Department of Health and Human Services

DEPARTMENTAL APPEALS BOARD

Civil Remedies Division

Cibola General Hospital
(CCN: 32-0037),

Petitioner

v.

Centers for Medicare and Medicaid Services,

Respondent

Docket No. C-09-401

Decision No. CR2208

Dated: August 10, 2010

DECISION

Cibola General Hospital (CGH) contests a determination of the Centers for Medicare and Medicaid Services (CMS) that it is ineligible to participate in the Medicare program as a "critical access hospital" (CAH). CAHs are small, limited-service hospitals that are, for most Medicare purposes, distinct from traditional acute-care hospitals. A facility is eligible to participate in Medicare as a CAH if it meets two statutory location requirements: first, it must be located in a rural area (or an area treated as rural under the Medicare statute); second, the facility must be more than a 35-mile drive from another hospital or CAH.

CGH is located in a rural area; however, it is only an 18.9-mile drive from Acoma-Canoncito-Laguna Hospital (Acoma), a facility that the Indian Health Service (IHS), a federal agency within the U.S. Department of Health and Human Services (HHS), owns and operates. The dispositive issue in this case is whether Acoma is a "hospital" for the purpose of determining CGH's compliance with the 35-mile requirement. I hold that

Acoma is a hospital for that purpose. Further, because CGH is located within a 35-mile drive of Acoma, I sustain CMS's determination that CGH is ineligible to participate in Medicare as a CAH.

Legal Background

Title XVIII (sections 1801-1899A) of the Social Security Act (Act)[1] establishes the Medicare program, which CMS administers on behalf of the HHS Secretary.

Under section 1820 of the Act, a state may establish a Medicare rural hospital flexibility program (RHFP) to promote the creation of "rural health networks" consisting of one or more CAHs.[2] Act § 1820(a)-(b), (d)(1)(A).

Under its RHFP, a state may "designate" a facility as a CAH if the location, staffing, and other criteria specified in section 1820(c) are satisfied. Relevant here, section 1820(c)(2)(B)(i)(I) provides that a facility seeking designation as a CAH must be "located more than a 35-mile drive . . . from a hospital" or another CAH.[3]

A facility that a state designates as a CAH may participate in, and receive payment from, the Medicare program as a CAH, if the Secretary certifies its eligibility to do so. Section 1820(e) provides that the Secretary "shall certify a facility as a critical access hospital," if it: "(1) is located in a State that has established a Medicare rural hospital flexibility program in accordance with [section 1820(c)]; (2) is designated as a critical access hospital by the State in which it is located; and (3) meets such other criteria as the Secretary may require."

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[1] The current version of the Social Security Act can be found at www.ssa.gov/OP_Home/ssact/comp-ssa.htm. Each section of the Act on that website contains a reference to the corresponding United States Code chapter and section.

[2] Section 1820 authorizes HHS to provide grants to states and hospitals to support the development and operation of rural health networks. Act § 1820(g).

[3] The statute requires only a 15-mile separation when "mountainous terrain" exists, or when the facilities are located in an area with only "secondary roads." Act § 1820(c)(2)(B)(i)(I).

Once certified as a CAH, a facility becomes eligible for higher-than-ordinary Medicare payments.[4] In rulemakings and in its program manuals,[5] CMS has said that the purpose of CAH certification is "to keep hospital-level services in rural communities, thereby ensuring access to care, through provision of reimbursement on a more favorable basis than that available to participating hospitals." *See* State Operations Manual, CMS Pub. 100-07, § 2256F (rev. 32, issued Jan. 18, 2008); *see also* 72 Fed. Reg. 66,580, 66,878 (Nov. 27, 2007).

The IHS delivers services to the American Indian/Alaska Native population through a network of hospitals, clinics, and other facilities. *See* 42 C.F.R. Part 136, subpart B; 66 Fed. Reg. 55,246, 55,284-85 (Nov. 1, 2001). The Act generally prohibits Medicare payment to any "Federal provider of services or other Federal agency." *See* Act § 1835(d); *see also* Act § 1814(c). Exempt from that prohibition are Medicare payments for health care services provided to Medicare beneficiaries in IHS hospitals and skilled nursing facilities. *Id.* (stating that the prohibition on payment to Federal providers is "[s]ubject to section 1880," which authorizes Medicare payment to eligible IHS hospitals and skilled nursing facilities).

Case Background

On April 2, 2007, CGH filed an application with the State of New Mexico to be designated as a CAH under the state's RHFP. P. Ex. 6. New Mexico approved the application and recommended that CMS certify CGH for Medicare participation as a CAH. P. Ex. 15.

On October 27, 2008, CMS determined that CGH was ineligible for certification, because it did not meet the 35-mile requirement in section 1820(c)(2)(B)(i)(I). P. Ex. 9. After CGH filed a request for reconsideration, CMS upheld its original denial, stating:

[4] Medicare pays most hospitals for their inpatient services under a prospective payment system (PPS). Act § 1886(d); 42 C.F.R. Part 412. CAHs, on the other hand, are eligible for "reasonable cost" reimbursement, the amount of which is determined retrospectively based on provider cost reports. Act §§ 1814(l), 1834(g), 1861(v); 42 C.F.R. § 413.1 *et seq*.

[5] Medicare program manuals are available on CMS's website at https://www1.cms.gov/Manuals/IOM.

> We determined that a hospital in full operation [namely, Acoma] is located within the 35 mile radius of [CGH]. Furthermore, in reviewing the file of [Acoma], we concluded that it meets the definition of a hospital. That hospital has an active Medicare provider agreement and is currently accredited by the Joint Commission (TJC). A hospital accredited by TJC is deemed to meet the Medicare Conditions of Participation.

P. Ex. 1.

Dissatisfied with the reconsideration determination, CGH requested an ALJ hearing, after which the parties filed cross-motions for summary judgment supported by documentary evidence and briefing. That briefing included: CGH's August 28, 2009 brief in support of its motion for summary judgment (CGH Br.); CMS's October 30 brief supporting its cross-motion for summary judgment and responding to CGH's motion (CMS Br.); CGH's November 19, 2009 response to CMS's cross-motion (CGH Response); CMS's January 21, 2010 reply (CMS Reply); and CGH's February 4, 2010 surreply (CGH Surreply).

On April 7, 2010, I requested supplemental briefing to address certain legal and factual issues. On May 7, 2010, CMS filed a supplemental brief with supporting exhibits (CMS Supp. Br.). CGH responded to CMS's supplemental brief on May 21, 2010 (CGH Supp. Br.). The parties then filed replies to the each other's supplemental briefs on June 1 (CMS Supp. Reply) and June 9, 2010 (CGH Supp. Reply).

Discussion

Summary judgment is appropriate when the record shows that no genuine issue exists as to any material fact, and the moving party is entitled to judgment as a matter of law. *Celotex Corp. v. Catrett*, 477 U.S. 317, 322-25 (1986). In evaluating a motion for summary judgment, I follow Rule 56 of the Federal Rules of Civil Procedure and related federal case law. *Civil Remedies Division Procedures* ¶ 7 (available at http://www.hhs.gov/dab/divisions/civil/procedures/divisionprocedures.html).

Because CGH seeks to participate in Medicare as a CAH, CGH bears the burden of demonstrating that it meets applicable eligibility criteria in section 1820 of the Act and in the corresponding regulations. *Cf. Hillman Rehab. Ctr.*, DAB No. 1611, at 8-10, 64, 85 (1997) (finding that CMS bore the initial "burden of production" to show that it had a legally sufficient basis to terminate the provider from the Medicare program but placing the burden of persuasion on the provider to demonstrate substantial compliance with the relevant conditions of Medicare participation), *aff'd*, *Hillman Rehab. Ctr. v. United*

States, No. 98-3789 (GEB) (D.N.J. May 13, 1999).[6] The extent to which a party has carried its evidentiary burden under the relevant substantive law is a factor in evaluating whether the prerequisites for summary disposition have been met. *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 252-55 (1986) (noting that in ruling on a motion for summary judgment, the judge must view the evidence presented through the prism of the substantive evidentiary burdens).

A. *Undisputed Material Facts*

CGH is a 25-bed acute-care hospital located in Grants, New Mexico. P. Ex. 6.

Acoma is an IHS facility located in San Fidel, New Mexico. CMS Ex. 1. CGH is an 18.9 mile drive from Acoma. P. Ex. 21.

In June 1981, CMS (then known as the Health Care Financing Commission) accepted Acoma's application to participate in the Medicare program based on the results of surveys that the state of New Mexico conducted to certify its compliance with Medicare conditions of participation. *See* CMS Exs. 4-10.

Acoma has participated in the Medicare program since 1981. CMS Ex. 9.

Acoma participates in Medicare under a Health Insurance Benefit Agreement (also known as a "provider agreement") that HCFA accepted on June 1, 1981. CMS Ex. 10, at 2.

The Joint Commission (formerly known as the Joint Commission on Accreditation of Healthcare Organizations (JCAHO)) presently accredits Acoma as a hospital.[7] CMS Exs. 2, 15.

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[6] In *Hillman*, the Board found "no distinction, relevant for who bears the burden of proof, between a provider first seeking to participate in the program and a provider whose agreement is terminated." *Hillman*, DAB No. 1611, at 9.

[7] "The Joint Commission is a private non-profit accrediting organization run by the American Medical Association, the American Hospital Association, the American College of Physicians-American Society of Internal Medicine, and the American Dental Association." *Am. Nurses Ass'n v. Leavitt*, 593 F. Supp. 2d 126, 128 n.1 (D.D.C. 2009).

B. *Conclusions of Law*

Although a facility must meet multiple requirements to participate in Medicare as a CAH, the parties agree that this appeal implicates only one – namely, the 35-mile requirement in section 1820(c)(2)(B)(i)(I) of the Act. *See* Joint Notice of Issues for Summary Judgment (June 25, 2009). The parties also agree that the 35-mile requirement is not met if Acoma is a "hospital," as that term is used in section 1820(c)(2)(B)(i)(I). Based on the following analysis, I conclude that no genuine dispute of material fact exists and that CMS lawfully determined that Acoma is a hospital within the meaning of section 1820(c)(2)(B)(i)(I).

1. *As used in section 1820(c)(2)(B)(i)(I) of the Act, "hospital" means an institution that meets the requirements in paragraphs one through nine of section 1861(e).*

Section 1820 of the Act does not define the term "hospital." However, both parties contend that section 1861 supplies the appropriate definition. *See* CGH Br. at 15; CGH Response at 2-3; CGH Supp. Br. at 1; CMS Supp. Reply at 1.

Section 1861 defines numerous terms used throughout the Medicare statute, including "hospital" (in section 1861(e)) and "critical access hospital" (in section 1861(mm)(1)).[8] With certain explicit but irrelevant exceptions, section 1861(e) states that a hospital is an "institution" that meets the requirements in paragraphs one through nine of that section. These enumerated requirements – known as "conditions of participation" (*see* 42 C.F.R. Part 482) – are the minimum health and safety standards that an institution must meet to participate in Medicare as a hospital.

The prefatory words in section 1861 state that its definitions – including the definition in section 1861(e) – are "[f]or purposes of this title [XVIII]." Title XVIII's "purposes" undoubtedly include the certification of a facility's eligibility to participate in Medicare as a CAH. For that reason, I apply the definition of "hospital" in section 1861(e) to determine whether CGH has met the requirement in section 1820(c)(2)(B)(i)(I) that a

[8] Sections 1864 and 1866 indicate that Medicare pays for health services furnished by "providers of services" that are certified as eligible to participate in the program. Section 1861(u), in turn, defines a "provider of services" to include a "hospital" and a "critical access hospital." Section 1861(e) states that "[t]he term 'hospital' does not include, unless the context otherwise requires, a critical access hospital (as defined in section 1861(mm)(1))."

facility be no more than a 35-mile drive from another hospital.[9] *Cf. Stenberg v. Carhart*, 530 U.S. 914, 942 (2000) ("When a statute includes an explicit definition, we must follow that definition . . . ."); *Ratzlaf v. United States*, 510 U.S. 135, 143 (1994) ("A term appearing in several places in a statutory text is generally read the same way each time it appears."). More specifically, because CGH's eligibility to participate as a CAH hinges on whether Acoma is a hospital within the meaning of that statutory provision, I consider whether a valid basis exists to conclude that Acoma meets the definition of a hospital in section 1861(e). As noted, that definition calls for the institution to comply with the requirements in section 1861(e)'s nine numbered paragraphs.

2. *The record establishes that Acoma meets section 1861(e)'s definition of a "hospital."*

Section 1865(a) of the Act provides that an institution that the Joint Commission accredits as a hospital "shall be deemed to meet the requirements of the numbered paragraphs of section 1861(e)," except for:

- the requirement in 1861(e)(6)(A) relating to utilization review;
- the requirement in section 1861(e)(6)(B) relating to discharge planning; and
- "any standard, promulgated by the Secretary pursuant to [1861(e)(9)] which is higher than the requirements prescribed for accreditation by such Commission."[10]

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[9] If section 1861(e)'s definition were inapplicable, then the Secretary could, in theory, deny CAH certification to a facility based on its proximity to a so-called hospital that does not meet Medicare's conditions of participation for hospitals or CAHs – conditions that prescribe standards for the availability of various hospital services and health professionals within hospital facilities. *See, e.g.*, 42 C.F.R. §§ 482.23, 482.25-.27, 485.618-.643. I can discern no reason why Congress would permit such a result given that a stated goal of CAH certification is to "improve[] access to hospital and other health services for rural residents[.]" Act § 1820(b)(1)(A)(iii).

[10] I base my analysis on the text of section 1865(a) that was in effect prior to the Medicare Improvements for Patients and Providers Act of 2008 (MIPPA), Pub. L. No. 110-275, which was enacted on July 15, 2008. *See* 42 U.S.C. § 1395bb (2006). Section 125 of the MIPPA amended section 1865 by striking subsection (a) and redesignating subsections (b), (c), (d), and (e) as subsections (a), (b), (c), and (d), respectively. Pub. L. No. 110-275, § 125(a), 122 Stat. 2519-2520. Section 125(d) of the MIPPA contains a "transition rule," which states that the amendments to section 1865 "shall apply with respect to accreditations of hospitals granted on or after the date that is 24 months after the date of enactment of this Act." *Id.* This transition rule further states the amendments

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Section 1865(a) also authorizes the Secretary of HHS to find that an accredited institution complies with the requirements in section 1861(e)(6), if the Joint Commission, as a condition of accreditation, requires a utilization review plan and discharge planning process (or imposes requirements that "serve[] substantially the same purpose").

The Joint Commission currently accredits Acoma as a hospital. Thus, under section 1865(a), Acoma is "deemed to meet" the requirements in paragraphs (1) through (5), (7), and (8) of section 1861(e). *See* 42 C.F.R. §§ 488.10(b), 488.5. In other words, the fact that the Joint Commission accredits Acoma as a hospital constitutes sufficient evidence that Acoma meets those statutory requirements.

In addition, the record establishes that Acoma meets the other requirements of section 1861(e) not covered by section 1865's deeming provision – namely, the requirements of section 1861(e)(6)(A) (utilization review), section 1861(e)(6)(B) (discharge planning), and section 1861(e)(9).

Section 1861(e)(6)(A) requires an institution to have a "utilization review plan which meets the requirements of" section 1861(k). In accordance with section 1861(k), CMS's regulations create two exceptions to the utilization review requirement. 42 C.F.R. § 482.30(a). One of the exceptions is for any hospital that has an agreement with a Quality Improvement Organization (QIO) that has a contract with CMS to assume "binding review for the hospital." *See id.* § 482.30(a)(1); *see also* 42 C.F.R. § 488.14 (providing that a QIO's review activities are in lieu of the utilization review requirement of section 1861(e)(6)). CMS has submitted evidence that Acoma has an agreement with the New Mexico Medical Review Association, a QIO under contract with CMS, to assume binding review of Acoma. CMS Exs. 17-18. In addition, CMS certified as early as 1981 that Acoma qualified for section 1861(k)'s external-review exception, and no evidence exists that CMS has ever found Acoma ineligible for that exception. CMS Ex. 10, at 1 (stating "[t]he Statutory Utilization Review requirements are met by [Acoma's] participation in the PSRO [Professional Standards Review Organization]," the precursor to the QIO). Consequently, the record demonstrates that Acoma is compliant with section 1861(e)(6)(A).[11]

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to section 1865 "shall not effect the accreditation of a hospital by the Joint Commission . . . for the period of time applicable under such accreditation." *Id.* I base my analysis on section 1865(a)'s pre-MIPPA text, because Acoma received its most recent Joint Commission accreditation prior to 24 months after the MIPPA's enactment (that is, prior to July 15, 2010). *See* CMS Ex. 15.

[11] Acoma signed its QIO agreement in March 2009, shortly after CMS issued its reconsideration determination in this case. CGH implies that I am bound by the facts that

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The record also shows that Acoma meets the discharge planning requirement in section 1861(e)(6)(B). As indicated, section 1865(a) expressly authorizes CMS to determine that an institution is compliant with section 1861(e)(6), based on an equivalent accreditation standard that the Joint Commission imposed. In a December 1994 Final Rule, CMS announced its determination that the Joint Commission's accreditation standard for hospital discharge planning is equivalent to the discharge planning requirement in section 1861(e)(6)(B) and the regulation that implements that requirement. Final Rule, *Medicare and Medicaid Programs; Revisions to Conditions of Participation for Hospitals*, 59 Fed. Reg. 64,141, 64,144-45 (Dec. 13, 1994). In view of that determination, Acoma's Joint Commission accreditation is sufficient evidence of its compliance with section 1861(e)(6)(B).

Finally, CMS asserts that the requirement in section 1861(e)(9) is not implicated in this case, because the Secretary of HHS has not promulgated any requirements pursuant to section 1861(e)(9) that are higher than the requirements prescribed for Joint Commission accreditation.[12] *See* CMS Supp. Br. at 8. CGH does not dispute that assertion. Accordingly, the record establishes that Acoma meets the requirement in section 1861(e)(9).

CGH does assert that Joint Commission accreditation creates only a "presumption" of compliance with section 1861(e)'s requirements and that the presumption is "subject to verification and cannot cure actual deficiencies." CGH Supp. Br. at 8. CGH further asserts that the presumption of Acoma's compliance with section 1861(e)(7) has been rebutted in this case. *Id*. at 8-10. Section 1861(e)(7) states that where state or local law provides for the licensing of hospitals, the institution seeking hospital status in the Medicare program must be either: (1) "licensed pursuant to such law;" or (2) "approved, by the agency of such State or locality responsible for licensing hospitals, as meeting the standards established for such licensing." According to CGH, the presumption of Acoma's compliance with section 1861(e)(7) has been rebutted, because CMS has

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existed at the time of the initial or reconsideration determinations (or at the time of its application for certification). CGH Supp. Br. at 11; CGH Supp. Reply at 5 n.7. However, CGH offers no legal argument to support that position, and I am unaware of any legal authority that binds me in the manner that CGH suggests.

[12] Section 1861(e)(9) states that an institution must "meet[] such other requirements as the Secretary finds necessary in the interest of the health and safety of individuals who are furnished services in the institution."

admitted in this proceeding that Acoma is not licensed as a hospital by the State of New Mexico, and because the New Mexico Department of Health (DOH), which licenses hospitals, has indicated that it does not survey Acoma for compliance with state law. CGH Supp. Br. at 8.

I reject this argument, because any presumption created by section 1865(a) is not rebuttable in this context. Section 1865(d) provides that a hospital that is deemed to meet – by operation of section 1865(a) – a condition of participation may lose that status "if the Secretary finds that [the hospital] has significant deficiencies (as defined in the regulations pertaining to health and safety)[.]" Pursuant to section 1865(d), CMS has promulgated regulations specifying how it will enforce the conditions of participation at accredited hospitals. *See* 42 C.F.R. § 488.7. Under those regulations, CMS may survey the accredited hospital to validate its compliance with Medicare conditions of participation. 42 C.F.R. §§ 488.7, 488.10(b)-(c). An accredited hospital "will no longer be deemed to meet the conditions of participation," say these regulations, if it "*is found after a validation survey* to have significant deficiencies related to the health and safety of patients[.]"[13] *Id.* § 488.10(c) (italics added).

Considered as a whole, these enforcement provisions indicate that any presumption of compliance arising from a hospital's Joint Commission accreditation can be rebutted only in the context of a CMS-initiated validation survey. Furthermore, a hospital that is deemed to be compliant with conditions of participation by virtue of Joint Commission accreditation may lose its deemed status only if CMS finds "significant deficiencies" relating to patient health and safety. Here, no evidence exists that CMS (or a CMS-contracted state agency) has initiated or performed a survey of Acoma to validate its compliance with Medicare requirements in section 1861(e). Nor is there any evidence that CMS has found Acoma to have "significant deficiencies" relating to patient health and safety. In addition, no evidence exists that CMS has determined *in any context* that Joint Commission accreditation provides inadequate assurance of Acoma's compliance with Medicare health and safety requirements. Thus, for present purposes, Acoma's Joint Commission accreditation is legally sufficient evidence of its compliance with section 1861(e)(7). *Cf.* 42 C.F.R. § 488.10(d) (stating that CMS "may treat the provider or supplier as meeting" conditions of participation when it finds that accreditation "provides reasonable assurance" the conditions are met).

[13] If subject to a validation survey, an accredited institution must authorize the Joint Commission to release to CMS a copy of its most recent accreditation report to retain its deemed status. 42 C.F.R. § 488.10(b)(2).

For all the reasons discussed, the undisputed facts establish that Acoma meets Medicare's definition of a hospital in section 1861(e) and is therefore a "hospital" within the meaning of the 35-mile requirement in section 1820(c)(2)(B)(i)(I).

3. *CMS has reasonably interpreted the term "hospital" to include Acoma.*

Assuming, for discussion purposes, that the meaning of the term "hospital" in section 1820(c)(2)(B)(i)(I) is unclear, I consider whether CMS has reasonably interpreted that term to include Acoma. In general, when a statute or regulation administered by the federal agency is silent or ambiguous about the issue presented, it is appropriate for an ALJ or the Board to defer to the agency's reasonable interpretation of that law. *Missouri Dept. of Soc. Servs.*, DAB No. 2184, at 2 (2008).

In its initial response to CGH's motion for summary judgment, CMS contended that the criterion in section 1861(e)(1) that an institution be "primarily engaged" in providing inpatient services was the only requirement that had to be met to treat Acoma as a hospital in these circumstances. CMS Br. at 7-8. CMS abandoned that position in its May 7, 2010 supplemental brief, stating: "[a]fter further consideration of the applicable statutory language, and other considerations, CMS hereby clarifies that it interprets the term 'hospital,' as used in section 1820(c)(2)(B)(i)(I), to mean an institution that has a provider agreement to participate in the Medicare program as a hospital (i.e. that meets the requirements in subparagraphs (1) through (9) of section 1861(e))." CMS Supp. Br. at 3-4. "Thus," said CMS, "a hospital seeking CAH designation must be located more than a 35-mile drive from another CAH or a hospital that has a provider agreement to participate in the Medicare program." *Id.* at 4.

CMS's interpretation of the term "hospital" – as an institution with a provider agreement to participate in the Medicare program as a hospital – is reasonable. Possession of such a provider agreement is some evidence that the institution meets the statutory definition of a hospital in section 1861(e), a definition that is generally applicable throughout the Medicare statute. *See* Act § 1866(b)(2)(B) (providing that the Secretary may refuse to enter into an agreement or may terminate an agreement after determining that a hospital fails substantially to meet the conditions of participation); 42 C.F.R. § 489.10(a) (providing that an entity must meet the conditions of participation to participate in Medicare). The interpretation is also consistent with the way in which CMS has interpreted the term "hospital" in a statutory provision that immediately precedes the 35-mile requirement. Clause (i) of section 1820(c)(2)(B), which prefaces the 35-mile requirement in sub-clause (I), provides that a State may designate a facility as a CAH if the facility "is a *hospital*" located in a rural area (italics added). CMS has implemented

clause (i) in 42 C.F.R. § 485.612. With certain irrelevant exceptions, section 485.612 provides that a facility seeking CAH status must be a "hospital that has a provider agreement to participate in the Medicare program as a hospital at the time the hospital applies for designation as a CAH."[14]

CGH urges me to disregard CMS's interpretation, because CMS did not promulgate a regulation, or publish a statement, embodying that interpretation prior to issuing the initial determination in this case. *See* CGH Br. at 14, 24-27; *see also* CGH Surreply at 7-8 (asserting that "there is no properly adopted rule of any kind requiring a 35-mile distance from an IHS facility to obtain critical access hospital status"). It is well-established, however, that an agency may interpret its statute case-by-case through adjudication, in lieu of rulemaking. *Conn. Dept. of Soc. Servs.*, DAB No. 1982, at 21 (2005) (citing cases). Thus, CMS was not obligated to issue a regulation or interpretative rule before denying CGH's certification request.

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[14] CGH suggests that CMS's interpretation is unreasonable, because, it says, section 1880(b) of the Act authorizes Medicare to pay IHS hospitals "without regard to the extent of its actual compliance" with applicable conditions of participation. CGH Supp. Br. at 12. CGH's reliance on section 1880(b) is misplaced. That provision, which was enacted on September 30, 1976, states that an IHS hospital

> which does not meet all of the conditions and requirements of this title which are applicable generally to hospitals . . . but which *submits to the Secretary within six months after the date of the enactment of this section an acceptable plan for achieving compliance* with such conditions and requirements, shall be deemed to meet such conditions and requirements (and to be eligible for payments under this title), without regard to the extent of its actual compliance with such conditions and requirements, *during the first 12 months after the month in which such plan is submitted*.

Act § 1880(b) (italics added); Pub. L. No. 94-437 § 401(b), 90 Stat. 1400. By its own terms, section 1880(b) had only temporary effect following its September 1976 enactment. The provision authorized Medicare payment to a noncompliant IHS hospital: (1) only if the hospital submitted a compliance plan within six months after the provision's enactment; *and* (2) only for a period of 12 months following the Secretary's acceptance of the compliance plan.

An agency may not, of course, change its view about the meaning of a statute or regulation and apply the new interpretation to an entity that has reasonably relied to its detriment on the prior interpretation. *See Alaska Dept. of Health and Soc. Servs.*, DAB No. 1919, at 14 (2004). CGH suggests that CMS has done just that, claiming that the challenged determination is "inconsistent with [CMS's] prior certification of critical access hospitals within 35-miles of [IHS] facilities[.]" CGH Br. at 28, 29-30.

In general, it is "incumbent on a party complaining of inconsistency in administrative action" to prove the inconsistency. *South Shore Hosp., Inc. v. Thompson*, 308 F.3d 91, 102-03 (1st Cir. 2002). CGH has not done so here.

In support of its claim of inconsistency, CGH submitted evidence of eight facilities that CMS certified as CAHs, even though they were located less than a 35-mile drive from IHS hospitals. *See* P. Ex. 26. These eight facilities are: Big Horn County Memorial Hospital; Cordell Memorial Hospital; Lincoln County Medical Center; Southwestern Memorial Hospital; Presentation Medical Center; St. Andrews Health Center; and Jane Phillips Nowata Health Center. *See id.*; *see also* CGH Br. at 12.

Of these eight facilities, seven obtained their CAH certification prior to January 1, 2006. *See* P. Ex. 25, at 2, 16, 17, 19, 20, 21 (setting forth column indicating the effective date of CAH status). That date is significant. As originally enacted, section 1820 authorized a state to waive the 35-mile requirement for any facility that it chose to certify as a "necessary provider of health care services to residents in the area." Act § 1820(c)(2)(B)(i)(II) (1997). In 2003, Congress amended section 1820 to remove that waiver authority effective January 1, 2006. Pub. L. No. 108-173 § 405(h)(1), 117 Stat. 2269. Thus, it is possible that some or all of the seven facilities whose CAH status became effective prior to January 1, 2006 secured that status as "necessary providers" without having to meet the 35-mile requirement, rendering irrelevant the location of any IHS facility. CGH offered no evidence to rule out that possibility.

CGH points to an email written by an employee of HHS's Office of Legislation and addressed to the office of Senator Bingaman of New Mexico. P. Ex. 14, at 1. The email indicates that Lincoln Medical Center (Lincoln) in Ruidoso, New Mexico was certified as a CAH despite being located less than a 35-mile drive from Mescalero Indian Hospital (Mescalero). *Id.* The email also refers to a "note in the file" (whose author is unidentified), which stated that Lincoln was "more than 35 miles from the nearest licensed general hospital." *Id.* Although it appears from the email that the location of Mescalero was not considered in the decision to certify Lincoln as a CAH, the email is insufficient proof that CMS had formulated a clear position concerning Mescalero's legal status under the 35-mile requirement, because the email indicates that the state of Mexico, not CMS, made the decision to certify Lincoln. *Id.* (stating that that Lincoln's "eligibility determination was made by the NM Office of Rural Health in 2002" and that

"CAH eligibility determinations are no longer made by the states but are now determined by the respective [CMS] regional offices"). Moreover, the email does not rule out the possibility that Lincoln had been designated as a "necessary provider."[15] P. Ex. 14.

As for the one facility whose CAH status became effective after January 1, 2006 – Cobre Valley Community Hospital (Cobre) – the fact of its certification is also insufficient evidence that CMS had formulated a position on the legal issue now before me. It is possible that Cobre was certified as a CAH despite its proximity to the IHS facility only because CMS determined that factual circumstances unique to the nearby IHS facility disqualified it from hospital status under section 1861(e), and not because CMS determined that an IHS facility cannot, *as a matter of law*, be regarded as a hospital within the meaning of the 35-mile requirement.

Given the absence of evidence about the legal and factual underpinnings of CMS's prior certifications, I cannot draw the inference that CGH apparently wants me to draw – which is that prior to April 2007, when CGH filed its application for certification, CMS interpreted the term "hospital" in section 1820(c)(2)(B)(i)(I) as excluding *any* IHS facility, regardless of its participation or eligibility to participate in the Medicare program. I thus reject the contention that CMS has changed its interpretation of the law or otherwise inconsistently applied the 35-mile requirement to similar situations. I also find no reason to suspect that CMS's present interpretation of section 1820(c)(2)(B)(i)(I), as expressed in its May 7, 2010 supplemental brief, is not the product of fair and considered judgment. Accordingly, I find CMS's interpretation to be worthy of deference. *See Auer v. Robbins*, 519 U.S. 452, 462 (1997) (holding an agency interpretation advanced in litigation may be worthy of deference so long as it reflects the agency's "fair and considered judgment" on the matter in question). Applying that interpretation, I find that Acoma is a hospital, because it participates in the Medicare program as a hospital under a valid provider agreement.

4. *CGH's other objections to CMS's determination concerning Acoma's legal status are unfounded or unpersuasive.*

I have considered but reject all of CGH's other contentions concerning CMS's determination that Acoma is a "hospital." I discuss only some of those contentions here.

[15] Lincoln's certification became effective prior to January 1, 2006. P. Ex. 25, at 19.

a. CMS's determination does not usurp the state's authority under section 1820.

CGH contends that CMS's determination in this case "usurp[s] the State's statutory right to determine whether the 35-mile distance requirement is met." CGH Br. at 14, 21-24. According to CGH, section 1820(e)(2) of the Act "directs CMS merely to ensure that the State has 'designated the hospital a critical access hospital,' not to determine whether that designation is correct." *Id.* at 22 (citing section 1820(e)). In other words, CGH contends that if a state designates a facility as a CAH pursuant to section 1820(c)(2), CMS must accept the state's legal findings supporting that designation, including any finding that the facility meets the 35-mile requirement.

I reject that contention, because CMS's authority to require compliance with the 35-mile requirement as a condition of certification can be found, at minimum, in section 1820(e)(3) of the Act, which requires a facility to meet "such other criteria as the Secretary may require." Pursuant to section 1820(e)(3), the Secretary has issued regulations containing requirements that a facility must meet to participate in Medicare as

a CAH. 42 C.F.R. §§ 485.601-.647. Those regulations provide that CMS will certify a facility as a CAH only if the state designates the facility as a CAH, *and* the facility is found to meet the "conditions of participation" for CAHs. *Id.* § 485.610(a)(1). Those conditions of participation include the 35-mile requirement. *Id.* § 485.610(c).

b. CMS's determination is not inconsistent with how Medicare program treats IHS facilities vis-à-vis non-IHS providers.

CGH contends that "CMS's decision to treat [Acoma] the same as a 'hospital' *in this one limited and counterintuitive area* is inconsistent with the many ways CMS draws common-sense distinctions between [IHS] facilities and hospitals." CGH Br. at 30 (italics added). In support, CGH points out that IHS facilities, unlike other Medicare providers, may deny access to their services based on a patient's race (i.e., based on whether the patient is an American Indian or Alaska Native). *Id.* at 17, 30. In addition, CGH asserts that certain Medicare program practices and policies demonstrate that CMS does not recognize IHS facilities as "hospitals" as that term is "typically used for Medicare purposes." CGH Supp. Br. at 13. For example, according to CGH, CMS does not collect wage data from Acoma (as it does from non-IHS facilities), does not pay IHS facilities directly (as it pays non-IHS providers), exempts IHS facilities from the usual Medicare cost reporting requirements, does not treat IHS facilities as hospitals payable under the outpatient hospital prospective payment system, and directs the state survey agencies not to survey IHS facilities or to investigate complaints at those facilities. CGH Br. at 30-31.

The statute and regulations refute CGH's suggestion that CAH certification is the *only* context in which the Medicare program recognizes an IHS facility as a hospital. The Medicare statute refers to an IHS hospital as a "Federal *provider of services*." *See* Act § 1814(c) (prohibiting payment to any federal provider of services except as provided in section 1880, which authorizes Medicare payments to IHS hospitals). Under section 1861(u), the term "provider of service" includes a "hospital" as defined in section 1861(e). Section 1861(e), in turns, defines a hospital as any "institution" that meets the enumerated requirements and does not exclude federal facilities from its scope. Meanwhile, section 1880(a) provides that a "*hospital* . . . of the Indian Health Service" (italics added) may receive Medicare payment for services provided to program beneficiaries if the conditions and requirements "applicable generally" to hospitals are met. In addition, Medicare's regulations state that Medicare payment may be made for services that "participating hospitals" of the IHS furnish. 42 C.F.R. § 411.6(b)(3). Read as a whole, these provisions recognize that an eligible IHS hospital, such as Acoma, may participate in (receive payment from) Medicare *as a hospital*, as the Medicare statute defines that term.

CMS's program manuals confirm that the Medicare program confers hospital status on eligible IHS facilities. The Program Integrity Manual (PIM), for example, instructs an IHS facility that wishes to enroll in Medicare as a hospital to check either "Indian Health Service facility" or "hospital" or "perhaps both" on the enrollment application and further states that CMS "processes IHS applications in the same manner (and via the same procedures) as it would with a [non-IHS] hospital[.]" PIM, ch. 10, § 2.1.9 (rev. 320, issued Dec. 23, 2009). Another CMS manual, the Medicare Claims Processing Manual (CPM), states that an IHS hospital may be deemed to meet Medicare conditions of participation for hospitals by virtue of its Joint Commission accreditation. CPM, ch. 19, § 40.2 (rev. 1040, issued Aug. 25, 2006).

The fact that Acoma does not serve the general population does not negate its status as a hospital under the Medicare program. Compliance with federal anti-discrimination law is not an element of the statutory definition of "hospital" or of the regulations that implement the conditions of participation established by that definition.[16] *See* 42 C.F.R

[16] Apart from the conditions of participation, the Medicare regulations obligate a hospital to meet "*applicable* civil rights requirements of . . . Title VI of the Civil Rights Act of 1964, *as implemented by 45 CFR part 80*, which provides that no person in the United States shall, on the ground of race, color, or national origin, be excluded from participation in, be denied the benefits of, or be subject to discrimination under, any program or activity receiving Federal financial assistance (section 601)[.]" *See* 42 C.F.R. § 489.10(b)(1) (italics added); *see also id.* § 489.2(a) (stating that subpart A of Part 489 "sets forth the basic requirements for submittal and acceptance of a provider agreement under Medicare"). The HHS regulations that implement Title VI provide that with

(Continued. . .)

Part 482, subpart C. The other distinctions in program administration that CGH cited also do not affect Acoma's status as a hospital. The bottom line is that CMS may lawfully treat Acoma as a hospital if it meets the statutory definition in section 1861(e), a definition that does not exclude federal facilities.[17]

c. CMS's determination is not arbitrary or capricious.

Next, CGH contends that "CMS's refusal to certify the State's critical access hospital designation is inconsistent with its prior assurances to the New Mexico Department of Health that the proximity of an [IHS] facility would not be considered in its certification decision." CGH Br. at 28. CGH asserts that "[t]he State, on behalf of CGH General Hospital, was specifically 'assured by CMS staff that Federal hospitals, including Indian Health Service facilities, were not licensed by the State, and did not provide services to the general public, and as such were not to be considered in calculating the 35-mile distance requirement[.]'" *Id.* at 31. CGH also asserts that "[t]he CMS regional office . . . likewise specifically assured the State that the 'the CGH . . . application would not need to conform with Necessary Provider provisions of the Federal rules,' which would have provided an alternative path to critical access hospital status." *Id.* (quoting P. Ex. 22). According to CGH, these assurances "lulled the State and CGH General Hospital into foregoing pursuit of critical access hospital status through necessary provider certification[.]" *Id.* at 32. CGH asserts that "[i]t is clearly arbitrary and capricious for CMS to make these assurances, holding out one interpretation of the statute, and then, without warning, reversing course." *Id*.

(. . .Continued)
respect to "Indian Health" services, "[a]n individual shall not be deemed subjected to discrimination by reason of his exclusion from benefits limited by Federal law to individuals of a particular race, color, or national origin different from his." 45 C.F.R. § 80.3(d).

[17] Section 1820(g)(3) of the Act authorizes grants to "eligible small rural hospitals" and defines an eligible small rural hospital to mean "a *non-Federal*, short-term general acute care hospital" (italics added). The appearance of the term "non-Federal" in this provision suggests that Congress knew what language to use had it intended to exclude "federal providers" – such as IHS hospitals – from the scope of the 35-mile inquiry. *Cf. Russello v. United States*, 464 U.S. 16, 23 (1983) ("[Where] Congress includes particular language in one section of a statute but omits it in another section of the same Act, it is generally presumed that Congress acts intentionally and purposely in the disparate inclusion or exclusion.").

The evidence that CGH cited in support of these assertions is Petitioner's Exhibit 22 – a June 1, 2009 letter from the DOH to CGH. That letter, written after CMS issued its initial determination in this case, refers to "discussions" between DOH and CMS's regional office "exploring whether the CGH application would need to conform with Necessary Provider provisions of the Federal rules." P. Ex. 22, at 1.

The June 1, 2009 letter does not indicate when DOH's alleged discussions with CMS occurred. The only date mentioned in the letter is November 30, 2007, the date that CMS's contractor recommended approval of CGH's April 2, 2007 application for CAH status. CGH does not allege that it consulted with CMS prior to submitting that application, and no allegation or proof exists of any pre-April 2007 discussions between CMS and DOH. *See* CGH Br. at 9, ¶ 21 (indicating only that DOH conferred with CMS before DOH recommended approval of CGH's application). In addition, CGH's application makes no mention of any consultative efforts by DOH on CGH's behalf. P. Ex. 6 (summarizing the work of CGH's governing board and other staff to formulate the application). Given these circumstances, the only reasonable inference I can make is that the discussions described in the June 1, 2009 letter occurred sometime *after* CGH filed its application for CAH status with the State of New Mexico. If so, then the June 1, 2009 letter at most proves that *while considering CGH's request for certification, and before issuing any determination about that request*, CMS changed its mind about CGH's eligibility for CAH status. Absent other contextual details, that reversal cannot reasonably be regarded as arbitrary and capricious conduct but merely evidence of deliberation by CMS about a novel, and perhaps difficult, legal issue. It is important to note that CMS's formal determinations were consistent, as both the initial and reconsideration determinations advised CGH that it was ineligible for CAH status. P. Exs. 1, 9.

Moreover, the facts (as alleged) do not prove that CMS improperly "lulled" CGH into "foregoing pursuit of critical access hospital status through necessary provider certification." The state's authority to designate CGH a "necessary provider" expired on January 1, 2006, 15 months before CGH filed its application for CAH status. *See* P. Ex. 6; Act § 1820(h)(3). Nothing in DOH's June 1, 2009 letter, or any other document, indicates that CGH ever sought, or contemplated seeking, "necessary provider" status. CGH Exs. 6, 22.

To the extent that CGH asserts an estoppel claim based on CMS's alleged "assurances," *see* CGH Br. at 32-33, that claim must fail, because I lack the authority to order equitable relief and because estoppel against the federal government, if available at all, may not be imposed unless all of that remedy's traditional elements (including detrimental reliance) are present and there is also proof of "affirmative misconduct" by the government. *US*

Ultrasound, DAB No. 2302, at 8 (2010); *Family Health Servs. of Darke County, Inc.*, DAB No. 2269, at 18-20 (2009). CGH has not demonstrated that it meets the traditional elements of estoppel (particularly detrimental reliance), much less proved affirmative governmental misconduct.

d. CMS's determination does not thwart the legislative purpose of CAH certification

Emphasizing that IHS facilities generally bar access to persons who are not American Indians, CGH asserts that it is "the only facility in a radius of more than 65 miles that will treat the majority of the population in the service area who are non-Indians[.]" CGH Br. at 19. CGH also asserts that Cibola County, New Mexico "is a federally-designated *medically underserved area* due to a shortage of primary care providers, high infant mortality, high poverty and/or high elderly population." *Id.* In addition, CGH asserts that IHS hospitals are not required to have the resources to provide emergency care services, implying that some county residents have – or in the future may have – difficulty obtaining those services. *Id.* at 20. CGH asserts that these facts put CMS's determination in conflict with a key legislative purpose of section 1820, which is to improve rural residents' access to hospital services. *Id.* at 20-21. According to CGH, "not designating [it] as a critical access hospital because of the presence of a facility that

does not provide access to care to the majority of the area's residents violates Congress's plainly stated goal of increasing access to care and must therefore be nullified: '[A] rule out of harmony with the statute is a mere nullity.'" *Id.* at 21 (quoting *Manhattan Gen. Equip. Co. v. Commn'r*, 297 U.S. 129, 134 (1936)).

I disagree that CMS's determination is antithetical to the statute's purpose. Congress evidently wanted to preserve or increase rural residents' access to hospital services, but Congress also put limits on the tools it created to achieve that goal. The Secretary may promote access to rural hospital services by certifying facilities as CAHs, but her use of the certification tool is constrained by the 35-mile requirement. Thus, even if certifying CGH as a CAH would (in some measure) improve the rural population's access to hospital services, denying certification does not necessarily subvert the statute's purpose, because Congress intended to limit the extent to which certification may be used to promote such access.

Furthermore, the degree (if any) to which denial of certification would, in these circumstances, undermine the legislative purpose is unclear at best. As a preliminary matter, CGH's application for CAH status does not state that rural residents of Cibola County presently have significant difficulty obtaining hospital services. *See* P. Ex. 6. Also, contrary to CGH's suggestion, the record indicates that Acoma does, in fact, provide emergency services, which IHS facilities are authorized to provide to the general

public. *See* CMS Ex. 2, at 4; 42 C.F.R. § 136.14(a). CGH indicated in its application that its "declining financial performance" may in the future reduce residents' access to emergency care and other hospital services. *See* Ex. 6 (section of application entitled "Anticipated Impact of Hospital Designation"). However, in this proceeding, CGH did not submit any financial, demographic, or health data to support that claim.

Cibola County is, as CGH asserts, a federally designated "medically underserved area" (MUA) (*see* P. Ex. 4); however, it is unclear whether that designation is indicative of the population's lack of access to *hospital services* or, rather, to health services in non-hospital settings. CGH's application and briefs are short on specifics about how CAH status will help it alleviate health manpower shortages, either within or outside the hospital.[18]

It is true that the non-American Indian population of Cibola County generally does not have access to Acoma's hospital services. However, it is also true that a substantial portion of the county's population (approximately 40 percent, according to the 2000 census) is American Indian and presumably eligible to receive services at Acoma.[19] It is not implausible to think that Congress may have wanted the Secretary to account for the presence of an IHS hospital in these circumstances, believing that the IHS and non-IHS facilities would *collectively* ensure that all of the rural area's residents have sufficient access to hospital services. What Congress actually thought, if anything, about this

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[18] The Medicare statute requires a state to assure that its rural health network will promote access to both hospital services and to "other health" services. Act § 1820(b)(1)(A)(iii). HHS defines a "medically underserved area" to include a facility, geographic area, or population group. *See* 42 C.F.R. § 62.22 (defining "medically underserved area" to mean a "health manpower shortage area" as defined in § 62.2), § 62.2 (defining a "health manpower shortage area" to mean a "geographic area, the population group, the public or nonprofit private medical facility, or other public facility which has been determined by the Secretary to have a shortage of health manpower under section 332 of the Act and its implementing regulations (42 CFR part 5)"); *see also* http://bhpr.hrsa.gov/shortage/muaguide.htm (HHS website indicating that a MUA designation involves application of a data index that incorporates four variables: "ratio of primary medical care physicians per 1,000 population, infant mortality rate, percentage of the populations with incomes below the poverty level, and percentage of the population age 65 or over").

[19] *See* the U.S. Census Bureau's demographic profile of Cibola County at http://quickfacts.census.gov/qfd/states/35/35006.html; *see also Citizens Fin. Group, Inc. v. Citizens Nat. Bank of Evans City*, 383 F.3d 110, 127 n.2 (3d Cir. 2004) (taking judicial notice of federal census data).

particular situation is unclear, however. (Neither party uncovered any pertinent legislative history). It is therefore appropriate to defer to CMS's reasoned judgment in applying the statute.

In short, CGH's argument about legislative purpose boils down to a request that I overlook the fact that Acoma is a "hospital" under a statutory definition whose applicability and meaning is not in dispute. I cannot do so, however, unless applying the statutory definition would produce an absurd or irrational result. *Cf. American Dental Ass'n v. Shalala*, 3 F.3d 445, 448 (D.C. Cir. 1993) ("We generally look beyond the clear language of a statute to determine congressional intent only in extraordinary circumstances, such as when the literal meaning leads to an absurd or irrational result."). For the reasons mentioned in this section, CGH has not demonstrated that CMS's determination is absurd or irrational.

Conclusion

CMS has lawfully determined that Cibola General Hospital is located less than a 35-mile drive from another "hospital," as that term is used section 1820(c)(2)(B)(i)(I) of the Act. Consequently, Cibola is ineligible to participate in the Medicare program as a critical access hospital.

/s/
Alfonso J. Montaño
Administrative Law Judge