Department of Health and Human Services

DEPARTMENTAL APPEALS BOARD

Civil Remedies Division

Grand Oaks Care Center
(CCN: 06-5023),

Petitioner

v.

Centers for Medicare and Medicaid Services.

Docket Nos. C-08-433, C-08-582

Decision No. CR2219

Date: August 13, 2010

DECISION

I sustain the determination of the Centers for Medicare and Medicaid Services (CMS) to terminate Petitioner, Grand Oaks Care Center, from participation in the Medicare program effective May 5, 2008.

I. Background

Petitioner is a long term care facility in Lakewood, Colorado. Petitioner participated in the Medicare program and in the Colorado Medicaid program. It participated in those programs pursuant to sections 1819, 1919 and 1866 of the Social Security Act (Act) and federal regulations at 42 C.F.R. Parts 483 and 488. The regulations at 42 C.F.R. Part 498 govern Petitioner's right to a hearing.

Both the Colorado Department of Public Health and Environment (CDPHE), the state survey agency, and CMS surveyed Petitioner's facility on numerous occasions, and, each time, the surveyors concluded that Petitioner was not complying substantially with federal participation requirements. I briefly describe below its history of noncompliance.

First, on November 5, 2007, CDPHE surveyed Petitioner and found it was not in substantial compliance with F Tag 368.[1] CMS Ex. 3. CDPHE directed Petitioner to

[1] An F Tag designation refers to the part of the State Operations Manual (SOM), available at http://cms.gov/manuals/Downloads/som107ap_pp_guidelines_ltcf.pdf, which pertains to the specific regulatory provision allegedly violated.

submit a plan of correction and informed Petitioner that "if substantial compliance was not achieved by May 5, 2008," its provider agreement would be terminated. Next, CDPHE surveyed Petitioner on December 19, 2007, finding substantial noncompliance with two quality of care participation requirements, F Tags 323 (Accidents and supervision) and 325 (Nutrition). CMS Ex. 24. CMS notified Petitioner that it would impose denial of payment for new admissions (DPNA), effective February 2, 2008, and termination if substantial compliance was not achieved by May 5, 2008. CMS Ex. 2. Then, on February 1, 2008, CMS conducted a survey of Petitioner. CMS Ex. 12. This survey also found that Petitioner was not in substantial compliance with participation requirements and that a pattern of deficiencies existed that constituted immediate jeopardy to resident health or safety and substandard quality of care. The surveyors cited Petitioner for F Tags 309 (Quality of care); 353 (Nursing services-sufficient staff); 425 (Pharmacy services); and 518 (Disaster and emergency preparedness). CMS continued the DPNA and imposed the additional remedy of temporary management, effective March 8, 2008. On February 13 and 14, 2008, CDPHE returned to the facility and found Petitioner substantially noncompliant with deficiencies constituting immediate jeopardy to resident health or safety and substandard quality of care, specifically, F Tag 323 (Accidents and supervision). CDPHE recommended continuation of the remedies previously imposed, as well as imposition of state monitoring. CMS Ex. 13. Finally, on May 1, 2008, CDPHE conducted revisit surveys to the February 1 and February 14 surveys to determine if Petitioner had achieved substantial compliance with the participation requirements. CMS Ex. 1. The surveyors determined that Petitioner had not achieved substantial compliance and that a pattern of deficiencies existed that constituted actual harm, but not immediate jeopardy. They found Petitioner was not in substantial compliance with: F Tag 309 (Quality of care); F Tag 425 (Pharmacy services); F Tag 431 (Pharmacy services); F Tag 323 (Accidents and supervision); and F Tag 441 (Preventing spread of infection). As a result of Petitioner's continued failure to meet Medicare and Medicaid participation requirements, CMS informed Petitioner that it terminated its provider agreement and that Medicare would not make payment for services furnished to patients admitted on or after May 5, 2008.

Petitioner requested a hearing, and the case was assigned to me for hearing and decision.[2] I conducted a hearing on February 2 and 3, 2010, in Denver, Colorado, and the parties received a transcript (Tr.) of the proceeding. CMS offered, and I admitted CMS Exhibits (CMS Exs.) 1-24. Tr. at 20, 26, 295. Petitioner offered exhibits (P. Exs.) 1-15, and I admitted P. Exs. 1-13, and 15. *Id*. I denied CMS's motion to dismiss Petitioner's May 5, 2008 request for hearing. The parties submitted posthearing briefs (CMS Brief and P. Brief) and reply briefs (CMS Reply and P. Reply). Petitioner also submitted a sur-reply (P. Sur-reply).

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[2] Petitioner initially requested a hearing, by letter dated May 5, 2008, of the recommendations set forth in the March 3, 2008 letter from CDPHE. That hearing request was docketed as C-08-433. Petitioner then filed a timely request for a hearing of CMS's May 5, 2008 determination to terminate Petitioner's participation in the Medicare program. That case was docketed as C-08-582. I consolidated the cases.

II. Applicable Law

The regulatory requirements for long-term care facilities that participate in the Medicare and Medicaid programs are set forth at 42 C.F.R. Part 483. Facility compliance with the participation requirements is determined through a survey and certification process. Sections 1819 and 1919 of the Act; 42 C.F.R. Parts 483, 488, and 498. State survey agencies and sometimes, CMS, perform these surveys on behalf of the Secretary of the Department of Health and Human Services.

"Deficiency" is defined as a facility's "failure to meet a participation requirement specified in the Act" or in 42 C.F.R. Part 483. 42 C.F.R. § 488.301. The term "substantial compliance" means "a level of compliance with the requirements of participation such that any identified deficiencies pose no greater risk to resident health or safety than the potential for causing minimal harm." *Id*. "Noncompliance" means "any deficiency that causes a facility to not be in substantial compliance." *Id.* And, "immediate jeopardy" means "a situation in which the provider's noncompliance . . . has caused, or is likely to cause, serious injury, harm, impairment, or death to a resident." *Id.*

CMS may impose one or more enforcement remedies on a facility based on deficiencies constituting substantial noncompliance with participation requirements that are found during a survey. 42 C.F.R. § 488.402 (b), (c). The enforcement remedies available to CMS include termination of a facility's Medicare provider agreement. 42 C.F.R. § 488.456. CMS may terminate if the facility –

> (i) Is not in substantial compliance with requirements for participation, regardless of whether or not immediate jeopardy is present . . . .

42 C.F. R. § 488.456(b)(i). CMS may terminate a provider agreement even after a single survey if the facility is not in substantial compliance.[3] *Rosewood Living Ctr.*, DAB No. 2019 (2006). Moreover, CMS is not required to give the facility an opportunity to correct the noncompliance before imposing termination. *Beechwood Sanitarium*, DAB No. 1906, at 27 (2004).

A single deficiency is sufficient to warrant termination, if the deficiency causes the facility to be out of substantial compliance. *Hermina Traeye Mem'l Nursing Home*, DAB No. 1810 (2002), *aff'd, Hermina Traeye Mem'l Nursing Home v. U.S. Dep't. of Health and Human Servs.*, No. 02-2076 (4th Cir., Oct. 29, 2003). Moreover, the dispositive issue is not whether a facility came back into substantial compliance before the effective date of the termination, but whether the facility was in substantial compliance as of the day that the survey was completed. *See Carmel Convalescent Hosp.*, DAB No. 1584, at 12 (1996) ("[W]hen the facility's participation is terminated because of alleged non-compliance, the critical date for establishing compliance is the survey date, not the subsequent effective date of the termination.").

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[3] CMS is statutorily required to terminate a facility's provider agreement if the facility is not in substantial compliance over a period of six months. Act § 1819(h)(2)(C); 42 C.F.R. §§ 488.412(a), (d), and 488.450(d).

The Act and regulations make a hearing before an administrative law judge (ALJ) available to a long-term care facility against which CMS has determined to impose a remedy. Act § 1128A(c)(2); 42 C.F.R. §§ 488.408(g), 498.3(b)(13). The hearing before an ALJ is a de novo proceeding. *Residence at Salem Woods*, DAB No. 2052 (2006); *Cal Turner Extended Care Pavilion*, DAB No. 2030 (2006); *Beechwood Sanitarium*, DAB No. 1906 (2004); *Emerald Oaks*, DAB No. 1800, at 11 (2001); *Anesthesiologists Affiliated*, DAB CR65 (1990), *aff'd*, 941 F.2d 678 (8th Cir. 1991). A facility has a right to appeal a "certification of noncompliance leading to an enforcement remedy." *See* 42 C.F.R. § 488.408(g)(1); *see also* 42 C.F.R. §§ 488.330(e), 498.3. However, CMS's choice of remedies or the factors CMS considered when choosing remedies are not subject to review. 42 C.F.R. § 488.408(g)(2). A facility may only challenge the scope and severity level of noncompliance that CMS found, if a successful challenge would affect the amount of the civil money penalty (CMP) that CMS could collect or impact upon the facility's nurse aide training program. 42 C.F.R. §§ 498.3(b)(14), (d)(10)(i). CMS's determination as to the level of noncompliance "must be upheld unless it is clearly erroneous." 42 C.F.R. § 498.60(c)(2). The Departmental Appeals Board (the Board) has long held that the net effect of the regulations is that a provider has no right to challenge the scope and severity level assigned to a noncompliance finding, except in the situation where that finding was the basis for an immediate jeopardy determination.[4] *See, e.g., Ridge Terrace*, DAB No. 1834 (2002); *Koester Pavilion*, DAB No. 1750 (2000).

III. Issues

1. Whether CMS was required to terminate Petitioner's Medicare provider agreement, because it was not in substantial compliance for six months.

2. Whether CMS was authorized to terminate the Petitioner's Medicare provider agreement, if the facility was not in substantial compliance with participation requirements.

IV. Analysis

I make the following findings of fact and conclusions of law (Findings), set forth below as separate headings in bold and italics, to support my decision in this case.[5]

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[4] Such a challenge only applies where CMS has imposed a per day CMP within the upper range; no such challenge is available if a per instance CMP or termination is imposed.

[5] I have reviewed the entire record, including all the exhibits and testimony. As I am not bound by the rules of evidence, I may admit evidence and determine later, upon a review of the record as a whole, what weight, if any, I should accord that evidence or testimony. To the extent that any contention, evidence, or testimony is not explicitly addressed or mentioned, it is not because I have not considered the contentions. Rather, it is because I find that the contentions were not supported by the weight of the evidence or by credible evidence or testimony.

1. CMS is required to impose the remedy of termination of Petitioner's provider agreement, as Petitioner failed to comply substantially with federal participation requirements for six months.

In this case, CMS argues that it was authorized to terminate Petitioner both on a mandatory and discretionary basis. CMS contends that it was required to terminate the facility, because it had been substantially noncompliant for six months (mandatory termination). CMS also contends that it was authorized at its discretion to impose the remedy of termination (discretionary termination) immediately, if Petitioner was not in substantial compliance with program participation requirements at the time of the May 1, 2008 survey. With respect to the contention that Petitioner was continuously out of compliance for six months, Petitioner essentially argues that, for each and every survey, it submitted a plan of correction that surveying agencies summarily approved and accepted, except for the May 1, 2008 survey. Petitioner contends that the May 1, 2008 survey identified deficiencies that were not identified in previous surveys, and, therefore, it cannot be considered continuously out of compliance.

Under the applicable law, CMS must terminate a facility that has been substantially noncompliant with participation requirements for six months and may act, at its discretion, immediately to terminate a facility based on a survey finding the facility is not in substantial compliance, even without affording an opportunity to correct the noncompliance. *Beechwood Sanitarium*, DAB No. 1906, at 27 (2004); 59 Fed. Reg. 56,116, 56, 213 (Nov. 10, 1994) ("Neither immediate jeopardy nor a full 6 months of noncompliance have to have occurred for the State or [CMS] to terminate a provider agreement."). I conclude that CMS was authorized under either basis to terminate Petitioner's facility.

The result of a facility's failure to come in to substantial compliance within six months from the last day of a survey is a mandatory termination, pursuant to section 1819(h)(2)(C) of the Act, and regulations at 42 C.F.R. §§ 488.412 and 488.450(d). *See Cary Health and Rehab. Ctr.*, DAB No. 1771, at 5 (2001); *Emerald Oaks* at 39-40. Petitioner does not contend the facility was in substantial compliance with participation requirements at the time of the November 5, 2007 survey that CDPHE conducted and did not appeal this determination or the remedies imposed. Instead, Petitioner contends that it was in substantial compliance with program requirements by May 5, 2008,[6] and the termination of its provider agreement was incorrect as the facility had corrected the November 2007 deficiencies. Once a facility is found to be out of substantial compliance, noncompliance is presumed to continue until the facility demonstrates that it has achieved substantial compliance. Also, a finding that deficiencies have been corrected is not tantamount to a determination that a facility has achieved substantial compliance. *Taos Living Ctr.*, DAB No. 2293, 20 (2009). Here, once CMS has shown that Grand Oaks failed to comply with participation requirements on November 5, 2007,

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[6] The critical date for establishing compliance is the survey date, not the subsequent date of the termination. *Carmel Convalescent Hosp.* at 12.

Petitioner has the burden to show that the facility returned to compliance by the termination date. *See, e.g., Georgian Court Nursing Ctr.*, DAB No.1866 (2003). As the subsequent surveys demonstrate, Grand Oaks continued to fail to substantially comply with participation requirements in the six months following the November 2007 survey. As a result, no basis exists for the Petitioner's unsubstantiated position that it was in substantial compliance with participation requirements within six months of the November 5, 2007 survey.

2. Petitioner was out of substantial compliance with the participation requirements at 42 C.F.R. § 483.25 and § 483.65 (F Tag 309 and F Tag 441).

CMS also contends it is authorized to terminate Petitioner's provider agreement based on the findings of the May 1, 2008 survey alone. Tr. at 31; Respondent's Post-Hearing Brief at 29; Motion for Summary Judgment at 24. During the May 1, 2008 survey, Petitioner, in pertinent part, was found out of substantial compliance with 42 C.F.R. §§ 483.25 and 483.65 (F Tag 309 and F Tag 441). CMS Ex. 4, at 1-14, 21-46. Based on these tags, CMS argues "the Petitioner cannot credibly argue that it was in substantial compliance" as of the survey that ended May 1, 2008. Motion for Summary Judgment at 23. As analyzed below, I conclude that CMS has proven its prima facie case that Petitioner was out of substantial compliance with participation requirements on May 1, 2008, and had the authority to terminate Petitioner's provider agreement.[7] *See Rosewood Living Ctr.* at 9 (holding CMS may act immediately to terminate a facility based on a survey finding that the facility is not in substantial compliance without affording an opportunity to the facility to correct the noncompliance).

F Tag 309

Each resident must receive, and the facility must provide, the necessary care and services to attain or maintain the highest practicable physical, mental, and psychosocial well-being, in accordance with the comprehensive assessment and plan of care. 42 C.F.R. § 483.25. The SOM notes the guidance at F309 is to be used for review of quality of care not specifically covered by 42 C.F.R. § 483.25 (a)-(m), and "tag F309 includes, but is not limited to, care such as end-of-life, diabetes, renal disease, fractures, congestive heart failure, non-pressure-related skin ulcers, pain, or fecal impaction." The SOM indicates a facility is in compliance with this requirement if staff:

[7] In the interest of judicial economy, I do not address, and therefore make no findings or conclusions regarding, CMS's deficiency citations under F Tag 323 (Accidents and supervision), F Tag 425 (Pharmacy services), and F Tag 431 (Pharmacy services). The two deficiency citations I discuss in this decision, F Tag 309 and F Tag 441, 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); *Cmty. Skilled Nursing. Ctr.*, DAB No. 1987, at 5 (2005) (holding that "ALJs are not required to make findings of fact and conclusions of law on deficiencies that are not necessary to support the [remedy] imposed").

• Recognized and assessed factors placing the resident at risk for specific conditions, causes, and/or problems;

• Defined and implemented interventions in accordance with resident needs, goals, and recognized standards of practice;

• Monitored and evaluated the resident's response to preventive efforts and treatment; and

• Revised the approaches as appropriate.

The record shows that Resident 3 was admitted to Grand Oaks on February 5, 2008, with an advisory that he had a rash and itching of an indeterminable source. CMS Ex. 8, at 22; P. Response, at 12. Over the next two months, Resident 3's rash and itching were treated per the resident's treating physician's directives.

The temporary manager testified that after he was placed at the facility on March 8, 2008, the entire facility was scrubbed down and cleaned. Tr. at 249. The record clearly demonstrates that Resident 3 continued to experience a rash and was not taken to a dermatologist (who took a skin biopsy to diagnose scabies) for assessment until March 27, 2008. CMS Ex. 8, at 31. CDPHE surveyors testified that no evidence existed that the facility's medical director was involved in resolving the treatment of Resident 3's rash, while the director of nursing testified the facility took active steps to get Resident 3's treating physician to agree to a dermatology consult and that the medical director concurred with the treating physician. Tr. at 102,141, 271. While Resident 3's rash was eventually diagnosed, the record demonstrates that on April 30, 2008, he continued to exhibit symptoms similar to those leading up to his diagnosis of scabies a month earlier and that the facility continued to follow the same course of action of attempting to contact the resident's treating physician for the unresolved rash and itching. CMS Ex. 4 at 33-34.

CMS has shown that Petitioner failed to effectively monitor and evaluate Resident 3's response to treatment and failed to revise its approach to Resident 3's treatment. The medical director failed to take an active role in the resident's treatment after his treating physician's directives failed to resolve the issue after almost three months. As such, I conclude that CMS proven its prima facie case, which Petitioner failed to rebut, that Petitioner was out of substantial compliance with the participation requirements at 42 C.F.R. § 483.25 (Tag F309).

F Tag 441

The SOM states, "[b]ecause of the clinically complex conditions of most nursing home residents, it is especially important for the facility to have a program in place for the prevention of disease." Each facility must establish and maintain an infection control program designed to provide a safe, sanitary, and comfortable environment and to help

prevent the development and transmission of disease and infection. 42 C.F.R. § 483.65 (Tag F441).

A CDPHE surveyor testified there was no documented evidence the facility took precautions with regard to the living environment of the other residents at the facility. Tr. at 148. A CDPHE surveyor testified that Resident 3 had a red bag in his room for laundry, but the two additional residents in the room did not. Tr. at 98, 99. Although the record indicates staff participated in an in-service training to discuss the facility's policy and procedure related to a scabies diagnosis, the surveyor noted that not all of the staff working at the facility the day of the survey expressed knowledge of a scabies outbreak. Tr. at 102; CMS Ex. 10 at 1. Staff reported that Resident 3 frequently wandered into other residents' rooms and had frequent contact with other residents. CMS Ex. 4, at 13. Skin audits of additional residents at the facility revealed rashes similar to Resident 3 on May 1, 2008. Tr. at 149, 152. No biopsies were conducted to determine if the additional residents had scabies. Tr. at 151-152. However, the medical director subsequently decided to treat the entire facility for scabies instead of having biopsies done on each resident. Tr. at 168-69.

The facility had a written procedure for responding to a scabies infection; however, based on the evidence of record, CMS has shown that Petitioner failed to take all reasonable steps to establish and maintain an infection control program designed to provide a safe, sanitary, and comfortable environment to help prevent the development and transmission of disease and infection, and Petitioner has failed to submit any evidence to rebut this finding. At most, Petitioner has shown that the facility was working towards substantial compliance. *See* Tr. at 224. As such, I conclude that CMS has shown, and Petitioner has failed to rebut, that Petitioner was out of substantial compliance with the participation requirements at 42 C.F.R. § 483.65 (Tag F441) on May 1, 2008.

3. CMS was authorized to terminate the Petitioner's provider agreement.

Subsequent to the May 1, 2008 survey findings, CMS's chosen remedy was to terminate Petitioner's provider agreement. CMS Ex. 1. In its briefs, Petitioner asserts that CMS misinterprets its own regulations and failed to offer any other alternatives other than termination of the provider agreement and the closure of the facility. *See* Tr. at 40. Petitioner also notes that it submitted all required plans of correction. P. Sur-reply at 1. CMS's choice of remedies, or the factors CMS considered when choosing remedies, are not subject to review. 42 C.F.R. § 488.408(g)(2). [8] I cautioned Petitioner that if the evidence supported CMS's conclusion of noncompliance with program requirements, I had no authority to review the chosen remedy. Tr. at 7, 40, 234. CMS was authorized to terminate the Petitioner's provider agreement, effective May 5, 2008. *See* 42 C.F.R. § 488.456(b)(i).

[8] While Petitioner contends that the facility should have been given the opportunity to correct any deficiencies, CMS is not required to give the facility an opportunity to correct the noncompliance with federal participation requirements before imposing termination. *See Beechwood Sanitarium* at 27.

V. Conclusion

Based on my review of all of the evidence and testimony in this case, I sustain CMS's finding that Petitioner was out of substantial compliance with participation requirements at the time of the May 1, 2008 survey and CMS had the authority to terminate Petitioner's provider agreement.

/s/
Alfonso J. Montaño
Administrative Law Judge