**Department of Health and Human Services**
**DEPARTMENTAL APPEALS BOARD**
**Appellate Division**

Kearney Regional Medical Center, L.L.C.
Docket No. A-15-12
Decision No. 2639
May 29, 2015

# FINAL DECISION ON REVIEW OF ADMINISTRATIVE LAW JUDGE DECISION

Kearney Regional Medical Center, L.L.C. (Kearney) appeals the September 10, 2014 determination of an Administrative Law Judge (ALJ) granting summary judgment in favor of the Centers for Medicare & Medicaid Services (CMS) and affirming CMS's denial of certification for Kearney to participate in the Medicare program. *Kearney Regional Medical Center, L.L.C.*, DAB CR3362 (2014) (ALJ Decision).

The ALJ upheld CMS's conclusion that Kearney did not meet the statutory definition of a hospital because for some time, including during its accreditation survey, Kearney did not serve any inpatients. Kearney contends that, as a new hospital, it reasonably decided to stop admitting inpatients until it was certified to participate in Medicare and bill for its services, but that it remained staffed and able to care for inpatients. We conclude that the statutory and regulatory provisions on their face require a facility to be presently engaged in serving inpatients as its primary activity, not merely capable of or prepared to do so. Kearney was not so engaged when CMS declined to certify it as a hospital.

For the reasons further explained below, we affirm the ALJ Decision.

## *Factual and procedural background*[1]

Kearney is a new $38 million facility in Nebraska with 40 patient beds. Kearney received a local Certificate of Occupancy as a hospital on September 27, 2013 and a state operating license on December 9, 2013, from which point on it had a full nursing staff and was prepared to care for inpatients. Between December 9 and December 30, 2013, Kearney admitted 21 inpatients. Kearney sought accreditation from the American Osteopathic Association Healthcare Facilities Accreditation Program (AOA) which conducted an onsite survey January 13-15, 2014. CMS Ex. 1.

[1] The summary in this section is drawn from the ALJ Decision and undisputed facts in the record and is not intended to replace, modify, or supplement any findings of fact.

The AOA surveyors reviewed the medical records for the prior inpatients admitted in December 2013. It is undisputed that no inpatients were being treated at Kearney at the time of survey (or at any time between December 30, 2013 and February 10, 2014). ALJ Decision at 7.[2] CMS has not disputed Kearney's contention that the head of the AOA survey team informed Kearney that it was not necessary to have inpatients present in the hospital in order to conduct the survey. ALJ Decision at 2, 4-5, 7-8 (and record citations therein); CMS Br. passim. Although the AOA survey found a number of deficiencies, Kearney submitted an acceptable plan of correction on January 28, 2014. CMS Ex. 1.

By letter dated February 7, 2014, AOA granted Kearney full accreditation effective January 28, 2014, and recommended that CMS approve deemed status for Kearney in the Medicare program. *Id*. at 1. The AOA notice explained that CMS had to review the survey findings and determine if Kearney met all CMS requirements before issuing a certification. *Id*.

On April 9, 2014, CMS denied Kearney's application to participate in Medicare because Kearney failed to meet the statutory definition of a hospital. CMS Ex. 2. Specifically, CMS explained "there were no inpatients at the time of the initial certification survey and the last inpatient discharge prior to the survey occurred on December 30, 2013," and that "[r]eview of information available to this office" showed that Kearney "is not primarily engaged in providing care to inpatients." *Id*. CMS informed Kearney that, even though it did not then "qualify as a provider of hospital services," it could take steps to correct the problem and reapply. *Id*. Further, Kearney could seek reconsideration if it disagreed with the decision, which Kearney did on April 11, 2014. *Id*.; CMS Ex. 3 (reconsideration request).

On April 17, 2014, CMS issued a reconsideration affirming that conclusion because Kearney had no inpatients during or "for a period of time prior to that survey." CMS Ex. 4, at 1. Based on this action by CMS, AOA withdrew its earlier accreditation of Kearney. CMS Ex. 5.

A later AOA accreditation survey took place on April 28-30, 2014 and found deficiencies which were corrected by a plan of correction on May 8, 2014, resulting in a second recommendation to CMS. P. Ex. 4. CMS granted Kearney deemed status to participate in Medicare effective May 8, 2014. P. Ex. 5.

[2] The ALJ noted that one of Kearney's affidavits referenced one patient possibly admitted overnight in January but rejected this vague allusion as providing any support for Kearney's claim to have been primarily engaged in treating inpatients. ALJ Decision at 7, n.5, citing P. Ex. 6 ¶ 8.

Kearney requested an ALJ hearing to challenge the April 17, 2014 reconsideration decision. Both parties filed motions for summary judgment and supporting exhibits. Kearney filed an opposition to CMS's motion; CMS did not respond to Kearney's motion. The ALJ granted summary judgment in favor of CMS.

Kearney asks us to review the ALJ Decision. We received briefing from the parties and, at Kearney's request, conducted oral argument on February 25, 2015. In addition, in the interest of ensuring that the issues raised on appeal were fully explored and absent opposition, by letter dated March 13, 2015, the Board accepted an amicus curiae brief filed by the Nebraska Hospital Association (NHA), finding that the applicable regulations, while not explicitly providing for amicus participation, do not prohibit the Board from accepting or considering amicus briefs. 42 C.F.R. Part 498; *Sunset Manor*, DAB No. 2155, at 10 n.8 (2008).

***Applicable legal authorities***

The Social Security Act (Act) defines the term "hospital" to mean an institution which (among nine numbered requirements) —

> **is primarily engaged** in providing, by or under the supervision of physicians, **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 . . . .

Act §1861(e)(1) (emphasis added).[3] In order to be approved to participate in Medicare, a prospective provider must meet the applicable statutory definitions, including those in section 1861, as well as the applicable conditions of participation. 42 C.F.R. § 488.3(a); *see also* 42 C.F.R. §§ 400.202 (definition of provider), 488.1 (definition of provider of services ), 489.10(a) (requirement to meet applicable conditions of participation). The applicable conditions of participation for hospitals are contained in Part 482.

Hospitals accredited by approved accrediting organizations, including AOA, are "deemed to meet all of the Medicare conditions of participation." 42 C.F.R. § 488.5(a). Such a hospital must release the results of its accreditation survey and any other related information requested to CMS. 42 C.F.R. § 488.5(c)(1). CMS "may use" such survey results and related information "to determine that a hospital does not meet the Medicare conditions of participation." 42 C.F.R. § 488.5(c)(2).

[3] The current version of the Act is at http://www.socialsecurity.gov/OP_Home/ssact/ssacttoc.htm with a reference to the corresponding United States Code chapter and section, or a cross-reference table for the Act and the United States Code can be found at 42 U.S.C.A. Ch. 7, Disp. Table.

A prospective provider that is dissatisfied with CMS's determination to deny participation in the Medicare program is entitled to a hearing. Sections 205(b), 1866(h)(1) of the Act; 42 C.F.R. §§ 498.5(a), 498.3(b)(1). An ALJ may grant a motion in the nature of summary judgment without an evidentiary hearing with witnesses and cross-examination when the record, viewed in the light most favorable to the non-moving party, shows that there is no genuine issue as to any material fact, and the moving party is entitled to judgment as a matter of law. *See, e.g., Lackawanna Med. Grp. Lab.*, DAB No. 1870 (2003); *Everett Rehab. &Med. Ctr*., DAB No. 1628, at 3 (1997), *citing Travers v. Shalala*, 20 F.3d 993, 998 (9th Cir. 1994); *Carmel Convalescent Hosp.*, DAB No. 1584 (1996).

The Board reviews a disputed finding of fact to determine whether the finding is supported by substantial evidence, and a disputed conclusion of law to determine whether it is erroneous. Guidelines for Appellate Review of Decisions of Administrative Law Judges Affecting a Provider's Participation in the Medicare and Medicaid Programs, http://www.hhs.gov/dab/divisions/appellate/guidelines/prov.html; *Batavia Nursing & Convalescent Inn*, DAB No. 1911, at 7 (2004), *aff'd, Batavia Nursing & Convalescent Ctr. v. Thompson*, 143 F. App'x 664 (6th Cir. 2005) . The Board reviews de novo the legal issue of whether the ALJ's grant of summary disposition was appropriate. *Lebanon Nursing & Rehab. Ctr.*, DAB No. 1918, at 4 (2004).

***Analysis***

1. Summary of ALJ Decision and arguments of the parties

The ALJ opined that the requirement to be "primarily engaged" in the care of inpatients in order to qualify as a hospital has been "narrowly interpreted," quoting at length from two Board decisions. ALJ Decision at 6-7, citing *Arizona Surgical Hosp., LLC*, DAB No. 1890, at 6-7 (2003) and *United Med. Home Care, Inc.*, DAB No. 2194, at 10 (2008). The ALJ noted that Kearney had not admitted any inpatients for 42 days and had no history of serving inpatients prior to December 9, 2014. ALJ Decision at 7. He concluded that, while Kearney "intended to operate as a hospital by having the capability to accept inpatients, it was not actually 'primarily engaged' in care for inpatients immediately prior to or following the survey that took place in January 2014." *Id*.

The ALJ rejected Kearney's contention that viewing the facts "as a whole" demanded a conclusion that it was indeed primarily engaged in inpatient care. *Id*. Kearney relied on a decision by a different ALJ in *Boone County Hospital*, DAB CR2526 (2012), which the ALJ here distinguished because Boone County had at least met the definition of hospital during a prior survey whereas CMS found that Kearney failed to do so on its initial survey. *Id*. The ALJ also noted that the result in *Arizona Surgical* did not hinge only on the four-month suspension of that facility but also on the 39-day period in which it

admitted no inpatients, a period analogous to the time frame in this case. *Id*. Finally, the ALJ declined to estop CMS from denying participation based on the erroneous information provided by the AOA representative about the need for inpatient presence during the survey. *Id*. at 7-8.

Kearney does not argue that summary judgment was improvidently granted because material facts remain in genuine dispute or because the ALJ did not follow the correct standards for granting summary judgment, but rather contends that the ALJ applied the wrong legal test in concluding that Kearney failed to meet the definition of a hospital. Kearney Request for Review (RR) at 1. According to Kearney, the undisputed facts, taken as a whole, show that "a brand new, fully-equipped hospital with 24/7 nursing coverage and over forty licensed beds is obviously in the business of providing services to inpatients." *Id*. at 3. Kearney contends that its decision not to admit inpatients after December 30, 2013 was "fiscally responsible" but that physicians would have been able to provide inpatient admissions during the survey but for the AOA surveyor's advice that it was not necessary to do so. *Id*. at 13, 15. Therefore, Kearney contends, CMS should have accepted the results of the January accreditation survey.

Alternatively, Kearney argues that the conditions of participation were surely met once it resumed admitting inpatients on February 10, 2014 which should therefore be the effective date of its participation in Medicare. RR at 4, citing *Harriett Cohn Ctr.*, DAB No. 1817 (2002) and 42 C.F.R. § 489.13(c).

CMS originally argued that the denial was proper for two reasons: (1) the absence of inpatients on the survey date made it impossible to conduct an adequate survey and (2) Kearney was not primarily engaged in treating inpatients. CMS Br. at 5-6. The ALJ rejected the first argument because it was not set out as a basis in the reconsideration decision from which the appeal arose. *Id*. at 6. Nevertheless, CMS contends that the ALJ correctly found that the second argument was well-founded because mere intent to operate as a hospital is insufficient to meet the requirement of being primarily engaged in inpatient care. *Id*. CMS argues that the lack of inpatients for a significant period before, during, and after the survey was sufficient to allow CMS to determine that Kearney did not qualify as a hospital under the narrow interpretation applied in prior Board cases. Further, CMS contends, even if the inadequacy of the certification survey is not an independent basis for the denial, CMS could still reasonably consider that fact in determining that Kearney was not qualified. *Id*. at 7.

As to Kearney's alternative argument, CMS argues that the effective date is not properly before the Board because it was not part of the ALJ Decision. *Id.* at 8.

2. Kearney was not "primarily engaged" in treating inpatients.

Kearney does not dispute that the statute and regulations cited above require a prospective provider seeking to participate in Medicare as a hospital to be "primarily engaged" in the care of inpatients. Act §1861(e)(1). Kearney's position is that CMS, and the ALJ, interpreted this requirement too narrowly when applying it to a new hospital in Kearney's situation.

The ALJ, and both parties, treated this issue as turning on whether the Board has applied in the past and should now apply a "narrow interpretation" of the phrase "primarily engaged" or should instead look at the facts as a whole. We do not agree, however, that we must resolve this dichotomy in order to apply the plain meaning of the statutory language in the context of the circumstances presented here. We view both the plain language of the statute and the undisputed facts here as supporting the conclusion that Kearney was not eligible to participate as a hospital at the time that CMS denied its certification.

In arguing that the facts as a whole support its position, Kearney offers a list of factors that it considers to have been treated as relevant to evaluating providers' primary engagement in prior cases before the Board.

- **The practical ability and demonstrated capacity to admit inpatients and provide services.** *See Ariz. Surgical Hosp.*, DAB No. 1890 (discussing a state sanction prohibiting the petitioner from accepting inpatients and its clear impact on the petitioner's operations and practical ability to provide services), and *United Med. Home Care, [Inc.]*, DAB No. 2194, at [11] (2008) (discussing the "absence of a demonstrated capacity to actually provide services" and the petitioner's failure to show "sufficient resources and clientele to maintain itself as a viable, compliant health care enterprise").

- **The presence of licensed individuals to provide care to inpatients.** *See A.M. Home Servs.*, DAB No. 2354 [(2010)] (noting the lack of any evidence that the petitioner "had in fact employed or contracted with a nurse to provide skilled nursing care").

- **The length of any periods of time without inpatients prior to the CMS action.** *See Ariz. Surgical Hosp.*, DAB No. 1890 (discussing a four-month ban on inpatients admissions, and stating that even prior to the state sanction, the petitioner was "functioning almost entirely as an outpatient surgical facility and not as an inpatient hospital"); *United Med. Home Care*, DAB No. 2194, at [11] (relying on a six-month period of inactivity); *A.M. Home Servs*., DAB No. 2354 (finding that the petitioner had not provided

services "for about 10 months"). *Cf. Boone County Hosp*., DAB No. CR2526, at 17-18 (finding that periods of inactivity of 76, 53, 47, 32, and 31 days did not support a finding that the petitioner was not primarily engaged in providing services to residents).

- **The provider's overall operational history before the CMS action.** *See Ariz. Surgical Hosp*., DAB No. 1890 (noting that inpatients admissions were a "rarity" prior to a four-month state ban prohibiting the petitioner from accepting inpatients, and explaining that only eleven patients had been admitted overnight from November 15, 1999, through January 28, 2002).

- **The reason for any lack of inpatient admissions.** *Id.* (discussing certain reasons for the lack of inpatients (*e.g.*, weather emergencies, environmental clean-up, and "sick building syndrome"), and explaining that they would not be addressed because they were not "comparable" to the state ban on inpatient admissions that the petitioner had faced).

- **The provision of services to previously admitted patients.** *Id*. (discussing the absence of any evidence that during a four-month state ban on inpatient admissions the petitioner "was engaged in providing services to previously admitted inpatients").

- **Patient admissions after the CMS decision appealed from.** *United Med. Home Care*, DAB No. 2194, at [12] (considering the admission of patients following a CMS termination notice letter).

- **The absence of any concerns regarding the quality of inpatient care**. *See Boone County Hosp*., DAB No. CR2526, at 18 (considering the absence of any such concerns in finding that the petitioner qualified as a provider).

RR at 6-7 (bold in original). Kearney then proceeds to apply these factors to its view of its own circumstances. Thus, Kearney asserts that it had the "practical ability and demonstrated capacity to admit inpatients"; it did employ staff that could care for inpatients; it only lacked inpatients from December 30, 2013 to February 9, 2014 "for financial reasons"; it admitted inpatients before the survey and could have done so during the survey "but for AOA's direction"; it followed up with prior patients and admitted

inpatients again after CMS's denial; and the initial survey did not identify condition-level deficiencies regarding patient care.[4] RR at 14-15. Kearney concludes its argument as follows:

> It cannot seriously be argued that a brand new, $38 million, fully-equipped and licensed facility, which **admitted patients**, continuously maintained a **full staff** to provide 24-hour care to patients, has at all times been ready and able to admit patients, was **accredited by AOA for a second time** on May 14, 2014, and was quickly **certified by CMS** on June 3, 2014, did not qualify as a "provider" at the time of the first AOA survey several months prior.

RR at 15 (emphasis in original).

With that conclusion, Kearney demonstrates its failure to understand the significance of the requirement to meet all applicable conditions of participation before being certified to participate in Medicare as a specific type of provider. Critical to determining if a prospective provider has met these conditions is that CMS must first determine which conditions apply, a determination that depends on meeting the definition of the specific type of provider status for which the facility is applying. Kearney's problem was not that it did not "qualify as a 'provider'" generally but that it did not meet the definition of a hospital at the earlier date.

The Board has indeed considered differing evidence in evaluating whether various providers have, at particular points in time, met the definition of a hospital without establishing a single "bright-line rule." Kearney Reply Br. at 2. What the Board has *never* done, however, is to treat the main defining characteristic of a hospital, i.e., being "primarily engaged" in treating inpatients, as somehow synonymous with "for the most

[4] Kearney also complains that the ALJ went beyond the scope of the reconsideration decision. RR at 17. Kearney notes that the reconsideration decision stated that Kearney had no inpatients at the time of the survey and "indeed had not provided any services to inpatients for a period of time prior to that survey." *Id.*, quoting CMS Ex. 4. Kearney argues that the ALJ erred by also considering the time period after the survey when no inpatients were served. *Id*. at 17-18. We disagree that considering the circumstances surrounding the absence of inpatients on the day of the survey, including the full period in which no inpatients were served, amounts to the ALJ's upholding the denial on a different basis than that relied on by CMS in the reconsideration. The basis for the denial set out in the reconsideration was that Kearney failed to meet the definitional requirement to be primarily engaged in treating inpatients. The ALJ did not err in considering all the evidence in the record that bore on that basis. Kearney itself argued that the ALJ should consider all the relevant facts in assessing whether the facility was primarily engaged in serving inpatients. By contrast, the ALJ correctly declined to reach CMS's claimed alternative reason for denial, i.e., that the survey was inadequate for lack of inpatients, because CMS did not set out the inadequacy of the survey as a basis for its denial in its notice or reconsideration. The Board has held that, in appeals under section 498.5(l)(2), CMS is limited to the legal basis or bases given for its action in the reconsideration decision. *Neb Group of Ariz. LLC*, DAB No. 2573, at 7 (2014); *Benson Ejindu, d/b/a Joy Medical Supply*, DAB No. 2572, at 5 (2014). For the same reason, we will not consider CMS's attempt to reinsert that issue on appeal to us. CMS Br. at 7.

part" having "embarked on" the provision of services to inpatients, as Kearney tries to suggest. *Id*. at 2-3. 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. For example, in *Arizona Surgical*, the Board rejected a nearly identical attempt to impose a strained reading on the same statutory phrase:

> Petitioner's resort to the dictionary definition of "primarily" to show a dispute requiring evidentiary proceedings overlooks the common meaning of the word that "primarily" modifies in section 1861(e)(1): "engaged." "Engage" and "engaged" have myriad definitions; those obviously applicable here include, as a verb, "to involve oneself or become occupied; participate," and as an adjective, "employed, occupied, or busy." . . . At the time of the March survey and the termination, Petitioner was under a state sanction that prevented it from accepting inpatients. Petitioner did not dispute CMS's findings that it had no inpatients and was not engaged in providing inpatient services as of the dates of the two Medicare complaint validation [surveys]. As of those surveys, then, Petitioner was not employed, occupied, busy, involved in or participating in providing services to inpatients. **We fail to see how Petitioner could have been "primarily engaged" in providing services to inpatients when it was not "engaged" in providing those services in the first place**. Given Petitioner's inability to comply with the statutory definition, the ALJ was not required to take additional evidence. The length of Petitioner's failure to engage in providing services to inpatients, which included the March survey and CMS's notice of termination, supports the ALJ's conclusion that Petitioner failed substantially to meet the provisions of section 1861(e) of the Act.

DAB No. 1890, at 6-7 (emphasis added).

Importantly, the statutory phrase is <u>in the present tense</u>. 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 <u>is</u>. It is not sufficient, therefore, to be mostly prepared to serve inpatients or to be embarking on providing such services. A hospital is a facility that <u>is</u> mainly serving inpatients.[5]

[5] Since we consider this element the core of the definition of hospital, we do not agree with Kearney that it can have "substantially" met the definitional requirement without first demonstrating that it was actually treating inpatients at the relevant time period. *Contra* RR at 16.

Our review of evidence of a provider's circumstances is thus for the purpose of determining whether that is an accurate statement about that provider at the relevant time. Kearney attempts to extract comments made about the particular circumstances of providers that failed to show they were currently engaged in serving inpatients and suggest that the absence of precisely the same circumstances in its situation should establish that it was so engaged. We do not accept that approach. We must ask whether Kearney has shown that it met the definition based on the evidence of its activities, not whether the reasons that led to negative answers to that question in other cases necessarily apply to Kearney as well.

In considering the question in this case, we must look at the specific context of Kearney's situation as a new facility. The Board cases to which Kearney cites mostly involved providers that had been participating for a significant period of time but which were subject to termination on the grounds that they no longer fulfilled the definitional requirements. Many of the specific facts mentioned by the Board in relation to Arizona Surgical Hospital's termination, for example, responded to claims that its prior participation demonstrated that it was an on-going provider of inpatient services (having reportedly treated inpatients for 30 years). DAB No. 1890, at 6. Thus, the Board highlighted the facts that Arizona Surgical Hospital had not been admitting significant numbers of inpatients even before it was subjected to a 4-month state ban on admissions and was not involved in following up with or treating those patients admitted before the ban. *Id*. at 8. The Board concluded that it need not even consider whether an otherwise compliant participating hospital forced into a brief period of suspending admissions by unforeseen circumstances could retain its identity as a hospital.[6] *Id*. at 8.

By contrast, Kearney was seeking new entry as a hospital, with no prior history of having operated as a compliant hospital services provider. Kearney recognizes the distinction but suggests that a "brand new hospital built from the ground up" should face "only a modest threshold for inpatient admissions" while "more weight" should be placed instead "on the facility's practical ability and demonstrated capacity to admit patients (*e.g.*, whether it is licensed, has a governing body and administrators, and is appropriately constructed and equipped to treat inpatients)" and has staff. RR. at 10 (footnote omitted).

We find no basis in the statute for setting some lower threshold, or treating the definition of a hospital as met simply based on mere capacity or intention, rather than current activity, of serving inpatients, in the case of new facilities. On the contrary, a facility that demonstrably treated inpatients as its main business activity for a long period of time may

[6] The Board did not suggest, in this context of declining to address hypothetical contingencies such as emergency evacuations, that demonstrating a particular "reason for any lack of inpatient admissions" was in itself sufficient to overcome a failure to meet the statutory definition. In any case, we do not find any basis to conclude here that choosing to suspend inpatient services for weeks to save money while still seeking to qualify as a hospital is in the nature of an emergency interruption of services.

more plausibly argue that a brief interruption in the presence of inpatients does not mean that it is no longer providing those services as its main business. Here, Kearney admitted a handful of patients for only a few weeks before affirmatively deciding to suspend all admissions and then continued to operate with no inpatients for more than five weeks.[7]

Second, we must consider whether Kearney qualified specifically as a hospital. Kearney cites without distinction cases involving other kinds of providers. Specifically, Kearney implies that the fact that the provider in *United Medical Home Care* was inactive for six months should mean that Kearney's 42 days without inpatients was less significant.[8] RR at 6. United Medical participated as a home health agency not a hospital. It had been a Medicare provider for more than eight years, but had ceased seeing clients while under a payment suspension. DAB No. 2194, at 3-5. The agency was then terminated because it was no longer primarily engaged in "providing skilled nursing services and other therapeutic services" as required by the definition of home health agencies in section 1861(o) of the Act. *Id*. at 9-10. United Medical argued that it had never intended to cease operations, had taken steps to stay viable, such as training staff, and had maintained its state license, but financial concerns made it necessary to stop seeing patients. *Id*. at 4-6, 9-11. The Board concluded, analogizing to *Arizona Surgical*, that United Medical could not be primarily engaged in an activity that it was no longer actively performing. *Id.* at 10-11. Although the Board recognized that its discussion in *Arizona Surgical* left open the possibility that a provider's operational history might have some relevance in considering whether the provider met a "primarily engaged" criterion, it concluded that a six-month failure to meet definitional requirement was "too long, regardless of United's history." *Id*. at 12, n.3.

It is not at all clear that a particular length of a hiatus in providing operations or patient care has the same significance for inpatient hospital services as it may in home health care. We need not decide this question now, however, or resolve what weight, if any, to give operational history in general. Whatever relevance prior operations may have in

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[7] The 21 patients admitted during December 2013 essentially generated just enough patient records to meet the minimum number of records that must be available to even schedule a survey by the AOA. *See The Accreditation Process,* AOA, *available at* http://www.hfap.org/AccreditationPrograms/accreditationProcess.aspx (noting that new facilities such as Kearney Medical Center must have "at least 20 patient records for the surveyors to review before a survey is scheduled"). The AOA website was cited by Kearney, along with several other Internet materials. CMS did not object to Kearney's reliance on these materials. We therefore review and consider them as incorporated as part of Kearney's argument before us but do not admit them as documentary evidence.

[8] The provider in *A.M. Home* was also a home health agency. It was apparently in the process of closing one location and opening another but had no active patients when surveyed, and its administrator told the surveyor that it had not been treating patients for 10 months. DAB No. 2354, at 4-6. The Board rejected A.M. Home's argument that "it was 'engaged' because it was in the 'ready mode' to provide services." *Id*. at 5. The provider denied that it was "dormant" based on documentation about its ongoing activities. *Id*. The Board found, however, that A.M. Home sought to take "the word 'engaged' out of context," because, even though documentation showed that it "may have been engaged in some activities at the time of the survey, that documentation does not show that [it] was primarily engaged in providing skilled nursing services and other therapeutic services. . . ." *Id*. at 5-6.

determining whether a provider is now primarily engaged in the activity that defines its asserted provider type, we find the ALJ reasonably concluded here that a history of providing inpatient care for about three weeks (and that outside of the Medicare program) does not outweigh a period of almost twice as long (more than five weeks) in which Kearney engaged in no inpatient care.

Finally, Kearney points out that neither of the AOA surveys identified condition-level deficiencies or patient safety problems and that it was ultimately certified by CMS in June 2014. The regulation at 42 C.F.R. § 488.3(a) clearly establishes that meeting the applicable statutory definition is a distinct requirement apart from complying with the applicable conditions of participation. Had Kearney been found out of compliance with the conditions of participation, that failure would have constituted an independence basis to deny certification. The fact that AOA determined Kearney had only standard-level deficiencies, and that it provided acceptable plans of correction for those deficiencies, does not establish that Kearney met the definitional requirements of a hospital at the time of its denial. As the Board has long observed, determining whether an entity may enroll as a provider "is not limited to determining whether it meets the quality of care or health and safety requirements," and "meeting any aspect of the statutory definition of a hospital" is itself a prerequisite to showing qualification as a provider. DAB No. 1890, at 10, citing *Specialty Hosp. of Southern California-La Mirad*a, DAB No. 1730, at 8-9 n.9 (2000), *aff'd, Specialty Healthcare Servs. v. Thompson*, No. 00-08438-ABC (CTX) (S.D.Ca. Aug. 1, 2001).

We note that Kearney relies on *Boone County* to establish that Board has held that "even if certain facts 'could be viewed as sufficient to raise an inference' that a facility was not 'primarily engaged,'" all the facts may be relevant and a "simple lack of inpatients does not alone establish" failure to meet the definition. RR at 9. *Boone County* is not a Board case, but rather a single ALJ decision with no precedential weight. *Universal Health Care – King*, DAB No. 2383, at 9 (2011), *aff'd Universal Healthcare/King v. Sebelius*, 499 F. App'x 299 (4th Cir. Dec. 14, 2012); *Singing River Rehab. & Nursing Center*, DAB No. 2232, at 11 n.7 (2009).

In addition, we note that Kearney's references to the advice given by an AOA surveyor cannot serve to change the statutory definition of a hospital. As the ALJ pointed out, even if an employee of an accrediting organization could be viewed as speaking for the government, the government cannot be estopped by such statements, certainly in the absence of affirmative misconduct. ALJ Decision at 8, and cases cited therein. Furthermore, Kearney's assertion is merely that the lead surveyor who arrived on the day of the unannounced survey was told that no inpatients were present and advised Kearney that the survey could still proceed by reviewing patient charts and conducting telephone interviews with prior patients. P. Motion in Opposition to CMS Motion for Summary Judgment at 9. Kearney has not alleged that anyone at AOA had advised Kearney to stop admitting inpatients when it did so before the survey date or told Kearney that it need not

admit inpatients thereafter. Whatever relevance the surveyor's advice might have for the question of the adequacy of the survey, we, like the ALJ, have declined to permit CMS to proceed on that basis. We do not find the advice relevant to the determination of whether Kearney was primarily engaged in caring for inpatients in light of the 42-day voluntary gap in providing such services at all.

We conclude that CMS's position in this case is consistent with both the statutory language and with the prior actions and interpretations to which Kearney points. For the reasons discussed, it is also consistent with our prior decisions. To the extent the ALJ decision in *Boone County* may be read as inconsistent with our understanding of the definitional requirement, we do not find it persuasive and decline to follow it.

3. The Board is not a proper forum to debate the policy considerations relating to conditions of participation of new hospitals in Medicare.

At the center of Kearney's contentions is its view that the definitional bar for participation as a hospital should be lowered in order to encourage new entrants. For example, Kearney asserts that it "makes no sense" for expensive new facilities to have to come up to speed only to "wait an indeterminate and extended period of time (nearly two months in this case, equating to substantial losses)" before being able to bill for its Medicare for its services. RR at 10. A more liberal policy that allowed "limiting" inpatient admissions prior to certification would, in Kearney's view, better serve CMS's goals of "strengthening and modernizing the nation's health care system." RR at11, quoting CMS Strategy: The Road Forward, 2013-2017, at 2 (March 2013) available at http://cms.hhs.gov/About-CMS/Agency-Information/CMS-Strategy/Downloads/CMS-Strategy.pdf (Road Forward).[9] The main contribution offered by the amicus brief is to provide additional context for this view with specifics about the high costs of entry into the hospital market, the financial stresses in the industry, and the benefits of new hospitals equipped with up-to-date technology. NHA Br. at 1-3.

We note the claim that CMS's position in this case forces news hospitals to "ramp up to full inpatient capacity while they await Medicare certification" significantly overstates the statutory requirement. NHA Br. at 3; *see also* RR at 10. New hospitals need not be

[9] This reference is another online citation by Kearney to which CMS did not object and which we therefore consider as part of Kearney's argument, However, it is not admitted as documentary evidence. The CMS paper does not address hospital certification but announces an overall agency strategic plan, including the stand-up of a Center for Medicaid and Medicare Innovation within CMS, as part of implementing the Affordable Care Act. Road Forward at 1-3. The quoted phrase summarizes multiple strategic objectives which include strengthening consumer protection and program integrity, improving quality of care and preventive health, and transforming business operations. *Id.* at 6-9. Whether or not the more relaxed definition of "hospital" that Kearney and the amicus advocate here would best serve these overall objectives, it is clear that, as we later explain in this section, the role of balancing these competing or complementary goals in making policy choices lies exclusively with Congress and CMS.

operating at "full inpatient capacity[,]" but the Act does require that a facility be currently caring for inpatients as its primary activity before Medicare will recognize and reimburse the facility as a hospital.

Still, Kearney argues that a broader view would be more "consistent with CMS's statement to Congress that it will interpret the 'primarily engaged' requirement on a 'case-by-case basis.'" RR at 6, citing HHS, Interim Report on "Development of a Strategic Plan Regarding Physician Investment in Specialty Hospitals," at 5 (May 9, 2006) (Interim Report), available at http://www.cms.gov/Medicare/Fraud-and-Abuse/PhysicianSelfReferral/specialty_hospital_issues.html.[10] The referenced statement was made in the context of declining to adopt a quantitative requirement, such as ratio of inpatients and outpatients or percentage of inpatient services as part of interpreting the "primarily engaged" definition, because CMS had not identified a quantitative measurement that would distinguish problematic specialty hospitals from small community hospitals. Interim Report at 5. CMS pointed out to Congress its recent termination of "an Arizona hospital" and denial of enrollment to a facility with 25 emergency bays and two inpatient beds as examples of case-by-case application of the definition. *Id*. CMS's statement nowhere implies that facilities that were not currently admitting inpatients might nevertheless meet the definition of being primarily engaged in the care of inpatients. CMS simply declined to set numerical standards to determine when a facility with a mix of inpatient and outpatient services adequately demonstrated that the former constituted its primary business.

NHA argues that requiring new hospitals to begin providing services before they can receive compensation from Medicare (or other payors that require Medicare certification) "would place more strain" on facilities that bring the newest technology and would "set them on a path toward financial distress." NHA Br. at 3. According to NHA, this may discourage new hospitals from opening and would "not be good policy." *Id*.

It is evident, however, that the policy decision to require that a facility be already in operation as a hospital before being certified in Medicare underlies the entire certification process. As Kearney recognized, no survey could even be requested until enough inpatients had already been served to generate at least 20 patient records. Furthermore, the very sources cited by Kearney illustrate that countervailing concerns may require discerning carefully which facilities are indeed primarily inpatient services providers. Thus, Kearney seeks to distinguish the facility in *Arizona Surgical* as only "masquerading as a hospital" because it was mainly functioning as an outpatient surgical

[10] The Interim Report to which Kearney cites is available only as an appendix to the Final Report, dated August 9, 2006, which is in turn accessible from the citation given. The Final Report indicates that Congress had placed a moratorium on new enrollments of physician-owned specialty hospitals. CMS was required to report on recommendations to deal with questions about self-referral, quality of care, transparency, and charity care in small physician-owned specialty facilities seeking to participate in Medicare as hospitals.

center at the time of its termination. In support of this argument, Kearney cites to an article to say that the "primarily engaged" criteria is properly employed in that situation. Kearney Reply Br. at 2, citing Mark Faccenda, *CMS Enforcement against Hospitals for Failure to be Primarily Engaged in Inpatient Care*, ABA Health eSource, Vol. 10 No. 8, *available at* http://www.americanbar.org/publications/aba_health_esource/2013-14/april/cms_enforcement.html (April 2014) (ABA Article). The article speculates that CMS may be motivated to enforce the "primarily engaged" definition by –

> its understanding that hospitals with low inpatient volume are more appropriately recognized as ambulatory surgical centers, but that such facilities have enrolled in the Medicare program as inpatient hospitals in order to obtain greater reimbursement under the hospital outpatient prospective payment system.

ABA Article. The article also points out that CMS's actions have "instructed hospitals that merely having the potential to provide inpatient care is not the equivalent of actually having provided such care, and thus the mere capacity to provide inpatient care may not necessarily permit a facility to qualify as a hospital 'primarily engaged' in the delivery of inpatient services." *Id*. The issue raised in this category of facilities seeking enrollment as hospitals that are better viewed as primarily outpatient, as well as the issue discussed earlier of physician self-referral to small specialty hospitals, indicates that regulators may have reasons to need to see a facility in actual operation in order to determine how to properly classify it. While this need may result in some burden to what Kearney describes as "bona fide hospitals" (Kearney Reply Br. at 2), we are not in the best position to determine the trade-offs to be made or the best policy resolution. Such decisions belong with the legislators and regulators, rather than adjudicators.

Ultimately, the only answer we can give to Kearney's advocacy of a less demanding definition of "hospital" for new entrants is the same one the Board gave to similar public policy contentions proffered in the *United Medical* case:

> We find these concerns unavailing because the ALJ and the Board are not empowered to make policy or to resolve disputes based on their conceptions of what is the best or most efficacious "public policy." Our review is limited to ascertaining whether there is a legally sufficient factual basis for the federal agency's decision.

DAB No. 2194, at 15.

In this case, as in that one, we find that the ALJ did not err in concluding that a legally sufficient factual basis supported CMS's decision.

4. The Board cannot approve an earlier effective date.

Finally, Kearney asks in the alternative we alter the effective date of its participation in Medicare to February 10, 2014 on the ground that it then began admitting inpatients and therefore could establish it met the statutory definition. RR at 19-20; Kearney Reply Br. at 5-6. Kearney bases this request on section 489.13(c) of the regulations which provides rules for determining the applicable effective date for a provider, when all health and safety standards are not met by a provider on the survey date but no "other Federal requirements remain to be satisfied." Section 498.13(c) then goes on as follows: "However, if other Federal requirements remain to be satisfied, notwithstanding the provisions of paragraphs (c)(1) through (c)(3) of this section, the effective date of the agreement or approval may not be earlier than the latest of the dates on which CMS determines that each applicable Federal requirement is met." Kearney argues that, even if it was viewed as not having met the federal requirement of being primarily engaged in inpatient care at the time of the survey, by February 10, 2014, it was again treating inpatients and cared for 31 inpatients between that date and its certification by CMS on May 7, 2014. RR at 20. Therefore, Kearney reasons, its effective date may be set "no later than" the date it resumed inpatient care. *Id*. Further, Kearney asserts that the Board has "sufficient evidence" to make the underlying factual findings to support this determination and should therefore proceed without remand to alter the effective date. Kearney Reply Br. at 6.

We disagree with Kearney that the effective date of its eventual certification is properly before us in this appeal (or that it was properly before the ALJ either). Kearney appealed the April 17, 2014 reconsideration decision upholding the denial of certification. The issue before the ALJ was whether that reconsideration decision demonstrated a sufficient basis in law and fact for the denial. As fully addressed above, the ALJ correctly found that it did. The reconsideration decision did not set any effective date because it denied Medicare participation altogether.

It is true that Kearney has submitted evidence that CMS later granted accreditation based on deemed status after another AOA survey at a point when Kearney was admitting and providing services to inpatients. P. Exs. 4, 5. That accreditation determination was the action that set the effective date of Kearney's participation as May 8, 2014. P. Ex. 5. Kearney chose not to seek reconsideration of that effective date determination (so far as we are aware) and the time to seek such reconsideration has long passed. Under 42 C.F.R. § 498.5(l)(2), the right to ALJ review of enrollment determinations by prospective providers arises from a reconsideration decision. *See also* 42 C.F.R. § 498.3(b)(15) (effective date determinations are among those subject to appeal under part 498).

Kearney's effective date determination is thus not ripe for ALJ review, and hence not ripe for Board appeal.

***Conclusion***

For all of the foregoing reasons, we affirm the ALJ Decision.

/s/
Stephen M. Godek

/s/
Constance B. Tobias

/s/
Leslie A. Sussan
Presiding Board Member