Department of Health and Human Services

DEPARTMENTAL APPEALS BOARD

Civil Remedies Division

Michigan Neurology Associates, P.C.,
(NPI: 1581824725),

Petitioner,

v.

Centers for Medicare & Medicaid Services.

Docket No. C-14-1820

Decision Number. CR3704

Date: March 10, 2015

DECISION

The Centers for Medicare & Medicaid Services (CMS) denied Petitioner enrollment in the Medicare program as an ambulatory surgical center (ASC) based on a survey that the Accreditation Association for Ambulatory Health Care (AAAHC) conducted on November 25 and 26, 2013. The AAAHC survey found Petitioner out of compliance with Medicare participation requirements. CMS concluded that the noncompliance was serious enough to constitute noncompliance with four Medicare conditions for coverage, and therefore CMS was "not required to, and in fact could not, allow enrollment . . . ." CMS Brief (Br.) at 1.

Petitioner appealed CMS's denial of enrollment. Petitioner does not dispute whether it was noncompliant at the time of the AAAHC survey. Petitioner's position is that CMS's denial of its enrollment is "incorrect and/or unlawful" because by the time it applied for enrollment, AAAHC had accepted Petitioner's plan of correction (POC) and accompanying proof of correction, determined that Petitioner did not need to be re-surveyed, accredited Petitioner for a three-year period, and recommended Petitioner be enrolled in Medicare. Thus, Petitioner argues it should be enrolled in Medicare based on

AAAHC's ultimate findings of compliance and subsequent recommendation for accreditation.

CMS moved for summary judgment to affirm the denial of Petitioner's enrollment. For the reasons set forth below, I grant CMS's motion for summary judgment because, as a matter of law, once CMS properly determined that Petitioner was out of compliance with conditions for coverage, CMS was not obligated to enroll Petitioner based on AAAHC's acceptance of Petitioner's POC and accreditation recommendation.

I. Background

Petitioner sought to participate in Medicare Part B as an ASC. Petitioner applied for a survey and accreditation through AAAHC, a national accrediting organization that CMS recognizes as having deeming status to determine compliance with Medicare requirements pursuant to 42 C.F.R. § 488.6. AAAHC conducted a survey of Petitioner on November 25 and 26, 2013. On December 16, 2013, AAAHC notified Petitioner that it discovered four "standard" level deficiencies. AAAHC requested that Petitioner submit a POC. Petitioner did so and, after some revision and supplementation, AAAHC accepted the POC. AAAHC declined to re-survey Petitioner, and it instead accepted Petitioner's POC and proof of corrections. By letter dated January 21, 2014, AAAHC issued full accreditation to Petitioner and recommended that CMS enroll Petitioner in Medicare. Petitioner then attempted to enroll in Medicare as an ASC based on its achievement of full accreditation through AAAHC. CMS Exs. 1, 3.

On June 12, 2014, CMS denied Petitioner enrollment, alleging that Petitioner did not meet Medicare participation requirements. CMS stated that based on AAAHC's November 25 and 26, 2013 survey, Petitioner was noncompliant not only with Medicare standards but also with Medicare conditions for coverage found at 42 C.F.R. §§ 416.43 (Quality Assessment and Performance Improvement), 416.44 (Environment), 416.45 (Medical Staff), and 416.47 (Medical Records). CMS stated Petitioner might "take steps to correct the deficiencies and reapply to establish eligibility." However, CMS also explained to Petitioner that "current survey funding levels (as appropriated by Congress) may not allow for a resurvey. CMS' priority for use of the limited funds available [is] to ensure the health and safety of Medicare beneficiaries at currently participating facilities. Contact the State agency for the status of initial surveys of non-participating facilities." CMS Ex. 2.

Petitioner requested reconsideration on June 22, 2014. On August 7, 2014, CMS affirmed its denial of Petitioner's enrollment. CMS acknowledged that AAAHC "recommended [Petitioner's] facility be deemed to participate as an ASC . . . ." However, CMS stated that its review of the results of the November 25 and 26, 2013 AAAHC survey showed CMS that Petitioner "was not in compliance with several of the Medicare Conditions for Coverage at the time of the survey." CMS stated that Petitioner

could "take steps to correct the deficiencies and reapply to establish eligibility." However, CMS noted, as it did in its initial denial on June 12, 2014, that survey funding levels might not allow for a resurvey. CMS Ex. 4.

Petitioner requested a hearing on August 25, 2014. Petitioner argued specifically that "***at the time of enrollment,*** Petitioner was in compliance with all Conditions for Coverage, irrespective of the fact that ***at the time of the survey,*** it may not have been." Petitioner's hearing request (H.R.) (emphasis in original). The case was assigned to me for hearing and decision, and I issued an Acknowledgment and Pre-Hearing Order (Order) on September 15, 2014, setting a schedule for the parties to file pre-hearing exchanges. CMS filed a motion for summary judgment, pre-hearing brief, and seven exhibits (CMS Exs. 1 – 7). Petitioner filed a response to CMS's motion and pre-hearing brief (P. Br.), accompanied by 23 exhibits (P. Exs. 1 – 23), including the written direct testimony of three witnesses. Petitioner does not object to the exhibits CMS filed, and I admit CMS Exs. 1 – 7.

On December 2, 2014, CMS filed objections to Petitioner's exhibits. Specifically, pursuant to 42 C.F.R. § 498.56(e), CMS objects to P. Exs. 8 through 16. CMS asserts that Petitioner neither identified the evidence as new nor made the showing of good cause to admit the documents required by paragraph 6 of my September 15, 2014 Order. CMS asserts these documents "appear to be undated, unsigned draft policies and related documents, which Petitioner's witnesses have not identified or explained . . . [t]hus . . . they have little or no evidentiary value." Petitioner has not responded to CMS's objection to explain why there is good cause for the submission of these documents at this level of review. At most, it appears the documents may relate to Petitioner's accomplishment of its POC, but whether or not Petitioner accomplished its POC is not relevant to my decision. Accordingly, I do not admit P. Exs. 8 through 16, although they remain in the case record.

CMS also objects to certain paragraphs in the written direct testimony of two of Petitioner's witnesses.[1] With regard to the written direct testimony of R.V. (P. Ex. 19), CMS objects to paragraphs 17 and 21, asserting that whether Petitioner was in compliance with regulatory requirements at any time is a legal conclusion. CMS also objects to paragraph 22 on relevance grounds because it contains anonymous hearsay. I will admit R.V.'s testimony in its entirety and will consider CMS's arguments as to the weight I should assign to R.V.'s testimony rather than the admissibility of P. Ex. 19. With regard to the written direct testimony of J.C. (P. Ex. 21),[2] CMS objects to paragraphs 17 and 21 on the basis that whether Petitioner was in compliance with regulatory requirements at any given time is a legal conclusion. CMS also objects to

[1] I refer to witnesses by their initials.

[2] CMS references J.C.'s written direct testimony as P. Ex. 20, but it is actually P. Ex. 21.

paragraph 23 on relevance grounds and because it contains anonymous hearsay. For the same reasons I admit P. Ex. 19 in its entirety, I will also admit P. Ex. 21.

Finally, Petitioner objects to P. Exs. 1 – 7 and 17 and 18, asserting they are already included in CMS's exhibits, their admission is not in the interest of judicial economy, and that rejecting them will prevent confusion. CMS notes that highlighting has been added to some of the pages of Petitioner's exhibits. Although the exhibits may be duplicates, they are relevant to the case, and I admit them. However, where there are duplicate exhibits I refer only to CMS's exhibits. In sum, I admit P. Exs. 1 through 7 and 17 through 23. I reject P. Exs. 8 through 16, although they will remain in the electronic record of the case.

II. Issue

Whether the undisputed evidence establishes that CMS had a legitimate basis to deny Petitioner enrollment in Medicare as an ASC, despite the undisputed fact that AAAHC determined that Petitioner had corrected all its deficiencies of Medicare requirements at the time it applied to enroll in the program.

III. Findings of Fact and Conclusions of Law.

A. This case is appropriate for summary judgment.

The applicable standard for summary judgment is as follows:

> Summary judgment is appropriate when the record 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. . . . The party moving for summary judgment bears the initial burden of showing that there are no genuine issues of material fact for trial and that it is entitled to judgment as a matter of law . . . . 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. . . . In determining whether there are genuine issues of material fact for trial, the reviewer must view the evidence in the light most favorable to the non-moving party, drawing all reasonable inferences in that party's favor.

Senior Rehab. & Skilled Nursing Ctr., DAB No. 2300, at 3 (2010) (citations omitted). The role of an ALJ in deciding a summary judgment motion differs from the ALJ's role in resolving a case after a hearing. The ALJ should not assess credibility or evaluate the

weight of conflicting evidence. *Holy Cross Vill. at Notre Dame,* DAB No. 2291, at 4-5 (2009).

CMS argues that summary judgment is appropriate because the "crux of the dispute is whether AAAHC accepting [Petitioner's] POC and accrediting it means that CMS must approve its enrollment, even if CMS finds that the accreditation survey showed condition-level noncompliance." CMS Br. at 6. CMS notes that Petitioner did not challenge the factual accuracy of the survey findings or present evidence casting doubt on them. CMS further argues that even if I determine to rule on whether the survey findings rise to condition-level noncompliance, the case is still appropriate for summary judgment because the "undisputed evidence consisting of the AAAHC survey report (CMS Ex. 1) supports CMS's finding of condition-level deficiencies." CMS Br. at 6.

While Petitioner asserts that the issues raised in its request for hearing are not strictly legal issues, it argues that as of the date it applied for enrollment it had corrected the deficiencies that AAAHC found. It states that Petitioner immediately addressed all the deficiencies cited and corrected them by January 6, 2014. P. Br. at 1, 9. Petitioner acknowledges that CMS has the "ultimate authority to determine a supplier's satisfaction of conditions of coverage." Petitioner argues, however, that CMS's decision must be more than arbitrary. CMS should not be able to "willfully" ignore relevant information and facts related to the survey, such as the "plan of correction and proof of corrections accomplished by Petitioner, and acknowledged by the AAAHC." P. Br. at 9. However, even if I accept that Petitioner corrected all of its deficiencies that AAAHC identified as of the date Petitioner applied for enrollment, by law I must still affirm CMS's denial of its enrollment.[3]

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[3] It appears from the June 12, 2014 letter CMS sent to Petitioner denying it Medicare enrollment that Petitioner must now apply to the state agency for enrollment and undergo an initial survey. It also appears that given "current funding levels" CMS may not be able to ensure Petitioner a "resurvey." CMS's August 7, 2014 reconsideration determination echoes this statement. CMS Exs. 2, 4. I recognize also that AAAHC, as Petitioner notes, "praised Petitioner's staff for 'assistance and diligence in complying with AAAHC and CMS Standards,'" which "reflect[ed] on the high quality of care and safety your organization provides to its patients and the community." P. Br. at 6, citing P. Ex. 7. I have no authority, however, to address that assessment or order that CMS have the state agency resurvey Petitioner.

B. CMS had a legitimate basis to deny Petitioner enrollment in Medicare.

1. Applicable Law

Section 1832(a)(2)(F) of the Social Security Act (Act) (42 U.S.C. § 1395k(a)(2)(F)) authorizes Medicare Part B coverage for ASC services provided to Medicare beneficiaries. An ASC is a supplier to Medicare. 42 C.F.R. §§ 488.1; 498.2. A prospective supplier must meet applicable Medicare requirements to be approved for participation. 42 C.F.R. § 488.3(a). For an ASC, Medicare "conditions for coverage" are the requirements the ASC must meet to participate in Medicare. 42 C.F.R. § 488.1. The conditions for coverage for ASCs are found at 42 C.F.R. Part 416. Each Medicare condition represents a broad category of services, which the regulations divide into subparts called standards. 42 C.F.R. Part 416, Supbart C. Noncompliance with a Medicare condition for coverage exists "where the deficiencies are of such character as to substantially limit the . . . supplier's capacity to furnish adequate care or which adversely affect the health and safety of patients." 42 C.F.R. § 488.24(b). Compliance with a particular condition for coverage is determined by "the manner and degree to which the . . . supplier satisfies the various standards within each condition." 42 C.F.R. § 488.26(b).

A prospective supplier found to have deficiencies during a survey is allowed to submit a POC only when CMS has determined that the deficiencies are at less than a condition level. 42 C.F.R. § 488.28. The regulation permits a prospective supplier to submit a POC only when it "is found to be deficient with respect to one or more of the standards in the conditions," and it may participate only when the identified deficiencies neither "jeopardize the health and safety of patients nor are of such character as to seriously limit the provider's capacity to render adequate care" and it has submitted an acceptable POC for achieving compliance "within a reasonable period of time acceptable to the Secretary." 42 C.F.R. § 488.28(a)-(b).

Section 1865 of the Act (42 U.S.C. § 1395bb) allows CMS to treat a prospective supplier as meeting the Medicare conditions for coverage applicable to it based on accreditation from a CMS-approved accreditation organization. Accreditation organizations have their own requirements apart from the regulatory requirements. However, the accreditation organization's requirements must be at least as stringent as those in the regulations. CMS may deem a supplier accredited by such an organization in compliance with the appropriate Medicare conditions for coverage. 42 C.F.R. §§ 416.26; 488.6(a).

Accreditation, however, does not mean that a prospective supplier is automatically enrolled in Medicare. Section 1865(c) of the Act (42 U.S.C. §1395bb(c)) states that "[n]otwithstanding any other provision of this title, if the Secretary finds that a provider entity [such as a supplier] has significant deficiencies (as defined in regulations pertaining to health and safety), the entity shall, after the date of notice . . . be deemed not to meet the conditions or requirements the entity has been treated as meeting pursuant to

subsection (a)(1)." The regulations provide further that CMS is not required to accept an accreditation organization's finding of compliance. "CMS ***may*** deem the . . . suppliers the program accredits to be in compliance with the appropriate Medicare conditions." 42 C.F.R. § 488.6(a) (emphasis added). The regulations also provide that "CMS may determine that a provider or supplier does not meet the Medicare conditions on the basis of its own investigation of the accreditation survey or any other information related to the survey." 42 C.F.R. § 488.6(c)(2). Such information (which a supplier must authorize its accreditation organization to release to CMS and the applicable state survey agency), would include "a copy of its most current accreditation survey, together with any information related to the survey that CMS may require (including corrective action plans)." 42 C.F.R. § 488.6(c)(1).

Regulations specific to ASCs provide that CMS may treat an ASC as meeting Medicare conditions for coverage either based on accreditation by an accreditation organization or based on a recommendation from a state survey agency. 42 C.F.R. § 416.26(a)-(b). Whether an accreditation organization or a state agency verifies an ASC's compliance with the conditions for coverage, however, CMS retains the decisional authority to enroll the ASC in Medicare; it reviews the resulting recommendations and other evidence relating to the survey before deciding to accept an ASC as qualified to furnish ambulatory surgical services. 42 C.F.R. § 416.26(c). There is no requirement that an additional survey of a prospective supplier be performed before CMS makes its decision.

If CMS refuses to enter into a Medicare participation agreement with a prospective ASC, the regulations provide hearing rights to the ASC, incorporating the hearing procedures at 42 C.F.R. Part 498. 42 C.F.R. §§ 416.26(f); 488.24(c).

2. CMS is not required to accept AAAHC's recommendation to enroll Petitioner in Medicare.

CMS may "deem" an ASC to be in compliance with any or all of the conditions for participation if the ASC is accredited by a national accrediting organization such as AAAHC. 42 C.F.R. § 416.26. CMS is not required to accept the recommendation of an accreditation organization such as AAAHC to enroll an ASC. As noted above, CMS may treat an ASC as meeting Medicare conditions for coverage based on a recommendation from an accreditation organization. However, CMS retains the decisional authority to enroll the ASC after reviewing the evidence relating to the accreditation agency's determination, including a copy of the most current accreditation survey, as well as information related to the survey, including any POCs. Act, section 1865(c) (42 U.S.C. § 1395bb(c)); 42 C.F.R. §§ 416.26(a)-(c); 488.6(c)(1), (2).

3. CMS has the authority to deny enrollment based on the presence of condition-level deficiencies.

If CMS finds that a supplier has "significant deficiencies," as defined in regulations pertaining to health and safety, CMS is entitled to deny enrollment to the supplier despite a recommendation by an accreditation organization. Act, section 1865(c); 42 C.F.R. § 488.6(a); *see* 42 C.F.R. § 488.26(b).

A prospective supplier found to have deficiencies during a survey is allowed to submit a POC *only* when CMS has determined that the deficiencies are at less than a condition level. 42 C.F.R. § 488.28. The supplier is allowed to submit a POC when "[t]he existing deficiencies noted either individually or in combination neither jeopardize the health and safety of patients nor are of such character as to seriously limit the provider's capacity to render adequate care." 42 C.F.R. § 488.28(b); *Apollo Behavioral Health Hosp., L.L.C.,* DAB No. 2561, at 8 (2014); *see Profound Health Care,* DAB No. 2371, at 8-10 (2011). Moreover, CMS's decision not to accept a provider's POC does not constitute an initial determination subject to review, even if a petitioner had an opportunity to correct. *Apollo,* DAB No. 2561, at 9 (and cases cited therein).

4. CMS properly determined that Petitioner had condition-level deficiencies at the time of its survey because AAAHC found undisputed deficiencies that either individually, or in combination, could jeopardize the health and safety of patients or were of such character as to seriously limit Petitioner's capacity to render adequate care.

Although AAAHC determined Petitioner was noncompliant only with standards of compliance during the November 25 and 26, 2013 survey, CMS determined instead that the deficiencies that AAAHC cited at 42 C.F.R. §§ 416.43, .44, .45, and .47 constituted noncompliance with conditions for coverage, in that they either individually or in combination jeopardized the health and safety of patients or were of such character as to seriously limit Petitioner's capacity to render adequate care.

CMS asserts that undisputed evidence from the AAAHC survey supports its finding that the noncompliance was at a condition level and that Petitioner was not allowed to file a POC. For instance, with respect to credentialing and record keeping, CMS notes that with regard to 42 C.F.R. § 416.45, the condition for coverage regarding "Medical Staff," AAAHC found Petitioner had a systemic problem with staff credentialing because it found no verification of education and training in its credentialing files; two of the three files reviewed had no peer references at the time of credentialing; Petitioner did not verify education and training or check Drug Enforcement Administration (DEA) registration at the time of credentialing; and DEA registrations that were on file were not verified for currency or validity. CMS Br. at 11-12; CMS Ex. 1, at 16, 17, 19, 22. CMS asserts that it is important for patient safety to ensure that members of an ASC's medical

staff are actually qualified to perform the procedures they are performing. CMS Br. at 12. Petitioner admits that it was noncompliant at the time of survey but asserts it corrected the noncompliance by the time it applied to enroll. P. Br. at 8. Even assuming for purposes of summary judgment that Petitioner later corrected its deficiencies, I find the undisputed evidence supports CMS's determination that Petitioner had condition-level deficiencies at the time of the survey because the nature of the cited deficiencies could jeopardize the health and safety of patients or were of such character as to seriously limit Petitioner's capacity to render adequate care.

CMS asserts that with regard to 42 C.F.R. § 416.47, the condition for coverage regarding "Medical Records" requiring an ASC to maintain complete, comprehensive, and accurate medical records to ensure adequate patient care, AAAHC found Petitioner out of compliance with two requirements because individual pages in medical records reviewed did not consistently contain identification and, in some places, the only identification in the record consisted of the patient's signature. Most records were found to have a sticker sheet in the record, but they were not consistently adhered to each page of the record. Some of the stickers had the date of service in the date of birth area. Further, when patients had allergies, there was no documentation of the "untoward effect of the allergen" in seven of 11 medical records. Medication dosages were not consistently documented in ten of 11 medical records. CMS Br. at 12; CMS Ex. 1, at 61-63. Petitioner admits that it had these deficiencies at the time of survey, but it argues that it addressed and corrected them. P. Br. at 8-9. Even assuming for purposes of summary judgment that Petitioner later corrected its deficiencies, I find the undisputed evidence supports CMS's determination that Petitioner had these condition-level deficiencies at the time of the survey because they could jeopardize the health and safety of patients or were of such character as to seriously limit Petitioner's capacity to render adequate care. For example, patients could suffer an allergic reaction jeopardizing their health and safety if Petitioner did not properly document their allergies.

CMS asserts that with regard to 42 C.F.R. § 416.44, the condition for coverage regarding "Environment," that AAAHC found several deficiencies. CMS notes that while AAAHC did not cite noncompliance with this section of the regulations, instead citing to noncompliance with its own standards, CMS determined the report lists numerous ways in which Petitioner failed to comply with applicable regulatory requirements. CMS Br. at 13-18. For instance, AAAHC found that humidity is supposed to be monitored to ensure that it is between 30-60%. However, AAAHC found numerous dates on the 2013 temperature humidity logs where the temperature and humidity were not being monitored in the pre-op and post-op areas. CMS Ex. 1, at 78-79, 87. CMS asserts this violated the regulation at 42 C.F.R. § 416.44(a), which requires an ASC to provide a functional and sanitary environment for the provision of surgical services including that each operating room be designed and equipped so that the types of surgery conducted can be performed in a manner that protects the lives and assures the physical safety of all individuals in the area. CMS Br. at 13. CMS also determined that AAAHC's survey found numerous

deficiencies related to 42 C.F.R. § 416.44(b), which references the provisions applicable to Ambulatory Health Care Centers of the 2000 edition of the Life Safety Code (LSC) of the National Fire Protection Association (NFPA). CMS found condition-level noncompliance justified because Petitioner's emergency power and lighting systems did not comply with NFPA requirements; Petitioner was out of compliance with NFPA requirements dealing with storage of oxygen; and Petitioner was also out of compliance with NFPA requirements related to the passage of smoke. CMS Br. at 13-18; CMS Ex. 1, at 89-101. Petitioner does not assert that it was in compliance, but asserts only that it corrected the noncompliance. P. Br. at 7-8. Even assuming for purposes of summary judgment that Petitioner later corrected its deficiencies, I find the undisputed evidence supports CMS's determination that Petitioner had these condition-level deficiencies at the time of the survey because lack of proper sanitation and fire prevention protections could jeopardize the health and safety of patients or were of such character as to seriously limit Petitioner's capacity to render adequate care.[4]

5. Petitioner was not entitled to review of its POC for CMS's enrollment considerations because the undisputed evidence establishes that Petitioner had condition-level deficiencies at the time of its survey.

A prospective supplier found to have deficiencies during a survey is allowed to submit a POC only when CMS has determined that the deficiencies are at less than a condition level, i.e., only where the identified deficiencies neither jeopardize the health and safety of patients nor are of such a character as to seriously limit the supplier's capacity to render adequate care. 42 C.F.R. § 488.28. The regulation does not differentiate between accreditation organization and state agency surveys. Thus, when CMS properly determined that the AAAHC survey showed condition-level noncompliance, CMS was not required to consider Petitioner's POC for enrollment purposes, even though AAAHC eventually accepted Petitioner's POC as demonstrating compliance with Medicare requirements.

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[4] CMS also asserts that with regard to 42 C.F.R. § 416.43, the condition for coverage governing quality assessment and performance improvement, AAAHC found deficiencies. I do not address them because the other deficiencies I address amply support CMS's finding that Petitioner was out of compliance with conditions for coverage at the time of the survey.

IV. Conclusion

I grant CMS's motion for summary judgment. CMS had a legitimate basis upon which to deny Petitioner enrollment because Petitioner had undisputed deficiencies after its survey, which constituted condition-level violations that necessarily precluded any requirement that CMS later enroll Petitioner in the Medicare program based on AAAHC's acceptance of Petitioner's POC.

/s/
Joseph Grow
Administrative Law Judge