Department of Health and Human Services

DEPARTMENTAL APPEALS BOARD

Civil Remedies Division

Digestive Disease Centers
(CCN: 29-C0001018),

Petitioner

v.

Centers for Medicare and Medicaid Services.

Docket No. C-09-69

Decision No. CR2216

Date: August 13, 2010

DECISION

I grant summary judgment in favor of the Centers for Medicare and Medicaid Services (CMS) and against Petitioner, Digestive Disease Centers. In doing so, I sustain CMS's determination to impose the remedy of terminating Petitioner's Medicare agreement effective September 26, 2008. Summary judgment is appropriate as no genuine issues of material fact are in dispute, and the controlling issues may be resolved as a matter of law.

I. Background

Petitioner is an ambulatory surgical center (ASC) located in Las Vegas, Nevada. On April 22, 2008, the Bureau of Health Care Quality and Compliance, Nevada Department of Health and Human Services (state survey agency) surveyed Petitioner's center to determine Petitioner's compliance with Medicare conditions for coverage for an ASC. The survey results found Petitioner not to be in compliance with several conditions for coverage.[1] By letter dated June 2, 2008, the state survey agency notified Petitioner (CMS Exhibit (Ex.) 3) and provided Petitioner with a copy of the Statement of Deficiencies.

[1] The conditions required for coverage which Petitioner was alleged to not be in compliance with during the April survey, and which Petitioner challenges in this appeal include: 42 C.F.R. § 416.41 (Governing body and management); 42 C.F.R. § 416.43 (Evaluation of quality); 42 C.F.R. § 416.44 (Environment); and 42 C.F.R. § 416.45 (Medical staff). CMS Exhibit (Ex.) 3; CMS Ex. 1.

CMS Ex. 1. The letter advised Petitioner that if it remained out of compliance with any Medicare condition for coverage, the state survey agency would recommend that CMS terminate Petitioner's participation in Medicare. The letter also provided Petitioner with the opportunity to submit a credible allegation of compliance, which could be verified through a resurvey of Petitioner's center. CMS Ex. 3. In response, Petitioner submitted a plan of correction on June 13, 2008. *Id.* A revisit survey of Petitioner's center was conducted on July 16, 2008 to verify Petitioner's allegation of compliance. The survey disclosed that Petitioner continued to be out of compliance with three of four conditions cited during the April 22 survey and was not in compliance with an additional condition.[2] By letter dated September 3, 2008, CMS notified Petitioner that its Medicare participation would be terminated on September 26, 2008.[3] CMS Ex. 7.

Petitioner timely requested a hearing before an administrative law judge (ALJ) by letter dated November 3, 2008, challenging the findings and remedies resulting from the two surveys of its center. The case was assigned to me on November 7, 2008 for a hearing, related proceedings, and a decision. A prehearing conference was convened with the parties on April 2, 2009, at which time this case was set for hearing in Las Vegas, Nevada for June 2009. A prehearing order was issued on April 6, 2009, directing the parties to file their prehearing exchanges and briefs.

The parties filed their prehearing exchanges, and, on June 8, 2009, CMS moved for summary judgment and a stay to further proceedings pending resolution of the motion for summary judgment.[4] By order issued June 17, 2009, I stayed the hearing date and issued a briefing schedule to the parties. The parties completed their briefing[5] and CMS's motion for summary judgment is now before me. For purposes of the record, I receive CMS Exs. 1 through 45 and P. Exs. 1 through 11. Although I may cite to some of these

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[2] The findings Petitioner challenges from the July 16, 2008 resurvey allege that Petitioner continued to remain out of compliance with 42 C.F.R. §§ 416.41, 416.43, and 416.44. In addition, Petitioner was also found to not be in compliance with an additional condition outlined at 42 C.F.R. § 416.48 (Pharmaceutical services). CMS Ex. 7; CMS Ex. 2.

[3] CMS subsequently revised its September 3, 2008 letter by notice letter dated September 8, 2008, deleting a finding related to Petitioner's loss of its business license. CMS Ex. 8.

[4] On May 1, 2009, CMS filed its exchange, which included CMS Exs. 1-45. On May 18, 2009, Petitioner filed objections to CMS's exhibits. On May 26, 2009, Petitioner filed its witness list. On June 8, 2009, CMS filed its motion for summary judgment, and, on June 15, 2009, Petitioner filed its pre-hearing brief accompanied by P. Exs. 1-11.

[5] On July 17, 2009, Petitioner filed its opposition to CMS's motion for summary judgment and its own limited countermotion for summary judgment with one attachment identified as the declaration of Petitioner's owner and medical director, Osama Haikal, M.D. (Dr. Haikal). CMS filed its reply on July 31, 2009, and Petitioner filed its reply on August 20, 2009.

exhibits in this decision to describe undisputed material facts, I do not make findings as to the exhibits' evidentiary weight. In issuing summary judgment, I rely on the undisputed material facts, and I make no evidentiary findings.

II. Applicable Law and Regulations

Title XVIII of the Social Security Act (Act) provides for payment of part, or all, of the cost of covered services furnished to eligible individuals by qualified providers of services and suppliers. Section 1832(a)(2)(F) of the Act authorizes Medicare Part B coverage for services that an ASC furnished in connection with surgical procedures, which the Secretary of Health and Human Services (Secretary) specifies, that meets health, safety, and other standards and which the ASC has an agreement with the Secretary to participate and accept payment as an ASC. The Secretary has issued regulations at 42 C.F.R. Part 416, subpart C, which set forth Medicare conditions for an ASC's participation in Medicare by establishing general conditions for coverage at 42 C.F.R. §§ 416.40 through 416.52[6]

CMS can terminate an ASC's enrollment in Medicare as a supplier, if CMS determines that the ASC no longer meets the conditions for coverage as specified under 42 C.F.R. § 416.26. To effectuate a termination, CMS is only required to provide the ASC with notice of at least 15 days before the effective date of termination. 42 C.F.R. § 416.35(b); (b)(2).

An ASC is entitled to a hearing before an ALJ to contest the termination of its agreement. The regulations pertaining to an ASC's participation in Medicare incorporate by reference the hearing procedures of the request for review provisions in 42 C.F.R. Part 498, subparts D and E, and provide for hearing by an ALJ and review by the Departmental Appeals Board (Board). 42 C.F.R. § 416.35(b)(3).

III. Issues

The three issues before me are:

1. Whether summary judgment is appropriate;

2. Whether Petitioner failed to comply with one or more Medicare conditions for coverage for ASCs; and, if so,

3. Whether the termination remedy that CMS imposed was reasonable.

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[6] Subpart C of 42 C.F.R. Part 416 was amended effective May 18, 2009. 73 *Fed. Reg.* 68,502, 68,811 (Nov. 18, 2008). My citations are to the regulations that were in effect at the time of the surveys in April and July 2008.

IV. Discussion

A. Summary judgment is appropriate in this case, because no disputed issues of material fact exist.

An ALJ may decide a case on summary judgment, without an evidentiary hearing, when either the case presents no genuine issue of material fact and the only questions that must be decided involve application of law to the undisputed facts, or the moving party must prevail as a matter of law even if all disputed facts are resolved in favor of the party against whom the motion is made. *Livingston Care Ctr. v. Dep't. of Health & Human Servs.*, 388 F.3d 168, 173 (6th Cir. 2004).

The Board has long recognized the availability of summary judgment, and the Sixth Circuit has recognized the Board's interpretative rule. *Crestview Parke Care Ctr. v. Thompson*, 373 F.3d 743, 750 (6th Cir. 2004). A party opposing summary judgment must allege facts, which, if true, would refute the facts that the moving party relied on. *See, e.g.*, FED. R. CIV.P. 56(c); *Vandalia Park*, DAB No. 1939 (2004); *Lebanon Nursing and Rehab. Ctr.*, DAB No. 1918 (2004). To defeat an adequately supported summary judgment motion, the non-moving party may not rely on the denials in its pleadings or briefs; rather, it 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. *Matsushita Elec. Indus. Co. v. Zenith Radio Corp.*, 475 U.S. 574, 586 n.11 (1986);

In deciding a summary judgment motion, an ALJ may not make credibility determinations or weigh conflicting evidence but, instead, must view the entire record in the light most favorable to the non-moving party. Moreover, all reasonable inferences must be drawn in that party's favor. *Innsbruck HealthCare Ctr.*, DAB No. 1948 (2004); *Madison Health Care, Inc*., DAB No. 1927 (2004).

CMS has moved for summary judgment with respect to all cited deficiencies, asserting that Petitioner failed to establish any genuine issue of material fact in dispute, and a hearing in this matter is not necessary. As previously noted, CMS imposed the sanction of termination of Petitioner's Medicare agreement. Four deficiencies are alleged in the appeal before me, and any one of the cited conditions for coverage deficiencies, if proved, is sufficient to sustain CMS's termination. Therefore, if there is no disputed material fact and no genuine issue of material fact requiring an evidentiary hearing as to even one of the conditions for coverage deficiencies, then summary judgment can be entered as to that deficiency.

Petitioner argues that material facts are in dispute as to each of the alleged conditions for coverage violations and that its center was actually in compliance with all participation conditions at the time of the revisit survey. Petitioner bears the burden of showing that material facts exist that are disputed, and, if Petitioner cannot show that there exists some genuine issue for trial, then summary judgment is appropriate. *Everett Rehab. & Med. Ctr.*, DAB No. 1628 (1997).

I have carefully considered Petitioner's responses to the two survey findings and its arguments against summary judgment, and find that they do not raise issues of material fact which would defeat summary judgment in favor of CMS. Based on the record before me, arguments of the parties, and applicable law and regulations, I find that there are no material issues of fact in dispute requiring an evidentiary hearing. Accordingly, for the reasons set forth below, I find that this case involves only issues of law and that summary judgment is appropriate.

B. Petitioner was not in compliance with all the conditions for coverage requirement, as an ASC required for continued participation in the Medicare program.

1. Petitioner was not in compliance with the requirement of Governing Body and Management, as set forth at 42 C.F.R. § 416.41.

Section 416.41 of the regulation requires, in pertinent part, that:

> The ASC must have a governing body, that assumes full legal responsibility for determining, implementing, and monitoring policies governing the ASC's total operation and for ensuring that these policies are administered so as to provide quality health care in a safe environment.

CMS maintains that the April survey findings show that Petitioner's governing body was not carrying out its responsibilities and, that upon a revisit to Petitioner's center in July, the surveyors found that Petitioner's governing body failed to implement the corrective action plan that Petitioner submitted in response to findings from the initial April survey. CMS Prehearing Brief at 4; CMS Ex. 1; CMS Ex. 2.

After the April survey, Petitioner filed a plan of correction indicating that the majority of the deficiencies noted would be corrected by July 18, 2008 (CMS Ex. 1); however, the completion date for the corrective action was subsequently changed when Petitioner filed an amended plan of correction on June 27, 2009, stating that "completion dates for correction for the Desert Inn Digestive Disease Center will be changed from 7-18-08 to 7-9-08." *Compare* CMS Ex. 1 *and* CMS Ex. 41, at 4. Consequently, to confirm the that Petitioner corrective action averred, a revisit survey was scheduled. The resurvey concluded on July 16, 2008. On July 15, 2008, Petitioner's medical director and owner, Dr. Haikal, provided a letter to the surveyors, dated July 9, 2008, which stated that its facility was not ready to be surveyed. CMS Ex. 37, at 23. Moreover, on July 16, 2008, the last day of the resurvey, Dr. Haikal handed the surveyors another letter stating that the peer review and quality improvement policies were not completed due to staff changes, inspections, and vacations. CMS Ex. 37, at 21.

Thus, by its own admission, Petitioner had not implemented its plan of correction and, consequently, its governing body clearly failed to fulfill its responsibility for implementing and monitoring policies governing the center's operation – a violation of

the requirements of 42 C.F.R. § 416.41. The letters that Dr. Haikal provided to the surveyors support CMS's prima facie case that Petitioner was not in compliance with all of the conditions of coverage and, for purposes of my review, specifically, the condition for coverage requirement at 42 C.F.R. § 416.41. Although Petitioner consistently argues that it does have a governing body, Petitioner's failure to come into compliance accrues to the governing body, which is responsible to ensure Petitioner is administered in a manner that it can provide quality health care in a safe environment. Moreover, Petitioner's argument is unavailing, since CMS did not cite Petitioner for not having a governing body. Rather, Petitioner was cited for its governing body's failure to ensure that the center met the conditions for coverage and that the plan of correction was fully implemented by July 9, 2008, the date Petitioner noted. CMS Ex. 41, at 4. The role of Petitioner's governing body and management in providing oversight to the center's operations to ensure that quality healthcare services were provided in a safe environment was vital, particularly in ensuring that the center had appropriate systems in place and sufficient resources, including policies in place and qualified personnel to carry out those policies. The failure of an ASC's governing body to assume and act on its responsibilities as outlined in this condition limits its ability to ensure that its center furnishes adequate care to its patients.

2. Petitioner was not in compliance with the requirement of Evaluation of Quality as 42 C.F.R. § 416.43 sets forth.

Section 416.41 of the regulation requires:

> The ASC, with the active participation of the medical staff, must conduct an ongoing, comprehensive self-assessment of the quality of care provided, including medical necessity of procedures performed and appropriateness of care, and use findings, when appropriate, in the revision of center policies and consideration of clinical privileges.

The regulation requires Petitioner to conduct ongoing, comprehensive self-assessments of the quality of care it provided. Petitioner was found to not be in compliance with this condition during the April 2008 survey. During the July 16, 2008 resurvey, the surveyors found that Petitioner's quality improvement programs remained incomplete, and, consequently, Petitioner was cited for violating 42 C.F.R. § 416.43.

Petitioner has not disputed that the self-assessments were not completed by July 9, 2008, as outlined in Petitioner's June 27, 2008 amended plan of correction. CMS Ex. 41, at 4. Rather, Petitioner asserts that the allotted time to complete the correction was unreasonable and that its departing nurse manager wrote the June 27 amended plan of correction when the center's medical director, Dr. Haikal, was on vacation. Petitioner avers that Dr. Haikal had neither knowledge of nor consented to the amended plan of correction. However, Petitioner does not explain why it believed the 85 days it was afforded between the April 22 survey and the July 16, 2008 resurvey, and the 44 days between Petitioner's first notice of June 2, 2008 and the July 16 resurvey were not sufficient, or reasonable, for Petitioner to correct its deficiencies. To overcome an

adequately supported motion for summary judgment, Petitioner may not rely on denials in its pleadings or brief. Instead, Petitioner must furnish evidence of a dispute concerning a material fact. Petitioner has not met its burden here. Petitioner does not maintain that it achieved substantial compliance by July 9, 2008, nor does Petitioner raise before me any material facts as to the achievement of substantial compliance in issue.

3. Petitioner has not raised any material issues of fact to dispute CMS's assertions that Petitioner's failures had a potential to result in harm to patients.

CMS maintains that Petitioner was cited for condition-level deficiencies, which include deficiencies that have the potential to result in harm to patients. CMS Reply at 5, 6, (citing *Nat'l Hosp. for Kids*, DAB No. 1600 at 9, 11 (1997)). Petitioner states that CMS has failed to explain how the deficiencies actually put any patient at risk. P. Opposition Brief at 10. However, it is well-established that CMS does not have to prove actual harm; rather, CMS need only show the potential for harm. 42 C.F.R. § 488.24(b); *see Nat'l Hosp.*, DAB No. 1600, at 9 (holding potential for harm sufficient to find that provider's deficiencies are of such character as to limit its "capacity to [furnish] adequate care" or to "adversely affect the health and safety of patients" under 42 C.F.R. § 488.24). The failure of an ASC's governing body to assume and act on its responsibilities as established in this case limits its ability to ensure that its center furnishes adequate care to its patients. The failure to address cited deficiencies and correct them to provide adequate care for patients presents the potential for uncorrected deficiencies that result in harm to patients. Petitioner has not overcome CMS's assertion that Petitioner's failures had a potential placing its patients at harm. I find that relative to the potential for harm to patients, Petitioner has not advanced any genuine issues of material fact in dispute. If the alleged facts as to why Petitioner was not in compliance with the two conditions of coverage identified above are viewed in a light most favorable to Petitioner, as a matter of law, Petitioner would not prevail.

Accordingly, CMS has raised the issue of Petitioner's failure to meet the conditions of coverage, as 42 C.F.R. §§ 416.41 and 416.43 outlines, during the April survey and at the July 16, 2008 resurvey. Even weighting the facts in a light most favorable to Petitioner, Petitioner has not raised any material fact of dispute as to it being in compliance with the two conditions by the July resurvey. Therefore, I find that, as a matter of law, Petitioner cannot prevail on these issues. Having tendered an adequately supported motion for summary judgment, which Petitioner has not been successful in overcoming, I grant CMS's motion.

In the interest of judicial economy, I do not address, and therefore make no findings or conclusions regarding, Petitioner's alleged violation of 42 C.F.R. §§ 416.44 and 416.48. The two violations already discussed provide a sufficient basis for the termination remedy imposed. *Beechwood Sanitarium*, DAB No. 1824, at 22 (2002); *Alexandria Place*, DAB No. 2245, at 27 n.9 (2009); *Community Skilled Nursing Ctr.*, DAB No. 1987, at 5 (2005) (holding "ALJs are not required to make findings of fact and conclusions of law on deficiencies that are not necessary to support the [remedy] imposed"). In

reviewing the record in a light most favorable to Petitioner, even if Petitioner proffered evidentiary and testimonial evidence on facts for the other two conditions it was found not to be in compliance with, and, even if those facts were proven, this would not make a substantive difference in the results of this case as Petitioner's violation of 42 C.F.R. §§ 416.41 and 416.43 provide a sufficient basis for CMS to terminate its Medicare participation agreement.

V. The Termination Remedy That CMS Imposed Against Petitioner Was Reasonable.

A. CMS is authorized to impose the sanction of termination.

CMS established through the findings of the state surveys on April 22 and July 16, 2008 that Petitioner did not meet all the conditions for coverage, as required of an ASC to continue its participation in the Medicare program. Petitioner was provided with opportunity to remedy its non-compliance to avoid termination; however, it was unsuccessful in doing so. CMS determined that Petitioner's capacity to furnish adequate care to its patients was substantially limited by the governing body's failure to provide oversight to the center and Petitioner's failure to ensure its quality improvement and peer review programs were operating and current. As a result, termination of Petitioner's provider agreement was effectuated on September 26, 2008.

Nothing in the regulations provides me authority to review CMS's exercise of its discretionary authority. As noted, the applicable regulation makes it clear that the existence of a violation of even one condition for coverage establishes a rational basis for CMS to impose the remedy of termination against Petitioner. Petitioner has made no argument that would lead to a different result. Thus, as a matter of law, CMS is authorized to impose the sanction of termination.

B. The subsidiary arguments Petitioner raised are unavailing to mitigate the sanction imposed.

During the course of these proceedings, Petitioner raised several subsidiary arguments, which I do not weigh but which I must address.

First, Petitioner argues that CMS may not rely on the results from the April survey findings as a basis to terminate Petitioner's participation in Medicare and that it has a statutory right to correct the deficiencies. P. Opposition Brief at 8. Petitioner's argument does not raise any issue of material fact. As a matter of law, CMS may, but is not required to, provide an ASC the opportunity to correct its non-compliance with a condition of coverage before terminating it. *See Community Home Health,* DAB No. 2134, at 14 (2007) (citing *Excelsior Health Care Srvs., Inc.*, DAB No. 1529, at 6-7 (1995)). In the case before me, Petitioner was afforded an opportunity to submit an acceptable plan of correction. The June 2, 2008 notice advised Petitioner that, if upon resurvey it remained out of compliance with any condition for coverage, that the state survey agency would recommend to CMS that its Medicare participation agreement be

terminated. CMS Ex. 3. Petitioner was granted a reasonable amount of time to correct the deficiencies. Specifically, 85 days had lapsed between the April 22 survey and the July 16, 2008 resurvey, and 44 days had lapsed between Petitioner's first notice of June 2, 2008 and the July 16 resurvey. The purpose of the revisit survey was to confirm Petitioner's plan of correction and ensure that the deficiencies were, in fact, corrected. CMS does not have the same assurance based solely on a representation by a supplier that it has corrected the identified deficiencies. However, the surveyors found that not only did Petitioner not implement the plan of correction as submitted, but that additional deficiencies were noted under the same previously cited conditions. Petitioner does not dispute these facts.

Second, Petitioner's lengthy analysis of standard level deficiencies versus condition level deficiencies is irrelevant. The point is that deficiencies were found in the April survey of Petitioner's center, and Petitioner was afforded opportunity to correct the deficiencies. Petitioner submitted a plan of correction, and CMS returned to resurvey; however, it was determined that Petitioner continued to remain not in compliance with the condition of coverage at 42 C.F.R. § 416.41. Petitioner does not maintain that it achieved substantial compliance, nor does Petitioner place any material facts as to the achievement of substantial compliance in issue. Therefore, Petitioner cannot prevail as a matter of law.

Third, Petitioner states that it engaged a company, Healthsights, to perform an independent review of its facility in response to the deficiencies noted during the surveys at issue before me. Healthsights' report is dated October 30, 2008, and the review occurred after the July 16, 2008 survey. The report is irrelevant and does not raise any genuine material issue of fact as to whether Petitioner was in substantial compliance with all conditions of coverage during both the April and July 2008 surveys. P. Ex. 4, at 1.

VI. Conclusion

For the foregoing reasons, I grant summary judgment in favor of CMS and against Petitioner. In doing so, I sustain CMS's imposition of its termination sanction against Petitioner.

/s/
Alfonso J. Montaño
Administrative Law Judge