CENTERS FOR MEDICARE AND MEDICAID SERVICES
Hearing Officer Decision

In the Matter of

Guardian Healthcare, Inc.	*	
	*	Docket No. 2010 C/D App 13/14
Denial of Applications H7341 & H9779	*	
	*	

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 applications H7341 and H9779 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

[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.

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.

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]

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. * * *
>
> (1) Approval of Application. * * *
>
> (2) Intent to Deny.
>
> (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.
>
> (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.
>
> (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

[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."

[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."

§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

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

[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.

. . . .

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 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 application process in order to qualify to offer their product to current and new enrollees.[8]

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:
>
> > (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.
>
> * * * * *
>
> (3) *Specialty care*. Provide or arrange for necessary specialty care, and in particular give women enrollees the option of

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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/

[7] *Id*. at 1.

[8] *Id.* at 3.

> 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.
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> * * * * *

Additionally, as part of the recent regulatory revisions, CMS added the following provision (at subsection 10) to 42 C.F.R. §422.112(a) and explained that MA organizations that meet access and availability requirements must do so consistent with the prevailing "community pattern of health care delivery." The regulation also provided a non-exclusive list of unweighted, objective and subjective factors which CMS may consider when evaluating "community pattern of care."

> (10) Prevailing patterns of community health care delivery. Coordinated care and PFFS MA plans that meet Medicare access and availability requirements through direct contracting network providers must do so consistent with the prevailing community pattern of health care delivery in the areas where the network is being offered. Factors making up community patterns of health care delivery that CMS will use as a benchmark in evaluating a proposed MA plan health care delivery network include, but are not limited to the following:
>
> (i) The number and geographical distribution of eligible health care providers available to potentially contract with an MAO to furnish plan covered services within the proposed service area of the MA plans.
>
> (ii) The prevailing market conditions in the service area of the MA plan. Specifically, the number and distribution of the health care providers contracting with other health care plans (both commercial and Medicare) operating the service area of the plan.
>
> (iii) Whether the service area is comprised of rural or urban areas or some combination of the two.
>
> (iv) Whether the MA plan's proposed provider network meet Medicare time and distance standards for member access to health care providers including specialties.

(v) Other factors that CMS determines are relevant in setting an acceptable health care delivery network in a particular service area.

(Emphasis added.)

Applicants for MA contracts are also required to demonstrate that they are licensed by the State in which they propose to operate and demonstrate their fiscal solvency. The regulation at 42 C.F.R. §422.400 states, in relevant part:

> …each MA organization must –
>
> (a) Be licensed under State law, or otherwise authorized to operate under State law, as a risk-bearing entity (as defined in §422.2) eligible to offer health insurance or health benefits coverage in the State in which it offers one or more MA plans;
>
> (b) If not commercially licensed, obtain certification from the State that the organization meets a level of financial solvency and such other standards as the State may require for it to operate as an MA organization; and
>
> (c) Demonstrate to CMS that –
>
> (1) The scope of its license or authority allows the organization to offer the type of MA plan or plans that it intends to offer in the State; and
> (2) If applicable, it has obtained the State certification required under paragraph (b) of this subsection.

Subregulatory Authority

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

[9] *See* CMS Exhibit 2.

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/or maximum travel time to providers.[10] Beginning with contract year 2011, CMS utilized a new automated criteria check (ACC) in the HPMS. The ACC calculated whether an applicant's proposed network of contracted providers met the minimum standards for providers and facilities with respect to number and time and/or distance in each county in their proposed service area.[11] CMS provided applicants with four opportunities in January and February 2010 to test the adequacy of their proposed provider networks using the automated ACC tool so that applicants could remedy any deficiency identified by the ACC prior to the submission of their applications and/or could consider requesting an exception to the standard with their initial application.[12]

CMS also issued an exception memorandum[13] 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 only 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:

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

[10] *See* CMS Exhibit 3.
[11] *See* CMS Exhibit 1 at 3 and 4.
[12] *See* CMS Brief at 4-5.
[13] *See* CMS Exhibit 4.

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).

The MA-PD application also requires entities applying from MA contracts to make the following attestation concerning financial solvency:

> 1. Applicant maintains a fiscally sound organization. Specifically, a fiscally sound organization must have: 1) sufficient cash flow and adequate liquidity to meet obligations as they become due, 2) a recent balance sheet demonstrating that the State regulatory requirements are met, and 3) net income.
>
> Note: A net loss is acceptable if the organization's net worth is at least two times greater than the reported net loss for the accounting period.
>
> If "No", upload in the HPMS a financial plan which includes descriptive assumptions, and contains a projected date by which it will produce two successive quarters of net income.
>
> 2. Applicant is in compliance with all State requirements and is not under any type of supervision, corrective action plan, or special monitoring by the State regulator.
> If "No", upload in the HPMS an oversight disclosure which details a discussion of the State's reasons for the increased oversight and measures the Applicant is undertaking to address the reasons for the increased oversight.

2011 MA Part C Application at 29.[14]

[14] http://www.cms.gov/MedicareAdvantageApps/

Factual and Procedural Background

Guardian Healthcare, Inc. (Guardian or Applicant) is a South Carolina health insurer. In response to CMS' January 5, 2010, solicitation for applications for Medicare Advantage plans, Guardian filed two Medicare Advantage applications. One application, H7341, is an initial application for a network-based Private Fee-for-Service Plan (PFFS) in South Carolina, which would succeed Guardian's 2010 non-network PFFS plan (H4917).[15] The second application, H9779, is a service area application to expand Guardian's current Preferred Provider Organization (PPO) covering one South Carolina County to all 46 counties in South Carolina.[16] Both applications were filed on a timely basis by the February 25, 2010 deadline.

Application H7341

Application H7341 contained information concerning the proposed provider network for the PFFS plan as well as information with respect to the plan's solvency.[17] According to CMS, Guardian had difficulty uploading its provider network information in HPMS with its initial application submission and was allowed on February 26 and again in March to re-upload tables listing its network providers.[18] The upload on March was successful and a report was generated showing deficiencies in the Guardian provider network.[19]

CMS was contacted by the South Carolina Department of Insurance (SCDOI) on March 17 due to financial concerns it had about Guardian's current contract H4917. CMS learned from SCDOI that Guardian was "6 million in the negative" and SCDOI had instructed Guardian to infuse $4 million within 10 days and another $ 4 million within 30 days.[20]

On April 6 CMS issued a deficiency notice on H7341.[21] The deficiency notice stated that the Guardian provider network was deficient and referred to the ACC reports in HPMS. The deficiency notice also specified a list of areas which Guardian failed to address with respect to its financial solvency. The notice specified a time window during which Guardian could upload information into the HPMS system to address the items specified in the April 6 notice. According to CMS, Guardian had difficulty uploading its network information during the upload period available to respond to the deficiency notice. CMS again gave them additional time to correct the errors and resubmit. Guardian did not

[15] *See supra* at 4-5.
[16] See CMS Brief at 9.
[17] See CMS Brief at 6. The Applicant attested "yes" that it had a fiscally solvent organization, was incompliance with all State requirements, and was not under any type of supervisions, corrective action plan, or special monitoring by the State regulatory. The Applicant, however, did not submit required financial information to enable CMS to confirm these attestations.
[18] *See* CMS Brief at 7.
[19] The Hearing Office notes that Guardian did not participate in any of the four ACC tool pre-check opportunities that were available in January and February, which may have enabled the applicant to identify and correct network deficiencies prior to the February 25, 2010 application deadline.
[20] *See* CMS Exhibit 14.
[21] *See* Applicant Exhibit 6 and CMS Exhibit 15.

submit any information during this upload period to respond to the financial solvency issues listed in the deficiency notice.[22]

On May 5, via email, CMS issued a Notice of Intent to Deny with respect to H7341. The notice specified multiple deficiencies with respect to Guardian's provider network and stated that the Applicant had made "very little" improvements in the network. The notice also included several deficiencies with respect to Guardian's financial solvency, including its failure to provide adequate evidence that it met CMS' solvency requirements and the fact that Guardian was under an order from the State to infuse $8 million by April 30. The notice stated that Guardian had until May 15 to upload information into HPMS to respond to the deficiencies in the May 5 notice.[23]

Guardian submitted several items in response to the May 5 notice of intent to deny. With respect to the adequacy of the provider network, Guardian submitted updated data files in HPMS, new detailed narratives explaining the deficiencies and where Guardian had added additional providers, a letter from Roper St. Francis Hospital supporting the patterns of care in the tri-county area of the low-lands region of South Carolina, a letter from a South Carolina House member supporting the patterns of care in the tri-county area of the low-lands region of South Carolina, and a 1200-page excel sheet listing contracted providers and hospital-based specialists.[24]

Guardian submitted 5 documents in response to the financial solvency issues cited in the notice of intent to deny, including: a narrative response to the financial deficiencies cited in the May 15 notice;[25] audited financial statements for 2009 and for the quarter ending March 31, 2010;[26] and a report of forecasted financial data for Fiscal Years 2010, 2011 and 2012.[27] Guardian also submitted an affidavit from the President/CEO of New England Consulting Group, which stated that the organization had agreed to purchase Guardian stock and would transfer $8 million to Guardian on or before May 19, 2010.[28]

On May 15, CMS received a request from Guardian to drop 27 counties from its service area for H7341, leaving 19 counties in the proposed service area.[29] On May 21, CMS learned from the SCDOI that Guardian not been in compliance with the State's minimum net worth requirements since the end of 2009.[30]

[22] *See* CMS Brief at 7.
[23] *See* Applicant Exhibit 7 and CMS Exhibit 16.
[24] *See* Applicant Brief at 2-3 and Exhibits 14, 15, 16, 17, 18, and 19. *See also* CMS Brief at 8.
[25] *See* CMS Exhibit 17.
[26] *See* CMS Exhibits 18 and 19.
[27] *See* CMS Exhibit 20.
[28] *See* CMS Exhibit 21.
[29] *See* CMS Exhibit 23.
[30] *See* CMS Exhibit 22.

On June 7, CMS sent Guardian a denial of application H7341. The denial notice specified that Guardian's application had deficiencies with respect to financial soundness and network adequacy.[31] Guardian submitted a timely notice of appeal of the denial.

Application H9779

In calendar year 2010, Guardian had a contract (H9779) to operate a Medicare Advantage PPO plan in one county in South Carolina. Guardian submitted a service area expansion application to expand the PPO service area for contract year 2011 to all 46 counties in South Carolina.

According to CMS, as with H7341, Guardian had difficulty uploading its provider network information for H9779 in HPMS for its initial application submission and was a given extensions at each upload period to correct its data. [32] The uploads in March enabled the ACC reports to be generated.

With respect to fiscal solvency for H9779, Guardian attested in its application that it maintained a fiscally solvent organization and also that it "is in compliance with all State requirements and is not under any type of supervision, corrective action plan, or special monitoring by the State regulator."[33] Guardian initially submitted two licensure-related documents with the application – a copy of its State Certificate of Authority to do business in the lines of accident and health insurance[34]and a February 17, 2010 letter from the SCDOI stating that "1) Guardian can offer a Medicare Advantage PPO product under its current and active A&H Certificate of Authority and 2) the Department does not regulate Medicare Advantage PPOs. Accordingly, the [CMS] State Certification Form required in the context of the application process for the Medicare Advantage PPO for Guardian does not apply."[35] According to CMS, the application also failed to include other required financial documentation to support the attestations.[36]

On April 6, 2010, CMS issued a deficiency notice for H9779. CMS sent an amended deficiency notice on April 8 which added previously omitted standard language on exceptions requests.[37] The deficiency notice referred the Applicant to the network deficiencies found in the ACC reports, and specified the financial documentation that Guardian failed to include in its initial application.[38] Guardian uploaded revised network information and other information in response to the deficiency notice.[39]

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[31] *See* Applicant Brief at 3 and Exhibit 8. *See also* CMS Brief at 9 and Exhibit 24. The Hearing Officer notes that CMS stated that the final ACC report included additional counties and provider/facility types marked as "fail," but only included a subset of the deficiencies to address at the hearing. See CMS Brief at 9, note 7.
[32] *See* CMS Brief at 9-10.
[33] *See* CMS Exhibit 11.
[34] *See* CMS Exhibit 25.
[35] *See* CMS Exhibit 26.
[36] *See* CMS Brief at 10.
[37] *See* Applicant Brief at 2 and Exhibits 1 and 2. *See also* CMS Brief at 10 and Exhibit 27.
[38] *See* Id.
[39] *See* Applicant Brief at 2 and CMS Brief at 10.

On May 15, CMS received a request from Guardian to drop 27 counties from its service area for H9779.[40] On May 24, the SCDOI issued an order of administrative supervision with respect to Guardian Healthcare, finding that "the financial condition, management, and operation of Guardian Healthcare Guardian are such to render the continuation of its business hazardous to the public and its policyholders", and that Guardian failed to comply with directives to infuse capital, violating insurance laws. [41] CMS learned of this order on May 25.[42]

On May 27, CMS sent Guardian a notice of intent to deny H9779. This notice specified Guardian's failure to submit a fully and appropriately completed CMS State Certification Form demonstrating fiscal solvency, and referred to numerous network deficiencies.[43] In response to the May 27 notice, as it did with H7341, Guardian submitted updated network data files to address the network deficiencies, as well as additional materials.[44] Guardian also submitted additional materials in response to the fiscal concerns identified in the May 5 notice.[45]

On June 7, CMS sent Guardian a denial of application H9779. The denial notice specified that Guardian's application had deficiencies with respect to network adequacy.[46] The denial notice did not specify any deficiencies with respect to the financial soundness of the PPO plan.[47]

On June 17, the SCDOI informed CMS that the $8 million dollar cash infusion never occurred and that by the end of April 2010, Guardian had a net worth of negative $9 million. The State further increased the cash infusion requirement to $13 to 15 million dollars in order to support the State being able to financially certify the organization. [48]

Guardian submitted a timely notice of appeal. A hearing was held on August 3, 2010, on the denials of both H7341 and H9779.

Applicant's Contentions

Guardian contends that the case is about whether its proposed MA plans have the requisite provider networks to serve the 19 counties in the proposed service area, and the case should not be determined on the basis of whether Guardian's application fits the new and relatively untested automated ACC system or whether it filed exceptions in the proper

[40] *See* CMS Exhibit 29.
[41] *See* CMS Exhibit 28.
[42] *See* CMS Brief at 11.
[43] A Notice of Intent to Deny was originally sent on May 5th with regard to H9779. The version sent on May 27 was amended to include CMS' concerns with respect to Guardian's financial status. *See* Applicant Brief at 2 and Exhibits 3 and 4. *See also* CMS Brief at 11 and Exhibit 30.
[44] *See* Applicant Brief at 2 and Exhibits 14, 14a, 15, 17 and 19.
[45] *See* Applicant Exhibits 24-28, and CMS Exhibit 31.
[46] The Hearing Officer notes that CMS stated that the final ACC Report included additional counties and provider/facility types marked as "fail," but only included a subset of the deficiencies to address at the hearing. *See* CMS Brief at 12, note 10.
[47] *See* Applicant Brief at 3 and Exhibit 8. *See also* CMS Brief at 11-12 and Exhibit 32.
[48] *See* CMS Exhibit 33.

format. Unlike other plans that had fled the South Carolina Medicare market, Guardian is ready and able to serve the Medicare beneficiaries of the state, and care for beneficiaries enrolled in its existing plans should not be disrupted.[49]
Guardian contends that it met the standards for network adequacy, with respect to minimum numbers of providers, time and distance.[50] Guardian contends that CMS wrongly determined that applications H7341 and H9779 failed the distance requirements for 5 counties. It cites the Network Adequacy Criteria for 2011 which require applicants to have at least one provider or facility type within the time and distance criteria permit applicants to satisfy this requirement through providers outside of the application county if the providers serve county beneficiaries, and meet time and distance requirements.[51] Guardian contends that it met or exceeded the requirements for each of the 5 counties, and demonstrated this through the narratives submitted to CMS which contained supportive documentation on how Guardian met the failures identified in the ACC tables.[52] Guardian contends that it did not need to request exceptions for counties in which there were no in-county providers because it satisfied the network adequacy requirements by contracting with providers in contiguous counties.[53]

Guardian also contends it met the network adequacy standards for hospital based specialists in anesthesia, emergency medicine, pathology, and radiology, contrary to CMS' assertion that it did not.[54] In addition, Guardian contends that CMS should not have denied its application on the basis of these deficiencies because CMS did not provide Guardian with notice of these deficiencies in the initial deficiency notice or the Notice of Intent to Deny, thereby denying Guardian the opportunity to cure these deficiencies in violation of CMS procedures.[55]

Guardian contends that the time and distance requirement is not the only criteria considered by CMS in determining network adequacy, and that pursuant to 42 C.F.R. §422.112(a)(10), CMS considers the patterns of community health care delivery, including (i) the number and geographical distribution of eligible health care providers available to potentially contract with an MAO to furnish plan covered services within the proposed service area of the MA plans; (ii) whether the service area is comprised of rural or urban areas or some combination of the two; and (iii) other factors that CMS determines are relevant in setting a standard for an acceptable health care delivery network in a particular service area.[56] Guardian contends that it presented ample evidence demonstrating the patterns of care in the tri-county area of the low-lands region of South Carolina which showed the

[49] *See* Applicant Brief at 1 and Tr. at 10-11, 287-288, and 309-311.
[50] At the hearing, Guardian contended that no evidence had been presented to demonstrate that there was anything wrong with Guardian's network of doctors. *See* Tr. at 287-288.
[51] *See* Applicant Brief at 11 and Exhibit 12 at 3. At the hearing, Guardian asserted that it was unclear whether CMS reviewed any of the materials provided by Guardian to document its network adequacy. *See* Tr. at 289-290.
[52] *See* Applicant Brief at 9-10 and Exhibits 14 and 14a. The Hearing Officer notes that the Applicant submitted additional information to support its contentions in Applicant Exhibit 17, however, these were not submitted to CMS. See Applicant Brief at 10, note 1.
[53] *See* Applicant Brief at 12.
[54] *See* Applicant Brief at 18 and Exhibits 16, 17 and 19.
[55] *See* Applicant Brief at 19.
[56] *See* Applicant Brief at 13.

concentration of certain specialists in counties near the two major hospitals in Charleston County, and the scarcity of certain specialists in others.[57]

Guardian contends that the use of the automated ACC tool to determine network adequacy is arbitrary and capricious and contrary to CMS' regulations. It argues that the methodology behind the criteria and geocoding program used in the automated tool is largely secret and in CMS's hands. In addition, CMS has provided no information as to how the geocoding process will incorporate anything more than time and distance measurements - such as patterns of care, or distinguish special circumstances, or even apply the new regulation, Section 422.112(a)(10), which provides a list of criteria for establishing network adequacy that go beyond just time and distance. Guardian contends that there is no reason to believe that CMS tested its automated system on counties in South Carolina or large counties without specialty providers, or on any other counties that have specific or individualized circumstance that would affect the automated process' determination of adequate coverage.[58] Guardian contends that the ACC is not fully functional because CMS did not activate it to measure time except for in large metropolitan counties.[59]

Guardian contends that it used good faith and reasonable efforts to demonstrate coverage but could not know what results the automated process would determine. Guardian relied on available websites and programs to determine distance requirements, such as Medicare.gov and Google.com. It contends that the "find-a-doctor" tool on Medicare.gov can find specialty providers within 25 miles of a city entered, and was used by Guardian to determine whether contracted providers were within the time/distance requirements. Guardian also used Google maps to confirm time/distance for providers from certain cities and counties. Guardian also used the South Carolina Medical Board website to find licensed specialty providers. Guardian contends that it is arbitrary and illogical that CMS would create a provider coverage process that comes up with different results than the medicare.gov website. Guardian's contends that its extensive list of contracted specialty providers shows that Guardian met its burden to establish and provide coverage pursuant to the regulations.[60]

Guardian contends that application H7341 should not have been denied on fiscal solvency grounds. In accordance with CMS requirements, Guardian submitted with its application SCDOI certification that the plan met the state's financial requirements.[61] Guardian contends that during the first quarter of 2010, it experienced a dramatic increase in enrollment, which resulted in increased reserve requirements and an inquiry by SCDOI as to whether there existed a premium deficiency. Guardian contends that an independent actuarial analysis demonstrates that there was no premium deficiency during the first two quarters of 2010[62], and that the SCDOI concurs with these actuarial report findings.

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[57] In its brief, Guardian stated that it provided detailed information about community patterns of care in the Narratives (*See* Exhibits 14, 14a, and 17). Guardian also provided letters from Roper St. Francis Healthcare and a South Carolina House member. *See* Applicant Exhibits 15 and 16. *See also* note 4 *supra*.
[58] *See* Applicant Brief at 14-16and Tr. at 288.
[59] *See* Tr. at 288-289.
[60] *See* Applicant Brief at 17 and Exhibit 18.
[61] *See* Applicant Brief at 20 and Exhibit 28.
[62] *See* Applicant Exhibit 20 and Tr. at 292-293.

Guardian contends that given its fiscal performance, the SCDOI, has been supportive of Guardian plans to ensure continued fiscally sound operations throughout 2010.[63] Guardian also contends that it revised its administrative systems and pared costs, without compromising its members' patient care or services. Guardian contends that the 2011 plan benefit design is less rich that the plan design for 2010 while still offering Medicare beneficiaries very competitive benefits and co-payments. Guardian contends that these measures demonstrate the past, current, and future fiscal soundness of the plan.[64] At the hearing, Guardian requested that the window be left open until September 1 to address the financial soundness of the PFFS plan (H7341) and demonstrate that it would be financially solvent going forward.[65] At the hearing, Guardian contended that CMS could not argue that H9779 had been denied based on solvency issues because those issues had not been specified in the May 27 denial notice.[66]

CMS Contentions

CMS contends that this case is about ensuring that Medicare beneficiaries are served only by Medicare Advantage organizations that are fully fiscally solvent and have appropriate contracted networks to provide adequate access. Under applications H7341 and H9779, Guardian failed to demonstrate its fiscal soundness and failed to demonstrate an adequate network to support either application, and therefore the denials of both applications should be upheld.[67]

CMS contends that the process used to evaluate MA applications is a standardized regulatory process, and that it applies the process equally across all applicants. CMS contends that Guardian responded to the same application instructions and processes as did all other applicants. CMS contends that Guardian was not required to participate in the ACC pre-check process and instead chose to use its own methods to assess its network adequacy and determine how the proposed Guardian network compared to the CMS requirements. CMS contends that the Guardian assessment methodology was not concurrent with the CMS criteria and system.[68] CMS contends that had Guardian chosen to use the ACC pre-checks, it may have gained information that would have led to the submission of exception requests with the initial applications. Guardian should not be allowed to go back after the applications were denied and rely on the manual evaluation of information that would occur in an exception approach.[69]

CMS contends that Guardian failed to meet the requirement that it have a network supported by written agreements sufficient to provide adequate access to covered services because it failed to meet the standardized access criteria or qualify for exceptions. For both H7341 and H9779, CMS asserted that the Applicant had failed to meet standardized criteria for at least 8 counties. Guardian further failed to request exceptions upon initial

[63] *See* Applicant Brief at 21 and Exhibit 28.
[64] *See* Applicant Brief at 22 and Exhibit 21.
[65] *See* Tr. at 300.
[66] *See* Tr. at 13 and 297-299.
[67] *See* CMS Brief at 12-13.
[68] *See* Tr. at 300-301
[69] *See* Tr. at 307.

submission for provider categories which did not meet the ACC criteria, which could have allowed them to vary from the set criteria.[70]

CMS contends that Guardian is a financially unstable organization that does not qualify to expand its PPO or transition its current PFFS plan to a network based PFFS plan, and that CMS would be shirking its regulatory duty to protect beneficiaries by approving a fiscally unsound organization. CMS contends that Guardian failed to provide assurance of its compliance with South Carolina solvency requirements under both applications, and untruthfully attested to its fiscal soundness in both applications. CMS contends that Guardian repeatedly failed to comply with several directions from the SCDOI to infuse cash into its operation (initially $8 million but later increased to $13 million), and that Guardian never met the State's timeline for the cash infusions.[71]

CMS contends that Guardian was not fiscally solvent in February 2010, when its application was submitted, and that the State's certification of Guardian's financial solvency was as of September 30, 2009. CMS contends that there is substantial evidence that Guardian was out of compliance with State solvency requirements for all of 2010, and as of the date of the hearing, was not solvent and in fact had a negative net worth.[72] CMS contends that it would not be allowable for the Hearing Officer to treat Guardian differently than other organizations and allow them an extension until September 1 to demonstrate its solvency for purposes of application H7341. The denial of H7341 for failure to meet solvency requirements should be upheld.[73]

With respect to its omission of Guardian's failure to meet fiscal solvency requirements as a basis for denial of application H9779 in the May 27 denial notice, CMS acknowledged that the fiscal solvency concerns were inadvertently omitted from the notice. CMS contended that it could reopen the denial to include the fiscal solvency deficiencies as a basis for denial, and that this would give Guardian an opportunity to re-request a hearing on the amended notice of denial.[74] However, CMS contends that there was no prejudice to Guardian because of the omission. There is no distinction between the legal entities that would hold the contracts under applications H7341 and H9779 – for both applications the entity is Guardian. The same entity is currently under on-site State supervision and is still subject to the State requirement to infuse capital. Guardian received the notice of denial for H7341 before the notice of denial for H9779, and the notice for H7341 contained all of the information with respect to Guardian's failure to meet solvency requirements that Guardian would have been required to address with respect to H9779.[75]

Decision

[70] *See* CMS Brief at 13.
[71] *See* Tr. at 16 and CMS Brief at 12-13.
[72] *See* Tr. at 16 and 302.
[73] *See* Tr. at 301.
[74] *See* Tr. at 18.
[75] *See* Tr. at 302-305.

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). 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,[76] 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 applicable 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 is effective June 7, 2010 (and applies to applications for contract year 2011 (the year at issue) forward).[77] 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 criteria, 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.[78] CMS 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.[79] The assessment of whether an individual applicant met the number and time/distance requirements was done through the ACC tool. CMS also established and published a process providing applicants the opportunity to request exceptions to the network adequacy requirements.[80] The regulations 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.[81]

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[76] The Hearing Officer notes that for the PPO application (H9779) the deadline was June 6, 2010 because an amended Notice of Intent to Deny was issued by CMS on May 27, 2010. CMS Exhibit 30.

[77] 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.

[78] *See* CMS Exhibit 2.

[79] *See* CMS Exhibit 3.

[80] *See* CMS Exhibit 4.

[81] The Hearing Officer notes that the Applicant referenced subsection 42 C.F.R. §422.112(a)(10) as controlling and/or suggestive authority to support its contention that when CMS evaluates an application for network access and adequacy, it must consider factors other than the number of providers and the time and distance requirements. The Hearing Officer finds that this subsection, however, is not controlling as it specifically defines and addresses the narrower concept of "patterns of care," as opposed to the broader network access/adequacy. The pattern of care characteristics is a factor upon which CMS has determined

The Hearing Officer finds that CMS clearly established through its application, and subregulatory guidance and ACC, the categories of providers and facilities required for an adequate provider network, the criteria it would use in evaluating the number of providers and facilities and the time and/or distance standards. The Hearing Officer finds that the CMS' methodologies related to the application and exception request criteria and processes were not inconsistent with the controlling statutory and regulatory authorities.

The Hearing Officer further notes that applicants were given four opportunities prior to submitting their applications to test their proposed networks and assess whether it would be necessary to file a timely exception request from the plan specific network adequacy requirements in the ACC. The instructions for exception requests clearly states that applicants will only be able to request exceptions with the initial application submission and that no late exception requests will be accepted.[82] Generally, if an applicant did not request an exception with the initial application for either a provider or facility, they were effectively required to ultimately meet the CMS standards in the ACC. However, even after applicants had filed their initial application through the end of the deadline to cure, applicants could review their ACC Reports and were still permitted to remove counties if they failed to meet the network access standards to avoid receiving a denial for having an application with a service area that neither met the ACC benchmark nor received an approved exception.[83]

Moreover, the Hearing Officer notes that the deficiencies that formed the network adequacy related basis of CMS' denials resulted from failures to meet the benchmark standards in the ACC Reports in categories for which the Applicant did not request exceptions.[84] The procedure did not include addressing any failure to meet the standards in the ACC through alternative methods, such as submitting a narrative explanation after filing the initial application or testimony at hearing. Accordingly, CMS was legally justified in not reviewing the Applicant's subsequent narratives.[85] Nevertheless, the

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may warrant an exception when an applicant is unable to meet network adequacy criteria and only if other contracted network providers facilities are available in nearby service areas. *See* CMS Exhibit 4.

[82] CMS Exhibit at 1.

[83] The Hearing Officer notes that Applicant indicated that it had CMS' training materials that explained the pre-check and exception process and reviewed them prior to submitting their application. Tr. at 123-4. The Applicant indicated they knew exception requests had to be submitted or they had to meet the ACC and that they submitted exception requests with their initial application. Tr. at 127. The Applicant did not participate in any of the four pre-checks prior to submitting its application. Tr. at 66.

[84] Tr. at 175. The Hearing Officer observes that, in its Brief, CMS relied upon a subset of failures in the ACC to support its denial. CMS Brief at 9 and 12, Notes 7 and 12. The Hearing Officer notes that the Applicant claims that it was not notified of deficiencies related to anesthesia, emergency medicine, pathology and radiology in the Notice of Intent to Deny. Applicant Brief at 19. The Hearing Officer observes that if the ACC Reports associated with the Notice of Intent to Deny actually specified these deficiencies, the Applicant would have had notice. However, because the administrative record does not contain the ACC to verify whether or not the ACC cited these deficiencies, the Hearing Officer did not consider such alleged deficiencies in upholding CMS' denial.

[85] CMS indicated at the hearing that the reason exception requests are only accepted with the initial application is to permit time to properly evaluate them. Tr. at 179.

Hearing Officer finds that the Applicant did not provide sufficient evidence to prove that its proposed network met the network adequacy criteria in the ACC.[86]

Moreover, the Hearing Officer finds that the small sampling of deficiencies CMS highlighted in its brief to support its denial of the Applicant's final provider network constituted significant bases for denial.[87] CMS' brief cited 8 counties with deficiencies in laboratory services, 6 separate provider deficiencies in Calhoun County, 5 separate provider categories in Dorchester County and 3 separate provider categories in Horry County. All together, there were 22 deficiencies cited in the Applicant's provider network. The Hearing Officer finds that these 22 deficiencies alone support CMS' determination that

[86] The Hearing Officer notes that applicants may utilize providers outside of the county, if they serve the county beneficiaries, *See* CMS Medicare Advantage Network Adequacy Criteria Development Overview, CMS Exhibit 3 at 3, and, more specifically, if a certain percentage of the applicant's provider network meets the established time and distance requirement. *Id*. at 2 (CMS indicated that it initially utilized a 90% standard for the provider network and later changed it to an 80% standard, CMS Brief at 3, note 2). The Hearing Officer further observes that the system CMS utilized in the ACC to measure time and distance does not merely look at the distance from one point in a county to a provider location, but instead looks at the distance to provider locations from the location of Medicare beneficiaries in the county by zipcode . Tr. at 251.

The Applicant provided copies of the narrative supporting documentation it submitted into the HPMS by May 15, 2010 regarding their provider failures. *See* Applicant Exhibits 14 and 14A. The Hearing Officer finds that these narratives did not provide time or distance information. For e.g., the Applicant did not meet the network adequacy standard for OB/GYN providers in Calhoun County. *See* CMS Brief at 9 and 12. The Applicant's supportive narrative, *See* Applicant Exhibit 14 and 14A at 5 and 6, notes that various sources confirm that there are no OB/GYN providers in Calhoun County, that the Applicant did not submit an exception request with the initial application because it planned to provide these services with contracted providers in contiguous counties and that it had 47 contracted OB/GYN providers in contiguous counties. The specific location of providers was not provided. Another example is Neurosurgery providers for Calhoun County. The Applicant's narrative, *See* CMS Exhibit 14 at 6, provides a similar rationale to that used for OB/GYN providers, i.e., there are no Neurosurgeons in Calhoun County and no exception was requested because the Applicant planned to meet enrollee needs with contracted providers in contiguous counties. Again, no specific location of providers was provided. In addition, the Applicant was deficient in laboratory services in 8 counties. *See* CMS Brief at 9 and 12. The Applicant indicated that it provided a narrative with respect to this issue, Tr. at 94, however, no such narrative was in the record. The Hearing Officer notes that testimony at the hearing, Tr. at 94-96, was not specific enough to determine whether the proposed network for laboratory services met the established time and distance requirements.

The Hearing Officer notes that the Applicant subsequently provided more detailed information arguing that that the distance of some of their providers, from central locations in a county, were within the distance criteria established by CMS. *See* Applicant Exhibits 17 and 18. For e.g., for OB/GYN providers in Calhoun County, the Applicant indicated that it had one provider within 25 miles from St. Mathews, which is in the center of the county, and the distance standard was 30 miles. Likewise, for Neurosurgeons in Calhoun County, the Applicant indicated that it had three providers within 25 miles from St. Mathews, which is in the center of the county and the distance standard was 30 miles. *See* Applicant Exhibits 17 at 8 and 9. As noted above, the ACC utilized by CMS did not set distance standards from a central location in the county; as a result, this information alone is insufficient to prove that they met the standard that CMS used in the ACC.

Finally, the Hearing Officer observes that the narratives in the record suggest that the Applicant should have requested and could have possibly been granted exceptions for many of the deficiencies under several of the categories in CMS' exception policy such as insufficient providers/facilities in the service area, no providers/facilities that meet the time and distance standards in the service area, or the pattern of care in the service area do not support the need for requested number of provider/facility type (*See* CMS Exhibit 4 at 1).

[87] *See* CMS Brief at 9 and 12.

the Applicant provider network did not meet network adequacy standards for both applications.

Next, the Hearing Officer notes that the regulations and application require that an applicant provide evidence of fiscal solvency. CMS' final denial of the Applicant's PFFS application cited fiscal soundness as one of the reasons for the denial;[88] however, CMS' final denial of the PPO application did not technically cite fiscal soundness as a reason for the denial.[89] The Hearing Officer finds that there was significant evidence in the record to support CMS decision to deny the PFFS application due to fiscal soundness. First, the Applicant's CMS State Certification Form[90] indicated that the Applicant met the state's fiscal solvency requirements but only as of September 30, 2009, eight months prior to the application. Second, on March 18, 2010, CMS received a call from the South Carolina Department of Insurance indicating that they had financial concerns with the Applicant and that it would need to infuse additional capital to meet the state's requirements.[91] Third, CMS issued the Applicant a deficiency notice concerning its application on April 6, 2010,[92] in which it noted that the Applicant failed to submit a 2008 annual audit and an audited financial statement for 2009 or a 2009 Annual NIAC Health Blank. Fourth, on May 5, 2010, CMS issued the Applicant a Notice of Intent to Deny its applicantion,[93] which noted that the Applicant failed to provide adequate evidence that it met CMS fiscal solvency requirements.[94] Fifth, while the Applicant did provide information including a narrative, audited financial statement for 2009 and the first quarter of 2010, a report forecasting financial data for fiscal years 2010, 2011 and 2012 and an affidavit from its President/CEO indicating that it was expected an infusion of the $8 million in capital by the May 15, 2010 deadline for submitting information into the HPMS, CMS determined that the Applicant

[88] CMS Exhibit 24.
[89] CMS Exhibit 32. The Hearing Officer notes that the Applicant argued that the Denial Notice for the PPO application did not indicate that fiscal solvency was a reason for the denial and accordingly, the alleged solvency issue should not be considered for the PPO application. The Applicant claims it was procedurally disadvantaged in responding to this issue for the PPO application at the hearing. The Hearing Officer finds that there is sufficient evidence in the record to substantially support a CMS decision to deny the PPO application due to fiscal solvency issues. The Hearing Officer notes that both applications are from the same company and that CMS looks to the underlying fiscal solvency of the company running the plans. Tr. at 263. Moreover, the PPO Notice of Intent to Deny indicated that the issue of fiscal solvency was at issue. Since the issue for both applications was the fiscal solvency of the underlying company and the Applicant fully addressed that issue at the hearing, the Hearing Officer finds that the Applicant was not severely prejudiced on a practical basis. Nevertheless, the Hearing Officer also notes that the Applicant's PPO application was properly denied based upon an inadequate provider network. As a result, the Hearing Officer need not reach the issue of whether the Hearing Officer has jurisdiction over the solvency issue for the PPO application given the technical omission in the final denial.
[90] CMS Exhibit 13.
[91] CMS Exhibit 14.
[92] CMS Exhibit 15.
[93] CMS Exhibit 16.
[94] It further noted that as of April 27, 2010, the Applicant was under a regulatory action to infuse $8 million by April 30, 2010 and had reported negative net worth. CMS Exhibit 16 at 2. It also stated that the Applicant failed to provide an adequate Health Blank and the Health Blank submitted showed a negative net worth which contradicted its attestation that "Applicant maintains a fiscally sound organization. Specifically, a fiscally sound organization must have: 1) sufficient cash flow and adequate liquidity to meet obligations as they become due, 2) a recent balance sheet demonstrating that the State regulatory requirements are met, and 3) net income." *Id.*

had a negative network of $7.5 million,[95] and on May 21, 2010, CMS learned that the Applicant had not received the expected cash infusion.[96] Finally, at hearing, it was noted that the state had increased the amount that the Applicant needed to infuse to approximately $13 million and that no infusion of capital had taken place.[97] The Hearing Officer finds that CMS' denial of the Applicant's PFFS applicant based on fiscal solvency was proper.

Conclusion

Accordingly, the Applicant has not proved by a preponderance of the evidence that CMS' denials of applications H7341 and H9779 were inconsistent with the requirements of 42 C.F.R. §§422.501 and 422.502. CMS' denials are sustained.

Paul Lichtenstein
Hearing Officer

Date: August 31, 2010

[95] *See* CMS Exhibits 17, 18, 19 and 20 and CMS Brief at 8, note 6.
[96] CMS Brief at 8.
[97] Tr. at 268.