

Department of Health and Human Services

DEPARTMENTAL APPEALS BOARD

Civil Remedies Division

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In the Case of:)	
)	
Dialysis Center at Moreno Valley, Inc.,)	Date: February 6, 2008
(CCN: 05-2749))	
)	
Petitioner,)	
)	
- v. -)	Docket No. C-08-5
)	Decision No. CR1733
Centers for Medicare & Medicaid)	
Services.)	
_____)	

**DECISION GRANTING SUMMARY JUDGMENT
TO CENTERS FOR MEDICARE & MEDICAID SERVICES**

I grant summary judgment to the Centers for Medicare & Medicaid Services (CMS) and against Petitioner, Dialysis Center of Moreno Valley, Inc., sustaining CMS's determination to terminate Petitioner's participation in the Medicare program.

I. Background

Petitioner participated in the Medicare program as a supplier of dialysis services for the treatment of end stage renal disease (ESRD). In order to qualify for participation in Medicare an ESRD supplier must comply with the requirements of section 1881 of the Social Security Act and with implementing regulations at 42 C.F.R. Part 405, Subpart U. Failure by a ESRD supplier to comply with one or more of the conditions of participation established by the regulations is a basis for terminating its participation in Medicare.

An ESRD supplier who is dissatisfied with a determination by CMS that it has not complied with ESRD regulatory or statutory requirements is entitled to an administrative hearing. The supplier's hearing rights and the hearing process are governed by regulations at 42 C.F.R. Part 498.

On August 7, 2007, CMS advised Petitioner that it had determined to terminate Petitioner's participation in Medicare based on Petitioner's alleged failure to comply with one or more conditions of participation established by governing regulations. Petitioner timely requested a hearing and the case was assigned to me for a hearing and a decision. On November 23, 2007, CMS moved that I compel Petitioner to amend its hearing request, asserting that Petitioner had failed to state a basis for contesting CMS's determination. I denied that motion. On December 21, 2007, CMS moved to dismiss Petitioner's hearing request and moved, alternatively, for summary judgment. Petitioner opposed CMS's motion with a letter brief dated January 14, 2008.

On January 31, 2008, CMS moved for leave to file a reply brief and for oral argument. I deny these requests because CMS's motion and Petitioner's reply clearly support a decision favorable to CMS. Additional briefing and oral argument would add nothing of value.

II. Issues, findings of fact and conclusions of law

A. Issues

In its motion CMS raises two issues. First, it contends that Petitioner's hearing request is on its face inadequate to respond to the allegations of noncompliance made by CMS. It urges that I dismiss the hearing request for the reason that it fails to comply with the requirements of 42 C.F.R. § 498.40(b) that a hearing request identify the specific findings of fact and conclusions of law with which the affected party disagrees and specify the basis for contending that the findings and conclusions are incorrect. Alternatively, CMS urges that I grant it summary judgment, contending that Petitioner has not contested allegations of fact which are, on their face, sufficient to establish that Petitioner has contravened ESRD participation conditions.

I find it unnecessary to address CMS's motion to dismiss. In this decision I address CMS's alternative argument that summary judgment is appropriate.

B. Findings of fact and conclusions of law

I make findings of fact and conclusions of law (Findings) to support my decision in this case. I set forth each Finding below as a separate heading. I discuss each Finding in detail.

1. Summary judgment is appropriate where there are no disputed issues of material fact.

The regulations governing hearings at 42 C.F.R. Part 498 do not explicitly provide for summary judgment as a means of deciding cases. But these regulations have been interpreted universally to allow for summary judgment in circumstances that are analogous to those for which summary judgment is appropriate under Rule 56 of the Federal Rules of Civil Procedure.

Rule 56 permits summary judgment where there is no dispute as to the material facts of a case. A fact is “material” where it is necessary to deciding a case’s outcome. Summary judgment may be granted when a moving party alleges facts which, if not disputed, would be sufficient to establish a basis for that party to prevail on the merits.

Allegations of facts which if undisputed establish a basis for a judgment favorable to the moving party impose a burden on the party opposing summary judgment to allege facts which create a genuine dispute. A party opposing a motion for summary judgment need not prove that the weight of the evidence in the case supports its position in order to prevail on the motion. But, at a minimum, it must allege facts which, if ultimately proven, would create a genuine controversy as to the facts of a case.

2. The undisputed material facts alleged by CMS support a finding that Petitioner failed to comply with a condition for participation as an ESRD supplier.

CMS’s allegations of condition-level noncompliance by Petitioner are based on a compliance survey performed on July 16, 2007. That survey was in fact a revisit to verify that noncompliance identified at a previous survey had been corrected by Petitioner. At the July 16 survey it was determined that Petitioner failed to comply with ESRD supplier conditions stated in the following regulations:

- 42 C.F.R. § 405.2136 (governing body and management);
- 42 C.F.R. § 405.2140 (physical environment); and
- 42 C.F.R. § 405.2161 (medical director).

In its motion for summary judgment CMS made fact allegations concerning all three of these conditions. In its reply to the motion Petitioner asserted facts which, if proven, might support a finding that it had in fact complied with some, but not all, of the elements

of the conditions stated at 42 C.F.R. §§ 405.2136 and 405.2161. However, it failed to offer facts and argument to refute CMS's allegations of noncompliance with the requirements of 42 C.F.R. § 405.2140.

In deciding this case it is unnecessary that I find that Petitioner failed to comply with all three of the conditions that were cited by CMS. As I discuss below, failure by Petitioner to comply with even one of these conditions gives CMS grounds to terminate its participation in Medicare. For that reason I do not address Petitioner's compliance with the requirements of 42 C.F.R. §§ 405.2136 and 405.2161. Rather, I enter summary judgment in favor of CMS as to its allegations that Petitioner failed to comply with the condition governing physical environment.

The applicable regulation states as a condition of participation that an ESRD supplier must furnish a physical environment for its services that affords a functional, sanitary, safe, and comfortable setting for patients, staff, and the public. The regulation spells out in detail the criteria that an ESRD supplier must satisfy in order to be in compliance. Among other things, an ESRD supplier must: comply with water quality requirements developed by the Association for the Advancement of Medical Instrumentation (42 C.F.R. § 405.2140(a)(5)); maintain and equip its facility in order to provide a comfortable and sanitary environment for patients (42 C.F.R. § 405.2140(b)); and develop and implement policies and procedures to prevent infections (42 C.F.R. § 405.2140(b)(1)).

CMS asserts that Petitioner failed to comply with these requirements. In the report of the June 16 survey (attached as CMS Ex. 1 to CMS's November 23, 2007 motion to compel Petitioner to amend its hearing request), it was explicitly alleged that Petitioner failed to comply with applicable water quality requirements, ensure that patient care areas and water treatment rooms were clean and sanitary, and ensure that policies and procedures regarding infection control were written and implemented. Additionally, the report alleged that Petitioner failed to ensure immediate availability of emergency oxygen to patients.

These allegations, if supported at a hearing, would be prima facie proof that Petitioner failed to comply with the requirements of the condition governing physical environment. In order to create genuine issues of fact Petitioner must contest them with specific allegations of compliance refuting CMS's assertions. Petitioner manifestly failed to do so.

In opposing CMS's motion Petitioner did not allege specifically that it complied with the physical environment condition. It did not allege or offer any facts showing that it complied with applicable water quality standards, nor did it offer facts showing that it maintained its patient care areas and water treatment areas in a clean and safe manner.

Nor did it aver that emergency oxygen was immediately available to patients. And, it did not assert that it developed and implemented infection control measures. Indeed, Petitioner's January 14, 2008 letter in opposition to CMS's motion is silent as to these issues of fact.

Nor did Petitioner contest directly in its request for a hearing CMS's allegations concerning its facility maintenance. The hearing request does not explicitly address the allegations of noncompliance with 42 C.F.R. § 405.2140. It makes some scattered statements which one could interpret as relating to the issue of Petitioner's compliance with the regulation, but these statements, even when interpreted in a light most favorable to Petitioner, do not squarely refute CMS's allegations of noncompliance. Moreover, it is unclear from the hearing request whether Petitioner is even challenging the findings that were made at the July 16 survey. Arguably, its assertions relate to the previous survey, whose findings were not a basis for CMS's determination to terminate Petitioner's participation in Medicare.

In response to a finding that its bathrooms were not clean, Petitioner says only that:

while in reality we are one in a few of dialysis clinics that has a full-time cleaning staff employee. This is not a requirement but we also do not expect the cleaning person to clean the bathrooms after each patient use, unless so notified.

Petitioner's hearing request at 1. That statement simply avoids answering the question of whether Petitioner actually maintained clean bathrooms.

Similarly, Petitioner responded to allegations that its floors were grimy only by saying:

we have a full-time cleaning staff employee that cleans the floor on a daily basis and with approximately 40 people walking on the ceramic floor with shoes on that carry dust from the streets it is not expected that the floor would remain spotless, free from dust all the time regardless.

Id. As with the previous statement, this one does not answer CMS's allegation of noncompliance. Rather, it is an excuse for *not complying* with regulatory requirements. But, the regulation simply does not contain a "heavy traffic" exception to the requirement that a facility be kept clean.

The hearing request makes no assertions to refute CMS's allegations that Petitioner failed to maintain emergency oxygen equipment for its patients. It says nothing about allegations that it failed to develop or implement infection control procedures. As to allegations that Petitioner failed to comply with applicable water quality standards, Petitioner makes no specific refutation of them. It asserts only that:

No specific reference[s] were ever made by either The Department of Health or CMS that old equipment had to be replaced to current standards by any specific date. Regardless, we were proceeding with replacement of new tanks for the R.O. system and bicarbonate system. If asked we would have mentioned the date of completion time which was September 30, 2007.

Id. at 3. This statement not only fails to respond directly to CMS's allegations but it, in fact, admits that as of July 16, 2007 Petitioner's water treatment system was in the process of being replaced and that replacement would not be completed until a date that was well after the date of the survey.

Petitioner did not argue that its noncompliance with the elements of 42 C.F.R. § 405.2140 failed to comprise a condition level of noncompliance. It offered neither facts nor evidence to suggest that its noncompliance was at anything less than the condition level of noncompliance.

Petitioner argues that the findings of noncompliance in this case and the determination to terminate its Medicare participation are the consequence of a "vendetta" conducted against it, evidently by employees of the California Department of Health. However, Petitioner has offered no facts to show how any animus displayed towards Petitioner by anyone, if indeed there was animus, affected the findings of noncompliance that were made ultimately by CMS. Thus, Petitioner's assertions of a vendetta raise no disputed issues of material fact concerning the findings of noncompliance on which I base this decision.

3. CMS's determination to terminate Petitioner's participation in Medicare as an ESRD supplier is authorized by Petitioner's failure to comply with a condition of participation.

Failure by an ESRD supplier to comply with even one condition of participation authorizes CMS to terminate that supplier's participation in the Medicare program. 42 C.F.R. § 405.2180(a). Moreover, the regulation makes it clear that, with an exception, termination is a remedy that CMS *must* impose for a condition-level failure by an ESRD supplier to comply with Medicare participation requirements:

Except as provided in § 405.2181, failure of a supplier of ESRD services to meet one or more of the conditions for coverage . . . will result in termination of Medicare coverage of the services furnished that supplier.

Id. The exception provided in 42 C.F.R. § 405.2181 applies to a supplier who fails to participate in the activities and pursue the goals of the ESRD network that is designated to encompass an assigned geographic area where the failure does not jeopardize patient health and safety. In such a circumstance CMS may impose sanctions that are alternative to termination of participation such as denial of payment for services to patients that are first accepted for care after the effective sanction date. However, in the situation described at 42 C.F.R. § 405.2181, CMS retains the discretion to impose termination of participation for a condition level noncompliance. I do not have the authority to question CMS's exercise of discretion where condition level noncompliance is established.

Whether CMS's determination to terminate Petitioner's participation in Medicare is mandatory or is an act of discretion makes no difference to the outcome of this case. CMS plainly is authorized to terminate Petitioner's participation because Petitioner failed to comply with at least one condition of participation as an ESRD supplier.

/s/
Steven T. Kessel
Administrative Law Judge