CENTERS FOR MEDICARE AND MEDICAID SERVICES
Hearing Officer Decision

In the Matter of

Arcadian Health Care Plan, Inc.	)
Service Area Expansion Application	) Docket Nos. 2007-C/D-App-04,
Denials, H4529, H5783 and H6497	) 05 and 07
	)

Jurisdiction

This appeal is provided pursuant to 42 C.F.R. §423.650. The Centers for Medicare and Medicaid Services (CMS) Hearing Officer designated by the CMS Administrator to conduct this hearing is the undersigned, Benjamin Cohen.

Statutory and Regulatory Background

Section 101 of the Medicare Prescription Drug Improvement and Modernization Act of 2003 (MMA) (Pub.L. 108-173), amended Title XVIII of the Social Security Act (the Act) by establishing a voluntary prescription drug benefit and made changes to the Medicare managed care program known as Medicare Advantage (MA or Part C). Specifically, the MMA created coverage for prescription drug benefits and moved managed care toward a competitive bidding system, requiring submission of annual bids and annual contracting. Pursuant to 42 C.F.R. §§422.500 et seq. and 423.500 et seq.,[1] CMS has respectively established the general provisions for entities seeking to qualify as managed care organizations and/or Prescription Drug Plans (PDP or Part D).

Under the regulations at 42 C.F.R. §422.4(c)(1), a MA coordinated care plan seeking to expand its service area must offer qualified Part D coverage in the same service areas. MA plans seeking to expand to new services areas (service area expansions or SAEs) are required to submit a Part C application addressing Part C (MA) SAE requirements and a Part D SAE application addressing the prescription drug benefit requirements. Failure of an applicant to qualify in either the Part C or Part D will result in the denial of the SAE.

Applicants seeking SAEs have their applications reviewed by CMS to determine whether they meet the application requirements to enter into such a contract. The regulation at 42 C.F.R. §422.501(b)[2] states, in relevant part:

> (b) Completion of an application.

[1] 42 C.F.R. §422.500 indicates that MA organizations offering prescription drug plans must meet the requirements of Part 422 (Part C) and Part 423 (Part D) of the regulations. The Parts C and D regulations concerning contract determination and appeals are generally parallel.

[2] See similar language for Part D at 42 C.F.R. §423.502.

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

(Emphasis added).

Accordingly, for the 2009 contract year, CMS established an online application process for both Part C and Part D Plans called the Health Plan Management System (HPMS). All new applicants and requests to expand service areas had to submit their applications through the HPMS by deadlines established by CMS. CMS provided training and technical assistance to plans in completing their application and plan applications were evaluated solely on the materials they submitted into the HPMS system within CMS established windows.

After the initial March 2008 filing window closed, CMS reviewed plan submissions and in April 2008, provided the plans with a listing of their deficiencies. The HPMS system was reopened for a second window to submit data into the HPMS to correct the deficiencies.

Upon review of the materials submitted within the second window, some plans still had alleged deficiencies. Prior to issuing a contract determination denial, the regulations at 42 C.F.R. §422.502(c) require CMS to formally send an intent to deny notice which provides the plan ten days to cure their application. The regulation states:

> (c) Notice of determination. Within timeframes determined by CMS, it notifies each applicant that applies for an MA contract under this part of its determination and the basis for the determination. The determination is one of the following:

(1) Approval of application. If CMS approves the application, it gives written notice to the applicant, indicating that it qualifies to contract as an MA organization.

(2) Intent to deny.

(i) If CMS finds that the applicant does not appear to be able to meet the requirements for an MA organization and/or has not provided enough information to evaluate the application, CMS gives the contract applicant notice of intent to deny the application for an MA contract and a summary of the basis for this preliminary finding.

(ii) Within 10 days from the date of the intent to deny notice, the contract applicant must respond in writing to the issues or other matters that were the basis for CMS' preliminary finding and must revise its application to remedy any defects CMS identified.[3]

(Emphasis added).

During the ten day period plans were given a final opportunity to submit data into the HPMS to correct their deficiencies. On May 19, 2008, the window closed and plans were unable to formally file materials through the HPMS system. CMS reviewed the materials which were filed through timely filed in HPMS and on June 3, 2008 issued denial letters to the plans which had failed to correct their deficiencies.

If CMS denies a Medicare Advantage applicant, they have a right to a hearing before a CMS Hearing Officer under 42 C.F.R. §422.660.[4] The regulation states:

(a) The following parties are entitled to a hearing:

(1) A contract applicant that has been determined to be unqualified to enter into a contract with CMS under part C of Title XVIII of the Act pursuant to 422.501.
(2) An MA organization whose contract has been terminated pursuant to § 422.510.
(3) An MA organization whose contract has not been renewed pursuant to §422.506.
(4) An MA organization who has had an intermediate sanction imposed pursuant to § 422.752(a) through (b).

[3] See similar language for Part D at 42 C.F.R. §423.503.
[4] See similar language for Part D at 42 C.F.R. §423.650(a).

(b) The MA organization bears the burden of proof to demonstrate that it was in substantial compliance with the requirements of the MA program on the earliest of the following three dates: [5]

(1) The date the organization received written notice of the contract determination or intermediate sanction.
(2) The date of the most recent on-site audit conducted by CMS.
(3) The date of the alleged breach of the current contract or past substantial noncompliance as determined by CMS

(Emphasis added).

As part of the application process, all applicants (initial and expanding service area) are responsible for inputting their own organization's requested service area for the 2009 contract year directly into the CMS HPMS. Detailed instructions on how an applicant should input the service area were provided in the January 28, 2008 User's Manual available within HPMS.[6] In addition, existing sponsors are required to demonstrate that they meet the pharmacy access standards established under §1860D-4(b)(1)(C) of the Act. The standards require in part that each Part D sponsor secure the participation in their pharmacy networks by a sufficient number of pharmacies to dispense drugs directly to patients (other than by mail order) to ensure convenient access to covered Part D drugs by plan enrollees. To implement this requirement, CMS developed specific access rules delineated at 42 CFR §423.120. These rules require that Part D sponsors maintain retail pharmacy networks as follows:

- In urban areas, at least 90 percent of Medicare beneficiaries in the Part D sponsor's service area, on average, live within 2 miles of a retail pharmacy participating in the Part D sponsor's network;

- In suburban areas, at least 90 percent of Medicare beneficiaries in the Part D sponsor's service area, on average, live within 5 miles of a retail pharmacy participating in the Part D sponsor's network; and

- In rural areas, at least 70 percent of Medicare beneficiaries in the Part D sponsor's service area, on average, live within 15 miles of a retail pharmacy participating in the Part D sponsor's network.

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[5] The implementing Proposed Rule 70 Fed. Reg. 29367, 29377 states "Based on our experience with appeals of contract determinations, we have found the current regulations do not provide hearing officers with a particular "compliance date" to use as a reference point in issuing a ruling. This creates the potential inconsistency in the decisions issued by hearing officers. We believe our proposal to provide a framework for hearing officer to use in establishing a compliance date as a reference will lessen the potential for such inconsistency. See also 70 Fed. Reg. 68700 et seq. (Final Rule), December 5, 2007.

[6] CMS Exhibit 3 for all three cases.

Detailed instructions were provided to SAE applicants within Appendix III—Retail Pharmacy Network Access Instructions of the 2009 Part D SAE application. These instructions,[7] specify:

> By contract, Part D sponsors are required to meet the access standards in 42 CFR §423.120 (a)(1). Applicants should note that the Retail access standard requirement is applied at the Plan Benefit Package (PBP) level. It is important to note the reference to plan (and not contract ID) in the requirements defined in 42 CFR §423.120 (a)(1). **As part of routine monitoring and audit processes, CMS will review retail pharmacy access at the PBP level.** (Emphasis added.)
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> . . . .
>
> **Information Required to Qualify As Part D Sponsor**
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> CMS recognizes that the deadline for submission of the Part D application (March) precedes the plan bidding and finalization process (June). Further CMS recognizes that many (if not most) Part D sponsors continue work on defining their PBP service areas throughout their Bid formulation process. Therefore, it is difficult for Applicants to submit final pharmacy accessibility analyses for each PBP, and we will require a contract-level submission at this time. This circumstance is especially problematic for MA-PD sponsors that may choose to offer a PBP to a subset of their Contract Service Area. The impact on PDPs, RPPOs, and Cost Plans is minimal since those types of contracts must offer all PBPs with Part D throughout each specific PDP Region (PDPs), MA Region (RPPOs) or geographic area (Cost Plans).
>
> **Local MA-PD Service Area Expansion (SAE) Applicants for Part D should submit their pharmacy access analyses at the contract level, including the entire service area for the contract**. (Emphasis in original). GeoNetworks® reports provided at the contract level must include detail on the number of beneficiaries and the number of contracted pharmacies at the county level. MA-PD SAE Applicants for Part D are not required to submit separate geographic accessibility analyses for each unique PBP service area or each unique combination of PBPs offered in the same service area.

Appendix III also contains detailed geographic accessibility analysis instructions. It contains the following at page 42:

> **4. Defining the Plan Service Area**
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> Applicants should define their service area based on the service area for the entire contract. The service area defined in your report must EXACTLY match the service are you have specified in HPMS.

[7] CMS Exhibit 2 at page 39 for all cases.

(Emphasis in original).

Factual Background

Case No. 2008 C/D App 04

Arcadian has operated a health maintenance organization contract (H#4529) since January 2005 and began to offer the prescription drug benefit in January 2006 in 2 Texas counties (El Paso, Travis). Arcadian expanded into an additional 23 counties (Anderson, Camp, Cherokee, Franklin, Freestone, Gregg, Harrison, Henderson, Hopkins, Houston, Kaufman, Marion, Morris, Navarro, Panola, Rusk, Shelby, Smith, Trinity, Upshur, Van Zandt, Williamson, and Wood) in 2007. For the upcoming 2009 contract year, Arcadian submitted a Part D SAE application (under contract H#4529) on March 6, 2008 seeking to expand its service area to an additional 15 counties (Armstrong, Brazos, Burleson, Carson, Deaf Smith, Grimes, Hardin, Jefferson, Leon, Madison, Oldham, Orange, Potter, Randall, and Robertson) in Texas for the individual market and nationally in the employer market.

4CMS determined that Arcadian's original application submission did not contain information in the accessibility reports for the same counties as those Arcadian had identified in its proposed service area in HPMS. The GeoAccess report did not include the existing individual market counties as part of the accessibility analyses as required in the Retail Pharmacy Access Instructions within the Part D SAE Application.[8]
CMS provided all applicants on April 4, 2008 with an electronic mail notice of the status of their application indicating whether there were any deficiencies. The CEO-Senior Official for Contracting and the Part D Application Contact at Arcadian were sent an e-mail on April 4, 2008 [9] notifying them that the service area within HPMS did not concur with the service area provided in the Accessibility reports. All applicants receiving such a deficiency e-mail were afforded the opportunity between 9:00 a.m. EDT on April 15, 2008 and 8:00 p.m. EDT on April 16, 2008 to submit corrected materials through HPMS. Arcadian did not submit any correcting documents during the allotted time period.

Pursuant to 42 C.F.R. §423.503(c)(2)(i), CMS subsequently issued a Part D Notice of Intent to Deny[10] the 2009 Part D SAE application to the CEO-Senior Official for Contracting and the Part D Application Contact at Arcadian. The Notice of Intent to Deny was e-mailed and delivered via Federal Express to Arcadian on May 9, 2008. All applicants receiving a Part D Notice of Intent to Deny had from 9:00 a.m. on May 9th to midnight on May 19, 2008 to upload corrected materials into HPMS, consistent with the requirements stated at 42 C.F.R. §423.503(c)(2)(ii). The Notice of Intent to Deny listed subject matter expert contact information in the event that the sponsor had questions.

[8] CMS Exhibit 4 for Case No. 2008 C/D App 04.
[9] CMS Exhibit 5 for Case No. 2008 C/D App 04.
[10] CMS Exhibit 7 for Case No. 2008 C/D App 04.

On May 18th, CMS received via e-mail, a letter from Charro Knight-Lilly, Vice President of Compliance and Regulatory Affairs at Arcadian, requesting that 8 counties (Brazos, Burleson, Deaf Smith, Grimes, Leon, Madison, Orange, and Robertson) be removed from the individual market service area expansion.[11] On the basis of that request, CMS reduced the pending service area. Additionally, on May 19, in response to the May 9th Notice of Intent to Deny letter, Arcadian submitted a revised Accessibility report.[12] CMS staff reviewed the submission and was unable to determine whether the rural access standards were met as that submission contained 4 counties (Callahan, Jones, Nolan, and Taylor) which are not part of the individual market service area identified under H4529 in HPMS. Since the Accessibility report did not match the proposed service area, CMS could not determine whether Arcadian met the access standard for its proposed service area and therefore, denied the application.[13]

Case No. 2008 C/D App 05

Arcadian has operated a HMO contract (H5783) since January 2007 in 6 South Carolina counties (Berkeley, Charleston, Colleton, Dorchester, Greenville, Pickens) and expanded into an additional 2 counties (Allendale, Spartanburg) in 2008. For the 2009 contract year, Arcadian submitted a Part D SAE application (under contract H5783) on March 6, 2008 seeking to expand its service area to an additional 2 counties (Lexington, Richland) in South Carolina for the individual market and nationally in the employer market.

CMS determined that Arcadian's original application submission did not contain information in the accessibility reports for the same counties as those Arcadian had identified in its proposed service area in HPMS. The GeoAccess report did not include the existing individual market counties as part of the accessibility analyses as required in the Retail Pharmacy Access Instructions within the Part D SAE Application.[14]

By electronic mail notification on April 4, 2008, CMS Exhibit 5, CMS notified Arcadian that the service area within HPMS did not concur with the service area provided in the Accessibility reports. All applicants, including Arcadian were afforded the opportunity between 9:00 a.m. EDT on April 15, 2008 and 8:00 p.m. EDT on April 16, 2008 to submit corrected materials through HPMS. Arcadian did not submit any correcting documents during the allotted time period.

Pursuant to 42 C.F.R. §423.503(c)(2)(i), CMS subsequently issued a Part D Notice of Intent to Deny[15] the 2009 Part D SAE application to Arcadian. The Notice of Intent to Deny was e-mailed and delivered via Federal Express to Arcadian on May 9, 2008. All applicants receiving a Part D Notice of Intent to Deny had from 9:00 a.m. on May 9th to midnight on May 19, 2008 to upload corrected materials into HPMS, consistent with the

[11] CMS Exhibit 8 for Case No. 2008 C/D App 04.
[12] CMS Exhibit 9 for Case No. 2008 C/D App 04.
[13] CMS Exhibit 1 for Case No. 2008 C/D App 04.
[14] CMS Exhibit 4 for Case No. 2008 C/D App 05.
[15] CMS Exhibit 7 for Case No. 2008 C/D App 05.

requirements stated at 42 C.F.R. §423.503(c)(2)(ii). The Notice of Intent to Deny listed subject matter expert contact information in the event that the sponsor had questions.

On May 18th, CMS received via email, a letter from Charro Knight-Lilly, Vice President of Compliance and Regulatory Affairs at Arcadian requesting that Lexington County be removed from the individual market service area expansion.[16] On the basis of that request, CMS reduced the pending service area. Additionally, on May 16, in response to the May 9th Notice of Intent to Deny letter, Arcadian submitted a revised Accessibility report.[17] After the May 19th deadline, CMS staff reviewed the submission from Arcadian and was unable to determine whether the rural access standards were met as that submission contained Lexington County, which the applicant requested be removed from the service area. Since the Accessibility report did not match the proposed service area, CMS could not determine whether Arcadian met the access standard for its proposed service area and therefore, denied the application.[18]

Case No. 2008 C/D App 07

Arcadian has operated a HMO contract (H7179) since January 2008 in 24 Louisiana counties. For the 2009 contract year, Arcadian submitted a Part D SAE application (under contract H7179) on March 6, 2008 seeking to expand its service area to an additional 14 counties (Acadia, Avoyelles, Catahoula, Concordia, Grant, Iberia, Lafayette, LaSalle, Natchitoches, Rapides, St. Landry, St. Martin, Vermillion, and Vernon) in Louisiana for the individual market and nationally in the employer market.

CMS determined that Arcadian's original application submission did not contain information in the accessibility reports for the same counties as those Arcadian had identified in its proposed service area in HPMS. The GeoAccess report did not include the existing individual market counties as part of the accessibility analyses as required in the Retail Pharmacy Access Instructions within the Part D SAE Application.[19]

By electronic mail notification on April 4, 2008,[20] CMS notified Arcadian that the service area within HPMS did not concur with the service area provided in the Accessibility reports. All applicants, including Arcadian were afforded the opportunity between 9:00 a.m. EDT on April 15, 2008 and 8:00 p.m. EDT on April 16, 2008 to submit corrected materials through HPMS. Arcadian did not submit any correcting documents during the allotted time period.

Pursuant to 42 C.F.R. §423.503(c)(2)(i), CMS subsequently issued a Part D Notice of Intent to Deny[21] the 2009 Part D SAE application to Arcadian. The Notice of Intent to

[16] CMS Exhibit 8 for Case No. 2008 C/D App 05..
[17] CMS Exhibit 9 for Case No. 2008 C/D App 05.
[18] CMS Exhibit 1 for Case No. 2008 C/D App 05.
[19] CMS Exhibit 4 for Case No. 2008 C/D App 07.
[20] CMS Exhibit 5 for Case No. 2008 C/D App 07.
[21] CMS Exhibit 7 for Case No. 2008 C/D App 07.

Deny was e-mailed and delivered via Federal Express to Arcadian on May 9, 2008. All applicants receiving a Part D Notice of Intent to Deny had from 9:00 a.m. on May 9th to midnight on May 19, 2008 to upload corrected materials into HPMS, consistent with the requirements stated at 42 C.F.R. §423.503(c)(2)(ii). The Notice of Intent to Deny listed subject matter expert contact information in the event that the sponsor had questions.

On May 19th, CMS received via email, a letter from Charro Knight-Lilly, Vice President of Compliance and Regulatory Affairs at Arcadian requesting that 11 counties be reduced from the individual market service area expansion,[22] and based on that request, CMS reduced the pending service area. Additionally, on May 19th, Arcadian submitted a revised Accessibility report in response to the Notice of Intent to Deny.[23]

CMS staff determined that the Arcadian's May 19th submission contained LaSalle County, which was one of the counties Arcadian requested to be removed from the service area. Since the Accessibility report did not match the proposed service area, CMS could not determine whether Arcadian met the access standard for its proposed service area and therefore, denied the application.[24]

Issue

Was the CMS denial of Arcadian's applications for an SAE for its Part D plans for program year 2009, proper?

CMS' Contentions

CMS contends that in order to obtain approval of an application for an MA-PD contract, applicants must demonstrate that they meet the Part D program requirements to qualify as an MA-PD sponsor in the proposed service area. As noted above, MA organizations attempting to qualify as a Part D sponsor in a particular service area are obligated, under 42 C.F.R. §422.500(a) to follow the Part D qualification process governed by 42 C.F.R., Part 423. Pursuant to 42 C.F.R. §423.502(b)(2), applicants are required to describe thoroughly how they meet the Part D program requirements. In addition, under 42 C.F.R. §423.504(b)(1), an applicant seeking a contract as a Part D sponsor for a particular service area must demonstrate in its application that is has the capability to meet the requirements of 42 C.F.R., Part 423 in that service area. CMS is obligated under 42 C.F.R. §423.502(c) to determine whether an entity is qualified to contract as a Part D plan, and whether such entity meets all Part D program requirements. In light of these provisions, CMS reviews each Part D application under a strict application review standard. Any applicant that fails to meet applicable requirements in a service area in which the applicant has applied to offer a Part D plan is considered to be unqualified, and therefore, not entitled to a Part D sponsor contract covering that service area.

[22] CMS Exhibit 8 for Case No. 2008 C/D App 07.
[23] CMS Exhibit 9 for Case No. 2008 C/D App 07.
[24] CMS Exhibit 1 for Case No. 2008 C/D App 07.

While Arcadian's application demonstrated that it meets some Part D sponsor qualification requirements, the regulatory provisions identified above do not afford CMS the latitude to approve an entity's application when it does not demonstrate that it meets all Part D qualification requirements. There is no statutory or regulatory provision authorizing CMS to grant Part D sponsor qualification to applicants that only substantially meet Part D requirements.

CMS asserts in all three cases Arcadian's retail pharmacy access submission did not match the applicant's HPMS service area and that it is not possible for CMS to determine with certainty whether the sponsor has met the retail pharmacy access requirements. CMS argues that it cannot verify compliance with the retail pharmacy accessibility standard simply by looking at the report's results in the counties shown in HPMS and ignoring the report's analysis in the additional counties not shown in HPMS. CMS explains that the pharmacy access analysis performed by GeoAccess is calculated as an average across an entire service area. Accordingly, an applicant's failure to meet the pharmacy access standard in some counties may be offset by the fact that it exceeds the standard in other counties.

When a sponsor's access report service area does not match the service area shown in HPMS, it is possible that the results in the HPMS report are giving the applicant unfair credit for exceeding the accessibility standard in counties it does not intend to serve. The applicant's performance in the "excess" or "missing" counties may be masking the applicant's failure to meet the access standard in counties it does actually intend to serve.

CMS also asserts that it can not choose among competing versions of the applicant's service area. When CMS receives instructions from an applicant to reduce the applicant's service area in HPMS, CMS follows those instructions and rightly expects that the applicant's subsequent accessibility analysis will describe the changed service area. When an applicant submits an accessibility analysis that is inconsistent with its own instructions to CMS, CMS has no discretion or obligation to make an educated guess as to which service area the applicant truly wants to serve during CY 2009.

CMS asserts that Arcadian filed its request for a hearing pursuant to 42 C.F.R. §423.650 and that while the contract appeal regulation does not expressly discuss the burden of proof or standard of review for applicants that have been denied a Part D application, the burden of proof in demonstrating that Part D requirements are met is on the entity seeking to offer a Part D contract. This is because the CMS review process is designed to ensure that these requirements are met before approving a Part D plan in a given service area. Placing the burden of proof on the applicant in a contract determination appeal is consistent with other CMS appeals procedures (e.g., appeals under 42 CFR Part 498) and is supported by case law and general rules of administrative law.[25] In the absence of a

[25] "In administrative proceedings, the general rule is that an applicant for relief, benefits, or privilege has the burden of proof." 73 C.J.S. Public Administrative Bodies and Procedures, § 124.

regulation specifying the CMS Hearing Officer's standard of review, the same strict application review standard used by CMS should apply at hearing.

CMS notes that Arcadian argues that the standard of review is one of "substantial compliance," based on the use of this term in 42 C.F.R. §422.650(b). CMS notes that in recent MA and Part D notice and comment rulemaking proceedings, it amended its hearing appeals regulation to clearly establish that the burden of proof rests with the MA organization or Part D sponsor appealing a contract determination to prove it was in "substantial compliance" with the relevant MA or Part D requirements. 72 Fed. Reg. 68700 (Dec. 5, 2007). CMS claims that only existing contractors are bound by contracts to comply with requirements and therefore, the substantial compliance standard does not apply to contract applicants. As a result, CMS asserts that contract applicants must meet all qualification requirements, not just a "substantial number."

CMS also asserts that upon the issuance of a notice of intent to deny an application pursuant to 42 C.F.R. §423.503(c)(2)(i), applicants are afforded no more than 10 days to respond to the issues identified in the notice, per 42 C.F.R. §423.503(c)(2)(ii). The date of expiration of the 10-day period is the date by which any information must have been submitted to be considered in the SAE application approval decision for the following calendar year. As described above, CMS made its application denial determination based on the information provided in Arcadian's final resubmission on May 19, 2008. Thus, that was the information that was before CMS when it issued the Notice of Denial on June 3, 2008.

Applicants have no basis to believe that they could submit additional information after these deadlines, simply because they have filed an appeal to a hearing officer. CMS maintains that Arcadian should not be afforded an opportunity based on 42 C.F.R. §422.650(b)(1) to submit to the Hearing Officer documentation concerning its Part D qualifications that has not previously been reviewed by CMS during the CY 2009 application process and to permit the submission of such information would, in effect, extend the deadline for submitting an approvable application.

CMS states that it can not reasonably conclude that Arcadian simply made mistakes in submitting its application materials and should therefore give Arcadian the benefit of the doubt by approving its application. The regulations grant CMS no such discretion nor would such discretion promote the fairness and accuracy of the application review process. CMS cannot be asked to evaluate applicants' intentions because to do so would introduce ambiguity into a process that requires absolute accuracy. There is no way CMS could apply such discretion fairly and uniformly among all applicants. Furthermore, an applicant's failure to follow CMS' application instructions is not completely unrelated to an applicant's qualifications as such conduct raises serious concerns for CMS about the applicant's administrative and management capabilities, one of several qualification requirements described at 42 C.F.R. §423.504(b)(4).

At the hearing, CMS clarified that its denials were based solely on the failure of the service areas in the HPMS to match the Accessibility report. While CMS indicated that

accessibility is re-evaluated at the bidding process, plans are required to match service areas exactly matched during the initial contract application process.

Arcadian's Contentions

Arcadian asserts that its requests were denied because the GeoNetworks reports purportedly did not match the service area that Arcadian specified in the HPMS, or possibly because of a supposed lack a complete retail pharmacy list.

Arcadian believes that the language in Appendix III of the 2009 Part D Service Area Expansion Application, noted above, indicates that the plan service areas are likely to change and that ultimately plans will be assessed on their access at the PBP level and county level. To the extent that CMS is concerned with plan access for the entire service area, there is no requirement as part of the GeoNetworks report configuration or any Medicare regulation or guidance that require showing Part D access at an aggregate level for its entire contract service area.

With respect to Case No. 2008 C/D App 04, it states that its submitted GeoNetwork report included information on the entire service area in Texas in which the company wanted to expand in 2009 including those in the finally selected service areas. Moreover, through HPMS, it provided a list of pharmacies located in the service area. While it withdrew a number of the initially requested counties, its first and second GeoNetworks submissions[26] contain all of the data necessary to demonstrate compliance with the Part D retail pharmacy access in all of the proposed counties in Texas.

With respect to Case No. 2008 C/D App 05, Arcadian indicates it provided CMS with the evidence needed to support its request for Richland County. Through timely submitted GeoNetworks reports uploaded through HPMS,[27] Arcadian provided all of the data necessary to satisfy the Part D access requirements in the Medicare regulations. For the lone service area at issue (Richland County), the report submitted demonstrated the requisite level of access to retail pharmacies in this county, albeit in the earlier submission. The GeoNetworks reports,[28] demonstrate substantial compliance with the Part D pharmacy access standards defined in the Medicare regulations at both the PBP level (as the PBPs are defined above), and the county level.

With respect to Case No. 2008 C/D App 07, Arcadian again indicates that it provided CMS with the evidence needed to support this request. Through timely submitted GeoNetworks reports uploaded through HPMS,[29] it provided adequate documentation that it met the access requirements in the various expansion areas

[26] Plan Exhibits 1 and 3 for Case No. 2008 C/D App 04.
[27] Plan Exhibits 1 and 3 for Case No. 2008 C/D App 05.
[28] Plan Exhibits 1 and 3 for Case No. 2008 C/D App 05 together.
[29] Plan Exhibits 1 and 3 for Case No. 2008 C/D App 07 together.

Arcadian also states that for all three cases it provided a full National Retail Pharmacy List with its first GeoNetworks submission and there was no need to resubmit an updated Retail Pharmacy List. Both were submitted through the required HPMS system within the defined timelines established by CMS.

Decision

CMS' June 3, 2008 denials of Arcadian' SAE applications are upheld because Arcadian did not demonstrate they were in substantial compliance with the requirements of the MA-PD program.

Regarding the CMS's contention that applicants must demonstrate that they meet all of the filing qualification requirements in the application, the Hearing Officer finds that the appeal regulation at 42 C.F.R. §423.650 which outlines the substantial compliance standard, applies equally to both applicants and existing contractors. The regulation language applies the same burden of proof to initial (or SAE) applicants and existing plans and provides no distinctions between initial applicants or existing plans. Likewise, language in the preamble does not state that the substantial compliance standard only applies to existing contracts.

The Hearing Officer notes that while 42 C.F.R. §§422.501(b)(1) and 423.502(b)(1) allows CMS to dictate the form and manner of the application process, the §§422.501(b)(2) and 423.502(b)(2) language indicating that a plan must "thoroughly" describe how it met the requirements does not raise the bar for the filing requirements from a substantial compliance standard to a total compliance standard.

With regard to what evidence the Hearing Officer may consider when evaluating "substantial compliance" on the date of the June 3, 2008 contract determination, the Hearing Officer again notes that pursuant to 42 C.F.R. §§422.501(b) and 423.502(b), CMS may dictate the form and manner of the application process. In addition, 42 C.F.R. §§422.502(c)(2)(ii) and 423.503(c)(2)(ii) require that plans revise their applications within 10 days from the date of the intent deny letter. Accordingly, CMS was within its authority to only consider documentation which was filed through its HPMS system by May 19, 2008, the last day of the 42 C.F.R. §§422.502(c)(20(ii) and 423.503(c)(2)(ii) cure window. Therefore, when deciding if a plan was in substantial compliance on June 3, 2008, the Hearing Officer will evaluate whether the materials timely and properly filed with the agency by May 19, 2008 substantially complied with program requirements.[30]

[30] Reading 42 C.F.R. §§422.660(b) or 423.650(b) in isolation could be misleading as it suggests that the Hearing Officer may consider any documentation which was submitted to CMS (or which potentially existed) up to the date of denial, i.e. June 3, 2008. However, such reading would require reading this section within a vacuum and would effectively invalidate all other regulatory (and instructional) filing requirements and deadlines. The Hearing Officer accordingly finds, to interpret 42 CFR 422.660 and 423.650 , one must read the application, determination and appeals regulations together. Moreover, the Hearing Officer notes that 42 CFR 422.660(a)(1)and 42 CFR 423.650

As noted above, CMS has developed specific access standards in 42 C.F.R. §423.120. CMS has provided detailed instructions for providing access information in its instructions.[31] These instructions acknowledge that Plans are still formulating their bids and that the pharmacy access standards will ultimately have to be assured in the service areas for all Plan Benefit Packages offered. The specific instructions for the geographic accessibility analysis state that "[a]pplicants should define their service area based on the service area for the entire contract. The service area defined in your report must EXACTLY match the service are you have specified in HPMS." (Emphasis in original). The Hearing Officer finds these instructions are clear that, for purposes of the application approval, the plan has to demonstrate accessibility for the exact areas they propose to serve.

The Hearing Officer notes that the facts in the record support CMS' finding that the plan access reports did not contain the same services areas that were proposed in the HPMS. For Case No. 2008 C/D App 04, there were four additional counties listed in the access report that were not in the proposed service area; for Case No. 2008 C/D App 05, there was one county included in the access report that was not in the proposed service area and one county that was supposed to be in the proposed service area that was excluded; and for Case No. 2008 C/D App 07, there was one county included in the access report that was not in the service area.

The Hearing Officer notes that once CMS determined that the services areas did not match up, it conducted no further analysis and denied the applications. Arcadian claims that CMS could have corrected its submission and that CMS possessed the data to determine that it would have been in compliance with the access requirements. The Hearing Office finds that CMS provided reasonable administrative reasons why it can not correct a plans' incorrect submission including fairness, consistency, inability to discern the true intentions of the plans and the number of applications it receives.

The Hearing Officer also finds that CMS adequately explained that when the service area in the access report does not match the service area shown in HPMS, it is not possible to simply add or remove data from the individual counties. CMS pointed out the data from all counties is first broken down by urban, suburban and rural zip codes and then averaged together to determine whether the plan met the separate urban, suburban and rural standards for all of the counties together. If the plan's report includes or excludes counties in the service area, the results in the report may give the applicant unfair credit for exceeding the accessibility standard in counties that it does not intend to serve.

The Hearing Officer finds that CMS has the authority to set instructions pursuant to 42 C.F.R. §423.502(b); that the requirement that the service area in the access report match the proposed service area was reasonable; and that Arcadian was not in substantial

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(a)(1) explicitly reference 42 CFR 422.501 and 42 CFR 423.503, which address the application process.

[31] CMS Exhibit 2, Appendix III at 39 for all cases.

compliance because it failed to submit proper documentation of its network access as required by the instructions.

Conclusion

The Hearing Officer finds that CMS' June 3, 2008 denials were proper.

Benjamin Cohen
CMS Hearing Officer

Date: July 18, 2008