Department of Health and Human Services

DEPARTMENTAL APPEALS BOARD

Civil Remedies Division

Freedom Pain Hospital (CCN: 03-0135),

Petitioner,

v.

Centers for Medicare & Medicaid Services.

Docket No. C-15-2279

Decision No. CR4530

Date: February 10, 2016

DECISION

The Centers for Medicare & Medicaid Services (CMS) terminated the Medicare provider agreement of Freedom Pain Hospital (Petitioner) effective April 30, 2015, after CMS determined Petitioner did not meet the requirements to participate in the Medicare program as a hospital. CMS relied on a validation survey by the Arizona Department of Health Services (state agency) that ended January 15, 2015, which found Petitioner did not have any inpatients during the survey, and that over a one-year period ending January 3, 2015, only approximately 2% of Petitioner's overall patients were inpatients. CMS concluded that Petitioner no longer met the statutory definition of a hospital because it was not "primarily engaged" in the treatment of inpatients. Petitioner requested a hearing before an administrative law judge to challenge the termination of its provider agreement. The parties have now crossed-moved for summary judgment.

I find that the undisputed material facts, when considering all inferences drawn in favor of Petitioner, demonstrate that Petitioner was not "primarily engaged" in the treatment of inpatients and therefore did not comply with the definition of a "hospital." *See* 42 U.S.C. § 1395x(e)(1). As a result, Petitioner did not meet all of the requirements necessary to participate in the Medicare program as a hospital. Accordingly, I grant summary judgment in favor of CMS affirming the termination of Petitioner's Medicare provider agreement.

I. Statutory and Regulatory Background

Title XVIII of the Social Security Act (Act) establishes the health insurance program for the aged and disabled, known as the Medicare program. Part A of the Medicare program covers certain expenses that beneficiaries may incur for services provided by hospitals, home health agencies, and hospices, among other facilities. *See* 42 U.S.C. § 1395c. Payment for services furnished to a beneficiary will only be made to a provider of services that has a provider agreement with the Medicare program. *Id.* §§ 1395f(a), 1395cc. The Secretary of Health and Human Services (Secretary) has defined a "provider agreement" as an "agreement between CMS and one of the providers specified in § 489.2(b) [of title 42 of the Code of Federal Regulations] to provide services to Medicare beneficiaries and to comply with the requirements in [42 U.S.C. § 1395cc]." 42 C.F.R. § 489.3.

The Act defines the types of services that Part A covers as well as the requirements each provider type must meet in order to participate in Medicare and receive payment for covered services furnished to beneficiaries. 42 U.S.C. § 1395x; 42 C.F.R. § 489.1(a)(1). A "hospital" must meet nine specific statutory requirements. 42 U.S.C. § 1395x(e)(1)-(9). Relevant here, a "hospital" is an institution that "is *primarily engaged* in providing ... *to inpatients* (A) diagnostic services and therapeutic services for medical diagnosis, treatment, and care of injured, disabled, or sick persons, or (B) rehabilitation services for the rehabilitation of injured, disabled, or sick persons." *Id.* § 1395x(e)(1) (emphases added).

In addition, the Act authorizes the Secretary to implement by regulation additional Medicare enrollment requirements for each type of provider as well as the general enrollment process for providers. 42 U.S.C. § 1395cc(j); *see also id.* § 1395x(e)(9). The Secretary has established conditions of participation (CoPs) for hospitals in 42 C.F.R. part 482. A hospital, like any provider, must meet all applicable CoPs to participate in the Medicare program. 42 C.F.R. § 488.3(a). The Secretary permits certain national accreditation programs to accredit hospitals, and if a hospital is accredited under such a program, then CMS may deem that hospital as meeting all CoPs. *Id.* §§ 488.5(a), 488.6. CMS may also require a validation survey to ensure that the hospital continues to meet all CoPs. *Id.* § 488.7. A state survey agency performs the validation survey on behalf of CMS, and CMS may then use the results of that survey to determine whether the hospital meets or continues to meet all CoPs. *Id.* §§ 488.7(a), 488.5(c).

The Act provides circumstances where the Secretary may refuse to enter into a provider agreement or may terminate an existing provider agreement. *Id.* § 1395cc(b)(2). The Secretary may terminate a provider agreement if, among other reasons, the Secretary "has determined that the provider fails substantially to meet the applicable provisions of [42 U.S.C. § 1395x]," which sets forth the statutory requirements for each provider type.

Id. § 1395cc(b)(2)(B). In addition, the Secretary may terminate a provider agreement if the provider does not meet applicable regulatory requirements specific to its provider type or the provisions of its provider agreement. 42 C.F.R. § 489.53(a)(1). A provider whose Medicare provider agreement has been terminated may request a hearing before an administrative law judge to challenge that termination. 42 C.F.R. § 489.53(e).

II. Case Background and Procedural History

The following facts are undisputed unless otherwise noted. Petitioner is located in Arizona and has described itself in these proceedings as a "one of a kind specialty hospital for pain." Petitioner Brief (P. Br.) at 12. In early 2014, Noridian Healthcare Solutions (Noridian), a CMS administrative contractor, received an application from Petitioner to enroll in the Medicare program as a hospital. *See* CMS Exhibit (Ex.) 5 at 1. Noridian then forwarded Petitioner's enrollment application to the state agency and notified Petitioner that the next step in its process to enroll as a hospital would be a survey or site visit from the state agency or "a CMS approved deemed accrediting organization to ensure compliance with the required Conditions of Participation." CMS Ex. 5 at 1. Soon after, Det Norske Veritas Healthcare, Inc. (DNV Healthcare), an approved accrediting organization, determined that Petitioner was in compliance with all CoPs for a hospital in 42 C.F.R. part 482, and accredited Petitioner for three years. CMS Ex. 7.

The CMS Western Division of Survey and Certification later notified Petitioner that CMS accepted Petitioner's Medicare provider agreement effective retroactively to the day DNV Healthcare accredited Petitioner. CMS Ex. 8 at 1. CMS clarified that the agreement was "restricted," and was only issued pending final approval from the U.S. Department of Health and Human Services' Office for Civil Rights (OCR). If OCR did not grant approval to Petitioner, then CMS would recoup any Medicare payments made for services provided after the provider agreement took effect. CMS Ex. 8 at 1. Several months later, OCR advised Petitioner that it was in compliance with the necessary regulations and had "civil rights clearance" to participate in the Medicare program. CMS Ex. 9. On the same day as OCR's letter advising Petitioner of its civil rights compliance, the state agency began its survey of Petitioner's facility, which would soon lead to the termination of Petitioner's Medicare provider agreement.

The state agency conducted a four-day validation survey from January 12, 2015 through January 15, 2015. CMS Ex. 1. Surveyors determined that Petitioner did not treat any inpatients for the duration of the survey, which Petitioner's Chief Nursing Officer and Patient Access Coordinator confirmed. CMS Ex. 1 at 1. Surveyors also found that for the 12 months from January 1, 2014, through January 3, 2015, only 2% of Petitioner's overall patients were inpatients. CMS Ex. 1 at 1. Finally, surveyors found that Petitioner discharged its last inpatient on January 4, 2015, and did not have any other inpatients

"scheduled for the remainder of January 2015." CMS Ex. 1 at 2. Based on these findings, the surveyors concluded that Petitioner "does not primarily provide inpatient services." CMS Ex. 1 at 2.

Soon after, CMS advised Petitioner, based on the findings from the state agency's survey, Petitioner was not in compliance with the CoPs for a hospital in the Medicare program, and its Medicare provider agreement would be terminated effective April 30, 2015. CMS Ex. 10 at 1. CMS concluded that Petitioner did not meet the definition of a "hospital" in 42 U.S.C. § 1395x(e) because it was "not primarily engaged in providing care to inpatients." CMS Ex. 10 at 2.

Petitioner subsequently requested a hearing before an administrative law judge. The case was assigned to me to decide, and on May 7, 2015, I issued an Acknowledgment and Prehearing Order (Prehearing Order) to establish procedures for record development. In my Prehearing Order, I permitted the parties to file for summary judgment, if appropriate. See Prehearing Order ¶ 4; see also Civil Remedies Division Procedures (CRDP) § 19(a). CMS timely filed a motion for summary judgment with a supporting brief (CMS Br.) with 13 supporting exhibits (CMS Exs. 1-13) including the written direct testimony of the state agency's surveyor. See CMS Ex. 11; CRDP §§ 16(b), 19(b). Soon after, Petitioner filed a motion for the issuance of a subpoena, which CMS opposed. On July 16, 2015, Petitioner timely filed an opposition to CMS's motion for summary judgment and a cross-motion for summary judgment with a supporting brief (P. Br.) and nine supporting exhibits (P. Exs. 1-9¹) including the written direct testimony of Petitioner's Chief Executive Officer. See P. Ex. 4. On August 17, 2015, CMS filed a response (CMS Resp.) in opposition to Petitioner's cross-motion for summary judgment as well as notice of its intention to cross-examine Petitioner's witness if the case went to hearing. Four days later, on August 21, 2015, Petitioner moved to strike CMS's notice of intent to cross-examine Petitioner's witness, arguing that CMS had untimely filed that notice. I need not resolve whether CMS's August 17 notice preserved its right to cross-examine Petitioner's witness because I decide this case on summary judgment in favor of CMS, without the need for an in-person hearing. See CRDP § 19(a).

III. Issues

This case presents the following issues:

1. Whether summary judgment is appropriate; and

¹ Petitioner labeled its exhibits as "FPH Ex." However, to be consistent with other decisions in the Civil Remedies Division as well as the CRDP, I will refer to Petitioner's exhibits as "P. Ex." *See* CRDP § 14(c)(ii).

2. Whether CMS was authorized to terminate Petitioner's Medicare provider agreement because it did not continue to meet the statutory requirements of a hospital.

IV. Ruling on Pending Subpoena Request

On June 30, 2015, Petitioner filed a motion (P. Motion) pursuant to 42 C.F.R. § 498.58 requesting the issuance of a subpoena that would require CMS to produce documents. Petitioner seeks the following documents:

- (1) A list of all hospitals terminated from the Medicare program based on low inpatient volumes, along with records sufficient to show inpatient and outpatient volumes at each such hospital during the year prior to termination.
- (2) A list of all hospitals terminated from the Medicare program because of the time in between inpatient admissions and discharges at each such hospital during the year prior to termination.
- (3) A list of all cases in which CMS has compared inpatient and outpatient hospital census numbers for the purposes of evaluating the hospital's initial or continued participating in the Medicare program, along with records sufficient to show the inpatient and outpatient census numbers evaluated at each such hospital and the outcome of each case.
- (4) A list of hospitals that have been evaluated for termination from the Medicare program within one year of their Medicare certification, together with records sufficient to show the reason for their termination or nontermination from the program.
- (5) A list of all pain management hospitals that CMS has evaluated for termination from the Medicare program, together with records sufficient to show the reason for their termination or non-termination from the program.

P. Motion at 2. Petitioner claims that the requested documents are directly relevant to CMS's basis for terminating Petitioner's Medicare provider agreement and to Petitioner's claim that CMS's decision to terminate Petitioner was arbitrary, capricious, and unprecedented. P. Motion at 3. Petitioner states that the requested documents may be available through a public records request, however, "government response times to FOIA [Freedom of Information Act] requests often exceed two months and there is no guarantee that the documents can be obtained through the FOIA process within the time needed to prepare for the hearing in this matter." P. Motion at 3. On July 13, 2015, CMS filed its objections to the motion.

I may issue a subpoena for the production of documents or testimony at the request of a party, or *sua sponte*, but only if I conclude that a subpoena is "reasonably necessary for the full presentation of a case." 42 C.F.R. § 498.58(a). I must determine in this case whether the termination of Petitioner's provider agreement was proper based upon the unique circumstances of Petitioner's facility, not by comparing the actions CMS took or did not take for other hospitals. The requested documents, assuming they exist, would not be necessary to Petitioner's presentation of its case. Petitioner has obtained the relevant documents on which CMS based its decision to terminate Petitioner in CMS's prehearing exchange; that basis did not rely on the actions CMS took against other hospitals or by comparing Petitioner's performance to that of other hospitals. Moreover, Petitioner is not entitled to an administrative hearing on whether CMS's actions were arbitrary and capricious. *See NMS Healthcare of Hagerstown*, DAB No. 2603, at 5-6 (2014). Therefore, I deny Petitioner's subpoena request.

V. Findings of Fact and Conclusions of Law

1. Summary judgment is appropriate.

Summary judgment is appropriate if there are "no genuine issues as to any material fact, and the moving party is entitled to judgment as a matter of law." Mission Hosp. Reg'l Med. Ctr., DAB No. 2459, at 5 (2012) (citations omitted); see also Crestview Parke Care Ctr. v. Thompson, 373 F.3d 743, 749-50 (6th Cir. 2004) (recognizing summary judgment procedures in cases governed by 42 C.F.R. part 498 as a valid interpretive rule). The moving party must show that there is no genuine dispute of material fact requiring an evidentiary hearing and that it is entitled to judgment as a matter of law. Id. If the moving party meets its initial burden, the non-moving party must "come forward with 'specific facts showing that there is a genuine issue for trial'" Matsushita Elec. Indus. Co. v. Zenith Radio Corp., 475 U.S. 574, 587 (1986). "To defeat an adequately supported summary judgment motion, the non-moving party may not rely on the denials in its pleadings or briefs, but must furnish evidence of a dispute concerning a material fact — a fact that, if proven, would affect the outcome of the case under governing law." Senior Rehab. & Skilled Nursing Ctr., DAB No. 2300, at 3 (2010). A party "must do more than show that there is 'some metaphysical doubt as to the material facts Where the record taken as a whole could not lead a rational trier of fact to find for the nonmoving party, there is no genuine issue for trial." Mission Hosp., DAB No. 2459, at 5 (quoting Matsushita, 475 U.S. at 586).

In examining the evidence to determine the appropriateness of summary judgment, I must draw all reasonable inferences in the light most favorable to the non-moving party. *See Brightview Care Ctr.*, DAB No. 2132, at 2, 9 (2007); *but see Cedar Lake*, DAB No. 2344, at 7 (2010) (upholding summary judgment where inferences and views of non-

moving party were not reasonable). However, drawing factual inferences in the light most favorable to the non-moving party does not require that I accept the non-moving party's legal conclusions. *Cedar Lake*, DAB No. 2344, at 7.

The parties dispute the total number of inpatients and outpatients that Petitioner treated during 2014, but as I discuss below, those disputes are not material to the outcome of the case and do not preclude summary judgment. The parties also dispute the amount of time that lapsed between the discharge of one inpatient and the admission of another inpatient. *See* CMS Br. at 2-3; P. Br. at 10. In the absence of other undisputed evidence, this factual dispute may indeed be material to preclude summary judgment. The length of time between inpatient admissions has been used in prior decisions to help determine whether a facility was "primarily engaged" in treating inpatients. *See, e.g., Ariz. Surgical Hosp.*, DAB No. 1890, at 6 (2003). However, I need not resolve that factual dispute to decide this case on summary judgment because the record contains other undisputed facts related to Petitioner's treatment of inpatients that allow me to conclude whether Petitioner was "primarily engaged" in such treatment.

CMS asserts that Petitioner's facility was only open and staffed for 12 hours a day, from 7:00 a.m. to 7:00 p.m., instead of 24 hours a day as required.² CMS Br. at 2, 6 (citing 42 U.S.C. § 1395x(e)(5)). Petitioner's witness testified that Petitioner used military time when listing its hours, so "07 to 07," as it is written in the state license renewal application, actually meant 24 hours a day, or 7:00 a.m. to 7:00 a.m. the following day. P. Ex. 4 ¶ 6. For purposes of summary judgment I will infer that Petitioner was open 24 hours daily. My decision in favor of CMS is based only on the undisputed evidence before me and the reasonable inferences I have drawn in favor of Petitioner.

a. It is undisputed that between January 1, 2014, and January 3, 2015, less than 3% of patients that Petitioner treated were inpatients.

The state agency found that for a period of just over 12 months, between January 1, 2014, and January 3, 2015, Petitioner had a total of 2,188 patients, only 45 of which, or 2.05% overall, were inpatients. CMS Ex. 1 at 1. CMS bases those figures on two documents that Petitioner's Chief Nursing Officer provided to surveyors and that CMS has offered in

² Neither the surveyor nor CMS in its initial determination considered Petitioner's hours of operation as a basis for terminating its Medicare provider agreement. *See* CMS Ex. 1 at 2; CMS Ex. 10 at 2. Accordingly, this is a new issue that CMS has raised in this forum, although there was no clear notice that CMS was adding a new factual basis for the underlying determination. 42 C.F.R. § 498.56(a). While I do not resolve this issue because I am affirming the original basis for terminating Petitioner's provider agreement, I note that Petitioner has had a full opportunity to address – and, in fact, adequately addressed – this new issue in its opposition to CMS's motion for summary judgment. *See* P. Br. at 10; P. Ex. 4 ¶ 4.

support of its motion for summary judgment. The first document is a roster of all patients during the relevant time period and includes a brief description of the services Petitioner provided to a specific patient and what appears to be the Current Procedural Terminology (CPT) code used for those services. *See* CMS Ex. 3. The second document is a chart titled "Inpatient and Observation Tracker 2014-2015." CMS Ex. 4. It includes the patient's admission date and time, discharge date and time, demographic information, the type of inpatient service provided (for example, "In-Patient" or "Surgery-Spine"), and the patient's general diagnosis. *See* CMS Ex. 4. There are a total of 54 patients listed on this chart. However, there is a handwritten notation at the top of the chart that says "highlighted = inpatient," and there are 45 patients that are highlighted on the chart. CMS Ex. 4 at 1.

Petitioner generally disputes the accuracy of the charts originally provided to surveyors and offers slightly different figures than those in CMS's exhibits. One chart that Petitioner offered with its cross-motion for summary judgment provides columns labeled "Line Item," which consists of consecutive numbers to track the total number of entries, "DOS," which includes dates, and "IP/OP," which says "OP" for every line entry. See P. Ex. 7. Under the circumstances "DOS" reasonably means "Date of Service," and "IP/OP" means "Inpatient/Outpatient." I will draw the inference in favor of Petitioner that the data presented in the chart lists a total number of outpatients that Petitioner treated between January 1, 2014 and December 31, 2014.³ Å second spreadsheet appears to be an annual billing summary, and includes, among other data, columns labeled "Total Patient Days" and "Total Patient Discharges." P. Ex. 6. Petitioner represents, and I accept for summary judgment, that the values in these fields are the total number of inpatients that Petitioner treated throughout all of 2014. According to Petitioner's figures, for the same 12 month period that surveyors referenced, it had 1,884 outpatients (P. Ex. 7) and 56 inpatients (P. Ex. 6), for a total of 1,940 patients. Based on these numbers, a total of 2.88% of the patients that Petitioner treated in 2014 were inpatients.

The parties genuinely dispute the exact number of total inpatients and overall patients that Petitioner treated during 2014. However, I find that the disputes the parties have about the exact number of patients and the percentage of inpatients in this case are inconsequential, and thus immaterial to preclude summary judgment. *See Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 248 (1986) ("Only disputes over facts that might affect the outcome of the suit under the governing law will properly preclude the entry of summary judgment."). The parties both agree that the chief legal question in this case

³ Petitioner has offered no authentication of this chart. There is no information in the record about who created the chart, what specific information it summarizes, or where that information was obtained. *See* Fed. R. Evid. 901(a), 1006; CRDP § 15. However, for the limited purpose of summary judgment and in order to draw all factual inferences in favor of Petitioner, I will consider the chart as showing the total number of outpatients that Petitioner treated during 2014.

turns on whether Petitioner was "primarily engaged" in treating inpatients. *See* CMS Br. at 4; P. Br. at 2; *see also* CMS Ex. 1 at 2; CMS Ex. 10 at 2. The evidence from both parties undisputedly shows that less than 3% of patients that Petitioner treated in 2014 were inpatients. That undisputed fact is enough to reach a legal conclusion in this case. If, as I conclude below, the measure of being "primarily engaged" in treating inpatients is, at least in part, the overall percentage of inpatients treated, then the difference between 2.05% and 2.88% is too insignificant to affect the ultimate outcome when I make the inference in the light most favorable to Petitioner.

b. It is undisputed that Petitioner's facility has 12 beds, all of which are designated as "inpatient" beds.

The surveyors described Petitioner's facility as "Medicare certified for twelve (12) inpatient beds." CMS Ex. 1 at 1; *see also* CMS Ex. 11 ¶ 4. Petitioner has also offered the sworn affidavit of Petitioner's Chief Executive Officer, who confirms that the facility has 12 inpatient beds and "no outpatient beds." P. Ex. 4 ¶ 4. Petitioner's state license also documents that the facility licensed for 12 "medical/surgical" beds, which supports the CEO's assertion that there are no designated outpatient beds. *See* P. Ex. 5 at 2. CMS does not dispute the number of inpatient beds in Petitioner's facility and in fact uses 12 beds as a multiplier in its calculation of Petitioner's overall inpatient availability. *See* CMS Resp. at 7. Therefore, I accept as undisputed that Petitioner has 12 beds, all of which are designated as "inpatient" beds.

c. It is undisputed that between January 1, 2014, and January 3, 2015, Petitioner utilized approximately 3% of available inpatient beds.

Petitioner offered evidence with its cross-motion for summary judgment that shows the total number of "patient days" during 2014. P. Ex. 6. Petitioner uses the same document as evidence of the total number of inpatients during 2014. P. Br. at 9. Based on Petitioner's use of this document in its argument, the only reasonable inference I can draw is that a "patient day" refers to a day that a patient was admitted to Petitioner's facility as an inpatient. The total number of "patient days," therefore, represents the total number of days that patients were admitted to Petitioner's facility as inpatients. During 2014, Petitioner had a total of 131 patient days. P. Ex. 6.

Each day, Petitioner's facility has 12 available "patient days" because, as noted above, Petitioner has 12 inpatient beds. *See* P. Ex. 4 ¶ 4; CMS Ex. 1 at 1. Thus, for all of 2014, Petitioner had 4,380 available patient days (12 inpatient beds for 365 days). Petitioner had 131 patient days out of a total of 4,380 patient days available, meaning that Petitioner used 2.99% of available patient days during 2014. *See* CMS Resp. at 7; P. Ex. 6. This figure is undisputed.

d. It is undisputed that Petitioner did not have any inpatients during the validation survey from January 12 through January 15, 2015.

Surveyors did not observe any inpatients in Petitioner's facility during the four-day survey from January 12 through January 15, 2015. CMS Ex. 1. Petitioner points out that it had an inpatient in early January 2015 as well as an inpatient later in the month but does not dispute that there were no inpatients in its facility at the time of the survey. *See* P. Br. at 9.

2. Petitioner did not meet the statutory definition of a hospital because it was not "primarily engaged" in providing treatment to inpatients.

The Act defines a "hospital" in part as an institution that "is *primarily engaged* in providing . . . *to inpatients* (A) diagnostic services and therapeutic services for medical diagnosis, treatment, and care of injured, disabled, or sick persons, or (B) rehabilitation services for the rehabilitation of injured, disabled, or sick persons." 42 U.S.C. § 1395x(e)(1) (emphases added). Neither the Act nor the Secretary's regulations define what it means to be "primarily engaged" in providing treatment to inpatients, and the parties strongly disagree over what factors I should consider in determining whether Petitioner is "primarily engaged" in treating inpatients.

In 2006, the Secretary submitted a Final Report to Congress, which referred to an earlier Interim Report that stated there had not been "a feasible way to define by regulation the statutory requirement in [42 U.S.C. § 1395x(e)] that a hospital is an entity that is 'primarily engaged' in furnishing services to hospital inpatients. Instead . . . CMS will continue to interpret 'primarily engaged' on a case-by-case basis as it continues to explore other options for addressing this issue." United States Department of Health and Human Services, Final Report to the Congress and Strategic and Implementing Plan Required under Section 5006 of the Deficit Reduction Act of 2005 at 79 (2006) (Final Report)⁴ (emphasis added). The Final Report concluded that the Department of Health and Human Services was "in no better position now than we were at the time of the Interim Report was issued to define 'primarily engaged' by regulation and, thus, are not committing at this time to engage in rulemaking." Id. The Final Report also noted that two major hospital organizations had differing views on whether "primarily engaged" should be clearly defined by regulation. Id. at 23, 79. Thus, the Secretary determined that, as of 2006, there would be no established definition of "primarily engaged" or a single set of criteria to determine whether a facility was "primarily engaged" in providing treatment to inpatients.

⁴ The Final Report is available on CMS's website addressing "Specialty Hospital Issues," at <u>https://www.cms.gov/Medicare/Fraud-and-Abuse/PhysicianSelfReferral/specialty_hospital_issues.html</u>.

In 2008, the Director of CMS's Center for Medicaid and State Operations, Survey and Certification Group, issued a memorandum addressing as its subject, "Requirements for Provider-based Off-campus Emergency Departments and Hospitals that Specialize in the Provision of Emergency Services." Survey & Cert. Memo. 08-08, at 1 (Jan. 11, 2008).⁵ In a section titled "Hospitals Specializing in Emergency Services," the Director wrote that "CMS has occasionally encountered interest from providers who seek participation in Medicare as a hospital that specializes in emergency services." *Id.* at 5. The Memorandum reminded providers that an applicant seeking to enroll as a hospital "must demonstrate that it satisfies the definition of a hospital in [42 U.S.C. § 1395x(e)], including the requirement that the provider is primarily engaged in the provision of services to inpatients." *Id.* The Memorandum continued:

In the case of an applicant specializing in emergency services, CMS would pay particular attention to the size of the applicant's ED [Emergency Department] compared to its inpatient capacity. A detailed analysis of the facts and the applicant's operations would be required.

We interpret the statutory requirement that a hospital be primarily engaged in the provision of inpatient services to mean that the provider devotes 51% or more of its beds to inpatient care. In the absence of other clearly persuasive data, CMS renders a determination regarding hospital status based on the proportion of inpatient beds to all other beds.

Id. (emphases added). The Memorandum thus provided state survey agencies with a clear numerical standard to determine whether a facility that specialized in emergency services was "primarily engaged" in providing treatment to inpatients.

The Departmental Appeals Board has interpreted "primarily engaged" to refer to a facility's actual provision of services, not its capability to provide those services. *See Kearney Reg'l Med. Ctr.*, DAB No. 2639, at 9 (2015); *Ariz. Surgical Hosp.*, DAB No. 1890, at 6-7 (2003); *see also United Med. Home Care, Inc.*, DAB No. 2194, at 11 (2008) (concluding that the facility did not provide any skilled nursing services, and thus was not "primarily engaged" in providing skilled nursing and other therapeutic services). In *Arizona Surgical*, the Board rejected an argument that a facility's *intent* to provide inpatient services to inpatients. DAB No. 1890, at 5-6. The Board wrote that it "fail[ed]

⁵ Petitioner offered this memorandum as an exhibit. *See* P. Ex. 3. However, because it is a published and publicly-available document on CMS's website, I will cite it according to its public reference number "08-08." It is available at <u>https://www.cms.gov/Medicare/</u><u>Provider-Enrollment-and-Certification/SurveyCertificationGenInfo/Policy-and-Memos-to-States-and-Regions.html</u>.

to see how [the petitioner] could have been 'primarily engaged' in providing services to inpatients when it was not 'engaged' in providing those services in the first place." Id. at 6. The Board more recently noted that it considers various types of evidence in evaluating whether a facility meets the definition of a hospital and has not established a "bright-line rule." Kearney, DAB No. 2639, at 8. The Board cautioned, however, that it has never considered "the main defining characteristic of a hospital, i.e., being 'primarily engaged' in treating inpatients, as somehow synonymous with 'for the most part' or 'having embarked on' the provision of services to inpatients" Id. at 8-9. Rather, the Board "has consistently read the statutory language requiring that a hospital be 'primarily engaged' to plainly mean that the bulk of its present activity consists of providing the required services to treat inpatients." Id. at 9 (emphasis added). Accordingly, a facility's ability to or mere intent to engage in the treatment of inpatients is not sufficient to meet the statutory definition of a hospital. As the Board noted, the statute "does not make the definition turn on what activities the facility previously engaged in, or plans to engage in, or is equipped to engage in, but on what its central activity currently is." Id. (emphasis in original).

Petitioner argues that the 2008 Survey and Certification Memorandum should control the analysis of whether it was "primarily engaged" in providing services to inpatients. P. Br. at 3-4. Petitioner notes that the 2006 Final Report struggled with whether CMS should apply a uniform definition and argues that the 2008 Memorandum, the "only written guidance on the issue," finally established a clear measure of whether a facility was "primarily engaged" in providing treatment to inpatients. P. Br. at 3. The Memorandum, as noted above, states in part that "[i]n the absence of other clearly persuasive data, CMS renders a determination regarding hospital status based on the proportion of inpatient beds to all other beds." Survey & Cert. Memo. 08-08, at 5. Petitioner's facility has 12 beds, all of which are inpatients beds. CMS Ex. 1 at 1; P. Ex. 4 at ¶ 4. Thus, according to Petitioner, because 100% of its beds are inpatient beds, it satisfies CMS's "only articulated test" for being "primarily engaged" in providing treatment to inpatients. P. Br. at 4-6. Petitioner also argues that any other interpretation of the statute "would necessarily exclude many community and specialty hospitals in the country based on recent data, which shows that these hospitals' provision of inpatients is limited." P. Br. at 6. Petitioner attempts to distinguish its case from that of *Arizona Surgical* by noting that the Board decided that case before CMS established its "bright line bed count definition" in the 2008 Memorandum. Petitioner also points out that the facility in Arizona Surgical, unlike Petitioner, was prohibited from admitting patients for an extended period, which meant it did not have any inpatients at all and could not engage in any inpatient treatment. P. Br. at 6-7. Petitioner also attempts to distinguish *Kearney*, arguing that it involved an initial Medicare enrollment, which resulted in a lack of inpatient care, while Petitioner was already enrolled in Medicare as a hospital and had a history of treating inpatients at the time CMS terminated its provider agreement. See P. Br. at 7, 9-10, 12.

CMS argues that prior Board decisions correctly interpret the statutory provision that defines a hospital. CMS Br. at 8-9; CMS Resp. at 2. According to CMS's reading of prior Board decisions, "two fact issues are consistently evaluated: the periods of time when a facility was not providing the required services and what portion of a facility's operations were devoted to the required services." CMS Resp. at 4. Relying on this interpretation, CMS argues that Petitioner's overall percentage of inpatients being less than 3% of its total patients and the periods when Petitioner did not have any inpatients in its facility demonstrate that it was not primarily engaged in the treatment of inpatients. CMS Br. at 6-8. CMS also argues that Petitioner relies on an "improper characterization of a passage taken out of context" from the 2008 Survey and Certification Memorandum. CMS Resp. at 2. CMS notes that Petitioner's interpretation of the 2008 Memorandum is inconsistent with the 2006 Final Report's assertion to Congress that a "case-by-case" approach to determining whether a facility is primarily engaged in providing treatment to inpatients would continue to be used going forward. CMS Resp. at 4.

I agree with CMS that Petitioner's reliance on the 2008 Survey and Certification Memorandum is misplaced in this case. First, the Memorandum is limited in scope. It must be read consistently with the 2006 Final Report, which stated that CMS would continue to use a "case-by-case" approach in determining whether a facility was "primarily engaged" in providing treatment to inpatients. See Final Report at 76. It is unreasonable that the Director of the Survey and Certification Group, within the Center for Medicaid and State Operations, within CMS, intended to or even had the authority to offer the *only* interpretation of the relevant statutory provision on behalf of the Secretary. Further it does not appear that the Memorandum went through the necessary notice and comment procedures to be a binding agency rule. See 5 U.S.C. § 553(b)-(d). Rather, the Memorandum offers an interpretation of a specific type of case that has become more frequent, namely the construction of free-standing facilities specializing in emergency services. See Survey & Cert. Memo. 08-08, at 1. Even more telling, the Memorandum Summary notes that in "*rare cases*, new providers are seeking certification as a hospital specializing in the provision of emergency services." Id. Accordingly, the Memorandum provides an approach only in the "rare cases" it describes rather than to any facility enrolling as a hospital. It does not apply to Petitioner, who is neither newly-enrolling nor specializing in emergency services.

Second, the Memorandum states that *newly-enrolling* facilities that specialize in emergency services must nevertheless meet the statutory definition of a "hospital," because there is no special designation in the Medicare program as an "emergency services hospital." *Id.* at 5. But, as CMS points out, a newly-enrolling facility that plans to specialize in emergency services is unlikely to have any record of treating inpatients. *See* CMS Resp. at 2. The Memorandum goes on to state that in such a case CMS would consider whether 51% or more of the facility's beds were inpatient beds. Survey & Cert. Memo 08-08, at 5. That measure was certainly not intended to be a "bright line rule" as Petitioner argues, because the Memorandum's own language qualifies that the ratio of

inpatient beds would be used only "[i]n the absence of other clearly persuasive data" *Id.* A facility's record of treating inpatients may certainly be "other clearly persuasive data," and the Memorandum seems to confirm this. It states in the same section that a "detailed analysis of the facts of the *applicant's operations* would be required." *Id.* (emphasis added). The "applicant's operations" would reasonably include inpatient data if the facility was already operating as a hospital. Also, the Memorandum does not call for an analysis of the applicant's *future* operations or *intended* operations but rather its actual operations. Accordingly, the Memorandum's use of 51% of inpatient beds as a measure of being "primarily engaged" in treating inpatients does not apply to Petitioner's case, which involves an enrolled hospital with a record of treating inpatients from time to time, and that does not provide or specialize in providing emergency services.

Nevertheless, the Memorandum is relevant in one way. It offers a numerical value of 51% to explain what it means to be "primarily engaged" in something. It is also consistent with the Board's interpretation that a "bulk" of activity is devoted to inpatient care. *See Kearney*, DAB No. 2639, at 9. In addition, other agencies have defined "primarily engaged" using greater than 50% as the appropriate threshold. *Cf.* 29 C.F.R. § 779.372(d) (defining "primarily engaged" in Department of Labor regulations as "over 50 percent" of the time). Therefore, in order to be "primarily engaged" in providing treatment to inpatients, a plain-language reading of the statute requires that more than half of a facility's treatment must be provided to inpatients. *See* 42 U.S.C. § 1395x(e)(1).

For a facility with an existing record of treating patients, a mere bed count, as the 2008 Memorandum suggests and for which Petitioner argues, is not consistent with the statutory language and is impractical when determining what factors determine whether more than half of a facility's treatments are provided to inpatients. As the Board first pointed out in Arizona Surgical, a facility must first "engage" in providing treatment to inpatients before it can even be considered "primarily engaged" in providing such treatment. DAB No. 1890, at 6. Thus, having "inpatient beds" without any actual inpatients cannot reasonably qualify as being "engaged" in providing treatment to inpatients. It is irrational to think that Medicare would enroll a facility as a hospital just to have the very beds used to qualify as a hospital go unused in providing any actual services. That is why the Board more recently noted that Congress drafted the statute in the present tense, meaning that the statutory definition of a hospital does not consider "what activities the facility previously engaged in, or plans to engage in, or is equipped to engage in, but on what the central activity currently is." Kearney, DAB No. 2639, at 9. A bed count alone shows what activities the facility is equipped to engage in but cannot demonstrate that the facility is actually engaged — let alone "primarily engaged" — in providing treatment to inpatients. Therefore, even though it is undisputed that all of Petitioner's 12 beds are designated as "inpatient beds," that fact does not demonstrate that Petitioner was actually engaged in using those beds to provide treatment to inpatients.

A strict present-tense reading of the statute, however, would preclude consideration of any factors other than the observations that surveyors make during a validation survey or during an accreditation visit. See id. ("The statute does not make the definition turn on what activities the facility previously engaged in"). Thus, under this interpretation, only the activities the facility is engaging in at the time of the survey would be relevant. In this case, it is undisputed that Petitioner did not have any inpatients during the validation survey from January 12 through January 15, 2015. CMS Ex. 1 at 2; P. Br. at 9. But that is likely too narrow of an approach to the statutory requirement, and more to Petitioner's point, could unintentionally and detrimentally impact small community or rural hospitals. See P. Br. at 6. There are factors beyond a hospital's control, such as location, population served, types of services provided, and so on, that could result in that hospital not having any inpatients for a brief time, yet still be "primarily engaged" overall in providing treatment to inpatients. Therefore, a review of past records, including whether any outpatients were treated during that time, is important to clarify whether the survey findings correctly depict the hospital's actual activities. The Board seems to have recognized this possibility. See, e.g., Kearney, DAB No. 2639, at 10. It has considered a facility's previous treatment records in assessing whether the facilities were "primarily engaged" in providing treatment to inpatients. See Ariz. Surgical, DAB No. 1890, at 7; Kearney, DAB No. 2639, at 11.

Here, it is undisputed that for all of 2014 less than 3% of Petitioner's overall patients were inpatients. CMS Ex. 1 at 2; P. Ex. 6; P. Ex. 7. The overall percentage of inpatients that Petitioner treated during an entire year was extremely low and certainly not close to being half of the patients to whom it provided treatment. This fact alone shows that nearly all of Petitioner's patients were outpatients and does not support that Petitioner was "primarily engaged" in providing treatment to inpatients. But the ratio of inpatients to overall patients may not on its own always be a clear measure of whether a facility is primarily engaged in providing treatment to inpatients in all cases. For example, if each inpatient was typically admitted for several days or weeks at a time, then the total number of inpatients that the facility treated may be less than half of its patients overall, but the facility would have nevertheless been consistently providing treatment to inpatient beds occupied at any given time would be a substantial percentage of the facility's overall inpatient capacity.

But in this case, according to Petitioner's data, which I accept as true for summary judgment purposes, Petitioner had only 56 inpatients during 2014. *See* P. Ex. 6. Those

⁶ Using Petitioner's facility as an example, if inpatients in Petitioner's facility averaged 7-day (week-long) admissions, and Petitioner was using all of its 12 available inpatient beds, it would average 12 inpatients per week and 624 inpatients for the entire 52-week year. That amount of inpatients is still substantially less than the number of outpatients Petitioner had in 2014 (*see* P. Ex. 7), yet Petitioner would have always been engaged in providing treatment to inpatients during that time.

56 inpatients accounted for a total of 131 patient days out of a possible 4,380 patient days available in Petitioner's facility. P. Ex. 6. Thus, Petitioner used only about 3% of its inpatient capacity, meaning that nearly all of its 12 inpatient beds were unused for most, if not all, of the year. Thus, with only 131 patient days, all 12 of Petitioner's inpatient beds must have been empty and unused for well over half of the 365 days in the year. *See* P. Ex. 6. The undisputed evidence shows that Petitioner undoubtedly focused its primary activities on the treatment of outpatients.

There can be little doubt that Petitioner's facility was established, and likely intended, to handle inpatients at any given time, but its treatment history confirms what the surveyor found, i.e., that it was not providing treatment to inpatients as its primary activity. All of the undisputed evidence, when taken together, shows that Petitioner was not "primarily engaged" in providing treatment to inpatients, and it therefore did not meet the statutory definition of a "hospital" in any reasonable construction of that requirement.

3. CMS, acting on behalf of the Secretary, has the authority to terminate Petitioner's Medicare provider agreement.

The Act authorizes the termination of a provider that substantially fails to meet the requirements of 42 U.S.C. § 1395x. *See* 42 U.S.C. § 1395cc(b)(2)(B). The Secretary's regulations setting forth the general participation requirements for providers state that to be approved for participation in, or coverage under, the Medicare program, a prospective provider must meet the statutory definitions applicable to its provider type in (among others) 42 U.S.C. § 1395x. 42 C.F.R. § 488.3(a); *see Ariz. Surgical*, DAB No. 1890, at 9. The Secretary may terminate a provider agreement if the provider does not meet all applicable regulatory requirements specific to its provider type or the provisions of its provider agreement. 42 C.F.R. § 489.53(a)(1). By regulation, CMS is authorized to carry out the termination of a Medicare provider agreement on behalf of the Secretary. *See generally* 42 C.F.R. § 489.53 (providing for termination "by CMS").

Here, Petitioner did not meet the statutory requirements of a hospital because it was not "primarily engaged" in providing treatment to inpatients. *See* 42 U.S.C. § 1395x(e)(1). As a result, Petitioner did not meet the regulatory requirement that a provider must meet the applicable statutory definition for its provider type. *See* 42 C.F.R. § 488.3(a). CMS, therefore, acting on behalf of the Secretary, was authorized to terminate Petitioner's Medicare provider agreement because it no longer met the applicable regulatory requirements for a hospital that, in turn, required Petitioner to continue to meet the statutory definition of a hospital. 42 C.F.R. § 489.53(a).

4. Petitioner's equal protection arguments are not appropriate in this forum.

Petitioner argues that CMS violated Petitioner's equal protection rights by terminating its Medicare provider agreement despite Petitioner's inpatient treatment data being similar to

other hospitals that CMS did not terminate. P. Br. at 13. But whether or not CMS has treated similarly-situated hospitals consistently in its termination of provider agreements is not a sufficient equal protection argument. See Sylvia Dev. Corp. v. Calvert Cnty., 48 F.3d 810, 819 (4th Cir. 1995) (citing Snowden v. Hughes, 321 U.S. 1 (1944)). When Petitioner asked that I issue a subpoena to make it possible obtain documents related to administrative actions that CMS has taken against other hospitals, that information would not further its equal protection claim. There must be some evidence that shows an actual intent to discriminate for a specific reason. Id. (citing Washington v. Davis, 426 U.S. 229, 239 (1976)). There is no evidence or allegation of such intent to discriminate on the part of CMS. Petitioner has argued that it is unique in being a facility that specializes in pain management. P. Br. at 12. CMS's action in this case, however, is not based on the nature of Petitioner's specialty but rather on the number of inpatients it has treated over the course of an entire year. See CMS Ex. 1; CMS Ex. 10. Thus, there is a neutral basis for CMS's actions that the Act and implementing regulations authorize. That CMS's action impacted a specialized facility is no basis to conclude that there was an equal protection violation.

In any event, I do not have the authority to reverse a termination action that the Act and Secretary's regulations clearly authorize. I am limited to reviewing whether there is a legally sufficient factual basis for the federal agency's decision. *United Med. Ctr.*, DAB No. 2194, at 15. In this case, I have determined that there is a legally sufficient factual basis for the termination of Petitioner's Medicare provider agreement, and my review must end there.

VI. Conclusion

The undisputed material facts of this case show that Petitioner was not "primarily engaged" in the treatment of inpatients and therefore did not comply with the definition of a "hospital." *See* 42 U.S.C. § 1395x(e)(1). Petitioner did not meet all requirements necessary to continue its participation in the Medicare program as a hospital. Therefore, I grant summary judgment in favor of CMS affirming the termination of Petitioner's Medicare provider agreement effective April 30, 2015.

/s/

Joseph Grow Administrative Law Judge