Department of Health and Human Services

DEPARTMENTAL APPEALS BOARD

Civil Remedies Division

Mercy Hospital Lebanon,
(CCN: 26-0059),

Petitioner,

v.

Centers for Medicare & Medicaid Services.

Docket No. C-14-236

Decision No. CR3320

Date: August 7, 2014

DECISION

Petitioner, Mercy Hospital Lebanon, has shown that its remote location in Rolla, Missouri met the provider-based status requirements of 42 C.F.R. § 413.65, including the public awareness requirement of 42 C.F.R. § 413.65(d)(4); the ownership and control requirement of 42 C.F.R. § 413.65(e)(1); and the alternative location requirement of 42 C.F.R. § 413.65(e)(3)(iii).[1]

I. Background

Petitioner is a general acute care, non-profit hospital located in Lebanon, Missouri. Petitioner seeks provider-based status for a remote location in Rolla, Missouri (remote location). Wisconsin Physicians Service (WPS), the Medicare contractor, received

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[1] Citations are to the 2011 revision of the Code of Federal Regulations (C.F.R.), unless otherwise stated.

Petitioner's application for provider-based status[2] for the remote location on February 27, 2012. The Parties' Stipulations of Fact and Joint Statement of the Issues (Jt. Stip.) ¶¶ 1-2, 7, 8.

On July 10, 2012, the Centers for Medicare & Medicaid Services (CMS) denied Petitioner's application for provider-based status for the remote location on grounds that the remote location did not meet the requirements for provider-based status established by 42 C.F.R. § 413.65(e)(1) and (3). Jt. Stip. ¶¶ 22-23; CMS Exhibit (Ex.) 1. Petitioner timely requested reconsideration on September 6, 2012. The initial denial of provider-based status was upheld on reconsideration. Jt. Stip. ¶¶ 27-28; CMS Ex. 2.

Petitioner requested a hearing by an administrative law judge (ALJ) by letter dated November 11, 2013. On November 25, 2013, the case was assigned to me for hearing and decision and an Acknowledgement and Prehearing Order (Prehearing Order) was issued at my direction. On May 8, 2014, CMS filed a motion for summary disposition, which I construe to be a motion for summary judgment (CMS Br.). Petitioner filed a cross-motion for summary judgment, also on May 8, 2014 (P. Br.). CMS replied to Petitioner's motion on June 9, 2014 (CMS Reply). Petitioner also filed its reply on June 9, 2014 (P. Reply). CMS filed CMS Exs. 1 through 8 and Petitioner filed Petitioner's exhibits (P. Exs.) 1 through 8. The parties have not objected to my consideration of the proffered exhibits and all are admitted for purposes of this decision on summary judgment.

II. Discussion

A. Issues

Whether Petitioner's remote location meets requirements for provider-based status; and

Whether summary judgment is appropriate.

B. Applicable Law

Petitioner, a hospital, is a "provider of services" (provider) under the Social Security Act (Act). Act § 1861(u); 42 C.F.R. § 400.202. Under Medicare Part A, a provider is entitled to reimbursement from Medicare for certain medical care and services provided to

[2] The regulation refers to the application as the "provider-based attestation." 42 C.F.R. § 413.65(b)(3).

Medicare eligible beneficiaries. Act §§ 1811-12, 1814-15. Since the beginning of Medicare, "main providers" have owned and operated other facilities, whether on the same campus as the main provider or remote from the main provider, which have been treated under Medicare as being "provider-based." Provider-based status is not mentioned in the Act. In 1983, provider-based status became more important to main providers due to the more favorable Medicare reimbursement available to provider-based entities verses that available to free-standing facilities. For example, Medicare reimbursement for a hospital outpatient clinic visit with a doctor includes a component for the facility and the professional services of the physician, while reimbursement for a physician visit in a physician's office, a free-standing facility, does not include a component for the facility. The Health Care Financing Administration (HCFA), the predecessor to CMS, proposed a new regulation, 42 C.F.R. § 413.65, to gain some control over provider-based status. 63 Fed. Reg. 47,552, 47,587-92 (Sept. 8, 1998). The final rule establishing 42 C.F.R. § 413.65 was issued on April 7, 2000. 65 Fed. Reg. 18,433 (Apr. 7, 2000) as amended at 65 Fed. Reg. 58,920 (Oct. 3, 2000) (delayed the effective date of the regulation); CMS Br. at 4-5.

A main provider, such as Petitioner in this case, must show that the requirements for provider-based status established by 42 C.F.R. § 413.65, are met in order to receive reimbursement at the provider-based rate for qualified medical care and services delivered to Medicare-eligible beneficiaries at its remote location. The regulation provides the following definitions pertinent to this case:

> *Main provider* means a provider that either creates, or acquires ownership of, another entity to deliver additional health care services under its name, ownership, and financial and administrative control.
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> *Provider-based entity* means a provider of health care services, or an RHC [rural health clinic] as defined in § 405.2401(b) of this chapter, that is either created by, or acquired by, a main provider for the purpose of furnishing health care services of a different type from those of the main provider under the ownership and administrative and financial control of the main provider, in accordance with the provisions of this section. A provider-based entity comprises both the specific physical facility that serves as the site of services of a type for which payment could be claimed under the Medicare or Medicaid program, and the personnel and equipment needed to deliver the services at that facility. A provider-based entity may, by itself, be qualified to

> participate in Medicare as a provider under § 489.2 of this chapter, and the Medicare conditions of participation do apply to a provider-based entity as an independent entity.
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> *Provider-based status* means the relationship between a main provider and a provider-based entity or a department of a provider, remote location of a hospital, or satellite facility, that complies with the provisions of this section.
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> *Remote location of a hospital* means a facility or an organization that is either created by, or acquired by, a hospital that is a main provider for the purpose of furnishing inpatient hospital services under the name, ownership, and financial and administrative control of the main provider, in accordance with the provisions of this section. A remote location of a hospital comprises both the specific physical facility that serves as the site of services for which separate payment could be claimed under the Medicare or Medicaid program, and the personnel and equipment needed to deliver the services at that facility. The Medicare conditions of participation do not apply to a remote location of a hospital as an independent entity. For purposes of this part, the term "remote location of a hospital" does not include a satellite facility as defined in §§ 412.22(h)(1) and 412.25(e)(1) of this chapter.

42 C.F.R. § 413.65 (a)(2) (emphasis in original). A facility that does not meet provider-based status requirements is treated as a free-standing facility. 42 C.F.R. § 413.65 (a)(2), (b).

The regulation provides that an entity is not entitled to be treated as provider-based, simply because the main provider believes the entity is provider-based. 42 C.F.R. § 413.65(b)(1). Facilities for which provider-based status is sought that are on the same campus as the main provider are treated differently than facilities that are remote from the main campus. 42 C.F.R. § 413.65(b)(2)-(4). All entities for which provider-based status is sought must meet the requirements of 42 C.F.R. § 413.65(d). An off-campus facility must meet the additional provider-based requirements in 42 C.F.R. § 413.65(e) and (h). Provider-based status related to a hospital triggers the additional requirements of 42 C.F.R. § 413.65(g). A main provider seeking provider-based status for an entity must submit to CMS an attestation that the applicable requirements of 42 C.F.R. § 413.65 are met so that CMS may "make a determination as to whether the facility or organization is provider-based." 42 C.F.R. § 413.65(b)(3). The regulation clearly requires that the main provider maintain and produce the documentation that is the basis for its attestation either

at CMS request or with the attestation. 42 C.F.R. § 413.65(b)(3)(i) and (ii). In a case such as this, where the main provider seeks provider-based status for a remote location, the main provider is required to submit evidence supporting its attestations with the attestations. 42 C.F.R. § 413.65(b)(3)(ii).

Determinations by CMS or its contractor pursuant to 42 C.F.R. § 413.65 that a facility qualifies for provider-based status or that a facility no longer qualifies for such status, are initial determinations subject to the right to request reconsideration and review by an ALJ and the Departmental Appeals Board (the Board). 42 C.F.R. §§ 498.3(b)(2), 498.22, 498.82; *Union Hospital, Inc.* DAB No. 2463 at 2 (2012). Procedures applicable to ALJ review and Board appeals of CMS determinations affecting participation in Medicare are established by 42 C.F.R. pt. 498. The procedures of 42 C.F.R. pt. 498 do not address the allocation of the burden of production (burden of coming forward with the evidence), the burden of persuasion,[3] or the evidentiary standards or quantum of evidence necessary to satisfy the burdens. In the absence of adequate regulations, the Board has found it necessary to adopt interpretive rules addressing the burden of proof and the evidentiary standard. Because the Board's decisions are only interpretative rules applicable in the individual case being adjudicated and not substantive rules of general application, it is necessary to analyze in each case subject to 42 C.F.R. pt. 498 the appropriate allocation of the burden of proof and the evidentiary standard to be applied. I find that the Board's analysis is persuasive and appropriately applied to this case. The hearing before an ALJ is a de novo proceeding, i.e., "a fresh look by a neutral decision-maker at the legal and factual basis for" the CMS action. *Life Care Ctr. of Bardstown*, DAB No. 2479 at 32 (2012) (citation omitted); *The Residence at Salem Woods*, DAB No. 2052 (2006); *Cal Turner Extended Care*, DAB No. 2030 (2006); *Beechwood Sanitarium*, DAB No. 1906 (2004); *Emerald Oaks*, DAB No. 1800 at 11 (2001); *Anesthesiologists Affiliated*, DAB CR65 (1990), *aff'd*, 941 F.2d 678 (8th Cir. 1991). The standard of proof is a preponderance of the evidence. CMS has the burden of coming forward with the evidence and making a prima facie showing of a basis for imposition of an enforcement remedy. Petitioner bears the burden of persuasion to show by a preponderance of the evidence that it met statutory or regulatory requirements or any affirmative defense. *Batavia Nursing & Convalescent Inn*, DAB No. 1911 (2004); *Batavia Nursing & Convalescent Ctr.*, DAB No. 1904 (2004), *aff'd*, 129 F. App'x 181 (6th Cir. 2005);

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[3] The burden of production and the burden of persuasion are, together, referred to as the burden of proof. *Black's Law Dictionary* 209 (8th ed. 2004).

Emerald Oaks, DAB No. 1800; *Cross Creek Health Care Ctr.*, DAB No. 1665 (1998); *Hillman Rehab. Ctr.*, DAB No. 1611 (1997) (*remand)*, DAB No. 1663 (1998) (*aft. remand*), *aff'd*, *Hillman Rehab. Ctr. v. United States,* No. 98-3789 (GEB), 1999 WL 34813783 (D.N.J. May 13, 1999).

C. Findings of Fact, Conclusions of Law, and Analysis

My conclusions of law are set forth in bold text followed by my findings of fact and analysis. I have carefully considered all the evidence and the arguments of both parties, though not all may be specifically discussed in this decision. I discuss in this decision the credible evidence given the greatest weight in my decision-making.[4] I also discuss any evidence that I find is not credible or worthy of weight. The fact that evidence is not specifically discussed should not be considered sufficient to rebut the presumption that I considered all the evidence and assigned such weight or probative value to the credible evidence that I determined appropriate within my discretion as an ALJ. There is no requirement for me to discuss the weight given every piece of evidence considered in this case, nor would it be consistent with notions of judicial economy to do so. Charles H. Koch, Jr., *Admin. L. and Prac.* § 5:64 (3d ed. 2013).

The specific issues before me are narrow. The July 10, 2012 CMS letter advising Petitioner of the initial determination to deny provider-based status for the remote location (CMS Ex. 1) cited two grounds:

- The remote location did not meet the provider-based location requirements of 42 C.F.R. § 413.65(e)(3); and

- The remote location did not meet the ownership and control requirements of 42 C.F.R. § 413.65(e)(1).

The letter explained in further detail the CMS determinations related to the specific attestations of Petitioner regarding location of the remote facility under the requirements of 42 C.F.R. § 413.65(e)(3). The regulation requires for provider-based status that the remote location meet at least one of the specified location requirements. CMS concluded that the following location requirements were not satisfied in this case.

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[4] "Credible evidence' is evidence that is worthy of belief. *Black's Law Dictionary* 596. The "weight of evidence" is the persuasiveness of some evidence compared to other evidence. *Id*. at 1625.

(1) The remote facility is 55 miles from Petitioner and does not satisfy the requirement of 42 C.F.R. § 413.65(e)(3)(i), that the remote location be within 35 miles of the main provider's campus.

(2) The remote facility is located in Phelps County, Missouri and Petitioner did not have an agreement with Phelps County to provide health care to low-income individuals not covered by Medicare or Medicaid in that county. Therefore, Petitioner did not satisfy the requirement of 42 C.F.R. § 413.65(e)(3)(ii)(C).

(3) Petitioner did not define the patient populations and Petitioner and the remote location do not serve the same patient population. Therefore, CMS concluded that Petitioner did not meet the 75 percent overlap requirement of 42 C.F.R. § 413.65(e)(3)(iii).

Regarding the ownership and control requirements of 42 C.F.R. § 413.65(e)(1), CMS explained:

(1) The lease for the remote location listed St. John's Health System, which was recently renamed Mercy Health System, as the tenant of the remote location rather than Petitioner. Based on this fact, CMS concluded that the remote location was owned and controlled by Mercy Health System rather than Petitioner.

(2) CMS also reviewed the websites for the remote location and Petitioner and determined that they show that the remote location and Petitioner are separate and unrelated entities in the Mercy Health System.

CMS Ex. 1 at 2. The denial of provider-based status for the remote location was upheld on reconsideration. CMS Ex. 2. The notice of the reconsideration decision dated September 13, 2013, advised Petitioner that the reconsideration official concluded that Petitioner's remote location did not meet the provider-based location requirements of 42 C.F.R. § 413.65(e)(3). On reconsideration Petitioner conceded that the remote location was more than 35 miles from Petitioner's main campus. Therefore, the reconsideration official considered the alternative location requirements of the regulation that Petitioner alleged it met. According to the reconsideration decision, Petitioner specifically argued that the remote location met the requirement of 42 C.F.R. § 413.65(e)(3)(iii)(A), the 75 percent overlap requirement. The reconsideration hearing officer rejected Petitioner's analysis of the application of the rule and also rejected Petitioner's argument that CMS failed to publish notice of the methodology it applied in this case and, therefore, the application of that methodology was impermissible. CMS Ex. 2 at 2-4. Petitioner also argued that it met the alternative location requirement of 42 C.F.R. § 413.65(e)(3)(ii)(C) because it served over 500 residents from Laclede County, Missouri, the county with which Petitioner does have a contract to provide health care services for low-income individuals. The reconsideration hearing officer rejected this argument stating that it was

unpersuasive for the same reason stated in the initial denial. CMS Ex. 2 at 4. Because the reconsideration hearing officer concluded that Petitioner's remote location did not satisfy the location requirements of 42 C.F.R. § 413.65(e)(3), she declined to address whether Petitioner met the ownership and control requirements of 42 C.F.R. § 413.65(e)(1). The reconsideration hearing officer states that "we reserve our right to consider this issue in the future, if necessary." CMS Ex. 2 at 4. In the initial determination, the websites of Petitioner and the remote location were considered and it was concluded that the websites indicate that Petitioner and the remote location were separate and unrelated entities in the Mercy Health System. The conclusion that Petitioner and the remote location were separate entities was cited in the initial determination that the ownership and control requirements of 42 C.F.R. § 413.65(e)(1) were not satisfied. CMS Ex. 1 at 2. The reconsideration hearing officer, however, concluded that the website evidence and additional evidence submitted on reconsideration showing signage at the remote location and a business card used by employees at the remote location showed that Petitioner failed to satisfy the public awareness requirement of 42 C.F.R. § 413.65(d)(4).

Petitioner has the burden to show that: it meets at least one of the alternative location requirements of 42 C.F.R. § 413.65(e)(3); it meets the ownership and control requirements of 42 C.F.R. § 413.65(e)(1); and it meets the public awareness requirements of 42 C.F.R. § 413.65(d)(4). The fact that 42 C.F.R. § 413.65(d)(4) was not cited in the initial determination as a basis for denial of provider-based status, does not relieve Petitioner of the burden to show that it satisfies that requirement at this level as this de novo review is to determine whether or not Petitioner's remote location meets the requirements for provider-based status. The regulation requires that Petitioner show that its remote location meets all the requirements for provider-based status, including those in 42 C.F.R. § 413.65(d) and (e). 42 C.F.R. § 413.65(b). Further, Petitioner was clearly given notice by the reconsideration decision that it was concluded by CMS that Petitioner did not satisfy the requirements of 42 C.F.R. § 413.65(d)(4). The failure of the reconsideration hearing officer to address whether or not Petitioner met the requirements of 42 C.F.R. § 413.65(e)(1) does not deprive me of jurisdiction to determine, whether or not Petitioner has established that it meets operation and control requirements. The reconsideration hearing officer suggests that her intent was to preserve for her subsequent review the issue of ownership and control, in the event the CMS interpretation of the application of the regulations is rejected on ALJ review or appeal to the Board. There is no statutory or regulatory authority that permits the agency to, in essence, compel a remand by declining to rule upon an issue specifically raised on reconsideration. To the contrary, 42 C.F.R. § 498.24(c) unambiguously requires that the reconsideration hearing officer make "a reconsidered determination, affirming or modifying the initial determination and the findings on which it was based." The regulation gives the reconsideration hearing officer no discretion to "reserve" on any issue on which there were findings and conclusions on the initial determination. Although, the reconsideration hearing officer's failure to address the issue of ownership and control under 42 C.F.R.

§ 413.65(e)(1) could be treated as being a waiver of that issue by CMS, I do not treat the issue as waived.[5] Rather, Petitioner received notice by the initial determination that there was an issue of whether it satisfied the requirements of 42 C.F.R. § 413.65(e)(1) and Petitioner bears the burden to prove it did, even though the reconsideration hearing officer erroneously failed to address that issue.

1. Summary judgment is appropriate.

The Secretary of Health and Human Services (Secretary) has granted Petitioner the right to request reconsideration by CMS and to review by an ALJ and the Board under the procedures established by 42 C.F.R. pt. 498. Generally, an oral hearing before an ALJ is contemplated under the Act and 42 C.F.R. pt. 498. *Crestview Parke Care Ctr. v. Thompson*, 373 F.3d 743, 748-51 (6th Cir. 2004). A party may waive appearance at an oral hearing, but must do so affirmatively in writing. 42 C.F.R. § 498.66. In this case, both parties have moved for summary judgment. However, Petitioner has advised me that if summary judgment is not deemed appropriate, it does not waive its right to an oral hearing or otherwise consent to decision based only upon the documentary evidence or pleadings. Petitioner also advised me that CMS does not object to having an oral hearing if summary judgment is not deemed appropriate. Letter from Petitioner's Counsel, regarding Mercy Hospital Lebanon v. CMS, Joint Status Report, dated May 13, 2014.

Summary judgment is not automatic upon request but is limited to certain specific conditions. The procedures established by 42 C.F.R. pt. 498 related to ALJ hearings in long-term care facility survey and enforcement cases do not include a summary judgment procedure. However, the Board has long recognized the availability of summary judgment in cases subject to 42 C.F.R. pt. 498 and the Board's interpretative rule has been recognized by the federal courts. *See e.g. Crestview*, 373 F.3d at 749-50. Furthermore, a summary judgment procedure was adopted as a matter of judicial economy within my authority to regulate the course of proceedings and made available to the parties in the litigation of this case by my Prehearing Order.

Summary judgment is appropriate and no hearing is required where either: there are no disputed issues of material fact and the only questions that must be decided involve application of law to the undisputed facts; or, the moving party must prevail as a matter

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[5] Applying the doctrine of waiver may have the beneficial effect of deterring future reconsideration hearing officers from failure to fulfill their regulatory duty. However, applying wavier in this case would also prevent consideration of whether or not provider-based requirements are actually met. I conclude it is better to consider the issue rather than potentially adversely affect the integrity of the program.

of law even if all disputed facts are resolved in favor of the party against whom the motion is made. The Board follows the general approach of the federal courts in evaluating whether or not summary judgment in lieu of a hearing is appropriate. The movant bears the initial burden of demonstrating that there are no genuine issues of material fact for trial and that the movant is entitled to judgment as a matter of law. When confronted with a properly supported motion for summary judgment, the nonmoving party "may not rest upon the mere allegations or denials of his pleading, but . . . must set forth specific facts showing that there is a genuine issue for trial." *Anderson v. Liberty Lobby, Inc*., 477 U.S. 242, 248 (1986) (quoting *First Nat'l Bank of Az. v. Cities Serv. Co.*, 391 U.S. 253, 249 (1968)); *see also*, Fed. R. Civ. P. 56(c); *Ill. Knights Templar Home*, DAB No. 2274, at 3-4 (2009); *Garden City Med. Clinic*, DAB No. 1763 (2001), *Everett Rehab. & Med. Ctr.*, DAB No. 1628, at 3 (1997) (in-person hearing required where nonmovant shows there are material facts in dispute that require testimony); *Big Bend Hosp. Corp., d/b/a Big Bend Hosp. Ctr.*, DAB No. 1814, at 13 (2002) (in some cases, any factual issue is resolved on the face of the written record because the proffered testimony, even if accepted as true, would not make a difference). In opposing the motion for summary judgment, the nonmovant bears the burden of showing that there are material facts that are disputed either affecting the movant's prima facie case or that might establish a defense. It is insufficient for the nonmovant to rely upon mere allegations or denials to defeat the motion and proceed to hearing. The nonmovant must, by affidavits or other evidence that sets forth specific facts, show that there is a genuine issue for trial. If the nonmovant cannot show by some credible evidence that there exists some genuine issue for trial, then summary judgment is appropriate and the movant prevails as a matter of law. *Anderson v. Liberty Lobby, Inc*., 477 U.S. 242, 247. A test for whether an issue is regarded as genuine is if "the evidence [as to that issue] is such that a reasonable jury could return a verdict for the nonmoving party." *Id*. at 248. In evaluating whether there is a genuine issue as to a material fact, an ALJ must view the facts and the inferences to be drawn from the facts in the light most favorable to the nonmoving party. *Pollock v. Am. Tel. & Tel. Long Lines*, 794 F.2d 860, 864 (3d Cir. 1986).

In *Venetian Gardens*, DAB No. 2286, at 10-11 (2009) and *Ill. Knights Templar Home*, DAB No. 2274, at 3-4, the Board provided very specific guidance. If CMS asserted in its motion for summary judgment the facts necessary to establish its prima facie case, the first question is whether the facility conceded all those facts. If the facility did not concede all those facts, the next question is whether the facility averred facts and proffered evidence sufficient to show a genuine dispute of material fact. If, when viewed in a light most favorable to the facility, the evidence might permit a rational trier of fact to decide in favor of the facility, summary judge is not appropriate. The Board explained, consistent with its prior decisions, that the ALJ's role in deciding summary judgment is different from deciding a case on the merits after a hearing. On summary judgment, credibility determinations are not made, the evidence is not weighed, and the ALJ does

not decide which inferences to draw from the facts. Rather, the evidence of record is construed in a light most favorable to the nonmovant without determining which version of the facts is more likely true. *Ill. Knights Templar Home*, DAB No. 2274, at 8.

I conclude based upon my review of the pleadings and the documentary evidence that summary judgment is appropriate in this case. This case turns upon the interpretation of the law and, once interpreted, the application of that law to the undisputed facts in this case.

2. Petitioner meets the ownership and control requirements of 42 C.F.R. § 413.65(e)(1).

The CMS initial determination was that Petitioner's remote location did not satisfy ownership and control requirements of 42 C.F.R. § 413.65(e)(1), because: (1) Petitioner was not listed on the lease for the remote location; and (2) the websites for Petitioner and the remote location showed that Petitioner and the remote location were separate and unrelated entities within the Mercy Health System. The reconsideration hearing officer did not make any findings and conclusions regarding ownership and control, but purportedly reserved the right to decide later.

The parties have resolved the ownership and control issue by stipulations. The parties stipulated that any irregularities previously noted by CMS regarding the lease for the remote location do not bar provider-based status for the remote location. The parties also stipulated that although CMS originally determined that Petitioner's website and the website for the remote location showed that the two were separate and unrelated entities, CMS concedes that the issue has been resolved and does not bar provider-based status. Jt. Stip. ¶ 31 c. and d.

3. Petitioner and the remote location meet the public awareness requirements of 42 C.F.R. § 413.65(d)(4).

The reconsideration hearing officer concluded that Petitioner and the remote location did not met the public awareness requirement of 42 C.F.R. § 413.65(d)(4). The regulation requires:

> (4) Public awareness. The facility or organization seeking status as a department of a provider, a remote location of a hospital, or a satellite facility is held out to the public and other payers as part of the main provider. When patients enter the provider-based facility or organization, they are aware that they are entering the main provider and are billed accordingly.

42 C.F.R. § 413.65(d)(4). The reconsideration hearing officer acknowledged that a photograph of the main door for the remote location clearly indicated that the departments at the remote location are departments of Petitioner. However, the reconsideration hearing officer found that interior signs and a business card used by staff at the remote location indicated that the departments at the remote location were still part of "St. John's Hospital-Lebanon," Petitioner's prior name. The reconsideration hearing officer was unconvinced that a patient entering the remote location would be aware that it was part of Petitioner. CMS Ex. 2 at 4.

The signs shown in photographs in evidence list "St. John's Hospital – Lebanon" rather than "Mercy Hospital – Lebanon." CMS Ex. 3 at 81 - 90. The sample business card lists "Mercy/St. John's." CMS Ex. 3 at 91. However, the parties stipulated that when Petitioner submitted its attestations that are in evidence as CMS Ex. 3, which includes the photographs of signs and the business card, Petitioner was in the process of changing its name from St. John's Hospital Lebanon to Mercy Hospital-Lebanon. The parties also stipulated that the name change was not due to a change of ownership. Jt. Stip. ¶ 5. Subsequent photographs reflect that the remote location is part of Petitioner as the signs reflect the name "Mercy." P. Ex. 7 at 1-2. The parties also stipulated that the websites for Petitioner and the remote location are not a bar to provider-based status in this case. Jt. Stip. ¶ 31d. Screen shots of the remote location webpages submitted as evidence reflect a relationship between the remote location and Petitioner. P. Ex. 7 at 3. Based on the documentary evidence admitted without objection; the parties' stipulations; and the fact that CMS does not argue to me that the public awareness requirements of 42 C.F.R. § 413.65(d)(4) are not met, I conclude that the public awareness requirements for provider-based status are satisfied.

4. Petitioner meets the alternative location requirements of 42 C.F.R. § 413.65(e)(3)(iii).

5. Petitioner's remote location in Rolla, Missouri does satisfy the requirements for provider-based status.

The regulation establishes alternative location requirements that must be met for a remote location of a main provider to be eligible for provider-based status. 42 C.F.R. § 413.65(b)(3)(ii) and (e)(3). The remote location must either be within a 35-mile radius of the main provider or meet one of the other location requirements established by 42 C.F.R. § 413.65(e)(3). In this case, there is no dispute that the remote location in Rolla, Missouri is more than 35 miles from the main campus of Petitioner in Lebanon, Missouri. Therefore, it is necessary for Petitioner to prove that its remote location meets one of the alternative location requirements for the remote location to be eligible for provider-based status. Petitioner argues that it meets both of the following alternative location requirements:

> (ii) The facility or organization is owned and operated by a hospital or CAH that has a disproportionate share adjustment (as determined under § 412.106 of this chapter) greater than 11.75 percent or is described in § 412.106(c)(2) of this chapter implementing section 1886(d)(5)(F)(i)(II) of the Act and is—
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> * * * *
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> (C) A private hospital that has a contract with a State or local government that includes the operation of clinics located off the main campus of the hospital to assure access in a well-defined service area to health care services for low-income individuals who are not entitled to benefits under Medicare (or medical assistance under a Medicaid State plan).

42 C.F.R. § 413.65(e)(3)(ii); or

> (iii) The facility or organization demonstrates a high level of integration with the main provider by showing that it meets all of the other provider-based criteria and demonstrates that it serves the same patient population as the main provider, by submitting records showing that, during the 12-month period immediately preceding the first day of the month in which the application for provider-based status is filed with CMS, and for each subsequent 12-month period—
>
> (A) At least 75 percent of the patients served by the facility or organization reside in the same zip code areas as at least 75 percent of the patients served by the main provider; or
>
> (B) At least 75 percent of the patients served by the facility or organization who required the type of care furnished by the main provider received that care from that provider (for example, at least 75 percent of the patients of an RHC seeking provider-based status received inpatient hospital services from the hospital that is the main provider).

42 C.F.R. § 413.65(e)(3)(iii). These requirements are discussed in the order in which they appear in the regulation.

a. 42 C.F.R. § 413.65(e)(3)(ii)

The regulation requires:

> (1) That the remote location be owned and operated by Petitioner;
>
> (2) That Petitioner have a disproportionate share adjustment greater than 11.75 percent; and
>
> (3) That Petitioner is a private hospital with a contract with a state or local government that provides for the operation of clinics located off the main campus of the hospital for the purpose of ensuring that health care services are available to low-income individuals who are not entitled to benefits under Medicare or Medicaid.

I conclude that Petitioner does not meet this alternative location requirement.

There is no dispute that the remote location in Rolla is owned and operated by Petitioner. Also, the parties stipulated that Petitioner has a disproportionate share adjustment of 12 percent, which is greater than 11.75 percent. Thus, the first two elements of the regulation are satisfied. But, Petitioner fails to meet the third element.

The parties stipulated that Petitioner has an agreement with Laclede County, Missouri to provide health care services for low-income individuals residing in Laclede County, Missouri. Jt. Stip. ¶ 15. The agreement between Petitioner and Laclede County is dated February 16, 2012, and purports to have been effective on February 1, 2012. The agreement provides that Petitioner "will provide health care services to low income individuals residing in Laclede County who are not entitled to benefits" under Medicare and Medicaid in an amount determined by Petitioner's board of directors. CMS Ex. 3 at 214. The parties stipulated that Petitioner is located in Laclede County but the remote location in Rolla, Missouri is in Phelps County. Jt. Stip. ¶¶ 1, 2.

There is no question that Petitioner is a private hospital with a contract with Laclede County to provide medical services to low-income individuals in Laclede County. However, those facts do not satisfy the third element of the regulation, even if Petitioner provides some medical services to low-income individuals from Laclede County at the remote location. The regulation, although not artfully drafted, specifically requires that "the operation of clinics located off the main campus of the hospital" be to assure access for low-income individuals who are not otherwise entitled to Medicare or Medicaid. Petitioner points to no evidence and does not argue that the remote location in Rolla was established to provide access to medical care for low income individuals from Laclede County. The parties stipulated that the remote location in Rolla actually served 500

patients from zip codes partially or totally within Laclede County during the 12-month period that ended January 31, 2012. Jt. Stip. ¶ 16; P. Br. at 4, 25-26. The parties did not stipulate that the 500 patients were low-income and not entitled to Medicare or Medicaid and they did not stipulate that the remote location in Rolla was established, at least in part, for the purpose of providing services to low-income individuals from Laclede County, Missouri. If Petitioner had an agreement with Phelps County and other evidence that the remote location was established, at least in part to serve low-income individuals without Medicare or Medicaid, that may have been persuasive, but those are not the facts in this case.

Accordingly, I conclude that Petitioner did not meet the alternative location requirement of 42 C.F.R. § 413.65(e)(3)(ii).

b. 42 C.F.R. § 413.65(e)(3)(iii)

In order to meet the alternative location requirement of 42 C.F.R. § 413.65(e)(3)(iii), Petitioner must show that there is a high-level of integration between Petitioner and the remote location. The regulation specifies that the high-level of integration requires a showing that:

> (1) All other provider-based criteria are met;
>
> (2) The remote location serves the same patient population as the main provider based on records for the 12-month period that ended the day before the first day of the month in which the provider-based application was filed with CMS or its contractor and for each subsequent 12-month period. The records must show:
>
>> (a) At least 75 percent of the patients served by the remote location reside in the same zip codes as at least 75 percent of the patients served by Petitioner; or
>>
>> (b) At least75 percent of patients served at the remote location who required care of the type provided by Petitioner, received that care from Petitioner.

I have concluded that Petitioner satisfied the ownership and control requirements and the public awareness requirements, and there is no dispute that Petitioner's remote location meets all other provider based criteria. Therefore, the first element is satisfied.

The 75 percent tests have caused the parties a great deal of consternation as there is disagreement as to the meaning and application of the two alternative tests. My conclusion is that the plain language of the regulation is clear and should control and no interpretation is required. Review of the regulatory history supports my conclusion that

the language is clear. The language of 42 C.F.R. § 413.65(e)(3)(iii) and its 75 percent tests was originally promulgated as 42 C.F.R. § 413.65(d)(7). 65 Fed. Reg. 18,433 (Apr. 7, 2000) as amended at 65 Fed. Reg. 58,920 (Oct. 3, 2000) (delayed the effective date of the regulation). HCFA adopted the 75 percent tests in response to comments to the notice of proposed rule-making that HCFA needed more specific tests to determine whether or not a main provider and remote location served the same patient population. HCFA commented:

> We agree that more precise criteria are needed. Therefore, we have revised the regulations to provide **that a prospective provider-based facility or organization will be considered to serve the same patient population as the main provider** if, during the 12-month period immediately preceding the first day of the month in which the application for provider-based status is filed with us, **at least 75 percent of the patients served by the facility or organization seeking provider-based status reside in the same zip code areas as at least 75 percent of the patients served by the main provider.** As an alternative, we would consider a facility or organization to serve the same patient population if, during the same 12-month period described above, at least 75 percent of the patients served by the prospective provider-based facility or organization who required the type of care furnished by the main provider received that care from the main provider. We require this "same patient population" test to be met for the 12-month period used to support an initial determination of provider-based status, and it must continue to be met for each subsequent 12-month period to justify a continuation of provider-based status.

65 Fed. Reg. 18,433, 18,516 (emphasis added).

In response to another comment, HCFA responded:

> We recognize that patient populations will not be identical in all cases, and thus have adopted a patient population criterion under which there may be a divergence of up to 25 percent between the main provider and the facility or organization seeking provider-based status. We believe this provides a reasonable allowance for differences in patient population.

Id.

HCFA's comments show that the drafters intended that the main provider and remote location serve the same patient population. The drafters were willing to conclude that the main provider and remote location serve the same patient population so long as there is an overlap at least 75 percent of the patient population. The patient population overlap is determined using the data of the main provider and the remote location for the 12 months ending prior to the first day of the month in which the application for provider-based status is made. The drafters created two alternative requirements:

- 75 percent of the remote location patients must have lived in the same zip codes as 75 percent of the patients of the main provider in the same 12-month period, or

- 75 percent of the remote location patients must have received care from the main provider.

The second of the 75 percent tests, which is clear in what it requires, is not at issue in this case. The first 75 percent test is at issue and what it requires is also clear from the plain language of the regulation. No statistician, mathematician, or accountant is required to apply the test. The following steps are required in applying the test in this case:

> Step 1 – Identify the pertinent 12-month period that ended the last day of the month prior to the first day of the month in which the provider-based application was filed. In this case, the application was received by WPS on February 27, 2012. Therefore, the pertinent 12-mongh period is February 1, 2011 through January 31, 2012.
>
> Step 2 – Compile a list of the zip codes for all patients served by the main provider during the period February 1, 2011 through January 31, 2012.
>
> Step 3 – Compile a list of the zip codes for all patients served by the remote location during the period February 1, 2011 through January 31, 2012.[6]
>
> Step 4 – Compare the list of zip codes compiled in steps 2 and 3 for the main provider and remote location and, based on that comparison, compile a new list of the zip codes that are common to both.

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[6] No argument has been made that 42 C.F.R. § 413.65(e)(3)(iv) should apply in this case because the remote location was not operational for the full 12-month period from February 1, 2011 through January 31, 2012.

Step 5 – Tally the number of patients served by the main provider in the common zip codes.

Step 6 – Tally the number of patients served by the remote location in the common zip codes.

Step 7 – Divide the number of patients served by the main provider in the common zip codes by the total of all patients served by the main provider during the period February 1, 2011 through January 31, 2012, and multiple that result by 100.

Step 8 – Divide the number of patients served by the remote location in the common zip codes by the total of all patients served by the remote location during the period February 1, 2011 through January 31, 2012, and multiple that result by 100.

Step 9 – If the product in both steps 7 and 8 is at least 75 percent, the alternative location test of 42 C.F.R. § 413.65(e)(3)(iii)(A) is satisfied for provider-based status.

The initial determination shows that CMS did not follow the test established by 42 C.F.R. § 413.65(e)(3)(iii)(A). The initial determination states that the test was applied as follows:

> The number of patients per zip code should be arrayed in order of the highest number of patients to the lowest for both the hospital and clinic. In order to show that the hospital and the clinic serve the same patient population, all of the zip codes that represent the top 75 percent of the patients served by the clinic should be included in the zip codes that represent the top 75 percent of the hospital's patients.

CMS Ex. 1 at 2. This approach may be summarized as follows:

Step 1 – Compile the list of zip codes for all patients served by the main provider during the pertinent period.

Step 2 – Compile the list of zip codes for all patients served by the remote location during the pertinent period.

Step 3 – Determine the number of patients served by the main provider during the pertinent period for each zip code.

> Step 4 – Determine the number of patients served by the remote location during the pertinent period for each zip code.
>
> Step 5 – Display the data from the largest number of patients per zip code to the least number of patients per zip code for the main provider.
>
> Step 6 – Display the data from the largest number of patients per zip code to the least number of patients per zip code for the remote campus.
>
> Step 7 – Starting with the zip codes with the largest number of patients served by the remote location, add the number of patients served in each of the zip codes until the number equals 75 percent of the total number of patients served during the pertinent period by the remote location.
>
> Step 8 – Starting with the zip codes with the largest number of patients served by the main provider, add the number of patients served in each of the zip codes until the number equals 75 percent of the total number of patients served during the pertinent period by the main provider.
>
> Step 9 – Compare the zip codes under Steps 7 and 8 that are treated as comprising the "top 75 percent" of patients. According to the initial determination, the test is satisfied only if the zip codes are the same.

The test as applied in the initial determination is inconsistent with the test required by 42 C.F.R. § 413.65(e)(3)(iii)(A). The test described in the initial determination compares patients served by geographic area as demonstrated by the CMS calculations in CMS Ex. 6.[7] The test required by 42 C.F.R. § 413.65(e)(3)(iii)(A) is based upon the pool of

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[7] CMS argues in its reply brief that the regulation requires "a geographically contiguous and homogenous area." CMS Reply at 2. CMS does not identify the actual language of the regulation that supports that interpretation. CMS does cite to a comment by the drafters during rule-making that proximity is an important indicator but the drafters did not state that a geographic test was adopted or that proximity is determinative of provider-based status. CMS Exs. 6 and 7 clearly show that the application of the test advocated by CMS focuses upon the geographic area served by the hospital and remote location rather than the patient population served that is common to both. For example, the largest number of patients served by the hospital is in the zip code which is the zip code for Lebanon, Missouri. The greatest number served by the remote location in Rolla is, as one would expect, from the Rolla, Missouri zip code. Ordering the data according to zip code has the effect of limiting the 75 percent to the pool of patients largely located
(Footnote continued next page.)

patients common to both the main provider and remote location that are served during the pertinent period. CMS argues that "[t]he regulations do not prescribe the methodology CMS must use to determine provider-based status." CMS Br. at 6. The CMS argument is clearly in error because 42 C.F.R. § 413.65 is extremely detailed regarding the requirements for provider-based status and the tests that must be met to satisfy the requirements. Indeed, 42 C.F.R. § 413.65(e)(3)(iii)(A) tells CMS exactly how to apply the 75 percent test. CMS offers no explanation for how or why the initial determination and the reconsideration determination, which simply restated the same test as the initial determination, departed so significantly from the test actually required by the regulation.[8] But, CMS argues that because the 75 percent test of 42 C.F.R. § 413.65(e)(3)(iii)(A) is not clear, CMS should be given deference to apply the test it sees fit. CMS Br. at 1, 7-10. Contrary to CMS's argument, 42 C.F.R. § 413.65(e)(3)(iii)(A) clearly sets forth the 75 percent test. Thus, there is no need for CMS to interpret the regulation, and the erroneous interpretation of CMS reflected in the initial and reconsideration determinations are entitled to no deference.[9]

(Footnote continued.)

around the hospital or remote location rather than determining whether each facility serves 75 percent of the patients from the pool of patients common to both, which was the test intended by the drafters of the regulation.

[8] I note that WPS concluded that Petitioner did meet the requirement of 42 C.F.R. § 413.65(e)(3)(iii) or (iv). CMS Ex. 3 at 15 (Item 2). WPS only questioned the source of the data Petitioner relied on to show it met the 75 percent test because the data was from Petitioner's own records, not an unbiased source. CMS Ex. 3 at 6, 8.

[9] CMS cites a number of federal cases in support of its argument that I should give deference to the CMS interpretation. CMS Br. at 1, 8, 10. Because the regulation is clear, no interpretation of the regulation is required, and the CMS application of the regulation that deviates from the plain language is entitled to no deference. I further note that the cases cited discuss whether the federal courts should give agency interpretations deference. Those cases are inapposite to ALJ de novo review and the Boards review both of which act for or on behalf of the Secretary in issuing final decisions on the Secretary's behalf. In practical effect, the CMS argument is that the Secretary must give deference to the actions of CMS, which acts with the delegated authority of the Secretary. CMS overlooks that it is the Secretary who is ultimately responsible for the administration of Medicare under the Act. CMS also overlooks the fact that it is no longer the final decision-maker on behalf of the Secretary when review of the CMS decision is requested. 42 C.F.R. §§ 498.74(b), 498.90(a), 498.103(b).

It is necessary to apply the actual 75 percent test of 42 C.F.R. § 413.65(e)(iii)(A) in this case. The parties stipulated that, considering all patients in all zip codes (in or out of state),[10] 98.33 percent of patients served at the remote location resided in the same zip codes as 92.66 percent of the patients that received services at Petitioner, that is, a single set of zip codes included 98.33 percent of the remote location patients and 92.66 percent of Petitioner's patients. Jt. Stip. ¶ 14. The undisputed data was admitted by CMS as CMS Exs. 3 at 207-09; 4 at 2-4. The parties stipulated that the calculations were based on patient data from the period February 1, 2011 through January 31, 2012. Jt. Stip. ¶ 11. The parties also stipulated to the procedure Petitioner used in applying the 75 percent test of 42 C.F.R. § 413.65(e)(3)(iii)(A), which I find is consistent with the procedure required by the regulation. Jt. Stip ¶ 11; CMS Ex. 3 at 20.

Accordingly, I conclude that Petitioner and the remote location in Rolla satisfied the 75 percent alternative location test established by 42 C.F.R. § 413.65(e)(3)(iii)(A). Therefore, Petitioner satisfied the location requirement for provider-based status.

III. Conclusion

For the foregoing reasons, I conclude that Petitioner meets all requirements for the remote location to be granted provider-based status.

/s/
Keith W. Sickendick
Administrative Law Judge

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[10] CMS expresses concern about the geographic dispersion of the patients with some patient zip codes from as far away as Texas. CMS Br. at 3, 6-9. The reasons why Petitioner and the remote location served patients with zip codes from as far away as Texas, is not a fact considered in comparing patient populations rather than the geographic distribution of the patient population. However, it is interesting to know that Lebanon and Rolla, Missouri are both on a major interstate highway that connects the southwestern United States to St. Louis; a major military installation, presumably with dependent families from across the nation, lies between both cities; and the area is an attraction for fishermen from across the country.