Department of Health and Human Services
DEPARTMENTAL APPEALS BOARD
Appellate Division

Wesley Medical Center, LLC, d/b/a Galichia Heart Hospital
Docket No. A-14-44
Decision No. 2580
June 30, 2014

REMAND OF ADMINISTRATIVE LAW JUDGE DECISION

Wesley Medical Center, LLC (Wesley), an acute care hospital doing business as Galichia Heart Hospital, appeals the December 13, 2013 Administrative Law Judge (ALJ) decision granting summary judgment in favor of the Centers for Medicare & Medicaid Services (CMS). *Wesley Medical Center, LLC, d/b/a/Galichia Heart Hospital,* DAB CR3033 (2013) (ALJ Decision). The ALJ sustained CMS's determination that the effective date of Wesley's Medicare participation is April 20, 2012. Wesley argued that it is entitled to an effective date of February 17, 2012.

For the reasons discussed below, we conclude that further development of the record is necessary in order to determine the effective date of Wesley's Medicare participation. Accordingly, we remand this matter to the ALJ for further development consistent with our instructions below.

I. Legal Background

To participate as a provider in Medicare, a hospital must enter into a provider agreement with CMS. Social Security Act (Act)[1] § 1866; 42 C.F.R. § 489.3. Before CMS will accept the provider agreement, the hospital must meet requirements specified in the Act and regulations. Act §§ 1861(e), 1861(k), 1866; 42 C.F.R. Parts 482, 489.

The health and safety requirements for hospitals, called conditions of participation, are codified in 42 C.F.R. Part 482. Each condition of participation represents a general health or safety requirement described in a single regulation, which is composed of subpart standards. A provider is not in compliance with a condition of participation "where the deficiencies are of such character as to substantially limit the provider's . . .

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

capacity to furnish adequate care or which adversely affect the health and safety of patients[.]" 42 C.F.R. § 488.24(b). Whether an entity is in compliance with a particular condition of participation "depends upon the manner and degree to which the provider . . . satisfies the various standards within each condition." 42 C.F.R. § 488.26(b). The Secretary may "refuse to enter into an agreement" with a provider that "fails to comply substantially" with the provisions of the provider agreement, the Act, or applicable regulations. Act § 1866(b)(2).

Generally, before entering into a provider agreement, a hospital must first be certified by a state survey agency as in compliance with the conditions of participation. Act § 1864; 42 C.F.R. Part 488. To carry out the survey and certification functions, state agency surveyors follow protocols in the CMS State Operations Manual (SOM). CMS Pub. 100-07, App. A, *Survey Protocol, Regulations and Interpretive Guidelines for Hospitals*.[2] Once a hospital has had an initial survey, been certified and entered into a provider agreement, it is subject to routine surveys to determine whether it continues to meet the Medicare conditions of participation.

Section 1865 of the Act and the regulations at Part 488 provide an alternative process to the state agency survey and certification process for a provider to be treated by CMS as meeting the conditions of participation. As we discuss in greater detail below, the Act and regulations authorize CMS to deem a hospital to have met the conditions if the hospital demonstrates through accreditation by a national accreditation organization (AO) under a CMS-approved accreditation program that all applicable conditions have been met or exceeded. Act § 1865(a); 42 C.F.R. §§ 488.4-488.9.

In September 2008, CMS published a notice in the *Federal Register* of its "decision to approve Det Norske Veritas Healthcare, Inc. [DNV] for recognition as a national accreditation program for hospitals seeking to participate" in Medicare for the period September 26, 2008 through September 26, 2012. 73 Fed. Reg. 56,588 (Sept. 29, 2008).

The effective date of a Medicare provider agreement is determined by applying section 489.13 of the regulations. Section 489.13 provides that when a hospital is surveyed by an AO "whose program has CMS approval in accordance with section 1865 of the Act," and the hospital is found to meet all conditions of participation but has lower-level deficiencies (and no other federal requirements remain to be satisfied), the effective date is the date "a CMS-approved [AO] program issues a positive accreditation decision after it receives an acceptable plan of correction for the lower-level deficiencies" or "CMS receives an approvable waiver request . . . ." 42 C.F.R. §§ 489.13(a)(1)(ii), 489.13(c)(2)(ii).

[2] The SOM is available at http://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/som107_appendixtoc.pdf

When a provider changes ownership, "the existing provider agreement is automatically assigned to the new owner, effective on the date of transfer, unless the new owner rejects that assignment" by providing notice to CMS that it is rejecting the assignment. *Eagle Healthcare, Inc. v. Sebelius*, 969 F.Supp.2d 38, 39 (D.D.C. 2013) (citing 42 C.F.R. § 489.18(c)). An assigned provider agreement is subject to all of the terms and conditions under which the agreement was originally issued. 42 C.F.R. § 489.18(d). If the new owner rejects assignment, then the seller's provider agreement terminates. 42 C.F.R. § 489.52.

II. Case Background

The following facts are drawn from the record and are not disputed.

On February 1, 2012, Wesley acquired Galichia Heart Hospital, an acute care hospital in Wichita, Kansas. CMS Ex. 1. Wesley notified CMS prior to the transaction that it would not accept assignment of the seller's Medicare provider agreement. *Id.*

Wesley contracted with DNV to conduct an accreditation survey of the hospital following the closing of the transaction. *Id.* On February 1, 2012, DNV conducted a survey of the hospital. CMS Ex. 2; P. Ex. 2. DNV issued a survey report on February 15, 2012, concluding that the hospital had several lower-level deficiencies, requiring a corrective action plan. *Id.* Wesley submitted a corrective action plan to DNV on February 17, 2012. *Id.*

By letter dated March 28, 2012, DNV advised Wesley that, as a result of the February 1, 2012 survey, DNV "awarded full accreditation" to the hospital effective February 1, 2012. CMS Ex. 2, at 1. DNV further stated that it was recommending the hospital for "deemed status in the Medicare Program." *Id.* The letter continued, "Please note that CMS makes the final determination regarding your Medicare certification and the effective date of Medicare participation in accordance with the regulations at 42 CFR 489.13." *Id.*

By letter dated April 4, 2012, DNV notified Wesley that the CMS Regional Office had challenged DNV's initial notification letter establishing the effective date of accreditation of February 1, 2012. P. Ex. 3. DNV stated that it subsequently had conferred with the "CMS Central Office" about the effective date of Wesley's accreditation under section 489.13. *Id.* DNV stated that it was "advised by the CMS Central Office that we could apply the date of receipt of the Plan of Correction, February 17, 2012, as the effective date of accreditation pursuant to 42 CFR § 489.13(c)(2)(ii)(A)." *Id.* at 2.

DNV enclosed with the April 4, 2012 letter a "re-issued Notification Letter [dated April 4, 2012] establishing February 17, 2012 as the effective date of accreditation." *Id.*; P. Ex. 5. The enclosed April 4, 2012 notice of accreditation stated that DNV "awarded full

accreditation" to Wesley effective February 17, 2012 and that DNV was "recommending [Wesley] for deemed status in the Medicare program." P. Ex. 5. The letter further stated, "Please note that CMS makes the final determination regarding your Medicare certification and the effective date of Medicare participation in accordance with the regulations at 42 CFR 489.13." *Id.*

On April 16, 2012, CMS told DNV that the February survey was not a "full, standard survey," which CMS said was required because Wesley had chosen to reject assignment of the previous owner's provider agreement. CMS Ex. 8, ¶ 6; P. Pre-hearing Br. and Cross-motion for Summary Judgment at 4.

On April 17-19, 2012, DNV conducted a second survey of Wesley and again found multiple lower-level deficiencies. P. Ex. 6. On April 20, 2012, Wesley submitted a plan of correction addressing the deficiencies. *Id.*

By letter dated May 2, 2012, DNV advised Wesley that its date of accreditation was April 20, 2012. Docket No. A-14-44, Transcript of May 22, 2014 Oral Argument (Tr.) at 4.

By letter dated May 11, 2012, CMS notified Wesley that CMS had determined that the effective date of Wesley's Medicare participation is April 20, 2012. P. Ex. 7. Wesley timely sought review of CMS's determination. July 6, 2012 Request for ALJ Hearing or, Alternatively, for Reconsideration by CMS.

CMS issued a reconsideration determination on April 30, 2013, sustaining the April 20, 2012 effective date of Wesley's Medicare participation. CMS Ex. 10; P. Ex. 8. CMS determined that DNV was obligated to follow "survey protocols commensurate with those of state survey agencies" and to conduct a full, "initial" hospital survey because Wesley chose not to accept assignment of the seller's Medicare provider agreement. *Id.* CMS concluded that DNV's February 1, 2012 survey was insufficient under the State agency survey protocols. *Id.* (citing SOM, App. A). CMS *further* explained that "DNV surveyors conducted a full 'initial' survey April 17-19, 2012," that the survey "found noncompliance with some Federal hospital regulations," and that on April 20, 2012 Wesley submitted to DNV a plan to correct the deficiencies. *Id.* Applying section 42 C.F.R. § 489.13(c)(2)(ii), CMS concluded, the Regional Office properly "certified the hospital effective April 20, 2012 . . . ." *Id.*

On the parties' cross-motions for summary judgment, the ALJ sustained CMS's determination that Wesley's effective date of Medicare participation is April 20, 2012.

Wesley timely appealed the ALJ Decision. After the parties filed their briefs on appeal, the Board held oral argument on May 22, 2014 in order to facilitate the Board's decision-making.

III. Standard of Review

Our standard of review on a disputed factual issue is whether the ALJ decision is supported by substantial evidence in the record as a whole. The standard of review on a disputed issue of law is whether the ALJ decision is erroneous. The bases for modifying, reversing or remanding an ALJ decision include the following: a finding of material fact necessary to the outcome of the decision is not supported by substantial evidence; a legal conclusion necessary to the outcome of the decision is erroneous; the decision is contrary to law or applicable regulations; a prejudicial error of procedure (including an abuse of discretion under the law or applicable regulations) was committed. *Guidelines – Appellate Review of Decisions of Administrative Law Judges Affecting a Provider's Participation in the Medicare and Medicaid Programs*, http://www.hhs.gov/dab/guidelines/prov.html.

Summary judgment is appropriate when there is no genuine issue as to any material fact, and the moving party is entitled to judgment as a matter of law. *Mission Hosp. Regional Medical Ctr.*, DAB No. 2459, at 5 (2012), *aff'd, Mission Hospital Regional Medical Ctr. v. Sebelius*, 2013 WL 7219511 (C.D.Cal. May 31, 2013); *Celotex Corp. v. Catrett*, 477 U.S. 317, 322-25 (1986). Whether summary judgment is appropriate is a legal issue that we address de novo, viewing the proffered evidence in the light most favorable to the non-moving party. *Community Hosp. of Long Beach*, DAB No. 1938 (2004).

IV. Analysis

A. *Deeming surveys must conform to CMS-approved accreditation program standards and procedures.*

As summarized above, section 1865(a) of the Act provides the authority for CMS to deem a hospital as meeting the conditions of participation based on accreditation by an approved AO. Section 1865(a) provides:

> (1) If the Secretary finds that accreditation of a provider entity . . . [by a] national accreditation body demonstrates that all of the applicable conditions or requirements of this title (other than the requirements of section 1834(j) or the conditions and requirements under section 1881(b)) are met or exceeded—
>
> > (A) in the case of a provider entity not described in paragraph (3)(B), the Secretary shall treat such entity as meeting those conditions or requirements with respect to which the Secretary made such finding; or
> >
> > (B) in the case of a provider entity described in paragraph (3)(B), the Secretary may treat such entity as meeting those conditions or requirements with respect to which the Secretary made such finding.

> (2) In making such a finding, the Secretary shall consider, among other factors with respect to a national accreditation body, its requirements for accreditation, its survey procedures, its ability to provide adequate resources for conducting required surveys and supplying information for use in enforcement activities, its monitoring procedures for provider entities found out of compliance with the conditions or requirements, and its ability to provide the Secretary with necessary data for validation.

The "provider entity described in paragraph (3)(B)" is a "a provider entity to which the conditions and requirements of sections 1819 and 1861(j) apply." Sections 1819 and 1861(j) establish the conditions and requirements for skilled nursing facilities (SNFs). In other words, section 1865(a)(1)(B) above applies to SNFs; while section 1865(a)(1)(A) applies to all other provider entities.

Wesley argues that under the language of 1865(a)(1)(A), Congress "mandated that CMS 'shall' treat a hospital accredited by a CMS-approved accrediting organization as meeting the 'applicable conditions or requirements of [Title XVIII].'" Request for Review (RR) at 4. Wesley asserts that in contrast, by using the word "may" rather than "shall" in section 1865(a)(1)(B), Congress gave CMS the discretion to treat an AO's accreditation determination as merely a recommendation in the case of SNFs alone. Consequently, Wesley asserts, because CMS granted deeming authority to DNV pursuant to section 1865(a)(1), CMS was bound by DNV's April 4, 2012 accreditation decision, which was based on the February 1 survey (and on CMS's April 2012 advice that February 17, 2012 was the effective date of participation). According to Wesley, CMS had no authority to look behind DNV's accreditation decision to assess the sufficiency of the survey on which the decision was based.

Wesley's reading of section 1865(a)(1) as compelling CMS to deem a hospital to be in compliance with the conditions of participation regardless of the nature of the survey underlying the AO's accreditation decision fails to recognize the context of section 1865(a)(1)(A) and the plain language of the implementing regulations. Read as a whole and consistent with the regulations, section 1865 provides for CMS to treat a provider as meeting the conditions of participation where an AO survey follows the standards and procedures established under a CMS-approved accreditation program.

As described in section 1865(a)(2) of the Act, Part 488, Subpart A of the regulations, and CMS's 2008 notice approving DNV's application for deeming authority, CMS's evaluation of an AO's application for deeming authority involves a review of detailed policies, standards and survey procedures. CMS reviews the AO program policies, standards and procedures to determine the "equivalency of [the AO]'s accreditation requirements of an entity to the comparable CMS requirements for the entity" and the "comparability of survey procedures to those of State survey agencies[.]" 42 C.F.R. § 488.8(a). Among other things, the AO must provide for CMS's review a "detailed

description of the organization's survey process," "the organization's survey forms, guidelines and instructions to surveyors," and "a detailed comparison of the organization's accreditation requirements and standards with the applicable Medicare requirements[.]" 42 C.F.R. § 488.4(a)(2)-(3); 73 Fed. Reg. at 56,589. The AO also must describe all types and categories of accreditation the organization offers and "a statement specifying the types and categories of accreditation for which approval of deeming authority is sought[.]" 42 C.F.R. § 488.4(a)(8).

Following the requirements in section 488.6 of the regulations, CMS's evaluation of DNV's application also involved review of the "the composition of the survey team, [and] surveyor qualifications," a comparison of DNV's "processes to those of State survey agencies," and DNV's "ability to provide [CMS] with electronic data and reports necessary for effective validation and assessment of [DNV's] survey process." 73 Fed. Reg. at 56,589. CMS explained in its notice of approval that DNV's application was "reviewed in accordance with the requirements at § 488.4 and §488.8 to ensure that [its] accreditation **program** meets or exceeds Medicare's requirements." *Id.* at 56,590 (emphasis added). CMS also summarized its approval as a "decision to approve [DNV] for recognition as a national accreditation **program** for hospitals seeking to participate in the Medicare or Medicaid programs." *Id.* at 56,588 (emphasis added).

Furthermore, section 488.1 of the regulations defines the term "accredited provider" to mean a provider "that has voluntarily applied for and has been **accredited by a national accreditation program meeting the requirements of and approved by CMS in accordance with §488.5 or §488.6.**" (Emphasis added.) Consequently, for Wesley or any other provider to achieve accredited, deemed provider status based on an AO survey, the survey must follow the AO program (i.e., standards and procedures) that CMS reviewed and approved. As CMS explained in a 2008 survey and certification memorandum: "AOs frequently offer, in addition to their CMS-recognized deemed status accreditation program, other accreditation program(s). . . . " S&C-09-08, Att. A, I-8. "For Medicare participation purposes," CMS continued, the "facility must be accredited under the AO's CMS-recognized deemed status accreditation program." *Id.* "Thus," CMS stated, "it is not sufficient for a health care facility seeking Medicare participation to document that it is accredited; it must document that a CMS-recognized AO has accredited it under its recognized deemed status program and that the AO has recommended that CMS grant the facility certification via deemed status." *Id.*

Section 489.13 of the regulations, which governs the effective date of a provider's participation in Medicare, similarly provides that when a hospital's participation is based on accreditation by an AO, the survey underlying the positive accreditation decision (and effective date determination) must have been conducted under a CMS-approved AO program. The introductory section of the regulation states that with certain exceptions not relevant here, the regulation –

> (a)(1) . . . applies to Medicare provider agreements with . . . entities that, as a basis for participation in Medicare are subject to a determination by CMS on the basis of—
>
> (i) A survey conducted by the State survey agency or CMS surveyors; or
>
> (ii) In lieu of such State survey agency or CMS conducted survey, accreditation by an **accreditation organization whose program has CMS approval in accordance with section 1865 of the Act** at the time of the accreditation survey and accreditation decision.

42 C.F.R. § 489.13(a)(1) (emphasis added). Section 489.13(c)(2) further provides that when a hospital is surveyed by an AO and all health and safety standards are not met on the date of the survey (but all other Federal requirements are satisfied), the effective date is the earlier of:

> (i) . . . the date of a **CMS-approved accreditation organization program's** positive accreditation decision, issued after the accreditation organization has determined that the provider or supplier meets all applicable conditions.
>
> (ii) The date on which a provider . . . is found to meet all conditions of participation, . . . but has lower-level deficiencies, and—
>
> > (A) . . . **a CMS-approved accreditation organization program** issues a positive accreditation decision after it receives an acceptable plan of correction for the lower-level deficiencies; or
> >
> > (B) CMS receives an approvable waiver request . . . .

(Emphasis added.) The regulatory language highlighted above thus limits the types of AO accreditation determinations that may serve as the basis for a provider to be deemed in compliance with the conditions of participation to accreditations that are based on CMS-approved programs rather than to all activities or types of accreditations that an AO may offer. *Cf. Oak Lawn Endoscopy*, DAB No. 1952 (2004) (concluding CMS reasonably interpreted similar language in section 498.13(d)(1) (2003) as limiting the applicability of deemed status determinations to approved programs).

Accordingly, while subsection (a)(1)(A) of section 1865 uses the compulsory term "shall" to direct the Secretary to treat a hospital accredited by an AO as meeting the conditions of participation, the language of section 1865 as a whole, consistent with the regulations, limits the applicability of deemed status treatment to providers whose accreditations are supported by surveys conducted in accordance with CMS-approved programs. Moreover, neither section 1865 nor any other section of the Act or regulations

precludes CMS from questioning or verifying whether a survey was conducted under an AO's approved program. Nor does section 1865 preclude the AO itself from concluding that its survey did not follow the approved standards and procedures, undertaking a subsequent survey conforming to its approved program, or revising an accreditation determination to meet the requirements of the Act and regulations.

B. *Wesley was required to undergo an initial survey before entering into a Medicare provider agreement.*

Wesley further argues that CMS exceeded its authority in requiring DNV to treat Wesley as a prospective provider and to conduct an initial, full survey of the hospital because Wesley chose not to accept assignment of the prior owner's provider agreement. RR at 15-16, n. 6, (citing 5 U.S.C. § 706(2) (providing that an agency action should be set aside if it is arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law)). According to Wesley, no statute or regulation imposes the requirement that a new owner that refuses to accept assignment of the seller's provider agreement must undergo a full, initial survey. Wesley acknowledges that the October 17, 2008 CMS survey and certification memorandum cited by CMS and the ALJ states that "if a new owner refuses to accept assignment of the Medicare provider number and does not accept any pre-existing liability then the new owner is treated as a new applicant to the Medicare program." RR at 16, n. 6, (citing S&C-09-08, "Accreditation and its Impact on Various Survey and Certification Scenarios," § VII-1.)[3] Wesley argues, however, that the memorandum "is sub-regulatory guidance that does not interpret a statute or regulation," nor does it "presumptively flow from" 42 C.F.R. § 489.18, the regulation addressing the effect of a change in provider ownership. *Id.*

Wesley's arguments ignore provisions in the Act and regulations governing Medicare provider participation, multiple federal court decisions analyzing the consequences of a buyer's refusal to accept assignment of a seller's provider agreement, and Board precedent. Section 1866 of the Act states that with certain exceptions not applicable here, "[a]ny provider of services . . . shall be qualified to participate under this title and shall be eligible for payments under this title if it files with the Secretary an agreement" meeting the terms specified under the Act. Thus, a hospital cannot participate in Medicare unless it has in effect a valid provider agreement with CMS. Part 489 of the regulations, "Provider Agreements and Supplier Approval," implements section 1866 and the statutory provisions for the Secretary to use state survey agencies and CMS-approved accreditation programs to ascertain whether a provider meets the applicable conditions of

[3] S&C-09-08 is available at http://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/SurveyCertificationGenInfo/Downloads/SCLetter09-08.pdf. The memorandum is addressed to state survey agency directors and is self-described as a "set of FAQs [that] has been prepared to provide comprehensive guidance on the interaction of a health care facility's accreditation by a CMS recognized AO 'deemed status' accreditation program and the various survey and certification actions that CMS may take with respect to that facility."

participation. 42 C.F.R. § 489.1; Act §§ 1864, 1865. The regulations "set[] forth the basic requirements for submittal and acceptance of a provider agreement . . and specif[y] the basic commitments and limitations that the provider must agree to as part of an agreement to provide services." 42 C.F.R. § 489.2.

Section 489.18(c) of the regulations provides that when a hospital changes ownership, "the existing provider agreement will automatically be assigned to the new owner." This "provision allows the new owner to bill Medicare for services provided by the acquired facility as soon as the acquisition takes effect." *Mission Hospital*, DAB No. 2459, at 6. Section 489.18(d) further provides that an "assigned agreement is subject to all applicable statutes and regulations and to the terms and conditions under which it was originally issued[.]" Consequently, the "new owner receives the assets and liabilities associated with that agreement or approval." 75 Fed. Reg. 50,042, 50,401 (Aug. 16, 2010*); see also Charter Behavioral Health Systems, LLC*, 45 Fed.Appx. 150, 151 n.1 (3rd Cir. 2002) ("If the new owner elects to take an assignment of the existing Medicare Provider Agreement, it receives an uninterrupted stream of Medicare payments but assumes successor liability for overpayments and civil monetary penalties asserted by the Government against the previous owner" (citing 42 C.F.R. § 489.18(d); *Deerbrook Pavilion, LLC v. Shalala*, 235 F.3d 1100, 1103-05 (8th Cir. 2000); *United States v. Vernon Home Health, Inc.*, 21 F.3d 693, 696 (5th Cir. 1994), *cert. denied*, 115 S.Ct. 575 (1994)).

Furthermore, the federal courts have recognized, the "assignee of a Provider Agreement is not required to prove that it meets the initial Medicare certification requirements." *Eagle Healthcare*, 969 F.Supp.2d at 39 (citing *Vernon*, 21 F.3d at 696). "This is because the new owner is merely stepping into the shoes of the prior owner—the healthcare facility remains the same." *Id.*

In contrast, when a buyer chooses to reject assignment of the seller's provider agreement, the seller's provider agreement is voluntarily terminated. 42 C.F.R. § 489.52. That is, having declined to assume the seller's outstanding Medicare liabilities, the buyer is unable to comply with the requirements in section 489.18 for assignment of a provider agreement. *Mission Hospital*, DAB No. 2459, at 6. Consequently, under section 1866 of the Act, the buyer is not "qualified to participate" or "eligible for payments" under Medicare because it does not have a provider agreement. The buyer is thus in the same position as any prospective provider and must "apply as a new applicant to participate in the Medicare program." *Vernon*, 21 F.3d at 695; *see also Eagle Healthcare*, 969 F.Supp.2d at 39 ("If . . . the new owner rejects the assignment, the prior owner's Provider Agreement terminates and the new owner must seek to enter the Medicare program as a new applicant."). "In this situation," CMS reiterated in an August 2010 *Federal Register* notice, "Medicare will not reimburse the provider . . . for services it provides before the date on which the provider or supplier qualifies as an initial applicant." 75 Fed. Reg. at 50,401. Moreover, CMS made clear, "new owners of existing providers . . . who do not accept the seller's existing Medicare provider agreement . . . and who intend to continue

Medicare participation are treated as new applicants to the Medicare program and must **submit to the same process** as any new provider . . . ." *Id.* at 50,404 (emphasis added); *see also Delta Health Group Inc., v. Leavitt*, 459 F. Supp. 2d 1207, 1210 (N.D. Fla. 2006) (a new owner that refuses assignment must "go through the initial certification process, enter into a new provider agreement, and, if authorized, obtain a new provider number.").

Applying the statutes and regulations governing provider agreements in the context of the accreditation and deeming process, CMS stated in S&C-09-08 that when a new owner does not assume the seller's provider agreement, and the seller participated in Medicare as an accredited, deemed provider, "the new owner is treated in the same way as any new applicant to the program." S&C-09-08, Att. A, VII-1.[4] CMS explained, "***for the new owner seeking Medicare participation via accredited deemed status, the AO must conduct a new survey of the entity, issue a new determination as to whether the facility satisfies all requirements for accreditation under the AO's Medicare deeming program, and make a new recommendation to CMS on certification of the facility via deemed status***." *Id.* (emphasis in original). The statement in the survey and certification letter thus is not a new substantive rule, as Wesley argues, but a description of the consequences of applying the statute and regulations governing provider agreements in circumstances involving a change in ownership of a provider that has participated in Medicare on the basis of deemed accredited status and a buyer's decision to reject assignment of the seller's provider agreement.

Furthermore, Wesley cannot complain that it did not have timely actual notice that as a consequence of its decision to reject the automatic assignment of the seller's Medicare provider agreement (of which Wesley gave advance notice), it would be required to undergo a full, initial survey to show that it satisfied all of the applicable conditions of participation. Most notably, the record includes copies of January 2012 e-mails from CMS plainly advising Wesley that as a consequence of its decision to reject assignment of the prior owner's provider agreement, "the deeming organization" would have to "conduct [an] initial survey," the survey could not occur "until the new hospital is licensed by the state, the CMS-855 [enrollment application] has been approved by the [Medicare Administrative Contractor], and a sufficient number of patients [had] been treated at the new hospital and [were] present in the hospital to demonstrate the new hospital's compliance with Federal hospital regulations." CMS Ex. 1, at 2 (January 19, 2012 e-mail from D.F., CMS/CQISCO to S.B., HCA Division Director, Reimbursement); *see also* CMS Ex. 1, at 1 (January 23, 2012 e-mail from D.F. to S.B.: "I want to continue

[4] Evidence in the record indicates that the seller of Galichia Heart Hospital participated in Medicare as an accredited, deemed provider before Wesley acquired the facility. CMS Ex. 5, at 1 (January 26, 2012 DNV e-mail attaching 2011 survey agenda and NIAHO approval of Galichia Heart Hospital).

to remind you that the DNV survey cannot take place before the date on which Wesley formally assumes responsibility for [the facility] and the staff at the new hospital has taken care of a sufficient number of patients to demonstrate its ability to meet Federal hospital regulations."). Wesley does not deny that it received these notifications.

Accordingly, we conclude that Wesley was required to undergo an initial hospital survey in order to participate in the Medicare program because it chose not to accept assignment of the seller's provider agreement. We further conclude that Wesley had timely actual notice of this requirement.

C. *Remand is necessary for further development of the record to determine Wesley's effective date of participation.*

As explained above, the determination of a hospital's effective date of Medicare participation is controlled by section 489.13 of the regulations. When a hospital is surveyed by an AO and the AO finds that the hospital meets all conditions of participation but has lower-level deficiencies (and no other federal requirements remain to be satisfied), the effective date of the hospital's provider agreement is the date "the CMS-approved accreditation organization program issues a positive accreditation decision after it receives an acceptable plan of correction for the lower-level deficiencies." 42 C.F.R. § 489.13(c)(2)(ii)(A).

Here, DNV conducted surveys of Wesley on February 1, 2012 and on April 17-19, 2012, both of which found the hospital as meeting the conditions of participation but having lower-level deficiencies. CMS Exs. 2, 4, 6; P. Exs. 1, 2, 6. The record further shows that Wesley submitted corrective action plans responding to both surveys and that DNV issued three different positive accreditation notices to Wesley: a March 28, 2012 notice of accreditation effective February 1, 2012; an April 4, 2012 notice of accreditation effective February 17, 2012; and a May 2, 2012 notice advising Wesley that its date of accreditation was April 20, 2012. CMS Ex. 2; P. Exs. 2, 4, 5, 6; Tr. at 4.

Because Wesley was required to undergo an initial hospital survey conforming to DNV's approved survey procedures before entering into a Medicare provider agreement, the following questions must be resolved in order to determine which positive accreditation decision controls Wesley's effective date of Medicare participation: 1) What were DNV's approved accreditation program standards and procedures for an initial hospital survey during the period at issue? 2) When did DNV first conduct an initial accreditation survey of Wesley conforming to DNV's approved program? 3) When did DNV receive an acceptable plan of correction for the lower-level deficiencies found during that survey? 4) When did DNV issue a positive accreditation decision after receiving that acceptable plan of correction?

On review of the evidence, we conclude that because the determinative issues were not clearly identified, the record has not been developed sufficiently to resolve these questions. Most notably, the record does not include a copy of DNV's CMS-approved accreditation program survey standards and procedures for the applicable period. At oral argument, counsel for Wesley acknowledged that the "relevant procedures are the DNV procedures that CMS approved back in 2008" but stated that Wesley did "not have and [was] not aware of the procedures that were submitted to and approved by CMS in 2008."[5] Tr. at 10, 44. Counsel for Wesley also stated that "the record contains not a scintilla of evidence or even an allegation that DNV failed to follow those CMS-approved procedures." *Id.* at 10. Wesley's counsel asserted that the "complaint CMS has advanced here about the process DNV used to perform its survey in February of 2012 stem[s] entirely from alleged departures from survey guidelines in the State Operations Manual for state survey agencies" and "[t]hose guidelines are not relevant here." *Id.* at 10.

Counsel for CMS stated with respect to DNV's approved survey procedures that he "was told there was an extensive amount [of material] submitted with . . . DNV's application for approval" as a deeming organization, but he did not have the materials or know if they are publicly available. *Id.* at 45. Counsel for CMS also stated that he had conducted research online and found on a DNV Website a current document titled "DNV Standard Interpretive Guidelines and Surveyor Guidance for Hospitals," but he was unaware of published, approved survey procedures for the applicable period. *Id.* at 43. After the oral argument, the Board confirmed that there was information online relating to DNV's deeming survey procedures and found that some information indicates that DNV's deeming survey procedures follow the SOM. *See, e.g.* NIAHO Accreditation Program Accreditation Process, Rev. 16, Effective 2012-08-09, at 3; NIAHO Accreditation Program Accreditation Process, Rev. 11, Effective 2008-10-23, at 3. [6] This information, however, is not available in the record of this appeal.

[5] The Board provided the parties advance written guidance for the oral argument describing the areas in which the Board sought further discussion. May 13, 2014 Guidance for Oral Argument. The Board noted that the regulations require an AO applying for deeming authority to provide CMS with a detailed description of the organization's survey process. *Id.* at 2. The Board advised the parties to address whether the record evidence shows whether DNV's February 1, 2012 survey was consistent with the survey procedures in its CMS-approved program and whether DNV publishes its CMS-approved survey procedures.

[6] http://cms.ipressroom.com.s3.amazonaws.com/107/files/20125/NIAHO_Accreditation_Process-DNV-Rev.16.pdf; http://www.mdahq.citymax.com/f/TAB_3__-_NIAHO_Accreditation_Process-DNV-Rev_11.pdf. In light of our decision to remand this appeal for further development of the record to include authentic evidence of DNV's CMS-approved survey standards and procedures, we do not take judicial notice of these documents.

In light of the lack of record evidence of DNV's approved accreditation program standards and survey procedures for the applicable period, including the protocols for an initial hospital survey, we conclude that remand is necessary for development of the record to include this evidence. With respect to Wesley's assertion that the procedures in the SOM are not relevant here, we note that CMS's September 2008 notice of its decision to approve DNV for recognition as a national accreditation program for hospitals explained that CMS compared DNV's survey process with the survey process in the SOM. 73 Fed. Reg. at 56,590. CMS stated that as a result of its evaluation, DNV modified multiple policies in its program to conform to provisions in the SOM.

Accordingly, on remand, the ALJ should develop the record to include evidence of DNV's CMS-approved accreditation program standards and survey procedures for the applicable period, including the protocols for an initial hospital survey. The ALJ should ascertain whether the approved program incorporates expressly or by reference any of the survey standards and procedures set forth in the SOM in order to determine the extent to which the SOM guidelines are relevant.

The ALJ should next evaluate the evidence relating to the February 1, 2012 survey to determine whether that survey was conducted in accordance with DNV's approved survey standards and procedures for an initial hospital survey. If the ALJ concludes that the February 1, 2012 survey conformed to DNV's approved survey standards and procedures, the ALJ should determine Wesley's effective date of participation based on the date on which DNV received an acceptable plan of correction for the lower-level deficiencies, pursuant to section 489.13(c)(2)(ii)(A). We note that CMS asserted below that assuming arguendo it "is bound by DNV's February 1, 2012 survey and associated findings," the hospital is entitled to an effective date of March 6, 2012 because that is the date on which DNV received an acceptable plan of correction for the lower-level deficiencies. CMS Pre-hearing Br. and Motion for Summary Judgment at 11-12, (citing CMS Ex. 2, pp. 3, 9, 11, 13).

In the event that the ALJ determines that the evidence of the February 1, 2012 survey shows that survey did not conform to DNV's approved initial hospital survey standards and procedures, the ALJ should review the evidence of the April 2012 survey to determine whether the later survey was conducted in accordance with DNV's approved standards and procedures for an initial hospital survey. If the ALJ concludes that the April 2012 survey conformed to DNV's approved protocols, the ALJ should determine the effective date of Wesley's participation based on the date on which DNV received an acceptable plan of correction for the lower-level deficiencies associated with that survey. We note that while the parties have represented that Wesley received a letter from DNV dated April 20, 2012 stating that Wesley's accreditation date is April 20, 2012, neither party included a copy of that letter in its exhibits. Because the letter may illuminate

whether the two surveys conformed to DNV's approved procedures, when DNV received acceptable plans of correction relating to the surveys, and DNV's own characterization of the April 20, 2012 accreditation decision, the ALJ should order Wesley to submit a copy of the letter into the record evidence.

VI. Conclusion

For the reasons discussed above, we remand this matter to the ALJ for further development of the record and application of the controlling statutes and regulations consistent with our instructions above.

/s/
Judith A. Ballard

/s/
Constance B. Tobias

/s/
Leslie A. Sussan
Presiding Board Member