CENTERS FOR MEDICARE AND MEDICAID SERVICES HEARING OFFICER DECISION

IN THE MATTER OF:

ORDER GRANTING MOTION FOR SUMMARY JUDGMENT

I. JURISDICTION

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

II. <u>Issue</u>

Whether CMS' denial of University Care Advantage's (UCA, or the Plan) application for a Service Area Expansion (SAE) of its Medicare Advantage – Prescription Drug (MA-PD) plan for contract year 2014 was an appropriate application of program contracting regulations.

III. PROGRAM BACKGROUND

The Medicare Advantage (MA or Part C) program offers Medicare beneficiaries the option of receiving health care benefits through a privately-operated coordinated care delivery system. Organizations that are approved to offer MA-PD benefits are required to maintain a provider network that ensures "adequate access to covered services" for its plan enrollees in each operative service area. This network must include a variety of providers, including primary care physicians, specialists, and hospitals. In addition, MA organizations must offer an outpatient prescription drug benefit in the service areas in which they offer a Part C benefit.

The Secretary of the United States Department of Health & Human Services (the Secretary) is authorized to contract with entities seeking to offer MA and MA-PD benefits. ⁴ Through regulation, the Secretary has delegated this contracting authority to CMS, which has established the general provisions for entities seeking to qualify as MA-PD plans. ⁵

¹ See 42 U.S.C. § 1395w-21 et seq.

² 42 C.F.R. § 422.112(a)(1).

³ 42 C.F.R. § 422.4(c)(1). See also, generally, 42 U.S.C. § 1395w-112 (Medicare Part D).

⁴ 42 U.S.C. § 1395w-27.

⁵ 42 C.F.R. §§ 422.400 et seq., 422.503(b) et seq.

Potential MA-PD organizations submit applications to CMS, in which the applicant organization must document that it has a provider network in place that meets CMS requirements. These applications must be completed "in the form and manner required by CMS." Presently, CMS requires the electronic submission of MA-PD applications via the Health Plan Management System (HPMS) program. Through HPMS, applicants must provide Health Services Delivery (HSD) tables that document their provider network. These HSD tables must show that the planned network meets the applicable travel time and distance requirements. To this end, MA applicants must demonstrate "that 90 percent of beneficiaries (or more) have access to at least one provider/facility, for each specialty type, within established time and distance requirements."

After receiving a MA-PD application, CMS makes a determination as to whether the applicant organization meets all of the relevant program requirements. This determination is based solely on information contained in the application or obtained by CMS through methods such as onsite visits. CMS conducts elements of the application review process using a computer program within HPMS known as the Automated Criteria Check (ACC). The ACC is used to assess the sufficiency of applicant care networks at both the provider and facility levels. 12

If the ACC assessment reveals network shortcomings, CMS issues a Deficiency Notice outlining the relevant issues. ¹³ Following the transmittal of a Deficiency Notice, applicants may review the ACC report, submit updated provider information, and file a timely Exception Request concerning any provider and service area criteria that it is unable to meet. CMS guidance notes that the agency will consider these requests for exceptions to the network requirements "under definite and limited circumstances." Each Exception Request must be accompanied by supporting documentation that shows "how local community patterns of care support the proposed network of providers/facilities and those specialty types for which the applicant is requesting an exception." ¹⁴ Furthermore, agency guidance establishes that plans have "one opportunity" to submit an Exception Request, and this occurs "immediately following the issuance of the CMS-generated [ACC] report generated after the receipt by CMS of the Applicant's response to the Deficiency Notice." ¹⁵ CMS requires Exception Requests to be submitted electronically via a dedicated request template. ¹⁶

http://www.cms.gov/Medicare/Medicare-Advantage/MedicareAdvantageApps/Downloads/CY2014-HSD-Provider-and-Facility-Specialties-Criteria-Guidancev2.pdf (last visited July 24, 2013).

⁶ 42 C.F.R. § 422.501(c)(2).

⁷ 42 C.F.R. § 422.501(c)(1).

⁸ CMS Memorandum and Motion for Summary Judgment (CMS Memorandum) at 3.

⁹ CMS Memorandum, Exhibit D, MA HSD Provider and Facility Specialties and Network Adequacy Criteria Guidance (Network Adequacy Guidance) at 2. *Also available at* http://www.cms.gov/Medicare/Medicare-Advantage/MedicareAdvantageApps/Downloads/CY2014-HSD-

¹⁰ 42 C.F.R. § 422.502(a)(2).

¹¹ 42 C.F.R. § 422.502(a)(1).

¹² CMS Memorandum at 3.

¹³ CMS Memorandum, Exhibit D. Network Adequacy Guidance at 10.

 $^{^{14}}$ *Id*.

¹⁵ *Id. See also* CMS Memorandum Exhibit E, HSD Instructions for CY 2014 Applications at 9 ("All Exceptions must be requested and supported with appropriate documentation within the timeframe established by CMS.")

¹⁶ CMS Memorandum, Exhibit D, Network Adequacy Guidance at 10.

Before final disapproval of an MA-PD application, CMS must provide a formal "Notice of Intent to Deny," which provides the basis for the denial and gives the applicant ten days to cure the deficiencies in its application. The regulatory requirement for curing an application is stated at 42 C.F.R. § 422.502(c)(2)(ii - iii) as follows:

- (ii) Within 10 days from the intent to deny, the 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.
- (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 that the applicant does not appear qualified or has not provided CMS enough information to allow CMS to evaluate the application, CMS will deny the application.

CMS guidance also indicates that if a Notice of Intent to Deny identifies a previously-submitted Exception Request, the applicant may submit a corrected Exception Request during the cure period, but only "for the same contract id (*sic*), county and specialty code as was originally submitted."¹⁷

If CMS denies a MA-PD application, the applicant organization is entitled to a hearing before a CMS hearing officer. ¹⁸ The regulation at 42 C.F.R. § 422.660(b)(1) dictates that "the applicant has the burden of proving by a preponderance of the evidence that CMS' determination was inconsistent with the requirements of [42 C.F.R. §§ 422.501 and 422.502]." ¹⁹ In addition, the regulations governing the hearing process provide that either party may ask the Hearing Officer to rule on a Motion for Summary Judgment. ²⁰

IV. FACTUAL AND PROCEDURAL BACKGROUND

In February 2013, UCA, a Part C organization operating in six Arizona counties, submitted an application to expand its service area into six additional counties (the Expansion Counties) for the 2014 contracting year. ²¹ CMS reviewed the application and determined that UCA had not

¹⁷ *Id*.

¹⁸ 42 C.F.R. § 422.660.

¹⁹ See supra p. 2. (The regulations at 42 C.F.R. §§ 422.501 and 422.502 establish the contract application requirements and review procedures).

²⁰ 42 C.F.R. § 422.684(b). *See also* Medicare Program, Revisions to the Medicare Advantage and Part D Prescription Drug Contract Determinations, Appeals and Intermediate Sanctions Processes, 72 Fed. Reg. 68700, 68714 (December 5, 2007) (Preamble to final rule stating, "In ruling on such a [Summary Judgment] motion, we propose that the hearing officer would be bound by the CMS regulations and general instructions. Where no factual dispute exists, the hearing officer may make a decision on the papers, without the need for a hearing.").

²¹ CMS Memorandum at 4. UCA is an authorized Part C plan sponsor in Pima, Santa Cruz, Pinal, Maricopa and Cochise Counties. The SAE application sought to extend services into Gila, Graham, Greenlee, La Paz, Yavapi, and Yuma Counties.

demonstrated a sufficient provider network within the Expansion Counties. This initial assessment was based in part on an ACC review of the information provided via the Plan's HSD tables. ²² Accordingly, on March 13, 2013, CMS provided an electronic Deficiency Notice to UCA outlining these shortcomings. This notice instructed the Plan to provide corrective materials by March 28, 2013.

In response, UCA timely submitted revised network information and 74 exception requests concerning provider and facility deficiencies. CMS reviewed this additional information and determined that 28 of the exception requests should be denied based on continuing network deficiencies. These denials included provider and facility shortcomings in five of the six Expansion Counties.²³

As a result of these remaining network failures, CMS issued a Notice of Intent to Deny to UCA on April 26, 2013.²⁴ This notice offered the Plan a final, ten-day opportunity to cure the deficiencies, and set a May 7, 2013 submission deadline. UCA responded by offering revised network data and revised exception requests. CMS determined that the revised network data did not sufficiently cure the remaining ACC failures. The revised exception requests led CMS to reverse a single exception denial, but left 27 exception denials in effect.²⁵ Accordingly, CMS issued a final Denial Notice to UCA on May 31, 2013.²⁶

On June 14, 2013, UCA requested the present appeal.

V. <u>UCA'S APPEAL CONTENTIONS</u>

UCA filed its Appeal Brief on June 24, 2013. In this submission, the Plan does not directly challenge any of the determinations that led CMS to deny its SAE application. Instead, UCA urges CMS and the Hearing Officer to revisit the decision based on additional information provided in its appeal materials:

This Brief and supporting documentation provide evidence that UCA has cured the deficiencies that were the basis for CMS' denial of its 2014 service area expansion application, or presented valid exceptions in the case where no providers were available that show that UCA can arrange for the delivery of care for that provider or facility type that is consistent with the local patterns of care.²⁷

²³ *Id.* CMS denied Exception Requests pertaining to each of Greenlee, Gila, La Paz, Yavapi, and Yuma Counties.

²² CMS Memorandum at 4.

²⁴ CMS Memorandum, Exhibit G, Notice of Intent to Deny.

²⁵ CMS Memorandum at 5. The May 7, 2013 submission by UCA led CMS to reverse the previous denial of an Exception Request concerning infectious disease specialists in Greenlee County. This was the only Exception Request that had been denied in the county.

²⁶ CMS Memorandum, Exhibit A, Denial Notice.

²⁷ UCA Appeal Brief at 4.

UCA presented information in order to further develop the Plan's history and unique role in the Arizona health care marketplace. First, the Plan explains its organizational structure by defining its role within with the University of Arizona Health Plan (UAHP) hierarchy. UCA notes that it is "the subsidiary health plan of UAHP that currently contracts with [CMS] only as a [MA-PD] Dual Eligible Special Needs Plan (D-SNP)." UCA explains, however, that changes to Arizona's state Medicaid program require Medicaid plans and D-SNP plans to move toward a more cohesive delivery system:

Beginning in 2014, Arizona's Medicaid program, the Arizona Health Care Cost Containment System (AHCCCS), requires that all D-SNPs have an AHCCCS contract in the same counties in which they operate their D-SNP. They will also require the converse, namely, that all AHCCCS contractors operate a D-SNP in the counties in which they have an AHCCCS contract. AHCCCS implemented this requirement because it increases the integration of Medicare and Medicaid coverage for the dual eligible beneficiary.²⁹

Therefore, when another UAHP-affiliated plan was approved for Medicaid service area expansion by AHCCCS, "UCA was required to apply to CMS for a [D-SNP] service area expansion into [the Expansion Counties]."³⁰

AHCCCS reviews plan bids during the course of a five-year procurement cycle, and did not announce its contract awards until March 22, 2013.³¹ The Plan contends that this timeline directly impacted the submission of its SAE application to CMS:

UCA secured contracts with a number of providers in the six counties for which we applied, but we were unable to complete our networks by the CMS application deadline of February 21 because the AHCCCS bid awards would not be announced for another month. Likewise, when our response to the CMS deficiency notice was due on March 28, 2013, it was just six days after the announcement of the AHCCCS bid awards. Although we were able to secure a few more contracts in that short timeframe, our network was still incomplete.³²

UCA elaborates on its difficulties in securing network contracts while AHCCCS bids were pending, by noting:

Many providers were reluctant (and in many cases refused) to enter into Medicare contract negotiations until the Medicaid bids were awarded. Their reluctance is understandable. Providers have no incentive to spend resources and potentially compromise their bargaining position by

³¹ *Id*.

²⁸ *Id.* at 5-6.

²⁹ *Id.* at 7.

³⁰ *Id*.

³² *Id.* at 7.

negotiating six or seven Medicare contracts when they will only have to negotiate one or two if they wait until AHCCCS announces the Medicaid bid awards.³³

Despite these difficulties, the Plan contends that it presently "cured almost all of the network deficiencies" cited by CMS, and includes evidence of these efforts in its appeal.³⁴ This material also addresses a range of issues including the difficulties of providing care in a sparsely-populated rural setting such as Arizona and specific health care access issues in each of the Expansion Counties.

Finally, the plan outlines the alleged consequences that the denial of its SAE application would have on the Arizona Medicaid system:

If our appeal of CMS' denial of our service area expansion is upheld, AHCCCS must determine whether they will offer only one Medicaid plan in the six counties for which we applied for service area expansion, or reopen the bid process and evaluate other candidates to determine if there is a viable alternative to [the UAHP Medicaid Plan] to serve as the second AHCCCS health plan in the six counties where we were awarded the AHCCCS contract.³⁵

The Plan's Appeal Brief also incorporates a number of exhibits. These materials include a letter from AHCCCS, in which the agency confirms the bid approval timeline that the Plan has cited, and vouches for UCA's qualifications and performance in health care delivery. Also included are 34 "Cured Exception Reports" which, UCA contends demonstrate its compliance with CMS provider and facility network requirements. The Plan also addresses the remaining network deficiencies by providing seven Exception Requests that purport to address network issues in four of the Expansion Counties. Additionally, the Plan offers information concerning the telemedicine provider network maintained by the UCA-affiliated University of Arizona. Finally, UCA offers a CD-ROM containing newly-updated HSD tables as evidence of its current compliance.

VI. CMS' CONTENTIONS

CMS states that it properly denied UCA's SAE application. In its Appeal Memorandum, CMS argues that there is no factual dispute that UCA did not meet CMS Network Standards prior to

³³ *Id.* at 7-8.

³⁴ *Id.* at 8.

³⁵ *Id.* at 7.

³⁶ See UCA Appeal Brief, Exhibit A, Letter from AHCCCS.

³⁷ See UCA Appeal Brief, Exhibit B, Cured Exception Reports and GeoNetwork Documentation. Whether CMS previously approved any portion of these "34 Cured Exception Requests" is unclear. *Supra* note 23.

³⁸ See UCA Appeal Brief, Exhibit C, Exception Requests.

³⁹ See UCA Appeal Brief, Exhibit D, University of Arizona Telemedicine Program.

⁴⁰ See UCA Appeal Brief, Exhibit E, HSD Tables.

the May 7, 2013 cure deadline. In addition CMS contends that it is undisputed that 26 of UCA's Exception Requests, as submitted, did not contain adequate information concerning local patterns of care. This fact, CMS argues, is underscored by UCA's claim that it was able to secure provider contracts that eliminated the need for exceptions subsequent to CMS' final denial of the application.⁴¹

Moreover, as to the remaining denied Exception Request, which concerns endocrinology services in Yavapi county, CMS disputes the Plan's contention that there are no providers within the service area that meet ACC standards. CMS notes that, per the medicare gov website, there are providers in the area who meet program requirements, and that "a provider's refusal to contract is not an acceptable reason for CMS to grant an exception."

CMS argues that it properly denied UCA's application based on the information timely provided through the MA SAE application process and that neither it, nor the CMS Hearing Officer, may consider any information provided by the Plan during the appeal process. CMS claims that "UCA cannot demonstrate at hearing, by a preponderance of the evidence, that it met all of the Part C requirements during the application process," and, since there is no material facts in dispute at issue, the case may be resolved as a matter of law. CMS therefore moved for Summary Judgment in this matter.

VII. UCA'S REPLY CONTENTIONS

UCA filed a Reply Brief with the Hearing Officer on July 8, 2013. This filing challenges CMS' construction of the appeal regulations and opposes the Motion for Summary Judgment. The Reply Brief frames the Plan's appeal as follows:

[T]he only issue in this appeal is whether UCA's application *must* be denied because its network within the new service areas did not become complete until June of this year. Contrary to CMS' suggestion, such a denial is not mandated. Nothing in the statute or regulations cited by CMS precludes CMS or the Hearing Officer from considering post-application developments.⁴⁵

The Plan contends that program regulations "[do] not preclude consideration of materials outside the [SAE] application."⁴⁶ The Plan argues that, "[t]here is a significant difference between the language of the regulation, which gives CMS the *option* to deny an application based on incomplete information and CMS' position that it 'may *only* consider materials appropriately considered as part of the application."⁴⁷ Likewise, UCA argues that the appeal Burden of Proof regulation at 42 C.F.R. § 422.660(b)(1), "says nothing about whether the Hearing Officer may

⁴¹ CMS Memorandum at 5.

⁴² *Id.* at 5-6 (citing UCA Appeal Brief at 8).

⁴³ CMS Memorandum at 6.

⁴⁴ *Id.* at 7.

⁴⁵ UCA Reply Brief at 2 (emphasis in original).

⁴⁶ *Id.* at 3.

⁴⁷ *Id.* (citing CMS Memorandum at 6)(all emphasis added by UCA).

consider post-application facts and it certainly does not preclude consideration of such facts. As such, there is nothing in the regulations cited by CMS that precludes the Hearing Officer from considering UCA's now fully complete network."⁴⁸

In support, UCA points to regulatory language that, it believes, authorizes CMS to consider materials outside of application submissions when reviewing a contract application. In particular, the Plan notes 42 C.F.R. § 422.502(a)(1), which states that CMS' determination concerning MA contract applications is confined to "the application itself *and any additional information that CMS obtains through other means* such as on-site visits." The Plan notes that this regulatory clause "has no temporal limitation" and could allow for CMS to obtain application material at any time. UCA therefore argues that the scope of its appeal is not confined as CMS contends, and that the Hearing Officer may consider "UCA's now fully complete network." States of the property of

UCA also reiterates the role that the state Medicaid program bid cycle played in its failure to timely secure a provider network prior to CMS' deadlines, claiming that such delays were "Unavoidable and Beyond UCA's Control." The Plan categorizes this situation as "primarily a problem of tremendously bad timing, not of substance." Finally, UCA appeals to "equitable considerations and public policy" as reasons that its appeal should be sustained and UCA's application deemed granted. The Plan claims that it is "Best Qualified", that AHCCCS supports its application, that "No Other MAPD/D-SNP Would Be Adversely Affected", and that disapproval of its application "Results in Inappropriate Hardship for Medicare Beneficiaries."

VIII. DECISION

The Motion for Summary Judgment is granted. UCA did not meet its burden of proof, set forth at 42 C.F.R. § 422.660(b)(1), in demonstrating that CMS' determination was inconsistent with program contracting requirements. The undisputed facts in this case indicate that CMS acted within its contracting authority in denying UCA's application.

In March 2013, CMS provided UCA with a Deficiency Notice concerning its SAE application. At that time, UCA responded by providing the agency with updated information concerning its provider network and 74 requests for exception to the network requirements. Of these 74 Exception Requests, CMS found that 28 should not be granted. This finding led CMS to issue a Notice of Intent to Deny UCA's SAE application.

In the Notice of Intent to Deny, CMS brought the remaining provider network flaws to the attention of the Plan and provided a final opportunity for UCA to cure its application. UCA took

⁵² *Id*.

⁴⁸ UCA Reply Brief at 4.

⁴⁹ *Id.* (citing 42 C.F.R. § 422.502(a)(1)(all emphasis added by UCA).

⁵⁰ UCA Reply Brief at 4.

⁵¹ *Id*.

⁵³ *Id.* at 7.

 $^{^{54}}$ *Id.* at 2.

⁵⁵ See UCA Reply Brief at 7-10.

action to address these deficiencies, including the submission of additional network data and Exception Requests. However, CMS determined that the network sufficiency issues were either not fully remedied or not adequately conveyed to CMS prior to the May 7, 2013 cure deadline. Accordingly, CMS denied the SAE application and, on May 31, 2013, issued the final determination from which this appeal stems.

UCA contends that it has now addressed the deficiencies outlined in the denial of its SAE application. The Plan further argues that the regulations do not bar CMS from considering materials that support this contention. In particular UCA contends that 42 C.F.R. § 422.502(a)(1) allows CMS to make a contract determination based on "any additional information that CMS obtains through other means." The Plan offers that this language allows CMS to reassess its SAE application based on materials provided through other channels and at other times, including through the appeals mechanism and at present. ⁵⁷

However, such a construction cannot be reconciled with other regulations governing both the application process and CMS' review procedure. First, 42 C.F.R. § 422.501(c) requires all contract applications to be completed "in the form and manner required by CMS." Furthermore, additional regulations, at 42 C.F.R. § 422.502(c)(2)(ii – iii), set forth the process for the submission and review of revised application materials following the issuance of a Notice of Intent to Deny as follows:

- (ii) Within 10 days from the intent to deny, the 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.
- (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 that the applicant does not appear qualified or has not provided CMS enough information to allow CMS to evaluate the application, CMS will deny the application.

This regulation establishes two elements that are crucial to this case. First, in subsection (ii), the regulation sets a firm, fixed, ten-day response period during which an applicant may provide materials to cure its submission following the issuance of a Notice of Intent to Deny. This clause establishes a firm deadline that confines final submission of application materials to the ten-day response period. In addition, subsection (iii) places applicants on notice that if, following the ten-day cure period, CMS is not satisfied that the applicant appears qualified, then the application will be denied.

Furthermore, UCA's application of the phrase, "any additional information that CMS obtains through other means" from 42 C.F.R. § 422.502(a)(1) is both misapplied, and taken out of its proper context. The regulation in question simply allows CMS to utilize materials that it affirmatively obtains through the exercise of its authority (i.e. through onsite audits). However,

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⁵⁶ Supra note 49.

⁵⁷ *Supra* note 50.

the regulation creates no rights for applicants to submit materials outside of the structured application process and timelines. UCA's interpretation of this regulation would stand in direct contrast to the specific terms of 42 C.F.R. § 422.502(c)(2)(ii), which, as noted above, clearly establishes a final submission deadline following a plan's receipt of a Notice of Intent to Deny.

In the present case, the Notice of Intent to Deny was issued on April 26, 2013. In accordance with the regulations, this notice established a cure deadline of May 7, 2013.⁵⁸ UCA provided additional materials for Hearing Office review, but states that "its network within the new service areas did not become complete until June of this year."⁵⁹ On the basis of the material at hand as of the May 7, 2013 deadline, CMS determined that the Plan did not appear qualified and issued a final determination denying the application.

On appeal, UCA has the burden of demonstrating, by a preponderance of the evidence, that this determination was inconsistent with the regulatory requirements set forth in 42 U.S.C. §§ 422.501 and 422.502. UCA concedes that its SAE provider network was not compliant by the lapse of the cure period following the Notice of Intent to Deny. The undisputed facts of this case therefore demonstrate that UCA is not able to meet its appeal burden.

Finally, while UCA raises a host of equitable and policy issues in support of its contract application, those arguments have no bearing on this determination. The appeal authority conferred on the Hearing Officer is limited only to the review of whether CMS' denial of an application was an appropriate exercise of its contracting authority.

The Plan has not demonstrated by a preponderance of the evidence that CMS' determination was inconsistent with program contracting regulations and the undisputed material facts indicate that this appeal may be resolved as a matter of law.

⁵⁹ *Supra* note 45.

⁵⁸ Supra note 24.

⁶⁰ *Supra* notes 18 and 19.

IX. CONCLUSION

The Hearing Officer finds that CMS acted within its authority in denying the Service Area Expansion of Contract No. H7352.

CMS' Motion for Summary Judgment is granted.

Michael J. McDougall Hearing Officer

July 24, 2013