considered network areas or not. For example, if an existing PFFS plan has some counties in its current service area that are network areas and other counties that are non-network areas, then in order to operate in this service area in plan year 2011 and subsequent plan years, the MA organization must establish a unique plan with service area consisting of the counties that are network areas and another plan with service area consisting of the counties that are non-network areas. Consequently, the PFFS plan operating in the counties that are network areas must establish a network of contracted providers in these counties in accordance with section 1852(d)(4)(B) of the Act in order to meet access requirements.

. . . .

For purposes of making the judgment of provider network adequacy for PFFS plans that will be required to operate using a network of contracted providers in plan year 2011 and afterwards, we will apply the same standards for PFFS plans that we apply to coordinated care plans." (Emphasis added).

[5] http://www.cms.gov/ManagedCareMarketing/Downloads/MIPPA_Imp_memo091208Final.pdf

[6] http://www.cms.gov/PrivateFeeforServicePlans/

contract year and members of those plans will be disenrolled to original Medicare.[7] In addition, current PFFS plans were required to complete the initial applications process in order to qualify to offer their product to current and new enrollees.[8]

The following regulations were discussed at hearing. The regulation at 42 C.F.R. §422.112 provides the general framework upon which CMS sets criterion, and ultimately evaluates, whether an MA organization has ensured that enrollees will have the requisite access to services. It states in relevant part:

> (a) *Rules for coordinated care plans*. An MA organization that offers an MA coordinated care plan may specify the networks of providers for whom enrollees may obtain services if the MA organization ensures that all covered services, including supplemental services contracted for by (or on behalf of) the Medicare enrollee, are available and accessible under the plan. To accomplish this, the MA organization must meet the following requirements:
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> (1) *Provider network*. (i) Maintain and monitor a network of appropriate providers that is supported by written agreements and is sufficient to provide adequate access to covered services to meet the needs of the population served. These providers are typically used in the network as primary care providers (PCPs), specialists, hospitals, skilled nursing facilities, home health agencies, ambulatory clinics and other providers.
> (ii) *Exception*: MA regional plans, upon CMS pre-approval, can use methods other than written agreements to establish that access requirements are met.
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> * * * * *
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> (3) *Specialty care*. Provide or arrange for necessary specialty care, and in particular give women enrollees the option of direct access to a women's routine and preventative health care services provided as basic benefits (as defined in §422.2). The MA organization arranges for specialty care outside the plan provider network when network providers are unavailable or inadequate to meet an enrollee's medical needs.

Subregulatory Authority

[7] *Id*. at 1.
[8] *Id.* at 3.

On November 20, 2009, CMS issued a memorandum to Medicare Advantage plans entitled Health Services Delivery Network Criteria Reference Tables and Exceptions Guidance. The memorandum[9] indicated, in relevant part:

> As part of the Medicare Advantage (MA) application process, applicant who apply to offer Coordinated Care plans (CCPs) and network Private Fee-For-Service (PFFS) plans must demonstrate that they have an adequate contracted provider network that is sufficient to provide access to covered services, as required by 42 CFR 422.112(a)(1). CMS has developed quantitative criteria and automated the network review process to simplify Health Service Delivery (HSD) submissions and reviews and increase transparency of CMS standards…. Applicants who fail to meet these new criteria must request and be approved for an exception in accordance within the HSD Exception Guidance.

CMS also established MA network adequacy criteria that were measured by the minimum number of providers, maximum travel distances to providers and maximum travel time to providers.[10] In 2011, CMS utilized a new automated criteria check (ACC) in the HPMS to determine whether applicants met the criteria for providers and facilities in each county in their proposed service area.[11]

CMS also issued an exception memorandum[12] that stated the follows:

CMS Health Services Delivery Tables-
Exceptions and Required Documentation for Medicare
Advantage Applicant Plans

CMS recognizes that, under limited circumstances, applicants' networks may not meet the network adequacy criteria for a particular provider/facility type in a specific county. In order to mitigate valid situations in which an applicant's network is not able to meet specific criteria, CMS has incorporated a process for requesting exceptions into the network submission and review process. Applicants can request an exception form the network adequacy criteria where these limited circumstances exist.

To request an exception, applicants must select from the pre-determined exceptions below and submit a narrative explanation, along with formal documentation described in detail below, as to why the standard network adequacy criteria cannot be met for the specific provider/facility type in a specific county. **Applicants will <u>only</u> be able to request exceptions during the initial application submission. Late exception request will not be accepted.**

I.Types of Exceptions

The list of pre-determined provider/facility exceptions include:

[9] CMS Exhibit 2.
[10] CMS Exhibit 3.
[11] *See* CMS Exhibit 1 at 3 and 4.
[12] CMS Exhibit 4.

1. ***Insufficient number of providers/beds in service area –*** This exception would apply in counties where there are insufficient numbers of providers/facilities/beds to meet the standard network adequacy criteria. Please note that this exception cannot be used where the Applicant has merely failed to obtain a sufficient number of contracts for the specific provider/facility type or where a provider/facility has simply refused to contract.
2. ***No providers/facilities that meet the specific time and distance standards in service area –*** This exception would apply in counties where there are no providers/facilities in the service area. Please note that approval of an exception on this basis does not relieve the Applicant from demonstrating access to the specific service provided by the provider/facility type.
3. ***Patterns of care in the service area do not support need for the requested number of provider/facility type –*** This exception would apply in instances where applicants are able to provide sufficient documentation to demonstrate a pattern of care different from CMS' standards.
4. ***Services will be provided by an alternate provider type/Medicare-certified facility –*** This exception would apply where the Applicant has arranged for a different provider/facility type to provide the services at issue. For example, such an exception might be appropriate where the Applicant has insufficient numbers of standard primary care providers (Geriatrician's, Internal Medicine, GPs) but has contracted with another provider type to provide these services and that other provider type is duly licensed or certified to provide these services.
5. ***Alternative Arrangements for Regional PPOs –*** Pursuant 42 CFR 422.112(a)(1)(ii), RPPOs can use methods other than written arrangements: to meet access requirements as approved by CMS. RPPOs will still need to demonstrate that the network overall is comprehensive. This exception can **only** be used by RPPOs.

(Added emphasis underscored).

Factual and Procedural Background

In February 2010, Universal Health Care Group submitted timely applications under its subsidiary Universal Health Insurance Company, Inc. (Applicant) for approval to offer MA-PD products across multiple states.[13] Under the two applications at issue in this case, H8098 and H8319, the Applicant proposed to offer an MA-PD Preferred Provider Organization (PPO) plan and an MA-PD Private Fee-for-Service (PFFS) plan based on identical provider networks in identical service areas consisting of multiple counties in Arizona, District of Columbia, Florida, Georgia, Louisiana, Maryland, Nevada, North Carolina, Ohio, Pennsylvania, South Carolina, Texas, Utah, and Virginia.[14] Based on the final network data submitted by the Applicant, CMS denied these applications for failure to ensure sufficient access to a variety of medical and surgical physician providers as well as facilities.

Prior to the submission of its application, the Applicant participate in the last of the four available pre-checks, using the CMS assessment tool, to determine whether their

[13] The Applicant withdrew its appeal of application number H4529 on July 18, 2010. At the hearing, CMS indicated that it would reverse its denial of application number H 8675. Tr. at 356.

[14] The service area for these two applications initially also included counties in Missouri, though the applicant withdrew these counties along with others in the listed States after being informed by CMS of application deficiencies.

provider/facility network would meet CMS network criteria.[15] With the Applicant's initial submission, it requested exceptions to meeting the standardized criteria for many Medicare utilized medical and surgical specialty types.[16]

On April 6, 2010, CMS sent the Applicant deficiency notices which indicated (among other things) that the organization's applications had deficiencies in meeting network requirements and referenced the online ACC Reports for details on the specific network issues.[17] These reports reflected that the Applicant's network failed to meet the ACC criteria or qualify for an exception for a wide range of provider/facility types in a number of the requested States/Counties. Within the deficiency notices, the Applicant was given specific advice for correcting its exception requests.

The Applicant submitted revised HSD Provider and Facility tables as well as documentation to cure other identified deficiencies during the post deficiency notice submission window. Based on review of this information, on May 5, CMS issued to the Applicant a Notice of Intent to Deny both H8319 and H8098, in part based on the lack of sufficient contracted network to serve the requested service area.[18] With respect to deficient exceptions, the Applicant (as were all other applicants with deficient exceptions)was again given guidance to cure its requests.[19]

On May 14, 2010, before the end of the ten day upload window following the issuance of the Notice of Intent to Deny, the Applicant submitted revised network information and other materials to cure its deficiencies. Also on May 14, 2010, the Applicant dropped identical lists of 75 counties in several states from the service areas from each of the two applications.[20]

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[15] The Applicant attempted to participate in all four pre-checks but encountered technical difficulties. Tr. at 108-113.

[16] *See* CMS Brief at 5.

[17] *See* CMS Exhibit 8 (deficiency notice – H8098), CMS Exhibit 9 (deficiency notice – H8319), CMS Exhibit 10 (H8098 ACC Provider Report based on data submitted 2/24/10 reflecting provider types for which the Applicant's provider network failed to meet the ACC criteria or qualify for an exception and H8098 ACC Facility Report based on data submitted 2/24/10 reflecting provider types for which the Applicant's facility network failed to meet the ACC criteria or qualify for an exception), CMS Exhibit 11 (H8319 ACC Provider Report based on data submitted 2/24/10 reflecting provider types for which the Applicant's provider network failed to meet the ACC criteria or qualify for an exception and H8319 ACC Facility Report based on data submitted 2/24/10 reflecting provider types for which the Applicant's facility network failed to meet the ACC criteria or qualify for an exception).

[18] *See* CMS Exhibits 12, 13 and 14.

[19] *See* CMS Exhibit 14 (CMS indicated that an identical email was sent with respect to H8319. CMS Brief at 8).

[20] CMS Exhibit 15. Testimony at the hearing indicated that CMS permitted applicants until May 15, 2010 to respond to their Notice of Intent to Deny with additional information. After the new information was uploaded and processed, applicants could determine what, if any, counties still did not meet CMS network criteria. CMS, however, permitted applicants until May 19, 2010 to drop counties from their applications. In the instant case, the Applicant uploaded additional information on May 14, 2010, before the May 15, 2010 deadline. The Applicant's May 14, 2010 submission, however, contained a zip code error for one of its acute inpatient hospitals. This error prevented the new information from uploading into the HPMS and generating new ACC Reports. The Applicant did not contact CMS about this error until June 3, 2010. CMS permitted the Applicant to correct the error and accepted the new information in its evaluation of its provider networks because the information was submitted prior to the May 15, 2010 deadline. This explains why the deficiency

On June 7, 2010, CMS sent the Applicant notices that applications H8089 and H8319 were denied based on deficiencies in the cited counties' provider network with respect to service providers/facilities for which exceptions were denied by CMS, and for service providers/facilities for which no exceptions were requested and the contracted network failed to meet the number or time/distance criteria.[21] The ACC Reports indicated that the Applicant's network failed to meet the criteria for 182 specific provider and facility categories in various States and Counties in the proposed service areas for which no exceptions were requested.[22] The ACC Report also indicated that CMS denied the Applicant's exception requests for 95 specialty types in the various States and Counties in the proposed service areas.[23]

The Applicant filed a timely appeal of its denial. A hearing was held on July 27, 2010.

CMS' Contentions

CMS contends that in the 2011 application cycle, it rolled out an enhanced process for assessing MA applicants' network adequacy in order to simplify data submission and increase consistency and transparency of health service delivery reviews.[24] The revised network review continued to focus on ensuring appropriate numbers of providers to support access according to local patterns of care but, whereas the network review was previously done entirely through a manual review of the submitted network data, it would now be done largely through an automated tool within the HPMS. It compared the network data submitted by each applicant against standardized criteria and generated two reports - the ACC Provider Report and ACC Facility report accessible within the system to reflect where the applicant stood at that point with respect to meeting the standardized criteria. The criteria assessed were minimum numbers of providers/facilities and time/distance established in subregulatory guidance.[25]

As the criteria were developed based on data generalized across geographic areas, CMS allowed applicants to request exceptions to meeting the standardized criteria under limited circumstances, for specific provider/facility type and county, if supported by appropriate documentation.[26]

CMS indicated that it held training on submitting network data through the automated review process with slides provided.[27] Applicants were instructed to list contracted providers and facilities along with the each State and County they would be serving. A

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tables generated by CMS are dated June 4, 2010. Unfortunately, the time period allowed for applicants to also modify their service area had already expired and the Applicant could not modify its service area. *See* Tr. at 272 – 285 and CMS Exhibit 26.

[21] *See* CMS Exhibits 17, 18, 19 and 20.

[22] *See* CMS Brief at 9-14.

[23] *See* CMS Brief at14-16.

[24] CMS Exhibits 1 and 2.

[25] CMS Exhibit 3.

[26] CMS Exhibit 4.

[27] CMS Exhibits 1, 5 and 6.

facility need not be located within the county in order for the applicant to rely upon it to serve the county in question, as long as it fell within the required time/distance requirements. In order to establish at the outset which path each provider/facility type in each State/County would follow (i.e., automated review or exceptions review), CMS required that applicants request exceptions when initially submitting the application.[28]

CMS asserts that it provided applicants with four opportunities to participate in "pre-checks" of how their networks fared against the standardized criteria by allowing applicants to submit their network data and have it run through the automated tools. This pre-check further allowed applicants to clarify those provider/facility types and counties for which they required exceptions. Due to technical problems, the Applicant only participated in one of the four available pre-checks.

CMS presented evidence that that the Applicant's ACC reports for both H8098 and H8319 provider network failed to meet either the minimum number of providers/facilities criteria and/or the standardized time/distance requirements for the counties in the requested service areas. Moreover, for a large number of criteria, as the Applicant did not request an exception upon initial submission of the application, it was required to meet the standardized criteria. In short, for each of these provider/facility types in the indicated State/County, the Applicant failed to document that its network included providers/facilities in accordance with CMS access requirements and procedures.

CMS also indicated that in many instances where the Applicant did request an exception, it failed to adequately document that the proposed alternate provider could adequately cover the full range of services which the original provider type could deliver. Pursuant to guidance provided at each step in the CMS review process, applicants were advised that, to support an alternate provider type exception, they needed to document that the alternate provider type could provide the range of services for which patients sought care from the original provider type, that the alternate provider was credentialed to provide these services and held themselves out as providing these services. CMS asserts that the Applicant made inadequate generic assertions as to the qualifications of the alternate providers.[29]

CMS also asserts that on denied pattern of care exception requests, and those Alternate Provider Type exceptions for which the applicant included pattern of care assertions, it failed to support its argument that its network was consistent with the actual pattern of care and that the pattern differed from that reflected by CMS' standardized access criteria.

CMS notes that the Applicant bears the burden of proof at hearing to show that CMS's determination was erroneous and that, based upon the information it timely submitted with its applications, both applications qualified to be approved. However, the network data

[28] CMS Exhibits 1 and 4.

[29] *See* CMS Exhibit 16 - Denied Exception Bases; CMS Exhibit 21 - Documentation submitted by the Applicant in support of deficient exceptions – initial submission; CMS Exhibit 22 - Documentation submitted by the Applicant in support of deficient exceptions – post deficiency submission; and CMS Exhibit 23 (Documentation submitted by the Applicant under H8098 in support of deficient exceptions -- post notice of intent to deny submission.

submitted by the applicant did not meet CMS access criteria across all of the pending counties nor did the supporting exceptions documentation demonstrate that it was entitled to an exception from those criteria.

Applicant's Contentions

The Applicant notes that it has an existing private fee-for service plan and that it non-renewal will have consequences for 11,000 Medicare beneficiaries currently enrolled in its plan and for it business and numerous employees. The Applicant argues that because its PFFS contract with CMS was renewable annually under 42 C.F.R. §422.505 and that it should have procedurally been given notice of non-renewal and the opportunity to file a corrective action plan (CAP) regarding its network adequacy under 42 C.F.R. §422.506. Under this procedure, CMS should have given the Applicant until January 1, 2011, when the new network standards became effective, to come into compliance, instead of inappropriately treating it as an initial applicant.

The Applicant claims that CMS' guidance did not include published standards for assessing provider networks. CMS did not specify which counties it was deficient making it impossible for it to respond properly and/or withdraw counties in which it was deficient. Despite the lack of standards, the Applicant asserts that it took reasonable action, with the assistance of its consultant, to meet CMS' requirements and removed 75 counties from its proposed service area.[30]

The Applicant claims that CMS' denial of its entire application is based on deficiencies in only 9 out of 114 counties.[31] The Applicant asserts that the network that it submitted is adequate "to meet the needs of the population served." 42 C.F.R. §422.112(a)(1).

Specifically, the Applicant assert that under the regulations at 42 C.F.R. §422.112(a)(1) and (3), it met the standards for adequate access to covered services because the regulation recognizes that 100% access may not always be achieved through written contracts and that specialists may be provided by "arranging for" specialty care outside the network. Furthermore, the Applicant claims that CMS' procedures for determining network adequacy were vague, inconsistently applied and constantly evolving throughout the process. While CMS published its criteria for its automated software criteria check in subregulatory guidance in October and November of 2009, the Applicant states that CMS made it clear that its standards did not require 100% compliance and that it modified its criteria of 90% of beneficiaries being within the time/distance standards to a lower standard. As a result, the Applicant was unaware of the actual standard CMS intended to apply. In addition, the Applicant states that further uncertainty regarding the standards was inherent in the exception process under which no clear standards were delineated and

[30] CMS Exhibit 15.

[31] The Hearing Officer notes that the Applicant only referenced the 9 counties actually listed in the Denial Notice under the section relating to exception requests (and the 45 separate specialties in those 9 counties that were denied exceptions). Tr. at 92 -100. The Hearing Officer notes that the Denial Notice generally and appropriately also referenced failures within counties in the two ACC Reports (Provider and Facility Tables), even though no specific counties were explicitly listed in the notices. *See* Applicant Exhibits 3 and 16B.

which could vary by reviewer. Furthermore, the Applicant claims that CMS approved some exception and denied other based on similar requests for exception.[32]
The Applicant also states that CMS' automated review process was new, that the standards were evolving and that CMS used software and information that were not available to plans.[33] The Applicant also indicated that CMS did not provide plans with adequate information or notice to enable plans to effectively amend their applications.[34] The Applicant indicated that in the 2011 application cycle, the Notices of Intent to Deny merely referred to the ACC reports. The ACC Reports indicated whether each provider specialty received a "pass" or "fail" in a particular county but the Applicant indicated that it believed that one did not need to receive a "pass" in every category in order to be approved. As a result, the Applicant claimed that it could not determine from merely reviewing the ACC report whether CMS would consider a particular county to be deficient.

The Applicant indicates that CMS set its automated criteria based on an assessment of the number of providers needed to serve an unrealistic plan size that would be greater than 95% of all MA plans in each county type. The Applicant indicates that setting such a high standard is contrary to reality and inconsistent with the permissible standard of adequate access. The Applicant also presented statistical evidence that based on its interpretation of the Denial Notice,[35] its network of providers was over 99 percent complete. The Applicant also indicated that even if one counted all of the 277 deficiencies identified in CMS' brief, it's network of providers was over 95 percent complete.[36]

The Applicant suggests that CMS' determination be modified to permit it to continue to serve its PFFS enrollees to avoid any disruption or, in the alternative, allow it to proceed with a contract in the areas/counties where it has demonstrated an adequate provider network.[37]

Finally, the Applicant states that its PPO application, H8319, which is based on a similar provider network, raises many of the same concerns with CMS' evaluation of its PFFS application, H8098. There were, however, two distinctions. First, even though the provider network is the same, the denial notice includes an additional county, El Paso, Texas, which was not included in the denial of H8098. Second, as the PPO is a new, not an existing plan, some of the arguments concerning H8039 relating to the type of notice CMS should have allegedly provided, is irrelevant.[38]

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[32] *See* Applicant Exhibit 5. At hearing, it was noted that Applicant Exhibit 5 did not contain all the information needed to support the Applicant's claim. Tr. at 227-238. The Applicant submitted additional information in Applicant Exhibit 30, marked Applicant Exhibit 30 in Support of Exhibit 5. The Hearing Officer notes that CMS provided in the record the reasons it denied exception requests, *See* CMS Exhibit 16, however, when it approved exception requests, it did not separately record the reasons for granting the requests and therefore, CMS's reasons for approving exception requests are not in the record. Tr. at 228.
[33] Applicant Brief at 12-13.
[34] Applicant Brief at 14.
[35] *See* Applicant Exhibit 26A.
[36] *See* Applicant Exhibit 26B.
[37] *See* Applicant Brief at 17-22.
[38] Tr. at 351-352.

Decision

The Hearing Officer notes that pursuant to 42 C.F.R. §422.501(b), CMS may set deadlines and dictate the form and manner of the application process (e.g., CMS has the right to require the use of the HPMS and to specify documentation requirements).[39] The Hearing Officer also notes that the regulation at 42 C.F.R. §422.502(a)(2) specifies that in evaluating an applicant, "CMS determines whether the applicant meets all of the requirements described in this part." (emphasis added). In addition, 42 C.F.R. §422.502(c)(2)(ii) requires that applicants revise their applications within 10 days from the date of the Notice of Intent to Deny letter. Accordingly, CMS is within its authority to only consider documentation which is filed through its HPMS system by May 15, 2010, the last day of the 42 C.F.R. § 422.502(c)(2)(ii) cure window. Therefore, when deciding if the application met the all of the program requirements, the Hearing Officer will evaluate only materials timely and properly filed with the agency by the May 15, 2010 deadline. The Hearing Officer also finds that the Applicant will bear the burden of proving by a preponderance of the evidence that CMS' determination was inconsistent with the requirements of 42 C.F.R. §§422.501-422.502. The Final Rule establishing this burden of proof is effective June 7, 2010 (and applies to applications for contract year 2011 (the year at issue) forward).[40] CMS' denial was issued on June 7, 2010, the effective date of CMS' new regulations.

The Hearing Officer finds that the Applicant has not proved by a preponderance of the evidence that CMS' determination was inconsistent with the requirements of 42 C.F.R §422.501 and 422.502. The Hearing Officer notes that 42 C.F.R. §422.112 provides the general framework upon which CMS sets criterion, and ultimately evaluates, whether an MA organization has ensured that enrollees will have the requisite access to services. As noted above, CMS issued subregulatory guidance on November 20, 2009, in a memorandum to Medicare Advantage plans entitled, Health Services Delivery Network Criteria Reference Tables and Exceptions Guidance.[41] CMS established MA network adequacy criteria that were measured by the minimum number of providers, maximum

[39] The Hearing Officer notes that the Applicant argues that its PFFS contract with CMS was renewable annually under 42 C.F.R. §422.505 and that rather than filing an initial application it should have been given an opportunity to respond to a notice of non-renewal and to apply to file a CAP regarding its network adequacy under 42 C.F.R. §422.506. The Hearing Officer notes that MIPPA modified the statutory provider access standards for some geographic areas and as a result, PFFS plans could no longer provide services in these areas without a contracted provider network. While the statute and regulation did not specify how CMS would transition existing PFFS plans, CMS issued clear guidance both in the preamble to the regulation making the change and in subsequent guidance. *See* Notes 4, 5 and 6, *supra*. The Hearing Officer finds no basis to find that PFFS contracts in the affected areas were renewable after the passage of MIPPA and that CMS' procedure to assess PFFS plan network adequacy through the initial application process was improper. Moreover, the Hearing Officer finds that the CAP process, which the Applicant suggests, would be inapplicable to the situation.

[40] Proposed Rule, 74 Fed. Reg. 54634 (October 22, 2009) and Final Rule, 75 Fed. Reg. 19678 (April 15, 2010). Prior to June 7, 2010 (for hearings involving determination regarding contract year 2010), the burden of proof regulations at 42 C.F.R. §§422.660 and 423.650 required the sponsor "to demonstrate that it was in substantial compliance with the requirements" of the Part C and Part D programs.

[41] *See* CMS Exhibit 2.

travel distances to providers and maximum travel time to providers.[42] CMS also established a process under which applicants could request exceptions to the network adequacy requirements.[43] The regulations (and implementing Federal Register)[44] neither mandate that exceptions be granted on any particular grounds, nor do the regulations preclude CMS from limiting the bases on which it will grant exceptions.

The Hearing Officer finds that CMS properly established through its application and subregulatory guidance, the categories of providers and facilities needed in an adequate provider network and the criteria it would use in evaluating the number of providers and facilities and the time and/or distance standards. Even though the Applicant disagreed with some of CMS' standards,[45] the Hearing Officer finds that CMS' methodologies were not inconsistent with the regulations at 42 C.F.R. §§422.501 and 422.502.[46]

The Hearing Officer notes that the Applicant claims that it was not provided with proper notice of which counties failed in the Denial Notices for each of the two contracts because the notices only explicitly listed 9 deficient counties.[47] The Hearing Officer finds that the Denial Notices and the earlier deficiency notices appropriately advised the Applicant of deficiencies in their HSD tables and exception requests.[48] They also referred the Applicant directly to the ACC Reports for further detail.[49] The ACC Reports listed all of the categories of providers and facilities by county for which the Applicant received a "fail."

[42] *See* CMS Exhibit 3.
[43] *See* CMS Exhibit 4.
[44] *See* note 5, *supra*.
[45] *See* Applicant's Contentions, *e.g.,* unrealistic plan size and number of providers needed to provide adequate access, *supra*.
[46] The Hearing Officer notes that the Applicant claims that CMS approved some exceptions and denied others based on similar requests for exception. Based on the documentation in the record, the Hearing Officer finds that the Applicant's assertion is not supported. More specifically, the Hearing Officer reviewed the two instances referenced in the Applicant's Brief as examples of its claim. *See* Applicants Brief at 11-12. The Applicant notes that CMS approved a request for an exception for psychiatry in Spartanburg County, SC and not in Caddo County, LA. The Hearing Officer notes that the exception requests for Caddo County, LA (dated 5/15/10) indicates that the Applicant has a contracted psychiatrist in Alexandria, LA which is 90-95 miles away. *See* Applicant Exhibit 30. CMS' denial of this exception, CMS Exhibit 16 at 3, states that the exception request was denied because closer providers were available. While the record does not contain CMS' reason for granting the Applicant's exception request in Spartanburg County, SC, the Hearing Officer notes that the Applicant's exception request (dated 2/25/10) indicates that there is a contracted psychiatrist in Greenville, SC. A Google map of the distance from Spartanburg County to Greenville, SC shows a distance of approximately 30 miles. The Applicant also noted that CMS approved a request for an exception for infectious disease in Polk County, FL and not in East Baton Rouge County, LA. The Hearing Officer notes that the exception request for East Baton Rouge County, LA (dated 5/15/10) indicates that the Applicant had contracted services in New Orleans, LA, which is listed as 52-60 miles away. Applicant Exhibit 30. CMS' denial of the Applicant's East Baton Rouge County exception request states that there were closer providers available. CMS Exhibit 16 at 4. While the record does not contain CMS' reason for granting the Applicant's exception request in Polk County, FL (dated 2/25/10) it indicates that the Applicant had a contracted immunologist in Lakeland, FL. A Google map of the distance from Polk County to Lakeland, FL shows a distance of approximately 25 miles away. The Hearing Officer also did not find sufficient evidence in the record to support the Applicant's assertion that CMS approved applications that did not meet its network adequacy requirements.
[47] *See* Note 30, *supra*.
[48] *See* CMS Exhibit 8 and 9.
[49] *Id.*

Moreover, the Applicant acknowledged that the deficiency notice referenced both the ACC Reports and exception requests; that the Applicant reviewed the ACC Reports in the HPMS to determine areas of failure; that the Applicant submitted revised information in response to the deficiencies; and that the Applicant used this information to determine which counties to drop from their application.[50] Even though the Denial Notices did not list specific counties that failed, the Hearing Officer finds that this information could easily and readily be discerned from the ACC Reports.[51]

The Hearing Officer finds that the Applicant's final submission contained significant numbers of deficiencies in its provider networks.[52] There were a large number of deficiencies (182) where the Applicant did not request an exception and failed to meet the CMS standards.[53] These deficiencies were located in numerous counties in 12 states. The Hearing Officer notes that in some counties such as Butler County, PA, there were 10 separate deficiencies, and in Galveston County, TX, there were 12 separate deficiencies. There were also a large number of deficiencies (95) because the Applicant had failed to justify its requests for exceptions.[54] These deficiencies covered numerous counties in 8 states. The Hearing Officer notes that there were 11 separate deficiencies of this type in Caddo County, LA and 9 separate deficiencies of this type in Howard County, MD. All together, there were 277 deficiencies in the Applicant's provider network. The Hearing Officer finds that the substantial number of deficiencies supports CMS' determination that the Applicant provider network did not meet network adequacy standards.

Finally, the Hearing Officer notes that the Applicant suggests that CMS' determination be modified to permit it to continue to serve its PFFS enrollees to avoid any disruption, or, in the alternative, it should be allowed it to proceed with a contract in the areas where it has demonstrated an adequate provider network. The Hearing Officer notes that the role of the Hearing Officer is to determine whether CMS' determination is consistent with the regulations at 42 C.F.R. §§422.501 and 422.502 and does not grant any discretion to modify CMS' determination.[55]

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[50] Tr. at 148-154 and 174-176.

[51] The Applicant indicated that despite the fact that it proposed similar networks for both its PFFS and PPO applications, its PPO application denial included an additional county, El Paso, TX. Tr. at 351-352. CMS did not address this issue except to say that the Applicant did not have a complete network. Tr. at 354-355. The Hearing Officer finds that even if CMS removed El Paso County, TX from the PPO denial, the number of other deficiencies in the application still precludes its approval.

[52] The Hearing Officer notes that applicants were given four opportunities prior to submitting their applications to test their proposed networks to assess whether an exception requests would be required. In addition, throughout the application process, applicants could review their ACC Reports and evaluate whether their networks met these standard. Furthermore, during the application process, up until May 19, 2010, applicants were permitted to remove counties if they failed to meet the network access standards. The Hearing Officer notes that, in this case, the Applicant updated its provider network and exception information and reduced the number of counties in its application by a significant amount. *See* CMS Exhibit 15. The Hearing Officer notes, however, the due an error on the Applicant's final submission to the HSD tables prior to May 15, 2010 deadline, it did not have updated deficiency information on which to base its decisions to possibly elect to remove additional counties from its service areas prior to the May 19, 2010 deadline.

[53] *See* CMS Brief at 9-14 and CMS Exhibits 19 and 20.

[54] *See* CMS Brief at 14-16 and CMS Exhibit 16.

[55] *See* 42 C.F.R. §§422.660(b) and 422.688.

Conclusion

Accordingly, the Applicant has not proved by a preponderance of the evidence that CMS' determination was inconsistent with the requirement of 42 C.F.R. §§422.501 and 423.502. CMS' denial is sustained.

Paul Lichtenstein
Hearing Officer

Date: August 25, 2010