Department of Health and Human Services

DEPARTMENTAL APPEALS BOARD

Civil Remedies Division

Wesley Medical Center, LLC, d/b/a Galichia Heart Hospital
(CCN: 170202),

Petitioner,

v.

Centers for Medicare & Medicaid Services.

Docket No. C-14-1789

Decision No. CR4772

Date: January 17, 2017

DECISION

In this case, I earlier ruled that the Centers for Medicare & Medicaid Services (CMS) properly determined the Petitioner hospital's effective date for participating in the Medicare program. *Wesley Medical Center, LLC, d/b/a Galichia Heart Hospital*, DAB CR3033 (2013). The case is back before me on remand from the Departmental Appeals Board to "develop evidence" and determine whether the two surveys (February and April 2012) conducted by the hospital's accrediting agency complied with CMS-approved standards and procedures. *Wesley Medical Center, LLC, d/b/a Galichia Heart Hospital*, DAB No. 2580 (2014).

For the reasons set forth below, I find that CMS properly determined the April 20, 2012 effective date for Petitioner's Medicare enrollment.

Background[1]

[1] On remand the parties submitted supplemental briefs addressing the jurisdictional issues and the adequacy of the February survey. In addition to the documents submitted

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Under the Medicare statute, a hospital is defined as an institution that is primarily engaged in providing diagnostic, therapeutic, and rehabilitation services to inpatients, under the supervision of physicians, and meets other specified requirements. Social Security Act (Act) § 1861(e). It may participate in the Medicare program as a provider of services if it meets the statutory definition and complies with regulatory requirements. Act § 1866; 42 C.F.R. §§ 488.3(a); 489.10(a); *see* 42 C.F.R. Part 482.

To determine whether prospective providers qualify for Medicare certification, CMS authorizes certain accreditation organizations to survey and accredit the applicants and recommend Medicare certification. Institutions accredited by approved accreditation bodies are generally "deemed" to comply with Medicare requirements. Act § 1865; 42 C.F.R. § 488.5. However, if CMS finds that the prospective provider has significant deficiencies, it will be deemed not to comply. Act § 1865(c). Ultimately, CMS makes that call, and its decision to reject the accreditation body's survey and recommendations based on that survey is not reviewable. *See* 42 C.F.R. § 498.3, and discussion, below.[2]

Here, prior to February 1, 2012, Wesley Medical Center, LLC, d/b/a Galichia Heart Hospital, was a Medicare-certified acute care hospital, located in Wichita, Kansas. On February 1, 2012, it acquired the assets of Galichia Heart Hospital, also located in Wichita. Prior to this change of ownership, Galichia had been a Medicare-certified provider; however, Petitioner did not accept assignment of Galichia's provider agreement. It therefore acquired a non-certified entity, which would be treated like any new applicant to the program. CMS Survey & Certification Letter 09-08 (October 17, 2008), *available at* https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/SurveyCertificationGenInfo/downloads/SCLetter09-08.pdf (last accessed January 11, 2017); *Wesley*, DAB No. 2580 at 9-12.

Det Norske Veritas Healthcare (DNV Healthcare) is a national accrediting organization, approved by CMS to accredit prospective providers and recommend Medicare certification. Petitioner contracted with DNV Healthcare to survey the hospital. On February 1, 2012, a three-person survey team visited the facility and conducted a one-day

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earlier (CMS Exs. 1-12; P. Exs. 1-10), CMS submitted 14 supplemental exhibits (CMS Supp. Exs. 1-14) and Petitioner submitted one supplemental exhibit (P. Supp. Ex. 1).

[2] Whether a prospective provider qualifies as a provider is, of course, reviewable (42 C.F.R. § 498.3(b)(1), but that issue is separate from CMS's administrative determination as to the adequacy of the deeming body's survey performance.

(8:30 a.m. to 4:30 p.m.) accreditation survey. CMS Ex. 4. In a letter dated March 28, 2012, DNV Healthcare told Petitioner that it would recommend certification, effective February 1, 2012. CMS Ex. 2 at 1; P. Ex. 4. However, because the surveyors cited deficiencies that had to be corrected, DNV Healthcare subsequently changed the recommended effective date to February 17, 2012, the date the hospital submitted an acceptable plan of correction. P. Exs. 2, 3, 5.

Thereafter, however, CMS determined that DNV Healthcare had conducted an inadequate survey, and, by letter dated April 16, 2012, Captain Cindy R. Melanson, the health evaluation officer for CMS's Office of Clinical Standards and Quality, advised the accrediting organization that its survey did not comply with CMS requirements for a full, standard survey. CMS Ex. 8 at 4 (Melanson Decl. ¶ 6). DNV Healthcare agreed to conduct promptly a more adequate survey. CMS Ex. 8 at 4 (Menlanson Decl. ¶ 7).

Surveyors from DNV Healthcare returned to the hospital and, from April 17 through 19, 2012, conducted another survey, again finding deficiencies. The hospital submitted a written plan of correction, which DNV Healthcare accepted on April 20, 2012. P. Ex. 6. By letter dated May 11, 2012, CMS advised Petitioner that, based on the survey findings and the hospital's acceptable plan of correction, the hospital met the applicable requirements for Medicare participation, effective April 20, 2012. P. Ex. 7.

Discussion

1. ***No statutory provision or regulation authorizes me to review CMS's refusal to accept as adequate DNV Healthcare's February 1, 2012 survey.***[3]

In my earlier decision, I held that I had no authority to review CMS's refusal to accept as adequate the February 1, 2012 survey. *Wesley*, DAB CR3033 at 5. As I explained, a provider's hearing rights are established by federal regulations: 42 C.F.R. Part 498. A provider dissatisfied with an initial determination is entitled to further review, but administrative actions that are not initial determinations are not subject to appeal. 42 C.F.R. § 498.3(a); *Fla. Health Scis. Ctr., Inc., d/b/a/ Tampa Gen. Hosp.*, DAB No. 2263 at 4-5 (2009). The regulations specify which actions are "initial determinations" and set forth examples of actions that are not. Insisting that an accrediting organization's survey comply with minimal federal requirements, as CMS did here, is not an initial determination under 42 C.F.R. § 498.3(b) and therefore not reviewable. *Wesley*, DAB CR3033 at 4-5. Thus, no statutory provision or regulation gives me the authority to

[3] My findings of fact/conclusions of law are set forth, in italics and bold font, in the discussion captions of this decision.

review CMS's refusal to accept as adequate an accrediting organization's survey, and, in reviewing my earlier decision, the Board did not cite to any such authority nor even suggest that it exists (which it does not).

Indeed, in an opinion issued shortly after I issued my earlier decision in this case, the Board addressed a similar question and reached the same result. *Apollo Behavioral Health Hosp.*, LLC, DAB No. 2561 (2014). There, an accrediting organization surveyed the applicant psychiatric hospital, found some deficiencies, and recommended certification. Although poised to enroll the hospital based on that recommendation, CMS ultimately declined to do so. Instead, it directed the state survey agency to conduct a validation survey (as opposed to allowing the accrediting organization to conduct the new survey, as CMS did here). Based on the state survey findings, CMS denied enrollment. Following a second accrediting organization survey, CMS eventually allowed the hospital to enroll in the Medicare program, but with an effective date that was much later than that originally recommended by the accrediting organization. As here, the hospital challenged CMS's actions and argued that it was entitled to an effective date based on the first survey. The Board disagreed and held that CMS's decision to reject the accrediting organization's recommendation – ordering a new survey instead – is not reviewable. *Id.* at 5-6.

2. DNV Healthcare's February survey did not comply with CMS-approved standards.

In any event, review of the parties' submissions confirms that, in February 2012, DNV Healthcare did not conduct a full standard survey as required. CMS approved DNV Healthcare to survey hospitals following the "National Integrated Accreditation for Healthcare Organizations" accreditation program. CMS Supp. Ex. 1. The program explicitly incorporates the provisions of CMS's State Operations Manual into its survey policies and procedures. CMS Supp. Ex. 1 at 3.

Among the reasons DNV Healthcare's February survey did not comply with CMS-approved standards are the following, any one of which would justify CMS's rejecting the survey:

- DNV Healthcare's three-person survey team conducted a survey that lasted only one day. CMS Ex. 4; CMS Ex. 8 at 3 (Melanson Decl. ¶ 5i); P. Ex. 1. The State Operations Manual and DNV Healthcare's CMS-approved survey protocol provide that a full survey of a mid-size hospital (which Petitioner is) would require two to four surveyors spending *three or more days* at the facility. CMS Supp. Ex. 1 at 6; SOM, Appendix A - Survey Protocol at 5 (Rev. 37, eff. 10/17/08), *available at* https://www.cms.gov/manuals/Downloads/som107ap_a_hospitals.pdf (last accessed January 11, 2017); *compare* P. Ex. 1 (survey team schedule,

showing what the team *actually* looked at) *with* CMS Supp. Ex. 6 (accrediting organizations survey form, showing what the team was *supposed* to look at).

- The survey team reviewed no more than 14 medical records; the State Operations Manual requires the team to review a minimum of 30. CMS Ex. 8 at 3 (Melanson Decl. ¶ 5ii), citing CMS Ex. 2 at 2-19;[4] *see* P. Supp. Resp. Br. at 4; SOM, Appendix A - Survey Protocol at 11-12 (Rev. 37, eff. 10/17/08), *available at* https://www.cms.gov/manuals/Downloads/som107ap_a_hospitals.pdf (last accessed January 11, 2017).

  In this regard, the survey team schedule allots just one hour, from 11:00 a.m. to noon, for the registered nurse, the sole-surveyor assigned to review medical records, to review all medical records. CMS Ex. 4 at 1. But the CMS-approved protocol calls for three to six hours for document review. CMS Supp. Ex. 1 at 4. As Captain Melanson reasonably observed, one hour is insufficient for adequate review of the required number of records. CMS Ex. 8 at 3 (Melanson Decl. ¶ 5ii).

- The hospital must have served enough patients to establish that it meets all Medicare participation requirements. The survey team went out on the first day the new owner operated the facility, too soon to evaluate its compliance. CMS Ex. 8 at 3-4 (Melanson Decl. ¶ 5iii); *see, e.g.*, CMS Ex. 2 at 2 ("Currently they are working toward updating all policies"); CMS Ex. 2 at 4 ("there is not enough data at this point to analyze and report to the [Quality Management System]"; CMS Ex. 2 at 6 ("the organization has begun implementation of use of specific performance data for comparison and as part of the reappointment process. However, this process has just begun and is not fully implemented").

- Finally, according to the CMS-approved survey protocol, the survey team must survey "all departments, services, and locations" that are considered part of the organization. CMS Supp. Ex. 1 at 5. Yet, DNV Healthcare explicitly instructed its survey team to "[r]emember that your review will encompass only a **sampling** of the organization, do not feel compelled to visit all areas of the hospital." CMS Ex. 5 at 1.

[4] CMS Ex. 2 is DNV Healthcare's form listing "nonconformity notes" and the hospital's corrective action plan. Although the parties agree that the surveyors looked at 14 medical records, I could not determine where this number came from. The nonconformity notes refer to the surveyors reviewing just 4 (CMS Ex. 2 at 14, 16) or 5 charts (CMS Ex. 2 at 12).

3. ***CMS accepted as adequate DNV Healthcare's April survey and Petitioner does not challenge that determination, which is therefore final.***

4. ***CMS properly determined the April 20, 2012 effective date for Petitioner's Medicare enrollment, because the undisputed evidence establishes that the hospital failed to meet program requirements prior to that date.***

For the reasons sets forth in my earlier decision, which I incorporate herein, I conclude that April 20, 2012 is the earliest possible effective date for Petitioner's participation in the Medicare program.

Conclusion

CMS properly determined the April 20, 2012 effective date for Petitioner's Medicare enrollment.

/c/
Carolyn Cozad Hughes
Administrative Law Judge