Department of Health and Human Services
DEPARTMENTAL APPEALS BOARD
Appellate Division

Wills Eye Hospital
Docket No. A-16-78
Decision No. 2743
October 25, 2016

FINAL DECISION ON REVIEW OF ADMINISTRATIVE LAW JUDGE DECISION

Wills Eye Hospital (Wills, Petitioner) appeals an Administrative Law Judge's decision granting summary judgment in favor of the Centers for Medicare & Medicaid Services (CMS) and affirming CMS's determination that Wills did not meet the definition of a hospital in the Social Security Act (Act) as required to participate in the Medicare program as a hospital. *Wills Eye Hosp.*, DAB CR4532 (2016) (ALJ Decision). The ALJ found that the undisputed evidence established that Wills, a former ambulatory surgical center (ASC) which had added four inpatient beds, was not "primarily engaged" in providing services to inpatients as required by the statutory definition.

We conclude that Wills was indeed obliged to show that it qualified as a hospital under the statutory definition, that CMS could lawfully take a case-by-case approach to evaluating individual prospective providers to determine if they so qualified (rather than adopting a numerical cutoff by regulation or otherwise), and that, in the present situation, CMS reasonably exercised its discretion in determining that the facts and circumstances surrounding Wills' operations did not demonstrate that it qualified as a hospital for Medicare purposes.

For these and other reasons given below, we affirm the ALJ Decision.

Applicable legal authorities

The Act defines "hospital," in relevant part, as an institution which --

> **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).[1] To be approved to participate in the Medicare program as a hospital, a facility provider must meet this statutory definition as well as the applicable Conditions of Participation (CoPs). Act § 1866(b)(2)(B); 42 C.F.R. §§ 482.1(a)(1), 488.3(a), 489.12(a)(4); *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), 409.3 (definition of "qualified hospital"). The applicable CoPs for hospitals are contained in Part 482.

A prospective Medicare provider dissatisfied with CMS's determination to deny participation in the Medicare program is entitled to a hearing. Act §§ 205(b), 1866(h)(1); 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 witness testimony 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).

Factual and procedural background[2]

After participating in the Medicare program as an ASC providing ophthalmic services in Philadelphia, Pennsylvania from 2002, Wills renovated its physical plant to meet Life Safety Code requirements for hospitals, and added four inpatient beds. ALJ Decision at 2, 3; Transcript of Oral Argument (Tr.) at 11. In 2013, Wills surrendered its state ASC license and obtained a state license as a hospital; asked that CMS terminate its Medicare participation as an ASC; and applied for Medicare enrollment as a hospital. ALJ Decision at 3, citing CMS Exhibits (Exs.) 5, at 6; 6; 7; *see also* CMS Ex. 2, at 2, 5.

The state licensing agency, the Pennsylvania Department of Health, surveyed Wills and, in September 2013, certified that Wills was in compliance with Medicare CoPs for hospitals. ALJ Decision at 10; CMS Ex. 5, at 1-2. The state agency therefore recommended that CMS certify the facility as a hospital. *Id*. On October 24, 2013, CMS denied Wills' application to participate in Medicare as a hospital on the grounds that

[1] 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. 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.

[2] 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.

Wills did not meet the statutory definition of a hospital under section 1861(e) of the Act "because it is not primarily engaged in providing inpatient services" and "[a] facility may not participate in the Medicare program as a hospital if it does not meet the statutory definition." CMS Ex. 4, at 1.

CMS stated that "[b]eing 'primarily engaged' in providing inpatient services means actually providing for the most part inpatient services" and that "[a]n institution that provides a greater volume of outpatient services than inpatient services is not primarily engaged in providing inpatient services and therefore not eligible to participate in the Medicare program as a hospital." *Id*. at 1. CMS found that, even if each of Wills' four inpatient hospital beds "were filled seven days per week with a different patient, that would constitute 1460 patients, or about 17%" of the "8400 out-patient surgeries per year" that Wills "estimates that it performs" at its location seeking hospital status. *Id*. at 2. CMS thus determined that "Wills Eye Hospital is not primarily engaged in providing inpatient services and does not meet the Medicare definition of a hospital." *Id*. CMS also stated that it thus considered moot Wills' request "to terminate its participation as an ASC effective with the certification as a hospital." *Id*. at 2.

CMS informed Wills that it could seek reconsideration if it disagreed with the decision, which Wills did on December 19, 2013. *Id*.; CMS Ex. 2 (reconsideration request). In the reconsideration request, Wills essentially argued that hospital status, with its higher reimbursement, was warranted because of the highly specialized and complex nature of the services it provides, and that CMS had arbitrarily and capriciously applied an unsupported "majority of services" test that Wills asserts would be failed by 84 percent of hospitals currently participating in Medicare. CMS Ex. 2.

Wills described itself "as the first hospital in the United States dedicated solely to the treatment of eyes" whose staff researchers have created "much of American ophthalmology" since it was established in 1832. *Id*. at 1. Wills recounted that it sold its inpatient ophthalmology program in 2006 to the Thomas Jefferson University Hospital (TJ) because new technologies and materials developed since 2000 "greatly reduced trauma to the eye and lessened recovery times" of its patients. *Id*. at 3. Wills reported that it now seeks to regain hospital status because TJ, a "general service" hospital, "cannot support the level of investment and attention required to maintain the extremely specialized and focused personnel, advanced equipment, and knowledge necessary for tertiary and quaternary ophthalmology." *Id*. at 4. Wills also explained that "the evolution of ophthalmology itself toward treatments that allow patients to go home the same day" has "limited" the number of ophthalmology inpatients the hospital has "at any one time." *Id*.

Wills asserted that the nature of the services it provides "never changed from hospital-level services" because it specializes in treating patients who have been "operated on before by surgeons at other facilities and present heightened risks of failure or complications" and who have had "rare or especially challenging diseases and conditions which demand a national center of excellence like ours." *Id*. at 3. Wills asserted that hospital status is needed to serve "these most complex patients" who need procedures such as "corneal ulcer treatment, complex retina procedures, ocular trauma, intravenous steroids for neuro-ophthalmology conditions such as giant cell arteritis, and ocular oncologic procedures involving the insertion and removal of radioactive plaques for eye tumors." *Id*. at 4. Wills argued that the higher level of Medicare payments hospitals receive for outpatient, as well as inpatient, services "fairly reimburses for the complexity, comprehensive nature, and cost of tertiary and quaternary care" it provides, unlike the "ASC fee schedule" that "never fairly captured the reality of Will Eye Hospital's services." *Id*. at 3.

Wills also argued that CMS, in ruling that Wills was not "primarily engaged" in providing services to inpatients, applied a novel and unsupported "mathematical test." *Id*. at 5-6. Wills argued that "overwhelming data shows that CMS does not, in fact, apply a mathematical majority standard" in determining hospital status and that applying that standard to Wills was thus "arbitrary and capricious as disparate treatment of similarly situated entities." *Id*. at 6. Wills cited a dictionary definition of "primarily" as "in the first place, originally" and argued it met that definition because "[h]ospital-level services, including inpatient services as required, have always been our original mission and our first priority and focus." *Id*. Wills accompanied its reconsideration request with data that Wills says supported its claim that 84% of Medicare hospitals would not pass the majority standard it says CMS applied and further asserted that "its own inpatient to outpatient statistics were similar to, or compared favorably with, those of other specialized eye hospitals . . . ." P. Request for Review of ALJ Decision (RR) at 8-9, citing CMS Ex. 2, at 5-6 (reconsideration request); and P. Ex. 2 (Ex. C to reconsideration request).

CMS, on January 23, 2014, affirmed the denial of participation as a hospital, concluding that "providing services to inpatients is not the focus of your institution" and that "[i]n our view, your institution is primarily engaged in providing services to outpatients, rather than primarily engaged in providing services to inpatients, as required by the statute." CMS Ex. 1, at 1. Wills timely requested an ALJ hearing to appeal CMS's determination. Request for Hearing (Mar. 21, 2014). Before the ALJ, Wills and CMS submitted proposed exhibits and witness statements, and each moved for summary judgment, which the ALJ granted in CMS's favor.

The ALJ Decision

The ALJ ruled that CMS was entitled to summary judgment "because the undisputed evidence establishes that Petitioner does not meet the statutory definition of a "hospital" (Act § 1861(e)), which requires that hospitals primarily engage in providing services "to inpatients." ALJ Decision at 2. The ALJ also rejected Wills' arguments that CMS had unlawfully changed its standards after having certified as hospitals many institutions that primarily provide services to outpatients. *Id*. at 7-9. Further, the ALJ ruled that CMS was "not bound by recommendations from the state agencies" on whether to grant enrollment or hospital status. *Id*. at 10.

The ALJ found that Wills "concede[d] that the vast majority of its services do not require inpatient hospitalization," and did not challenge CMS's estimate that Wills performed 8,400 outpatient surgeries per year or CMS's determination "that Petitioner's staffing levels were inconsistent with a facility that primarily provides services to inpatients." *Id*. at 3, citing CMS Exs. 4, at 2; 5, at 6; 10, at 2. The ALJ cited data Petitioner filed "showing that from July 2011 to June 2012, Petitioner performed 8,030 outpatient procedures and 370 inpatient procedures; thus, 95.6% of its procedures were outpatient[.]" *Id*., citing P. Ex. 4, at 1.

Next, the ALJ found that "a strict grammatical reading of the statute supports CMS's position: a hospital is an institution that primarily provides to inpatients the services listed," based on a grammatical analysis concluding that "[t]he indirect object 'inpatients' tells us to whom the institution primarily provides the listed services." *Id*. at 5. The ALJ rejected Wills' reliance on the declaration testimony of an attorney it described as a legislative drafting expert that the grammatical direct object of "primarily engaged in providing" in the definition of "hospital" is "services" and not "inpatients," so that the definition requires only that the facility provide (to inpatients) primarily the types of services listed in the definition, and not that the facility provide those services primarily to inpatients. *Id*. at 3, 5; P. Ex. 1, at 5-6. The ALJ concluded that the interpretation of a statute is "a purely legal question" that does not require "the taking of evidence," that "[e]xtrinsic evidence of the kind Petitioner urges me to consider cannot be used to create ambiguity where none exists" and that "where a statute's meaning is plain, a court's role is to enforce it." ALJ Decision at 4. The ALJ held that even if the statute were ambiguous, she would defer to CMS's interpretation, citing CMS's reports to Congress, congressional testimony and Federal Register notices as showing that CMS "has consistently interpreted section 1861(e)(1) to require that hospitals furnish the bulk of their services to inpatients." *Id*. at 7.

The ALJ also noted that Wills had cited no judicial or administrative decisions supporting its reading of the definition in section 1861(e)(1) of the Act, and the ALJ cited *Arizona Surgical Hospital, LLC*, DAB No. 1890 (2003) and *Kearney Regional Medical Center*, DAB No. 2639 (2015), as showing that "the adjudicators who have addressed the issue

have ruled that section 1861(e)(1) requires that an institution care for inpatients *as its primary activity* before Medicare will recognize and reimburse it as a hospital." *Id*. at 5 (ALJ italics). The ALJ described *Arizona* as holding that the facility was not a hospital "where the institution's inpatient stays were 'not [its] 'primary' service[,]'" and *Kearney* as holding, based on *Arizona*, that "primarily engaged" requires that "currently caring for inpatients" must be the facility's "primary activity before Medicare will recognize and reimburse the facility as a hospital." *Id*. at 5-6, citing DAB No. 1890, at 7-8; and DAB No. 2639, at 1, 8-9, 10, 14. The ALJ also cited federal court cases as holding that under the Act hospitals must be primarily engaged in providing services to inpatients, although the ALJ noted that neither she nor the parties had found any court cases involving a direct challenge to CMS's reading of section 1861(e)(1) of the Act. *Id*. at 6-7 (citations omitted).

The ALJ then rejected Wills' argument that CMS's denial of hospital status impermissibly changed the standard used to determine whether a facility qualified as a hospital without the rulemaking that section 1871(a)(2) of the Act requires to change or establish substantive legal standards governing an entity's eligibility to furnish services under Medicare. *Id*. at 8. The ALJ held that CMS had not changed the standards for inpatient hospitals, as the definition in the statute "has remained unchanged for 50 years" and Wills "points to no regulation, policy issuance, or other reliable evidence suggesting that the agency has deviated from this position." *Id*.

The ALJ accepted for the purpose of summary judgment Wills' contention that CMS has certified as hospitals institutions whose inpatient services represent an even smaller share of their overall services than Wills, but held that she "may not compound CMS's purported errors by compelling CMS to allow yet another unqualified institution to be certified" and "cannot ignore the fact that Petitioner does not meet the definition of a hospital, without regard to whether CMS has previously admitted other hospitals that also do not meet the definition." *Id*. at 9. The ALJ cited Board decisions as holding that CMS's actions regarding other facilities do not permit the ALJ to decline to enforce the statute's clear requirements or undercut a facility's responsibility to show that it is in compliance with applicable legal requirements. *Id*., citing *Ariz. Surgical Hosp.* and *Jewish Home of Eastern Pa.*, DAB No. 2254, at 15 (2009), *aff'd, Jewish Home of Eastern Pa. v. Ctrs. for Medicare & Medicaid Servs.*, 693 F.3d 359 (3rd Cir. 2012).

The ALJ also held that CMS did not have to defer to the state agency's recommendation to certify Wills as a hospital because the Act vests CMS with "the ultimate authority to determine whether an institution meets the provisions of section 1861" and the ability to decline a state agency's recommendation. *Id*. at 10, citing Act §§ 1864(a), 1866(b)(2). Finally, the ALJ denied Wills' requests for broad discovery of information relating to

other hospitals, as well as subpoenas to compel the testimony of CMS officials on the grounds that the requirements for subpoenas in the regulations "do not allow such broad requests for discovery or for the issuance of subpoenas that are not necessary to allow Petitioner to present its case." *Id*., citing 42 C.F.R. § 498.58(a), (c).[3]

Wills' appeal

On appeal Wills argues that CMS's "[c]urrent [i]nterpretation" of section 1861(e)(1) of the Act conflicts with the language of the statute and the regulations; that the ALJ and CMS erred in adopting a "[n]ew [e]nrollment [s]tandard" without notice-and-comment rulemaking; and that the ALJ erred in granting summary judgment (and in denying Wills' motion for summary judgment) because the evidence "[c]learly [s]howed that CMS applied the Medicare [s]tatute to Wills Eye in a [d]iscriminatory [m]anner," in violation of the Administrative Procedure Act and the Fifth Amendment to the Constitution. RR at 16, 25, 33.

Essentially, Wills argues that CMS and the ALJ wrongly denied it hospital status for the same reasons Wills argued below: that the "comparative volume" or bulk of inpatient-versus-outpatient services tests CMS and the ALJ applied are not founded in the statute or any regulations; are contrary to a correct grammatical analysis of the statutory language; constitute a change in standards that CMS may implement only through rulemaking; and are arbitrary and capricious, as they would result in "anywhere from 37% to over 80% of the hospitals currently participating in Medicare . . . not hav[ing] been enrolled in Medicare . . . ." P. Reply Br. at 1-2, 7-8; RR at 3, 8, 16-37.

Wills argues that the ALJ erred in dismissing the expert testimony of its legislative drafting expert as to the correct meaning of the statutory language, which Wills says raised a disputed issue that made summary judgment improper. RR at 21-25. Wills also argues that the ALJ erred in relying on the Board's decisions in *Kearney* and *Arizona Surgical Hospital* because both turned on whether a hospital has to furnish only "some inpatient care" or services at the relevant time, and in *Kearney* the facility "d[id] not

[3] Wills mentions the denial of discovery and subpoena requests at several points in its briefing on appeal (e.g., RR at 6 n.4, 9 n.9, 31 n.30), but nowhere asks us to overturn the ALJ's ruling on its requests, so we need not decide the correctness of her treatment. Wills does argue that the denial of discovery made summary judgment inappropriate, but that argument appears to be based on inapposite rules of procedure in federal courts which provide for broad discovery of material calculated to lead to admissible evidence. *See, e.g.,* RR at 32 n.32. By contrast, in these proceedings, discovery generally is quite limited and extends only to clearly relevant material. *See* 42 C.F.R. §§ 498.60(b) (ALJ receives in evidence "relevant and material" documents), 498.58(a), (c)(3) (ALJ may issue subpoenas if "reasonably necessary for the full presentation of a case;" applicant must specify "the pertinent facts the party expects to establish by the witnesses or documents"). In any case, to the extent that Wills sought to prove that a correct application of the statutory requirement could show that it was qualified, Wills had control of, and was free to submit, any relevant information about its history, operations or other circumstances. Moreover, as noted, the ALJ accepted for purposes of summary judgment that other facilities with the same or lower ratios of inpatient care had obtained certification as hospitals, obviating the expressed need for the testimony and documents to evaluate whether a factual underpinning of disparate treatment existed prior to summary judgment.

dispute" that a hospital must be "'primarily engaged' in the care of inpatients." RR at 18-19. The "obvious fact" that a facility "providing no inpatient services at all" cannot comply with § 1861(e)(1)," Wills argues, "does not support the additional and unstated conclusion that § 1861(e)(1) envisions a volumetric comparison of inpatient to outpatient services." RR at 20 (emphasis in original).

Wills argues that CMS "routinely has relied on the licensure status assigned by the State agency" until this case. Wills also argues that the fact that section 1861(ccc) of the Act defines a "long-term care hospital" as a hospital which "is primarily engaged in providing inpatient services" rather than "as a hospital that primarily provides certain types of services 'to inpatients,'" like section 1861(e)(1), shows that where "Congress wants to specify that a certain type of hospital is an entity 'primarily engaged in providing inpatient services,' it knows how to do so." RR 17.

Wills further argues that the ALJ erred by using a "bulk" test it considers different even from the relative or comparative volume test CMS applied. RR at 2; P. Reply Br. at 3-4. Moreover, Wills contends that the ALJ should not have considered CMS's allegation, which Will says was made for the first time on appeal, that Wills' staffing levels "were inconsistent with a facility that primarily provides services to inpatients." RR at 2, 19-20, citing ALJ Decision at 3; P. Reply Br. at 6. Wills argues that the ALJ thus violated the restrictions in 42 C.F.R. § 498.56(a) and (e) barring new evidence or new rationales on review of a CMS reconsideration determination in enrollment appeals. Wills also argues that the state agency "disagreed with Region 3's assertion that Wills Eye's staffing levels were inconsistent with being a hospital." RR at 20-21, citing CMS Ex. 10, at 6.

We note that, on August 23, 2016, Wills reported to the Board that the state survey agency had found it deficient as an ASC, based on its now holding only a hospital license and maintaining inpatient hospital beds. Wills asked the Board to order CMS to "await the completion of the enrollment appeals process before taking any further action against Wills Eye on the bases that it treats inpatients or that it lacks an ambulatory surgical facility license." Wills Letter to Board at 4 (Aug. 23, 2016). The Board denied this request because any ASC enforcement action against Wills was not properly before it. Ruling (Sept. 2, 2016). Wills also asked that CMS confirm that Wills' ceasing to treat inpatients or relinquishing its hospital license (both of which would apparently be required to maintain participation as an ASC), would not moot the instant case. Wills Letter to Board at 4 (Aug. 23, 2016). CMS provided such confirmation on September 1, 2016. CMS Motion to Strike at 5. On September 14, 2016, Wills reported that CMS terminated Wills' Eye's Medicare ASC supplier agreement effective November 1, 2016. Wills Letter to Board (Sept. 14, 2016). Wills enclosed a copy of the CMS termination notice, which states that Wills was not in compliance with "Conditions for Coverage" for ASCs in the regulations and "does not meet the regulatory definition of an Ambulatory Surgery Center at 42 C.F.R. § 416.2[.]" Att. E at 2 to Wills Letter to Board

(Sept. 14, 2016). We reiterate our earlier ruling that the termination of Wills' ASC agreement is not before the Board, and would not be prior to Wills' electing and completing the Part 498 ALJ hearing process referenced in the termination letter. Given CMS's assertion that it does not consider any changes made by Wills to its operation in response to the ASC enforcement process to be relevant to our review of whether CMS was authorized to deny certification to Wills as a hospital, we need not consider further these developments reported to us by Wills.

We note that both parties repeatedly made submissions without permission after the record closed. We would be within our authority to strike all these submissions, as each party requested at various points. In the interest of basing our decision on the most complete picture, we have instead included these submissions in the administrative record and have addressed any material in them to the extent it was relevant in this decision.

Analysis

1. Applicable procedural regulations and our standard of review

Both parties in the present matter appear to have been confused at times about the applicable procedures and the standard of review so we discuss these preliminary matters in more detail than we might otherwise.

a. Wills' appeal is governed by the procedures for an institution to challenge CMS's determinations that it is not a "provider" under Medicare law.

CMS notified Wills in the unfavorable reconsideration decision that Wills was entitled to a hearing before an ALJ under the procedures provided in the regulations at 42 C.F.R. § 498.40 *et seq*. CMS Ex. 1, at 1. The regulations make those procedures available to obtain review of determinations made by CMS that are specified at sections 498.1 and 498.3. Section 498.1 lists statutory bases for the hearing provisions including, as relevant to this discussion, section 1866(h) of the Act providing hearings for "any institution or agency dissatisfied with a determination that it is not a provider" and section 1866(j) of the Act providing hearings for "any provider or supplier whose application for enrollment . . . in Medicare is denied or whose billing privileges are revoked." 42 C.F.R. § 498.1(a), (g). The regulations at section 498.3(b) list the "initial determinations" by CMS for which appeal rights are provided under Part 498. These include:

> (1) Whether a prospective provider qualifies as a provider.
>
> * * *
>
> (17) Whether to deny or revoke a provider or supplier's Medicare enrollment in accordance with § 424.530 or § 424.535 of this chapter.

The procedures applicable to appeals arising under each of these subsections differ in some respects and the parties dispute which procedures apply. One important distinction relates to the scope of the issues before the ALJ. The "basic rule" under section 498.56 is the ALJ may, on request of either party or on the ALJ's own motion, "consider new issues," even ones on which CMS has not made an initial or reconsidered determination, and "even if they arose after the request for hearing was filed or after the prehearing conference," so long as the record has not closed. 42 C.F.R. § 498.56(a). This broad scope of review is qualified, however, by the phrase "[e]xcept for provider or supplier enrollment appeals which are addressed in § 498.56(e)." Section 498.56(e) provides as follows:

> (e) *Provider and supplier enrollment appeals: Good cause requirement*—
> (1) *Examination of any new documentary evidence*. After a hearing is requested but before it is held, the ALJ will examine any new documentary evidence submitted to the ALJ by a provider or supplier to determine whether the provider or supplier has good cause for submitting the evidence for the first time at the ALJ level.

Section 498.56(e) goes on to explain how good cause is to be determined and how the ALJ is to notify parties of excluded evidence. The Board has held that the net effect of these provisions is that, in appeals arising under section 498.3(b)(17), involving denial or revocation of Medicare enrollment under sections 424.530 or 424.535, the ALJ may only consider issues resolved in CMS's reconsideration decision and the appellant may only present documentary evidence for the first time at the ALJ level upon a showing of good cause as described in section 498.56(e)(2). *See, e.g., Neb Grp. of Ariz. LLC*, DAB No. 2573, at 7 (2014); *Precision Prosthetic, Inc*., DAB No. 2597, at 11 (2014); *Benson Ejindu, d/b/a Joy Med. Supply*, DAB No. 2572 (2014).

Wills argues that this case was an "enrollment appeal" and that the ALJ was therefore precluded from upholding CMS's action "based on a rationale not actually relied upon in the reconsidered determination itself." RR at 13-14; P. Reply Br. at 2-5.[4] Wills is mistaken, however, because the restricted scope of review exception does not, by its own

[4] Wills at times implies that the procedures are governed merely by whether an appeal has some relation to the enrollment process. *See*, *e.g*., P. Reply Br. at 5 ("By any other name, this is an enrollment appeal."). This belief is unfounded. The issue is not whether certification that a prospective provider qualifies for the category in which it has applied to participate is a step in the enrollment process; obviously, it is. The special procedural provisions are not made applicable to every case that might be called an enrollment appeal or involve elements of the enrollment process. As we explain, they apply only to cases challenging a contractor's determinations that a provider or prospective provider (or supplier) has not met the enrollment standards set out in 42 C.F.R. §§ 424.500-424.570. No such determination was made about Wills.

terms, apply to all appeals in which the enrollment of a provider is in question but only to those cases in which a provider appeals a denial or revocation taken by CMS based on the regulatory provisions at sections 424.530 (setting out reasons for denials and related provisions) or 424.535 (setting out reasons for revocations and related provisions).[5]

CMS did not take action against Wills under either of these regulations. Instead, CMS determined that Wills did not qualify for the provider category under which it applied because it failed to meet the statutory definition of a hospital. CMS Exs. 1 (CMS reconsidered decision); 4 (CMS initial decision). The appeal from this determination plainly arises under section 498.3(b)(1) ("[w]hether a prospective provider qualifies as a provider"). Consequently, the proceeding before the ALJ was governed by the "basic rule" that the ALJ could, so long as adequate notice existed, consider new issues. For the same reason, no good cause showing was required for Wills to be permitted to present new documentary evidence.

Wills also mistakenly asserts that, while providers in appeals arising under section 498.3(b)(17) may submit new evidence on a showing of good cause, "the regulations expressly preclude CMS from introducing new evidence." RR at 13-14, citing 42 C.F.R. §§ 498.56(e), 498.86(a). Neither regulation expressly precludes CMS from introducing new evidence. Section 498.86(a) addresses when new evidence may be admitted before the Board on appeal from an ALJ decision and provides as follows:

> Except for provider or supplier enrollment appeals, the Board may admit evidence into the record in addition to the evidence introduced at the ALJ hearing (or the documents considered by the ALJ if the hearing was waived) if the Board considers that the additional evidence is relevant and material to an issue before it.

In other words, in those cases in which the ALJ may only admit new documentary evidence on a showing of good cause and in which the issues are restricted to the basis of the reconsidered determination, the Board may not admit new evidence at the appellate level. In all other cases arising under part 498, the Board may admit additional evidence if it is relevant and material.

[5] Wills also suggests that the Board has in its prior decisions limited the issues before the ALJ to the basis set out in the reconsideration decision "even in the context of an appeal from a 'revocation' of provider participation, where the evidentiary rules are less restrictive." RR at 14. Again, Wills is confused. The regulatory limitation applies in the same way and by its explicit terms to revocations under section 424.535 as to denials under section 424.530.

Wills' confusion may have arisen during the proceedings below when the ALJ engaged in a largely mistaken discussion of Board cases on the scope of ALJ review in the narrow category of cases arising under section 498.3(b)(17) in which CMS by regulation restricted submission of evidence after its reconsideration determination. ALJ Order at 2 (May 6, 2015), citing *Precision Prosthetic, Inc.* at 11 (2014); *Ortho Rehab Designs Prosthetics & Orthotics, Inc.*, DAB No. 2591(2014); *Neb Grp. of Ariz.* at 7; *see Benson Ejindu, d/b/a Joy Medical Supply* at 5. The ALJ apparently believes that these cases may have altered the de novo standard of review in these cases or in all ALJ hearings under part 498. *Id*. They do not do so, but rather constrain CMS from proceeding on bases or issues not disclosed in its reconsideration determination in those provider enrollment cases in which the provider will not be permitted to bring forward new documentary evidence that might respond to a basis which it was not made aware that CMS was pursuing (or continuing to pursue sub silencio). *Precision Prosthetic, Inc.* at 10-12; *Ortho Rehab Designs Prosthetics & Orthotics, Inc.* at 8; *Neb Grp. of Ariz.* at 7; *Benson Ejindu, d/b/a Joy Medical Supply* at 8-9. In these and all other cases under part 498, an ALJ proceeds to evaluate the record as developed on appeal de novo. That is to say, the review is based on what the evidence adduced at the ALJ level shows as to the issues, and is not based on whether CMS properly evaluated the evidence as it appeared at the time of the reconsideration. The only difference in section 498.3(b)(17) cases is that an ALJ may not permit CMS to add new bases for its actions to those in its reconsideration decision and may not permit the provider to submit new documentary evidence absent good cause. In her Order, after expressing her views about the cited cases, the ALJ requested that the parties submit briefing on the "standard of review" for her decision. ALJ Order at 3 (May 6, 2015).

The ALJ does not appear to have issued any resulting ruling prior to her decision that might have clarified whether she meant to imply that the present appeal arose under section 498.3(b)(17). In any case, a review of the record before the ALJ and the ALJ Decision demonstrates that the ALJ conducted the proceeding in accordance with the requirements of cases arising under 42 C.F.R. § 498.3(b)(1). Her initial standard order setting procedures made no reference to the evidentiary constraints of section 498.56(e). Acknowledgment & Initial Pre-Hearing Order (Apr. 3, 2014). The ALJ did not apply the regulatory timeframes that apply to provider enrollment cases. 42 C.F.R. § 498.79. It does not appear that the ALJ restricted the evidence submitted by either party in support of the cross-motions for summary judgment. *See, e.g.*, CMS Exs. 1-10; P. Exs. 1-6. We find no reason to think that Wills was prejudiced by any misunderstanding or misapplication of the procedural rules.

It is true that the ALJ referred to CMS having denied Wills' enrollment application. ALJ Decision at 1. As CMS explains, and as the ALJ Decision as a whole makes evident, the action taken by CMS was a **denial of certification** of Wills as a hospital for purposes of Medicare participation. CMS Br. at 5 n.7. Certification of provider status by CMS is a

step in the process for a prospective hospital to participate in Medicare and occurs only after the enrollment application has been approved by the contractor and a survey has been completed certifying compliance with CoPs and acceptance as a hospital has been recommended. *See* CMS Br. at 3 n.3, 5 n.7 (citing State Operations Manual (SOM) (CMS Pub. 100-07), Ch. 2, "The Certification Process" § 2005), and 6-7. Nevertheless, we find the reference by the ALJ to be, at most, harmless error or use of shorthand.

For these reasons, we do not sustain Wills' renewed "objections to the consideration of any new evidence or rationales in support of CMS's position, particularly in the form of the Declaration of Dale Van Wieren (CMS Ex. 10 at 1-4)." Wills Letter to Board at 1 (Oct. 5, 2016). Wills renewed its objections in response to a memorandum from the DAB Civil Remedies Division transmitting the case file to the Appellate Division and indicating that all of CMS's exhibits had been "admitted into the record." CRD Memo at 2, 3 (Sept. 23, 2016). Wills based its objections on the restrictions in sections 498.56(a), (e) to the introduction, in enrollment appeals, of new evidence or new rationale for the CMS decision. As this case is not an "enrollment appeal," those provisions do not apply and provide no basis for Wills' belated objections which it failed to raise before the ALJ when the Van Wieren Declaration was submitted. (We also note that, even in provider enrollment appeals, new testimonial evidence is admissible before the ALJ, and only new documentary evidence is limited to a good cause showing.) Furthermore, the documents were not formally admitted by the ALJ because no hearing was held. Wills should have been well aware, long before receiving the transmittal memorandum, that the ALJ accepted the exhibits submitted by both parties with their cross-motions for summary judgment into the record for the purpose of resolving those motions.

b. On review of an ALJ grant of summary judgment, we consider de novo whether the prevailing party was entitled to judgment as a matter of law under the standards for summary judgment.

The ALJ, as we have noted, decided this case by granting summary judgment to CMS. The Board has explained its role on review of an ALJ grant of summary judgment in numerous prior decisions. Most recently, the Board articulated in detail the standard of review as follows:

> We review an ALJ's grant of summary judgment de novo, construing the facts in the light most favorable to the petitioner and giving the petitioner the benefit of all reasonable inferences. *See Livingston Care Ctr.*, DAB No. 1871, at 5 (2003), *aff'd, Livingston Care Ctr. v. U.S. Dept. of Health & Human Servs.*, 388 F.3d 168, 172-73 (6th Cir. 2004). Summary judgment is appropriate when there is no genuine dispute about a fact or facts material to the outcome of the case and the moving party is entitled to judgment as a matter of law. *Id.*; *Celotex Corp. v. Catrett*, 477 U.S. 317, 322-25 (1986).

The party moving for summary judgment (here, CMS) has the initial burden of demonstrating that there is no genuine issue of material fact for trial and that it is entitled to judgment as a matter of law. *Celotex*, 477 U.S. at 323. If the moving party carries that burden, the non-moving party must "come forward with 'specific facts showing that there is a genuine issue for trial."' *Matsushita Elec. Industrial Co. v. Zenith Radio Corp.*, 475 U.S. 574, 587 (1986) (quoting Rule 56(e) of the Federal Rules of Civil Procedure).[6]

"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), *aff'd*, *Senior Rehab. & Skilled Nursing Ctr. v. Health & Human Servs.*, 405 F. App'x 820 (5th Cir. 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. Regional Med. Ctr.*, DAB No. 2459, at 5 (2012) (*quoting Matsushita*, 475 U.S. at 587), *aff'd*, *Mission Hosp. Regional Med. Ctr. v. Sebelius*, No. SACV 12-01171 AG (MLGx), 2013 WL 7219511 (C.D. Cal. 2013). In examining the evidence to determine the appropriateness of summary judgment, an ALJ 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 Nursing Home*, DAB No. 2344, at 7 (2010); *Brightview* at 10 (entry of summary judgment upheld where inferences and views of non-moving party are not reasonable). Drawing factual inferences in the light most favorable to the non-moving party does not require that an ALJ accept the non-moving party's legal conclusions. *Cedar Lake Nursing Home* at 7.

[6] Effective December 10, 2010, Rule 56 of the Federal Rules of Civil Procedure was "revised to improve the procedures for presenting and deciding summary-judgment motions and to make the procedures more consistent with those already used in many courts." Committee Notes on Rules - 2010 Amendment, available at http://www.law.cornell.edu/rules/frcp/rule_56. The revisions alter the language of the rule, but the "standard for granting summary judgment remains unchanged." *Id.* Although the Federal Rules do not directly apply, the Board may use them as guidance.

> Our standard of review on a disputed conclusion of law is whether the ALJ Decision is erroneous. *See Guidelines - Appellate Review of Decisions of Administrative Law Judges Affecting a Provider's Participation in the Medicare and Medicaid Programs* at http://www.hhs.gov/dab/divisions/appellate/guidelines/prov.html.

Pearsall Nursing & Rehab. Ctr. – North, DAB No. 2692, at 5 (2016).

CMS couches its arguments on appeal throughout as showing that the ALJ Decision was supported by "substantial evidence" as to the factual findings. *See, e.g.*, CMS Br. at 6. "Substantial evidence" is the standard for review of disputed factual findings made by an ALJ. To support a grant of summary judgment in its favor, however, CMS must show that no material facts are in dispute (even taking the opponent's evidence as true and drawing all reasonable favorable inferences from it) and that judgment in CMS's favor is required as a matter of law based on those undisputed facts.

In the present case, as we explain below, we find that the parties indeed do not dispute any of the material facts underlying the question of whether Wills meets the statutory definition of a "hospital" for Medicare purposes. Instead, the issue before us turns on competing interpretations of what the definition means and how it may be applied.

In the remainder of this decision, we first address Wills' argument that the statute should be read as solely speaking to the nature of services to be provided to a putative hospital's patients, rather than to whether the focus of the hospital is on serving inpatients. Concluding that the statute does indeed demand that an institution seeking to participate as a hospital must primarily focus on providing services to inpatients, we next consider what standard CMS uses in applying this requirement and find that it has long taken a case-by-case approach to evaluate situations where a prospective hospital does not obviously meet the definition. We then address whether CMS has reasonably applied that approach in determining that Wills failed to show that it primarily serves inpatients. Finally, we consider other arguments by Wills seeking to reverse the ALJ Decision.

2. *The statutory definition of "hospital" includes a requirement that the institution primarily provide specified services to inpatients.*

The legal argument at the heart of Wills' appeal to us is that the ALJ wrongly interpreted the statutory definition of "hospital." RR at 16 *et seq*. Wills contends that, rightly read, the statute says nothing "volumetric" about the extent to which an institution treats inpatients but instead speaks only to the nature of the services which must be primarily provided to whatever inpatients arrive. *Id*. We agree with the ALJ that Wills' proposed re-interpretation of the statute is unsustainable and that CMS's interpretation is reasonable and permissible, and entitled to deference here.

The relevant statutory provision, quoted more fully above, states in relevant part that an institution, to qualify as a "hospital" must **be "primarily engaged in providing . . . to inpatients [either] (A) diagnostic services and therapeutic services . . ., or (B) rehabilitation services . . . ."** Act § 1861(e)(1) (emphasis added). Wills suggests that this requirement simply means that a hospital is a place that provides to its inpatients primarily the diagnostic, therapeutic and rehabilitative services mentioned. RR at 16-17. Wills says that it has provided such services to both inpatients and outpatients since 2011. *Id*.

A "fundamental principle of statutory construction" is "that every word and every phrase of the text must be given effect so that no word or phrase is rendered superfluous or to have no consequence." *Ridgeview Hosp.*, DAB No. 2593, at 7 (2014), citing 2A Norman J. Singer and J.D. Shambie Singer, *Sutherland Statutes and Statutory Construction* § 46:6 (7th ed.); *Tex. Office of the Attorney Gen.*, DAB No. 2124, at 10 (2007); and *N. Ridge Care Ctr.*, DAB No. 1857 (2002) (noting that the Board generally strives to apply or interpret statutory or regulatory language in a way that does not render some provisions superfluous). It is difficult to see how Wills' approach attributes **any** meaning at all to the term "primarily engaged" since Wills seems merely to assert that it provides services of the relevant type to all its patients. RR at 16-17. Elsewhere, however, Wills states that it reads "primarily" as "modif[ying] the types of services provided to those patients who are inpatients of general acute hospitals (as distinct, for example, from facilities providing acute psychiatric care)." *Id*. at 22. At best, then, we might construe Wills as reading the statute to mean that a hospital is any institution that provides such services primarily, as opposed to other types of services such as psychiatric care. This still leaves the phrase "to inpatients" as superfluous. Again, reading Wills' approach most generously, this phrase might mean that some token number of the individuals receiving primarily the named services (as opposed to other services) must be treated as inpatients. We find this position implausible on its face. It hardly seems likely that Congress, in adopting this definition more than 50 years ago, when, it is undisputed, most hospitals were organized precisely for the treatment of medical patients requiring inpatient hospitalization, used the phrase "to inpatients" merely to point out that a hospital ought to have at least a few inpatients included among those receiving its medical services.

Nevertheless, Wills argues that summary judgment was inappropriate on this point because it proffered a declaration from a purported expert in statutory drafting opining about a "'plain meaning' review" of the statute "from a grammatical standpoint" taking into account "punctuation." RR at 23, quoting *Elliot Coal Co., Inc. v. Dir., Office of Workers' Comp. Programs*, 17 F.3d 616, 629-30 (3rd Cir. 1994). First, we reject, as did the ALJ, the claim that the declaration raises a dispute of material fact. ALJ Decision at 4. The proper interpretation of an applicable law is an essential function of the judge in

resolving legal issues and generally not a topic suitable for expert opinion testimony. *See, e.g., Ball v. Kotter*, 723 F.3d 813, 825 (7th Cir. 2013), quoting *Sohaey v. Van Cura*, 607 N.E.2d at 253, 267 (Ill.App.Ct. 2d Dist.1992). While a party may certainly argue for a particular interpretation, the resulting dispute is one of law not fact, and therefore summary judgment remains an appropriate resolution.

The gravamen of the argument presented in the declaration is as follows: The verb phrase "primarily engaged in providing" is transitive in nature and requires a direct object, but may also take an indirect object. P. Ex. 1, at 5. The services are the direct object; inpatients are the indirect object. *Id*. at 6. The phrase should be read as modifying only the direct object; otherwise the drafters would have used a verb such as "treating" instead of "providing." *Id*. This argument is not persuasive. The use of "treating" would have be suitable only if the drafters intended to make inpatients the direct object and to omit the types of services a hospital must provide. Nothing in proper grammar dictates that the adverb "primarily" modifies only what services the actor is "engaged in providing" but not to whom the actor is "engaged in providing" them.

The declaration goes on to compare the definition of "hospital" in the Act with six other definitions of other kinds of providers. *Id*. at 7. The declarant notes that three of the seven total definitions mention inpatients, three mention outpatients, but all seven specify particular services, and concludes that the type of services provided is the "most important characteristic" distinguishing them. *Id*. This argument lacks logic. Health care provider types may indeed be importantly distinguished by the types of services they offer, but that does not negate the fact that many types of providers are also identified by whether they serve primarily inpatients or outpatients.

The ALJ found Wills' position, based on the declarant's theory of how to read the statute, unavailing. ALJ Decision at 4-5. As she pointed out, Wills' proposed interpretation of the statute "largely ignores the critical prepositional phrase 'to inpatients'" (noting correctly that this is actually an adverbial phrase modifying the verb "providing," but that it effectively serves the same role as an indirect object of the verb). *Id*.

We agree that the adverb "primarily" modifies the verb phrase "engaged in providing," and not the nouns "services" or "inpatients," although that somewhat begs the question at issue. As we have explained, we too find no grammatical basis for reading that modification of the verb as applying only to what services the entity is engaged in providing and not to which patients the entity is engaged in providing them.[7] Nor does

[7] The ALJ illustrated her grammatical analysis with an addendum diagramming the relevant clause. ALJ Decision at 12. Wills objected on appeal that the ALJ improperly engaged in a sua sponte analysis of the grammar and meaning of the statutory language which did not fully adopt either party's position on the grounds that the ALJ was thereby rebutting Wills' evidence. RR at 24-25. We find nothing improper about a judge independently evaluating the plain language of a statutory provision and do not consider the diagram to be evidence created by the ALJ but rather merely a visual demonstration of the analytical process reflected in the text of her decision.

anything in the punctuation support Wills's strained reading. On the contrary, the placement of the phrase "to inpatients" closer to the relevant words ("primarily engaged in providing") than the two alternative categories of services (labelled A and B) further emphasizes the significance of the category of patients which are to be receiving the services. (Congress did not choose to define a hospital as "primarily engaged in providing A and B to inpatients.")[8]

We conclude that the plain language of the statute requires that an institution seeking to participate in Medicare as a "hospital" must show that it is **primarily** engaged not only in providing services of the nature described but in providing them primarily **to inpatients**. Moreover, even were we to find ambiguity in the statute on this point, which we do not for the reasons explained, we would give deference to the agency's interpretation of the law which it implements, so long as that interpretation is reasonable and permissible and the party affected either had notice of it or did not rely on a different reasonable interpretation. *E.g.*, *Baylor Cnty. Hosp. Dist. d/b/a Seymour Hosp.*, DAB No. 2617, at 4 (2015); citing *Cibola General Hosp.*, DAB No. 2387, at 7-8 (2011).

CMS's interpretation of the statute is embodied first in its implementing regulation which provides in relevant part that:

> *Qualified hospital* means a facility that—
>
> (a) Is primarily engaged in providing, by or under the supervision of doctors of medicine or osteopathy, **inpatient services** for the diagnosis, treatment, and care or rehabilitation of persons who are sick, injured, or disabled; . . .

42 C.F.R. § 409.3 (emphasis added). One notable difference between the wording of the statute and the wording of the regulation appears relevant to the current dispute. The statute speaks of being primarily engaged providing specified services "to inpatients;" the regulation speaks of providing "inpatient services." By making inpatient a modifier of the services themselves, CMS implicitly emphasizes that the primary engagement of the institution must be on services for inpatients.

[8] Our understanding that the statute defines "hospital" as an entity primarily serving inpatients by offering the enumerated types of services to them is consistent as well with the definition in the same section of the Act of "inpatient hospital services" as meaning the enumerated "items and services" (such as bed and board, nursing, and diagnostic and therapeutic services ordinarily furnished by the hospital for the care of inpatients) that are "furnished to an inpatient of a hospital . . . ." Section 1861(b). Similarly, 42 CFR 409.10 defines "inpatient hospital services" to mean listed services "furnished to an inpatient of a participating hospital . . . ."

Wills did not discuss the wording of the regulation, but in its argument sought to distinguish the definition of "hospital" in the statute from the definition of "long-term care hospital" as "primarily engaged in providing inpatient services." RR at 17; Act § 1861(ccc). According to Wills, the use of "inpatient services" instead of services "to inpatients" demonstrated that Congress knew how to specify that an entity must be primarily engaged in providing inpatient services. Thus, Wills apparently believes that the use of the phrasing "inpatient services" better emphasizes that the focus is on the kind of patients, not just the type of services.[9] If that is so, CMS's choice of "inpatient services" clearly demonstrated, in a regulation the relevant language of which has been in effect since at least 1983 (48 *Fed. Reg*. 12,526, 12,542 (Mar. 25, 1983)), that CMS understood, and provided notice, that hospitals were required by definition to primarily engage in serving inpatients.

Moreover, CMS has consistently applied this understanding of the statutory definition in cases before the Board over many years and up to the present case. *Kearney* at 9 ("A hospital is a facility that is mainly serving inpatients.") (emphasis in original, footnote omitted) and *Ariz. Surgical Hosp.* at 7 (Petitioner did not provide evidence that it "was primarily engaged in providing inpatient services and thus met the statutory definition . . . ."). While, as we discuss further below, neither CMS nor the Board has articulated a single evidentiary test that can be applied in every case to determine whether a particular facility is primarily engaged in serving inpatients, both CMS and the Board have uniformly applied the statutory definition of such primary engagement as a threshold requirement to certification as a hospital.

Hence, even if we accepted that Wills' re-interpretation of the statute was a permissible one, which we do not, we, like the ALJ, would be compelled to accept CMS's interpretation because it represents that of the agency charged with implementing the statute, and is itself permissible and reasonable and furthermore has been made publicly clear through the prior Board decisions. ALJ Decision at 7, and citations therein; *see also Ark. Dep't of Health and Human Res.*, DAB No. 2201, at 12 (2008), *aff'd, Ark. Dep't of Human Servs. v. Sebelius*, 818 F. Supp. 2d 107 (D.D.C. 2011), and *Mo. Dep't of Soc. Servs.*, DAB No. 2184, at 27-35 (2008) (Board defers to an agency's reasonable and permissible interpretation of ambiguous statutory language absent proof of actual reliance on reasonable alternative interpretation). We conclude that the defining characteristics of a hospital for Medicare purposes include not only that it primarily provide the specified types of services but **also that it primarily provide those services to inpatients**.

[9] Wills' confidence in its opinion that the use of the phrase "inpatient services" instead of services "to inpatients" unambiguously determines that the services must be primarily provided to inpatients is made clear by its repeated references to "subliminal paraphrased 'edits'" by CMS officials, in CMS briefing and in the ALJ Decision. *See* RR at 22, and record citations therein. By subliminal edits, Wills also claims that referring to services "to inpatients" and "inpatient services" in summarizing the meaning of the statute constituted "noteworthy 'Freudian slips'" changing the meaning of the statute by importing the term from the definition of long-term care hospitals. *Id*. But the use of "inpatient services" to capture the meaning of the hospital definition is not an accidental error at all, but instead embodied in the applicable binding regulation implementing the hospital definition.

This conclusion does not suffice to resolve the case, however, because much of Wills' discussion about how to interpret the statute actually is more directed at how CMS is to measure or identify what it means to primarily engage in providing services to inpatients. In this regard, both parties discussed the earlier Board decisions involving putative hospitals. As we discuss next, however, while these decisions are informative in some ways, they do not conclusively settle how we should analyze that question in this case. In succeeding sections, we therefore consider what standard CMS actually used in this case, whether that approach is permissible, and what the undisputed evidence shows as to whether Wills meets the definition of a hospital as applied.

3. Prior Board decisions on the definition of "hospital" for Medicare participation shape but do not resolve the analysis of the present case.

The ALJ articulated the issue in this case as "limited and straight-forward" and turning on whether an institution provides "the bulk of its services to actual 'inpatients.'" ALJ Decision at 1. In support, the ALJ cited Board decisions as consistently holding that the definition of "hospital" for Medicare purposes requires "that an institution care for inpatients *as its primary activity*" to qualify as a hospital. *Id*. at 5 (ALJ italics), citing *Kearney* at 14 and *Ariz. Surgical Hosp.* at 10. Wills argues that the ALJ erred by creating a novel "'bulk of services' standard" (RR at 16) instead of ruling on the "inpatient days to outpatient procedures test" which Wills asserted that CMS "actually applied." RR at 18. Further, Wills argues that the ALJ misapplied the cited cases because they involved situations where no inpatients were present at all. *Id*. at 18-19.

We agree with the ALJ that the Board has repeatedly treated the definition of "hospital" as, on its face, requiring that the entity be primarily engaged in providing the required services **to inpatients**. The Board did so for essentially the same reasons we reached that conclusion in the previous section. However, the Board has not held, and does not now hold, that such primary engagement is conclusively determined by any single numerical test.

Moreover, despite the ALJ's comment at the start of her decision that the simple issue before her was whether a prospective hospital must "provide the bulk of its services to actual 'inpatients,'" the ALJ clearly understood that CMS's approach, both in this case and historically, has been a more nuanced one. ALJ Decision at 1. As she recognized, "[d]istinguishing between a hospital and an ASC is not always easy" and CMS has expressly "declined to set strict numerical standards for determining exactly when an institution establishes that its inpatient services constitute its primary business," instead assessing "case-by-case, whether the statutory definition is met." *Id*. at 8, citing *Kearney* at 14 and CMS Ex. 9, at 21. She also pointed to a CMS memorandum addressing prospective providers seeking to participate as hospitals that specialize in emergency

services and explained that they too must satisfy the statutory definition, including the requirement to be primarily engaged in the provision of services to inpatients. *Id*. at 7, 8 n.7, citing Survey and Certification Memorandum, S&C-08-08 (Jan. 11, 2008) (S&C 2008).[10, 11]

The *Kearney* case involved a new facility which admitted 21 inpatients in its first month of operation but then ceased all admissions because the accrediting organization informed Kearney that it was unnecessary to have inpatients present for the accreditation survey. *Kearney* at 1-2, 11. CMS denied Kearney's certification as a hospital because, with no inpatients, Kearney was "not primarily engaged in providing care to inpatients." *Id*. at 2, and record citations therein. Later, Kearney resumed admissions and was again surveyed; after correcting deficiencies found in that survey, Kearney was certified to participate in Medicare as a hospital. *Id*. at 2. Kearney sought to have the earlier denial reversed.

The Board agreed with Kearney that the Board had in other cases "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.'" *Id.* at 8. The Board stated, however, that it had never treated "the main defining characteristic of a hospital, i.e., being 'primarily engaged' in treating inpatients, as somehow synonymous with 'for the most part' having 'embarked on' the provision of services to inpatients." *Id*. at 8-9. Instead, as the Board stressed, the statute is written in the present tense and hence the focus is not on what a facility has done or will do but instead on whether "the bulk of its present activity consists of providing the required services to treat inpatients." *Id*. In context, the Board thus both emphasized the importance of enforcing the definitional requirement of actually being primarily engaged in inpatient services and declined to articulate a single bright-line test for what constitutes being "primarily" engaged in that activity in a case where the provider was not currently engaged in it.

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[10] https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/SurveyCertificationGenInfo/Downloads/SCLetter08-08.pdf.

[11] In its memorandum, CMS explained that it generally interpreted "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," but that it may also "examine other factors in addition to bed ratio" and that "detailed analysis of the facts of the applicant's operations" would be required in situations of such emergency specialty applicants. S&C-08-08, at 5. However, CMS stated it considered "the burden of proof (to demonstrate that inpatient care is the primary health care service) to reside with the applicant, and consider[ed] the burden to increase substantially as the ratio of inpatient to other beds decreases." *Id*. In the present case, as we discuss later, CMS from the beginning considered facts about Wills' operations that went well beyond a 51% bed test, and Wills failed to provide evidence of other factors to outweigh those on which CMS relied.

The facility in *Arizona* had been in operation for many years but had suspended inpatient admissions and was then subject to a state sanction forbidding inpatient admissions. *Ariz. Surgical Hosp.* at 3. CMS terminated its participation because it was not primarily engaged in serving inpatients. *Id*. at 3-4. The Board agreed with the ALJ that no material facts were in dispute, despite Arizona's proffered evidence that its "policies, history, and business model" showed "an intent to operate as a hospital." *Id*. at 5-6. The Board found that the record established that, even before inpatient admissions were entirely suspended, Arizona "was functioning almost entirely as an outpatient surgical facility and not as an inpatient hospital." *Id*. at 7. Inpatient admissions in the months before the surveys had been minimal. *Id*. The Board pointed to Arizona's failure to proffer evidence focusing on "its actual operations and the universe of patients to which it provided services," such as admission of "any significant number of inpatients" before the sanction, or continued provision of services to existing inpatients, proof of the number of inpatients actually served, or, in sum, that "for any length of time prior to the termination action it had attempted to exist as a going concern through the admission of a significant number of inpatients." *Id*. at 8.

We conclude that prior Board decisions reinforce that a hospital must be primarily engaged in inpatient services and establish that the definition cannot be satisfied when treatment of a significant number of inpatients is not taking place or when the actual operations do not show inpatient services are the focus of the ongoing business concern. They do not, however, provide us with a single numerical test of how to measure whether inpatient admissions and services are sufficient to make this showing.

4. *CMS ascertains on a case-by-case basis whether a facility does primarily provide services to inpatients.*

Having agreed with the ALJ that the statutory definition indeed states a requirement that the putative hospital primarily engage in providing its services to inpatients, we find that the present case requires us to venture further than we have previously had to go in evaluating multiple circumstances to ascertain whether this particular institution is so engaged. The facts to make this assessment are not in dispute, although their legal significance is, so summary judgment remains appropriate.

Wills argues that, even if it loses on its statutory interpretation argument (as we have found that it does), it should still prevail for two reasons. First, it argues that CMS should not be permitted to apply any standard to evaluate compliance with the statutory definition without issuing a regulation spelling out a test of general applicability to do so. RR at 25-32; *see also* Tr. at 15-16, 22-23. According to Wills, not only does the Act require all substantive standards to be promulgated by regulation, but CMS is acting inconsistently in creating a volumetric test that conflicts with its own prior practices, instructions and statements, making it all the more critical that such a change be made

through formal rulemaking. RR at 2-4, 20-28. Second, it argues that CMS's purported "volumetric" or "comparative volume" test is not only procedurally invalid but substantively novel and would, if consistently applied, eliminate many hospitals currently participating in Medicare, including some prominent ones. *Id*. at 26-34; *see also* Tr. at 8, 10, 14-16, 20-28, 30-31.

a. CMS is not required to undertake further notice-and-comment rulemaking before applying the "primarily engaged" requirement in the statute and regulations.

We disagree with Wills' premise that CMS is somehow barred from giving any effect to a binding statutory (and regulatory) definition unless it promulgates further regulations specifying precisely how it will assess compliance with every term of the definition. This argument is one that the Board has previously found unpersuasive because the regulations do define "qualified hospital," as we have noted above, as being "primarily engaged" in "inpatient services." *Arizona* at 9-10 n.6, quoting 42 C.F.R. § 409.3. Further, the Board pointed out that the CoP regulations expressly require that, to be approved to participate in Medicare, a provider "must meet the applicable statutory definitions in (among others) section 1861 of the Act." *Id*. at 9, citing 42 C.F.R. § 488.3(a) (providing that a prospective hospital "must (1) Meet the applicable statutory definitions" and "(2) Be in compliance with the applicable conditions . . . .") (footnotes omitted). Thus, the statutory language, which "was binding by itself and also imposed by regulation," was "clear enough that further interpretation was not required for application." *Id*. at 10.

In support of its position that further rulemaking was required, Wills relies on a 1987 amendment to the Act which barred CMS from issuing any "rule, requirement, or other statement of policy (other than a national coverage determination) that establishes or changes a substantive legal standard governing the scope of benefits, the payment for services, or the eligibility of individuals, entities, or organizations to furnish or receive services or benefits under this [title] . . . unless it is promulgated by the Secretary" through notice-and-comment rulemaking. RR at 26, 29, citing Act § 1871(a)(2) and *Yale-New Haven Hosp. v. Leavitt*, 470 F.3d 71, 75 (2nd Cir. 2006). The Second Circuit described this amendment as a "reframing of settled law under the Administrative Procedure Act [APA]" to express Congressional displeasure with certain coverage policies "'being developed without benefit of the public notice and comment period and, with growing frequency, . . . [and] being transmitted, if at all, through manual instructions and other informal means.'" 470 F.3d at 75, quoting H.R. Rep. No. 100–391, at 430 (1987).

Nothing in the provision cited by Wills suggests that CMS cannot enforce a statutory requirement without first issuing an interpretive regulation to explain how it will approach applying that provision. Such a constraint would go well beyond "settled law" under the APA, which as the Second Circuit pointed out, was essentially what was

codified by the 1987 amendment. On the contrary, administrative law recognizes that agencies may at times choose to act on a case-by-case basis to apply legal requirements. Indeed, the Ninth Circuit has recently made very clear that CMS may appropriately use this mechanism in applying Medicare requirements.

> [W]hile the agency *may* make coverage determinations via up-front rules, it is not *required* to do so; rather, the agency has discretion in whether to make coverage determinations by up-front rulemaking or by case-by-case adjudication. *See Almy [v. Sebelius]*, 679 F.3d at 303–04; *see also Heckler v. Ringer*, 466 U.S. 602, 617, 104 S.Ct. 2013, 80 L.Ed.2d 622 (1984) ("The Secretary's decision as to whether a particular medical service is 'reasonable and necessary' and the means by which she implements her decision, whether by promulgating a generally applicable rule or by allowing individual adjudication, are clearly discretionary decisions."). As the Fourth Circuit noted in *Almy*, "directly applicable Supreme Court precedent . . . makes clear that the Secretary enjoys full discretion to choose to proceed by adjudication rather than by rulemaking." 679 F.3d at 303.

Int'l Rehab. Scis. Inc. v. Sebelius, 688 F.3d 994, 1001 (9th Cir. 2012).

Indeed, were the Secretary required to engage in notice-and-comment rulemaking to explain the application of every term used in every regulatory or statutory provisions for every possible future situation that might be encountered in operating the Medicare program, it is evident that program implementation and enforcement would be stymied, if not completely halted. The agency must and does have flexibility to move forward with enforcing the law through case-by-case adjudication where general prospective guidance is not, or is not yet, workable. In other words, courts have long recognized that the law permits agencies, including CMS, to use both tools (rulemaking and adjudication) to serve different situations:

> Two principal characteristics distinguish rulemaking from adjudication. First, adjudications resolve disputes among specific individuals in specific cases, whereas rulemaking affects the rights of broad classes of unspecified individuals. Second, because adjudications involve concrete disputes, they have an immediate effect on specific individuals (those involved in the dispute). Rulemaking, in contrast, is prospective, and has a definitive effect on individuals only after the rule subsequently is applied. *Yesler Terrace Community Council v. Cisneros*, 37 F.3d 442, 448 (9th Cir.1994) (internal citations omitted) (alterations in original). A regulation is defined as a "rule or order, having legal force, usually issued by an administrative agency." *See* Black's Law Dictionary (8th ed. 2004). Here, SGM [Sequential Geographic Methodology] was promulgated not through notice

> and comment rulemaking, formal adjudication, or formal rulemaking, but rather came in a letter to the Hospitals, which stated it would be applied on a case-by-case basis. SGM likewise "did not affect the rights of a 'broad class' of people, and so no notice and comment was required," as it was not rulemaking. *See MacLean v. Dep't of Homeland Security*, 543 F.3d 1145, 1152 (9th Cir.2008). It was applied to "specific individuals in specific cases . . . ."

Providence Yakima Med. Ctr. v. Sebelius, 611 F.3d 1181, 1188 (9th Cir. 2010*), also citing RLC Indus. Co. v. Comm'r of Internal Revenue Serv.*, 58 F.3d 413, 417 (9th Cir. 1995) ("Rulemaking, the quasi-legislative power, is intended to add substance to the Acts of Congress, to complete absent but necessary details . . . Adjudication, the quasi-judicial power, is intended to provide for the enforcement of agency . . . regulations on a case-by-case basis.") (citations omitted); *Portland Audubon Soc'y v. Endangered Species Comm.*, 984 F.2d 1534, 1540 (9th Cir. 1993) ("Where an agency's task is to adjudicate disputed facts in particular cases, an administrative determination is quasi-judicial. By contrast, rulemaking concerns policy judgments to be applied generally in cases that may arise in the future.") (citations and internal quotations omitted).

Not only is CMS legally permitted to develop on a case-by-case basis its application of the hospital definition to various situations, but CMS provided notice to Congress of its intent to do so and its reasons. In 2005, CMS reported that it had studied the possibility of further defining by regulation what it meant to be primarily engaged in serving inpatients, including by consulting with hospital organizations.

> Representatives of both community and specialty hospital associations opposed the adoption of a fixed definition of "primarily engaged in furnishing services to inpatients." Some associations recognized that, given advances and improvements in medical technology, many procedures that previously could be performed on an inpatient basis only can now be safely performed on an outpatient basis. Community hospital associations opposed a fixed standard because some small rural hospitals might not meet new requirements. The Interim Report stated that CMS has not yet identified any quantitative method, such as percentage of services or ratio of inpatient-to-outpatient services, that could be used without disqualifying both community hospitals and specialty hospitals. Therefore, CMS currently did not intend to define by regulation the statutory requirement that a hospital is an entity that is "primarily engaged" in furnishing services to hospital inpatients for the purpose of differentiating specialty hospitals from community hospitals. 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.

CMS Ex. 9, at 20 (emphasis added). In its final report, CMS confirmed its conclusion that a bright-line regulatory test for whether an entity is "primarily engaged" in inpatient care was not a viable approach.

> We stated in the Interim Report that we had not identified a feasible way to define by regulation the statutory requirement in section 1861 (e) of the Act that a hospital is an entity that is "primarily engaged" in furnishing services to hospital inpatients. Instead, we said, **CMS will continue to interpret "primarily engaged" on a case-by-case basis** as it continues to explore other options for addressing this issue. FAH [Federation of American Hospitals] states that CMS must bring greater clarity to this definition, whereas AHA [American Hospital Association] stated that the Interim Report reflects the general consensus that it would be unwise to define "hospital" in terms of the proportion of inpatient to outpatient procedures, due to unintended consequences, especially for small rural hospitals. We are in no better position now than we were at the time the Interim Report was issued to define "primarily engaged" by regulation and, thus, are not committing at this time to engage in rulemaking.

Id. at 27 (emphasis added). The context for this report was that the Deficit Reduction Act of 2005 required CMS to study issues around physician investment in small specialty hospitals and their effect on general care "community" hospitals which provided more indigent care and more emergency services and placed a temporary moratorium on the formation of specialty hospitals. *See, e.g., id*. at 10-12, 16-17. Concern arose, especially from community hospitals, that physicians were recharacterizing what were essentially ASCs as cardiac or orthopedic specialty hospitals to "unfairly take advantage" of higher hospital rates for outpatient procedures, which CMS reported it was addressing through efforts to reform payment rates for similar procedures performed in ASCs and hospitals to try to reduce such incentives for the formation of specialty hospitals. *Id*. at 12-13, 27-28.

Several things are evident from this context. First, Congress was made explicitly aware that CMS understood the definition of "hospital" in the Act to require that the entity be primarily engaged in serving inpatients. *Id*. at 19, 27. Wills has not identified any action by Congress that would indicate disagreement with that understanding, which further reinforces our earlier conclusion that CMS's interpretation is consistent with the plain meaning of the definition. Second, the concern about reframing an ASC as a hospital because of what CMS called "imprecision" in payment rate systems is not new and the record here reflects that the resulting incentives remain a source of potential distortions. Third, and most important, CMS made plain to both Congress and the industry that it would continue to give effect to the statutory definition on a case-by-case basis without

attempting to issue a regulation setting a numerical standard to apply across-the-board. Again, there is no evidence that Congress treated CMS's report of its plans for case-by-case enforcement as inconsistent with rulemaking requirements or otherwise sought to constrain CMS from following the announced approach.

Wills submitted the recent decision in *Clarian Health West, LLC v. Burwell*, No. 14-cv-0339 (KBJ), 2016 BL 278905, at 16, 24 (D.D.C. Aug. 26, 2016), that it portrays as holding that CMS must use notice-and-comment rulemaking whenever its interpretation "(i) arbitrarily interprets a general statutory term through a numerical approach not dictated by the statute itself . . . or (ii) changes existing regulatory norms . . . ." Wills Letter to Board (Oct. 12, 2016). Even if we accept this portrayal, we find nothing in the decision that provides relevant guidance in the present case. CMS here has not adopted an arbitrary numerical approach to a general statutory term; that is exactly what CMS declined to do. And, as we next discuss, we do not find that CMS changed any existing regulatory norm.

We turn next to the question of whether CMS departed from its intention to use a case-by-case approach in its enforcement actions with regard to Wills.

b. CMS reasonably engages in a case-by-case approach to assess whether facilities, including Wills, are primarily engaged in providing inpatient services.

We disagree with Wills' position that CMS applied in this case some novel mechanistic test to determine that Wills did not primarily engage in serving inpatients rather than applying the announced case-by-case analysis. Wills argues that CMS (or the Regional Office involved in this decision) deviated from "the prevailing enrollment policies." RR at 28. Wills does not explain what it believes were the prior prevailing enrollment policies in regard to hospitals providing inpatient care, although it implies that they were much more permissive or entailed simply accepting all state licensed hospitals. Wills contends that the deviation in the present case is shown by data that it obtained from the American Hospital Association. Wills calculates from that data that, if one compared "'outpatient services . . . with inpatient bed days, 84% of the nation's hospitals would fail' under a simple majority (51%)" standard and 37.5% of participating hospitals would fail "[e]ven under the 17% benchmark representing Wills Eye's projected annual ratio." *Id.*[12]

[12] These ratios refer to projected inpatient bed occupancy compared to outpatient procedures. The ALJ noted evidence that, during the year from July 2011 to June 2012, Wills performed 8,030 outpatient procedures and 370 inpatient procedures, meaning inpatient procedures represented only 4.6% of procedures in that year. ALJ Decision at 3, and record citations therein. We do note, however, Wills' reconfiguration only took place in 2011 so it is not clear to what extent this ratio captures its ongoing operations. *See* RR at 5.

The assumption appears to be that CMS or its regional office determined to deny certification to Wills based on a simple new test comparing outpatient services to inpatient days with a cutoff of either 51% or 17%, and that it did so despite CMS having told Congress that it had decided that creating such an across-the-board cutoff by regulation was not a viable approach. *See* RR at 28, 30-32. This assumption is unsupported even by the very documents on which Wills relies to demonstrate such an account. *See id*. at 29, citing CMS Ex. 10.

Those documents provide insight into how CMS officials came to question, and ultimately disagree with, the state agency about whether Wills' reconfiguration met the definition of a hospital for Medicare purposes. They include a declaration by the CMS regional official responsible for the decision about Wills, Mr. Van Wieren, who has worked in that region since 1978 and is currently Branch Manager for Certification and Enforcement. CMS Ex. 10, at 1. Attached to the declaration are a series of email exchanges between Mr. Van Wieren and staff from the state agency reflecting a back-and-forth discussion of factors concerning how to view Wills's application to participate as a hospital instead of an ASC.

Mr. Van Wieren explains that what initially triggered his concern was his review of information in Wills' application along with his personal familiarity with Wills' operations.[13] *Id*. at 2. He focused on figuring out how the operations were to change and noticed that the "initial application included a large number of personnel, apparently because of the existing ASC practice." *Id*. Specifically, the application indicated that there would be "4 staffed inpatient beds," but "112.5 employees (full time equivalents), 45.2 of which were registered nurses." *Id*., citing CMS Ex. 5, at 6 (Hospital/CAH [Critical Access Hospital] Medicare Database Worksheet), 15 (Life Safety Code Survey report), and CMS Ex. 6, at 1-2 (voluntary termination of the ASC certification). In short, he questioned "what was going on" based on the "excessive number of personnel for a new hospital with a very small number of beds" with a long history as an ASC now seeking to "convert to a hospital." *Id*. These factors led him to believe that "the primary work of the facility was still the outpatient ASC practice, and that it did not meet the definition of a hospital primarily engaged in providing inpatient services." *Id*. One notable element of this account is that he did not begin by eliciting a particular formula to measure inpatient days or procedures versus outpatient activities, but rather was concerned by a contextual pattern that might suggest not the initiation of a small hospital but the tacking on of a minimal number of inpatient beds with little change to an ongoing ASC operation.

[13] He reported as follows on the latter point: "I was familiar with Wills Eye. Wills Eye was unique in that it is well known, is located 2-3 blocks from our office, and had been operating for years as an outpatient ASC. I had personally certified this facility as an ASC, and several of its affiliated outpatient surgery centers." CMS Ex. 10, at 2.

He communicated this concern to the state agency, noting that Wills would "have the opportunity to argue back that they primarily are a hospital," but asking if the state agency had information that suggested that he was mistaken. *Id*. The state agency responded that it did not agree, because Wills had met the CoPs for a hospital and because other "small capacity" hospitals in the state also had few beds and "robust outpatient operations," yet had qualified as Medicare hospitals. *Id*.

After reviewing Wills' website and considering information from the state agency, Mr. Van Wieren learned that Wills projected 8,400 surgeries per year at the site applying for certification. *Id*. at 3. The state agency also suggested in an email, if that every inpatient bed were filled with a new patient every day, the facility could theoretically serve 1,460 inpatients in a year, which would be "17.4 percent of the cases." *Id*. at 6.[14] Mr. Van Wieren concluded that this information reinforced, rather than undercut, his impression that the totality of circumstances showed Wills "was predominantly focused on outpatient business." *Id*. at 3. Mr. Van Wieren further stated that he discussed this situation with his predecessor in his position, Mr. Hock, who agreed with his conclusion:

> We discussed that CMS had not adopted a fixed definition of "primarily engaged" based on the proportion of inpatient and outpatient services. CMS determines if a facility is primarily engaged in providing services to inpatients by considering the specific facts and circumstances of the individual provider, on a case-by-case basis. Mr. Hock and I agreed that, given the large number of staff, the small number of inpatient beds, and the fact that it was a thriving ASC that continued to perform a large amount of outpatient business, it was clear that Wills Eye continued to primarily provide care to outpatients rather than inpatients.

Id. at 3-4.

Mr. Van Wieren also acknowledged in the email exchanges the state agency's position that other small capacity hospitals had been certified as Medicare hospitals, but made several comments about why that position did not persuade him that Wills could be viewed as meeting the definitional requirements. *Id*. at 6. While he agreed that one

[14] Information in the record suggests that the actual daily bed occupancy was more like 3 than 4, and nothing indicates that the average stay was a single overnight for each patient. CMS Ex. 5, at 6 (Hospital/CAH Medicare Database Worksheet showing average daily census of "3" for four "Staffed Beds"). Hence, the actual inpatient days might in reality be significantly lower and the resulting comparison of inpatient to outpatient services even less favorable. On the other hand, the state agency informed Mr. Van Wieren that Wills had communicated its intent to "never have open beds" and to have "inpatients 24/7, and that "Wills has been able to maintain a daily census of 5-6 inpatients in two area hospitals," and could potentially bring those patients "in house." CMS Ex. 10, at 7. We need not resolve what the actual census of inpatients was or would be likely to become, however. We need only recognize that CMS accepted the state agency's projections and still found that even that projected proportion of inpatient care was not sufficient to outweigh the various factors that indicated that inpatient care was not a primary focus on the operations.

facility (the name of which was redacted) was certified that had amounted to a "glorified ASC," he felt that facility was not a successful ASC either, and that, if it were up for certification now, CMS would probably "really scrutinize their business plan." *Id*. On the other hand, he stated that another regional office had terminated participating hospitals on the grounds they were not primarily engaged in inpatient care, including a recent instance in which the facility had provided services to 1,930 inpatients and 24,614 outpatients over 16 months, amounting to about 7% inpatient services. *Id*. The state agency pointed to "other hospitals hav[ing] 10, 12, 14, 15, 20 and 22 beds," and stated that it did not see how "any argument can be made that a 10 or 12 bed hospital is any more hospital than a 4 bed hospital if they all meet" the CoPs. *Id*. at 7. Mr. Van Wieren responded that it was not "a question of the COPs" but "a question of the law" requiring any hospital to primarily treat inpatients, and that "when Wills Eye reports 42.5 RNs for a 4 bed hospital, it is pretty glaring that their primary business is not inpatient hospital." *Id*. We find nothing in these documents to support Wills' portrayal of "a volumetric standard . . . adopted in a 'back room' by Regional personnel rather than by amending the CoPs." RR at 30.

Wills points to snippets of the statements quoted above from Mr. Van Wieren's Declaration and the attached emails to show that he "essentially admitted he was applying a new standard" to Wills. RR at 29.[15] We see nothing of the sort in his statements read in context.[16] On the contrary, what appears in the account and the contemporary exchanges is precisely the kind of case-by-case consideration that CMS reported to Congress that it would undertake rather than set a numerical cutoff. This is not to say that either the absolute number of inpatient beds or the ratio of inpatient to outpatient services are irrelevant or are (or should be) disregarded in the determination. It is clear, though, that CMS's analysis in this instance, consistent with its longstanding

[15] Wills also points to the ALJ as having "recognized," despite "hedging," that "'CMS has declined to set strict numerical standards for determining exactly when an institution establishes that its inpatient services constitute its primary business,' and previously 'had considered and determined not to define 'primarily engaged' by regulation.'" RR at 29, quoting ALJ Decision at 8. Wills cites repeated assertions in CMS's briefing to the effect that CMS has elected not to "'set a proportionate standard that must be met in all cases.'" *Id*., quoting CMS Br. at 16, also citing CMS Br. at 12. Wills concludes that these "acknowledgments . . . eviscerate any suggestion that CMS was not altering the prevailing enrollment policies in" Wills' case. *Id*. On the contrary, we find the statements of CMS counsel and of the ALJ entirely consistent with our conclusion that CMS has not changed its mind and adopted a single cutoff or numerical test to measure all entities seeking to participate as hospitals, but rather that CMS indeed continued to use a case-by-case approach, open to looking at non-numerical factors.

[16] We do not discuss Mr. Van Wieren's decision-making process in such detail in order to evaluate whether we would come to the same conclusions or put the same weight on particular circumstances that he did, if we were asked to determine in the first instance whether Wills qualified as a hospital primarily engaged in inpatient care. Nor do we seek to review how CMS internally arrived at its conclusion or question the propriety of the process. Instead, our role (and that of the ALJ) is simply to ask whether CMS could reasonably within its legal authority reach that conclusion. The reason that we have laid out the information provided about the decision-making process is because it plainly contradicts Wills' claim that CMS suddenly applied a different standard in this case than it has applied historically in enforcing the statutory definition and because Wills used the documentation of Mr. Van Wieren's decision-making to support its arguments. *See, e.g.*, RR at 6-8 (discussing these documents).

position, neither began nor ended with a single numerical cutoff. Instead, the history, current operations, staffing, location, and other facts and circumstances were part of the considerations. In short, we agree with the ALJ's statement, which Wills claims to have rebutted in its briefing on appeal, that Wills "points to no . . . reliable evidence suggesting that the agency has deviated from" its position by its actions in this case. *See* RR at 27, quoting ALJ Decision at 8.

Moreover, the emails on which Wills relies as demonstrating the application of a rigid formula actually show that CMS remained prepared to have Wills come forward with other evidence to show the primacy of inpatient services to its business. Thus, Mr. Van Wieren said in an email: "The good news with a denial is it is just the first shot. They can come back and rebut our assumptions." CMS Ex. 10, at 6; *see also id.* at 8 (Mr. Van Wieren wrote the state that he thought he had "found enough to deny them based on the prima-facie case, and let them come back and prove they are mostly set up for inpatient care."). We turn next to considering whether Wills has indeed come forward with evidence to show that the assumptions and preliminary factors that led to the conclusion that Wills was not "mostly set up for inpatient care" were incorrect or omitted critical facts showing the contrary.

5. *Wills has not demonstrated that it is primarily engaged in providing hospital services to inpatients.*

Rather than present evidence to show that CMS overlooked some critical factor or context which would demonstrate that it should be viewed as primarily focused on inpatient care, Wills has essentially taken the position that it should not be called upon to make any such showing until CMS provides a regulation spelling out what evidence would be accepted as proof.[17] Thus, Wills argues that CMS was obliged to engage in full notice-and-comment rulemaking to explore "weighty questions about the best means to quantify inpatient and outpatient care," including, apart from an outpatient procedures/inpatient days ratio, such metrics as the "relative square footage, relative costs of the services to the hospital (including, for example, capital costs to meet Life Safety Code standards), relative revenues, relative nurse staffing ratios . . ., or something else?" RR at 31. Wills contends that the "complexity and wide variation of potential approaches for adopting a comparative inpatient to outpatient standard would in itself warrant a process in which the agency vets the merits and shortcomings of various formulations through a public process." *Id*.

[17] Wills also suggests that it had "no cause to 'challenge'" the assertions about its staffing levels because they were in a declaration which was only provided as "new evidence" before the ALJ. RR at 20-21. We have already explained that restrictions on new evidence do not apply in this proceeding. Moreover, Wills does not show that it proffered any contrary evidence as to how its staffing patterns were consistent with a primary focus on inpatient care that was rejected by the ALJ for lack of good cause.

But the complexity and wide variation in situations are precisely why CMS decided against trying to develop a one-size-fits-all metric and to instead allow for consideration of particular circumstances and conditions that providers may present. And, as noted, CMS did so after consultation with hospital organizations, many of which opposed development of a single metric by regulation. While the case-by-case approach may offer less clarity and predictability than a regulatory standard might, it also permits more flexibility and responsiveness to changing patterns and needs within the framework required by the statutory definition.

Wills, however, made little effort to use that flexibility to present any alternative information that might demonstrate its primary engagement in inpatient care to overcome the information about its long focus on ASC services, its inpatient/outpatient ratio, its minimal number of inpatient beds, and its relative nurse staffing. For example, it proffered no evidence as to relative square footage, operating costs, or revenues to attempt to show a greater role for inpatient services than was evident from the factors noted in the initial and reconsidered determinations or those which were discussed between Mr. Van Wieren and the state agency staff.

At the oral argument too, counsel for Wills argued that many alternative approaches might be used to evaluate whether inpatient care was a primary focus of an institution.

> And if we want a measure of primarily, how do you do it? Does God drop down a tablet that says it's . . . inpatient days to outpatient procedures? It could be the number of inpatients to the number of procedures. It could be 12 outpatient procedures at an hour each equals 1 inpatient day. It could be relative spending on capital to pay for inpatient services such as the Life Safety Code versus what you would spend on capital investment for outpatient services. Could it be square footage?

Tr. at 30. The Presiding Board Member therefore inquired where in the record Wills "put forward" evidence to show a "basis on which it feels it demonstrated that, rather than looking at the particular comparison mentioned in the initial determination" some other measure "would nevertheless justify viewing" Wills as indeed engaged with "a primary focus" of treating inpatients "based on some other analysis." Tr. at 46. Counsel for Wills reiterated its position that, since CMS had declined to implement a standard for that assessment by regulation, Wills could not be asked to make a showing for any basis other than that alleged in the reconsideration, a position we have already rejected. Tr. at 47-48.

Counsel went on, however, to point to the caliber of Wills' services as demonstrating that it should be viewed as a hospital rather than an ASC.

> Wills Eye Hospital has the leading eye cancer treatment program in the United States. It provides not just surgical services; it provides medical services. It's on the leading edge of developing procedures for the treatment of eye diseases and injuries. So the complexity of the services, the operation of the largest residency program in the country in conjunction with Jefferson by Wills Eye, those are things that clearly indicate it's a hospital. When we think of an ASC that provides ophthalmological services, it's going to get laser surgery to correct blurred vision. That's not what this place does. This is one of the world's leading facilities for treating complex eye disease. Right now it's treating children with eye cancer. But if CMS has its way, a couple of months from now it won't be treating any children with eye cancer. It won't be curing blastoma. It's going to be out of business. So, yeah, the nature of the services are hospital services, and I think that's the best answer.

Tr. at 48.

In response to another question, counsel indicated that the residency program predated the addition of the inpatient beds, although of course the inpatient services were not provided in the institution before the renovation but rather at a nearby general hospital with which Wills cooperated. Tr. at 52-53. By Wills' account, its activities evolved from a large institution with a substantial inpatient component more than 100 years ago to become an ASC in more recent years in response to changing patient needs. Counsel explained this as follows:

> [T]he medical delivery in hospitals has changed rapidly over the last several decades, including a dramatic increase of outpatient relative to inpatient care all across country, and particularly with regard to specialty hospitals, which because of advances in medicine have managed to be able to treat patients on an outpatient basis and have them come back in for follow-up, rather than subject them to hospital infections, lengthy stays, costly stays, and to get them out of the hospital and then back in for follow-up.

Tr. at 9. Wills argues that these trends should not result in its being treated as not a hospital, contending that it is viewed nationally and internationally "as a leading eye hospital, not [a] leading eye ambulatory surgery center." *Id.*

This contention was also reflected in Wills' submission to CMS seeking reconsideration of the initial denial. CMS Ex. 2, at 3-4. Wills argued that "the evolution of ophthalmology itself toward treatments that allow patients to go home the same day" has "limited" the number of ophthalmology inpatients the hospital has "at any one time." *Id*. at 4. Wills went on to assert that the higher level of Medicare payments hospitals receive for outpatient, as well as inpatient services, more "fairly reimburses for the complexity, comprehensive nature, and cost of tertiary and quaternary care" that Wills provides. *Id*. Moreover, Wills contended that the "ASC fee schedule" had "never fairly captured the reality of Will[s] Eye Hospital's services." *Id*. at 3.

What these statements make clear is that Wills' attempt to transform itself back into a hospital by the addition of a small inpatient component is, at least in significant part, driven by the desire for higher payment rates that would make available for the preexisting outpatient services it has been providing as an ASC. We accept for purposes of this decision Wills' claim that it provides superior levels of care and finds the ASC payment rates inadequate to reimburse its resulting costs. The existing law does not, however, distinguish between hospitals and ASCs based on the quality of care they provide (although it does distinguish some procedures that may or may not be provided in an ASC setting). 42 C.F.R. § 416.2, 416.65; *see also* Medicare Claims Processing Manual, CMS Pub. 100-04, Ch. 14, § 20 (List of Covered Ambulatory Surgical Center Procedures).[18] The relevant defining characteristic of a hospital is not that it receives higher reimbursement rates or that it treats complex cases or that its quality of care is exceptional or widely recognized, but rather that its primary business is providing diagnostic, therapeutic, or rehabilitation services to inpatients. Wills may well have understandable reasons for seeking changes in how outpatient services are compensated but this proceeding, as we explain further below, is not the proper forum for policy debates.

Wills also argues that CMS should not have rejected its application as a hospital merely because it only had 4 inpatient beds. RR at 21. As Wills points out, CMS does not exempt hospitals of 4 inpatients or less from meeting life safety codes (LSC) standards (despite such exemptions in fire standards), and does not base qualification as a hospital on "number of inpatients," but Wills then mistakenly says that CMS "focuses" on the "nature of services" only in identifying a hospital. RR at 5, n.3, citing Survey & Certification Memorandum to State Agency Directors, S&C-11-05-LSC, at 2-3 (Feb. 18, 2011) (S&C 2011).[19] The CMS memorandum to which Wills cites first explains that

[18] https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/clm104c14.pdf.

[19] https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/SurveyCertificationGenInfo/downloads/scletter11_05.pdf.

"health care occupancy" is required for any hospital component facility on or off campus which is defined in fire codes as "[a]n occupancy used for the purpose of medical or other treatment or care of four or more persons where such occupants are mostly incapable of self-preservation because of age, because of physical or mental disability, or because of security measures not under the occupants' control." S&C 2011, at 2, citing 42 C.F.R. § 413.65(a)(2). Any facilities that do not provide 24-hour housing are "classified as other occupancies," but "hospital . . . facilities that provide sleeping accommodations and medical treatment or services on a 24-hour basis for patients mostly incapable of self-preservation must be classified as a Health Care Occupancy." *Id*. The S&C 2011 then explains that, in regard to Medicare, the Act "defines 'hospital' as being primarily engaged in providing care to inpatients and is not based upon a minimum number patients receiving treatment, care or services." *Id*. Hence, "CMS does not consider the number of patients in determining if a provider is a hospital . . . ; therefore, a CMS-certified hospital . . . does not need to have four or more inpatients at all times in order to be classified as a Health Care Occupancy." *Id*. at 2-3. The relevant core of this discussion is that, because, as we have said, a Medicare hospital must by definition be a facility housing and treating inpatients as its primary business, such a facility meets the standards as a health care occupancy without regard to whether four beds are filled at every moment. It does not follow that CMS was precluded from considering the very small number of inpatient beds added at Wills as part of the picture in assessing whether the facility was at bottom a very small-capacity new inpatient hospital or a large ASC adding a few beds to qualify for higher rates for all its procedures.

Wills has not shown that CMS's case-by-case analysis here was arbitrary or unreasonable or overlooked any relevant factor that would show that CMS exceeded its discretionary authority in determining that Wills did not qualify as a hospital by definition. Where CMS has applied reasonable judgment in applying an element of the statute which it is charged, and has the expertise, to implement, it is not our role to second-guess that application in a particular case. *See, e.g., N.Y. State Dep't of Soc. Servs.*, DAB No. 1023, at 9 (1989) (Board found no basis to conclude agency exceeded its authority, and where agency exercise of authority is reasonable, Board does not substitute its judgment for that of the agency designated to administer program), *citing Cal. Dep't of Soc. Servs.*, DAB No. 742, at 2 (1986).

Wills also argues it should be granted hospital enrollment because the state agency determined that Wills met the Medicare CoPs for hospitals, at 42 C.F.R. Part 482, which, Wills notes, "nowhere mention[]" any comparative volume test. RR at 17; *see, e.g.*, P. Reply Br. at 18 (given "absence of any dispute that Wills Eye satisfied all of the prevailing CoPs," Board should "order the enrollment of Wills Eye Hospital in Medicare retroactive to the date of the enrollment survey"). That argument fails for multiple

reasons. First, the hospital CoPs do in fact incorporate compliance with the statutory definition at section 482.1(a)(1), stating that "Section 1861(e) of the Act provides that - (i) Hospitals participating in Medicare must meet certain specified requirements." Furthermore, the identification of which CoPs apply to a prospective provider arises precisely from determining which provider category applies, so an institution must meet the definition of hospital as a logical prerequisite for demonstrating compliance with the hospital CoPs. 42 C.F.R. § 409.3 ("qualified hospital" definition). Ultimately, the fact that the text or application of the definition of a hospital is not spelled out in CoPs cannot excuse a facility from having to satisfy the statutory definition.

We thus find no basis to disturb CMS's denial of certification of Wills as a hospital.

6. Other arguments by Wills have no merit.

a. Disparate treatment

To the extent that Wills' proffered evidence regarding other Medicare hospitals which might fail various numerical tests to show they met the statutory definition amounts to an allegation of selective enforcement, the Board has long made clear that it is not empowered to refuse to enforce a valid statutory or regulatory requirement based on claims about other entities not subject to enforcement actions before it. As the Board put it in *Arizona*, "CMS's actions or lack thereof regarding other facilities" cannot provide a reason for an ALJ or the Board "to ignore or decline to enforce the statute's clear requirements." *Ariz. Surgical Hosp.* at 10.

Wills contends that the ALJ wrongly rejected Wills' argument that the termination constituted impermissible disparate treatment because, "[u]ntil this case, CMS had consistently enrolled (and not terminated) hundreds of hospitals with small complements of inpatient beds and far greater volumes of outpatient than inpatient services, including specialized hospitals closely comparable to Wills." RR at 33-34. The ALJ accepted that some institutions participating in Medicare as hospitals "may not qualify" as hospitals but found that "this does not change the statutory definition, and I may not compound CMS's purported errors by compelling CMS to allow yet another unqualified institution to be certified." ALJ Decision at 9, citing *Beverly Health & Rehab.— Spring Hill*, DAB No. 1696 (1999) (selective enforcement does not bar future enforcement actions), *aff'd, Beverly Health & Rehab Servs. v. Thompson*, 223 F. Supp. 2d 73 (D.D.C. 2002). The ALJ also cited *Jewish Home of Eastern Pennsylvania*, DAB No. 2254 (2009), as holding that "CMS's treatment of other facilities cannot undercut [Petitioner's] responsibility to show that it was in compliance with the applicable legal requirements or remove CMS's authority to take actions which it is authorized by statute . . . to take." *Id.*, citing DAB No. 2254, at 15.

Wills argues that the Board decisions the ALJ cited are not applicable because none "implicated the obligation to set uniform enrollment policies" under section 1871(a)(2) and all involved a party "being sanctioned for committing an offense and complaining that the sanctions were harsher than those for other providers" whereas Wills instead "challenges CMS's application of discriminatory enrollment criteria." RR at 34-35. Wills cites federal court cases that it says found selective, discriminatory enforcement of a facially valid law unconstitutional, and found selective enforcement of "an extremely broad prohibitory statute" to be "invidious discrimination." RR at 35, citing *Jewish Home of Eastern Pa.*, 693 F.3d at 363; *Holder v. City of Allentown*, 987 F.2d 188, 197-99 (3rd Cir. 1993).

Wills' argument fails because, as explained above, we do not accept Wills' premise that CMS applied to it, or only to it, a new or novel test to determine that Wills did not primarily engage in serving inpatients. We conclude in this decision that CMS instead permissibly determines whether facilities primarily provide services to inpatients on a case-by-case basis, that CMS has not attempted to apply a numerical standard across-the-board, and that CMS was prepared to permit Wills to come forward with evidence to show the primacy of inpatient services to its business. (Wills' ability to make that showing is, of course, subject to our conclusion that section 1861(e) requires that a hospital be primarily engaged in *providing services to inpatients*, and not simply that a hospital must provide inpatients with primarily the services listed in the statute, as Wills maintains.)

We also do not agree with Wills that Board decisions in appeals of enforcement actions are inapplicable to this appeal of CMS's determination that Wills does not qualify as a provider; in each case a facility on appeal must demonstrate its compliance with applicable legal requirements. *See* 42 C.F.R. § 488.3(a)(2) (prospective hospital "must . . . [b]e in compliance with the applicable conditions . . . ."). We thus decline under the facts here to distinguish our previous cases where the Board "held that 'allegations of disparate treatment, even if true, do not prohibit an agency of this Department from exercising its responsibility to enforce statutory requirements.'" *N.H. Dep't of Health & Human Servs.*, DAB No. 2399, at 19 (2011), citing *Municipality of Santa Isabel*, DAB No. 2230, at 12 (2009), quoting *Nat'l Behavioral Ctr., Inc.*, DAB No. 1760, at 4-5 (2001), and decisions cited therein.

Moreover, we do not agree with Wills that its data or calculations can prove that a denial of its certification as a hospital must necessarily cause a catastrophic expulsion of hospitals, large and small, around the country. *See, e.g.*, Tr. at 29 ("People are going to have to go to Cuba to get care under Medicare because you're not going to have any hospitals left in the United States."). CMS is not obligated to find out of compliance with the definition every hospital that was previously a long-functioning ASC, or every

hospital with 4 beds, or every hospital with outlier staffing ratios, or every hospital or every specialty hospital with nearby extensive general hospital beds that had previously met its inpatient needs, or even every hospital with the same or lower ratio of potential inpatient admissions to outpatient procedures as Wills. Wills presented a specific constellation of factors while other institutions with similar metrics on one measure may nevertheless demonstrate other facts about their operations, history and context that reasonably result in a different outcome.

b. Health care policy considerations

Finally, we have recognized that Wills makes a compelling presentation that it offers valuable, even unique, services that are not well accounted for by the structures built into Medicare financing system. Wills asserts, and we have no reason to question its assertion, that a "general service" hospital "cannot support the level of investment and attention required to maintain the extremely specialized and focused personnel, advanced equipment, and knowledge necessary for tertiary and quaternary ophthalmology" such as Wills offers. CMS Ex. 2, at 4. Wills contends, and we have no reason to doubt, that it always has, and still continues to, provide "hospital-level" care as its "[s]ole [f]ocus." *Id*. at 3. Yet, its dilemma is that, as it plainly explains, advancements in medicine have made it possible to provide the vast majority of that care in outpatient settings. As an ASC, it cannot provide the small component of inpatient care still needed nor can it receive the higher rates for its outpatient services that it feels the caliber of its services call for. As a hospital, it cannot treat inpatients as a mere add-on to an essentially outpatient operation. In its reconsideration request, Wills articulated the resulting frustration as follows:

> Regardless of license, however, the nature of the services we provided and provide at our new facility never changed from hospital-level services. We do not look like or act like an ambulatory surgical center. We do not select for "easy," high-paying procedures like many ambulatory surgical centers, especially those that are privately-owned. We participate in all Medicare and Medicaid third party insurance products. Our care is tertiary and quaternary in nature. The patients we treat have been operated on before by surgeons at other facilities and present heightened risks of failure or complications. The patients we treat have rare or especially challenging diseases and conditions which demand a national center of excellence like ours. The nature of a hospital reaches much farther than filling overnight beds. The nature of a hospital also very much relates to the acuity level of outpatient care provided. In addition, Hospital status enables us to care for patients that ASC licensure prohibited, such as longer surgical times and longer recovery times.

Id. This statement, while poignant, makes clear that the nature of Wills' operations remains largely what it has been as an ASC, regardless of any change in licensure. Unfortunately, we are aware of no category of Medicare providers reimbursed at higher rates for high-acuity outpatient care while also providing a small amount of inpatient care.

This reality may well reflect what the ALJ also noted, i.e., that "[m]edical practices may have outpaced the statute." ALJ Decision at 8 n.6. The ALJ also pointed to the possible sources of relief for the dilemma that Wills, and likely other prospective providers, face that "provide to outpatients increasingly sophisticated services, services that, in the past, required hospitalization" but "cannot be certified as hospitals," i.e., a "legislative or policy change." *Id*.

We agree with the ALJ that the adjudicative proceeding is "not the appropriate forum for effecting such changes." *Id*. As the Board has explained in many prior cases, we are bound by applicable law and regulations and do not engage in policy-making. *See, e.g., United Med. Home Care, Inc*., DAB No. 2194, at 15 (2008) (ALJ and 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,'" but review only to ascertain "whether there is a legally sufficient factual basis for the federal agency's decision."). If the categories of Medicare providers defined by statute are outdated, legislative action may be called for. If the payment systems provide perverse incentives or create unintended consequences, legislative or regulatory measures may be needed. Such changes call for careful study and expertise, and the balancing of innumerable, complex interactions in an undertaking as enormous as the Medicare system. A single appeal is not a vehicle capable of navigating such challenges and, in recognition of this, we decline to venture into opining on broader areas of healthcare policy and payment practices.

Conclusion

For the reasons we have explained, we affirm the ALJ Decision granting summary judgment in favor of CMS.

/s/
Christopher S. Randolph

/s/
Susan S. Yim

/s/
Leslie A. Sussan
Presiding Board Member