Department of Health and Human Services
DEPARTMENTAL APPEALS BOARD
Appellate Division

Grand Oaks Care Center
Docket No. A-11-7
Decision No. 2372
March 30, 2011

FINAL DECISION ON REVIEW OF ADMINISTRATIVE LAW JUDGE DECISION

Grand Oaks Care Center (Grand Oaks) appeals the August 13, 2010 decision of Administrative Law Judge (ALJ) Alfonso J. Montano upholding a determination by the Centers for Medicare & Medicaid Services (CMS) terminating Grand Oaks from participating in the Medicare program effective May 5, 2008. *Grand Oaks Care Center*, DAB CR2219 (2010) (ALJ Decision). CMS based its determination on surveys performed in 2007 and 2008.

The ALJ concluded that Grand Oaks was not in substantial compliance with the Medicare participation requirements at 42 C.F.R. §§ 483.25 and 483.65, and that, therefore, CMS had the discretionary authority to terminate the facility under 42 C.F.R. § 488.456(b)(i). The ALJ also concluded that section 1819(h)(2) of the Social Security Act (Act) required CMS to terminate Grand Oaks' participation because Grand Oaks was not in substantial compliance with Medicare requirements over a period of six months.[1]

For the reasons explained below, we affirm the ALJ's conclusion that Grand Oaks was not in substantial compliance with sections 483.25 and 483.65 as of the May 2008 survey and that CMS had the discretionary authority to terminate Grand Oaks' participation in Medicare on that basis.

Applicable Law

Long-term care facilities participating in the Medicare and Medicaid programs must comply with participation requirements that are set forth at 42 C.F.R. Part 483. "Substantial compliance" means a level of compliance such that "any identified deficiencies pose no greater risk to resident health or safety than the potential for causing minimal harm." 42 C.F.R. § 488.301. "Noncompliance," in turn, is defined as "any deficiency that causes a facility to not be in substantial compliance." *Id.*

[1] The current version of the Social Security Act can be found at http://www.socialsecurity.gov/OP_Home/ssact/ssact.htm.

Survey findings as to noncompliance are reported in a Statement of Deficiencies (SOD). The SOD identifies each "deficiency" under its regulatory requirement, citing both the regulation at issue and the corresponding "tag" number used by surveyors for organizational purposes. The requirements at issue here are 42 C.F.R. § 483.25 (F Tag 309) (quality of care) and 42 C.F.R. § 483.65 (F Tag 441) (infection control).

A long-term care facility found not to be in substantial compliance is subject to various enforcement remedies, including state monitoring, temporary management, and termination. 42 C.F.R. §§ 488.402, 488.406, 488.408. A facility may not appeal CMS's choice of remedy. 42 C.F.R. § 488.408(g)(2).

Under section 1819(h)(2)(C) of the Act, CMS may not continue to make payments with respect to a facility that is not in substantial compliance for more than six months, i.e., termination becomes mandatory if substantial compliance is not achieved within six months of the last day of the survey where the noncompliance was originally identified. *See also* 42 C.F.R. §§ 488.412(a), (d); 488.450(d).

Factual background[2]

On November 5, 2007, the state survey agency, the Colorado Department of Public Health and Environment (state agency), surveyed Grand Oaks and found it was not in substantial compliance with 42 C.F.R. § 483.35(f) pertaining to frequency of meals. ALJ Decision at 2, *citing* CMS Ex. 3. The state agency directed Grand Oaks to submit a plan of correction and informed Grand Oaks that "if substantial compliance was not achieved by May 5, 2008," its provider agreement would be terminated. *Id*.

Thereafter, on December 19, 2007, February 1, 2008, and February 13, 2008, the state agency or CMS surveyed Grand Oaks, finding noncompliance with multiple participation requirements during each survey. ALJ Decision at 2. CMS notified Grand Oaks that, if substantial compliance was not achieved by May 5, 2008, its provider agreement would be terminated. *Id*. After the February surveys, CMS and the state agency also imposed the additional remedies of temporary management, effective March 8, 2008, and state monitoring. *Id*.

On May 1, 2008, the state agency conducted a complaint and revisit survey for the February surveys to determine if Grand Oaks had achieved substantial compliance with the participation requirements. *Id*. *citing* CMS Ex. 1. The surveyors determined that Grand Oaks had not achieved substantial compliance and that a pattern of deficiencies existed that constituted actual harm, but not immediate jeopardy. Specifically, they

[2] The information in this section is drawn from undisputed findings of fact in the ALJ Decision and undisputed facts in the record before him and is presented to provide a context for the discussion of the issues raised on appeal. Nothing in this section is intended to replace, modify, or supplement the ALJ's findings of fact or conclusions of law.

found that Grand Oaks had failed to correct three previously cited deficiencies and that Grand Oaks was not in substantial compliance with two additional requirements.

As a result of Grand Oaks' alleged failure to meet Medicare participation requirements as of the May survey, CMS informed Grand Oaks that it was terminating its provider agreement and that Medicare would not make payment for services furnished to residents admitted on or after May 5, 2008. *Id.*; CMS Ex. 1.

ALJ Decision

The ALJ made the following three numbered findings of fact and conclusions of law (FFCLs):

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

2. [Grand Oaks] was out of substantial compliance with the participation requirements at 42 C.F.R. § 483.25 and § 483.65 (F Tags 309 and 441).

3. CMS was authorized to terminate [Grand Oaks'] provider agreement.

ALJ Decision at 5, 6, and 8.

Grand Oaks appeals all three FFCLs. For the reasons discussed below, we uphold FFCLs 2 and 3. We do not adopt FFCL 1 because we, like the ALJ, conclude that CMS had discretionary authority to terminate the participation agreement on the grounds that Grand Oaks was not in substantial compliance with 42 C.F.R. §§ 483.25 and 483.65 as of May 1, 2008. Therefore, we find it unnecessary to reach whether termination was also legally mandatory.

Standard of review

We review a disputed finding of fact to determine whether the finding is supported by substantial evidence on the record as a whole and a disputed conclusion of law to determine whether it is erroneous. *See* Departmental Appeals Board, Guidelines—Appellate Review of Decisions of Administrative Law Judges Affecting a Provider's Participation in the Medicare and Medicaid Programs, http://www.hhs.gov/dab/guidelines/prov.html.

Analysis

On the basis of the May 1, 2008 survey, CMS found Grand Oaks was not in substantial compliance with section 483.25 (Quality of Care); section 483.60(a), (b) (Pharmacy

Services); section 483.60(d), (e) (Pharmacy Services); section 483.25(h) (Accidents and Supervision); and section 483.65 (Infection Control).

The ALJ addressed and upheld the deficiencies cited under sections 483.25 and 483.65. These citations concerned (1) care provided to Resident #3 (R3) for a scabies rash he suffered February through April 2008 and (2) the facility's non-enforcement of its infection control policies before and after R3's scabies was diagnosed on March 28.[3]

Grand Oaks' infection control policy described scabies as follows:

> Scabies is an itching skin irritation caused by the microscopic human itch mite. The mite burrows into the skin's upper layers and eventually causes itching, tiny irregular red lines just above the skin, and an allergic rash. . . . Symptoms sometimes include severe itching, which worsens at night.

CMS Ex. 9, at 3.

Below we review the regulations, the facts, and Grand Oaks' arguments and explain why we uphold the ALJ Decision.

> **1. The ALJ's determination that Grand Oaks was not in substantial compliance with 42 C.F.R. § 483.25 is supported by substantial evidence in the record as a whole and free of legal error.**

Section 483.25 provides:

> 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.

The State Operations Manual (SOM), Appendix PP, which provides guidance to surveyors, states that a facility is not in compliance with this requirement if staff has not:

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

[3] "In the interest of judicial economy," the ALJ reviewed only two findings of noncompliance because they "provide[d] a sufficient basis for the termination remedy imposed." ALJ Decision at 6 n.7, *citing 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"). We find no error in the ALJ's decision to limit his review under these circumstances.

> • 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.

SOM, App. PP at F Tag 309.[4]

CMS argued that Grand Oaks was not in compliance section 483.25 because it "failed to meet the most basic needs of [R3] when it consistently failed to take necessary steps to diagnose and treat" a scabies rash that caused R3 to itch for months. CMS Br. at 22.

R3 was admitted to Grand Oaks on February 5, 2008, with "an advisory that he had a rash and itching of an indeterminate source." ALJ Decision at 7, *citing* CMS Ex. 8, at 22; P. Response at 12. Over February and March, the rash, which was eventually diagnosed as scabies on March 28, was unresponsive to the medicines ordered by his treating physician. Tr. at 139. By March 11, a nurse recorded that R3 had "raised red rash over entire body," which he "itch[ed]." CMS Ex. 8, at 13. His scratching was so intense that, on March 23, a nurse recorded that he had "open areas" on his arm and requested the doctor to prescribe gloves to keep R3 from injuring his skin further by scratching. *Id*. at 6. When interviewed by the surveyor in May, a unit nursing manager described R3 as having been "scratching his brains out for months." CMS Ex. 4, at 14; *see also* Tr. at 143; CMS Ex. 6, at 1.

Grand Oaks staff did periodically report the itching condition to R3's treating physician and followed her treatment orders. For example, the physician ordered the use of hydrocortisone cream on February 11 (CMS Ex. 8, at 72), prednisone on February 22 (*id*.), and then ordered hydrocortisone again on February 29 (*id*. at 75), and prednisone again on March 13 (*id*. at 77), even though both treatments had previously been ineffective (CMS Ex. 4, at 5). Indeed, none of the medications ordered by the treating physician prior to March 28 stopped the itching or the spread of the rash since they were not designed to treat scabies. Tr. at 139. Finally, on March 24, the treating physician ordered a dermatology consult for R3. CMS Ex. 8, at 83. R3 was seen March 27, a skin biopsy was performed, and he was diagnosed on March 28 as having scabies. *Id*. at 31. On March 29, R3 was treated with Elimite, a "topical medication for the eradication of scabies." CMS Ex. 4, at 9.

R3's scabies condition went without effective treatment for almost two months. Tr. at 173-177. The CMS surveyor testified that, towards the end of February, when it had

[4] Appendix PP of the SOM is indexed by F Tag designations pertaining to specific regulatory provisions and is available at https://www.cms.gov/manuals/Downloads/som107ap_pp_guidelines_ltcf.pdf.

become apparent that his physician's treatment strategies were ineffective, the Grand Oaks staff should have revised their approach to R3's rash by involving the facility's Medical Director in obtaining more effective treatment for R3, such as referral to a dermatologist for a second opinion as to the cause of the rash. Tr. 140-141, 174, 177. The ALJ agreed. ALJ Decision at 7.

On appeal to the Board, Grand Oaks argues that "both the facility nursing staff and [the facility's temporary manager] did exactly what was required medically to treat the resident . . . ." RR at 2 (emphasis in original). It disputes the ALJ's alleged determination that "the facility's Medical Director should have been directly involved in the care and treatment of this resident." *Id*. It asserts:

> The resident's physician is the primary caregiver and only in an emergency situation should the facility's Medical Director get involved in administering care and treatment. No emergency occurred and the Medical Director did exactly as he was required, overseeing the safety of the remaining residents and nursing staff.

Id.

As explained below, these arguments are unsupported by evidence in the record and misstate the responsibilities of a nursing facility and its medical director under federal performance standards.

First, the evidence establishes that Grand Oaks did not do "exactly what was required medically to treat the resident." Grand Oaks does not dispute that R3 had symptoms consistent with scabies as of his admission on February 5. Nor does Grand Oaks dispute the surveyor's testimony that the treatments R3 was given for his skin condition prior to March 29 were not intended to and did not treat scabies. Indeed, Grand Oaks' Director of Nursing (DON) testified that, "after a few weeks [i.e., by the end of February] we wanted the dermatology consult because he was not improving, [but] it took time for [the treating physician] to agree to that." Tr. at 271. Therefore, the ALJ correctly determined that, after it became apparent that the doctor's treatment regimen was ineffective (which the surveyor and the DON agree was at least by the end of February) and prior to obtaining an order for a dermatology consult on March 24, R3 was not receiving or being provided, as Grand Oaks asserts here, "exactly what was required medically to treat" R3's skin condition.

Second, to the extent Grand Oaks is arguing that it, as a nursing facility, did all that was "medically required" of it under the applicable federal performance standards, Grand Oaks is incorrect. As discussed below, under those standards Grand Oaks was not entitled to simply rely on the treating physician's orders here after it became apparent that they were ineffective in relieving R3's suffering. Further, as even Grand Oaks' Medical Director recognized, Grand Oaks is incorrect when it asserts that medical directors are required to

become involved with resident care only when there is an emergency situation. *See* CMS Ex. 4, at 36.

The preamble of the final rule implementing the Omnibus Budget Reconciliation Act of 1987 (OBRA '87) nursing facility reforms explicitly states that nursing facilities are responsible for questioning physician orders that they consider inappropriate. The Secretary explained that commenters had "[i]ndicated that it is unfair to hold the facility responsible for compliance with requirements involving activities that must be performed by the physician, over whom the facility has little control." 54 Fed. Reg. 5316, at 5340 (1989). The Secretary responded:

> Regarding the issue of facility responsibility for requirements that involve performance by a physician, the nature of the survey and certification process is such that our enforcement mechanism is primarily through the facility itself rather than through the individual practitioners that serve the facility's residents. When a physician gives orders that the facility considers questionable, the facility's responsibility is to ensure that these concerns are, in fact, raised with the physician. We believe that the individual staff members' business and professional codes already require them to question any orders which they believe to be inappropriate. OBRA '87 reinforces this responsibility, by adding new sections 1819(d)(4)(A) (for Medicare) and 1919(d)(4)(A) (for Medicaid) to the Act. These sections require the facility to comply not only with applicable Federal, State and local requirements, but also with "accepted professional standards and principles which apply to professionals providing services in such a facility." We are modifying the applicable portions of the Administration requirement, § 483.75(b) and (c), to reflect this.

Id.

Substantial evidence in the record as a whole establishes that Grand Oaks did not take appropriate action after it was apparent that R3's treating physician had failed to effectively diagnose and treat R3's condition. Grand Oaks does not dispute that R3 continued to suffer from the rash after weeks of unsuccessful treatment ordered by the treating physician. The surveyor testified that the treating physician's use of ineffective treatments (some of them used multiple times) should have caused Grand Oaks' staff, before the end of February, to take action to secure more effective treatment for R3. Tr. 137-141; at 174; at 177. Grand Oaks' DON testified that its nurses believed R3 needed a dermatology consult "after a few weeks" because he was not improving (*id*. at 271; *see also id*. at 276), and that after R3 saw the dermatologist he "started getting appropriate treatment" *(id*. at 280). The surveyor stated that the staff should have therefore "elevated" this issue to the Medical Director so that he could request the treating physician to refer R3 to a dermatologist or directly refer R3 outside the facility for additional testing. Tr. at 140-141; 172-177. The surveyors testified that they saw no "evidence that this issue of [R3's] itching rash had ever been elevated to the medical director . . . ." Tr. at 141; *see also id*. at 105; 173.

On appeal, Grand Oaks denies that it had an obligation to involve the Medical Director. RR at 2. This position is contrary to its Medical Director's representations to the surveyor. In the SOD, the surveyor reported that the Medical Director told her that one of his roles was to "act[] as a liaison between the facility and other providers [and that] he expected the facility to notify him regarding any difficulties with other providers." CMS Ex. 4, at 36. Grand Oaks did not call the Medical Director as a witness or even dispute that he made this statement to the surveyor. If, as the DON testified, "we wanted the dermatology consult because [R3] was not improving, [but] it took time for [the treating physician] to agree to that" (Tr. at 271), she should have brought this problem to the attention of the Medical Director and enlisted his aid in solving it.

At the hearing the DON testified that R3's rash actually was brought to the attention of the Medical Director in a Quality Assurance (QA) meeting on March 8 and that the Medical Director "concurred with the treating physician." Tr. at 272-273; 277-278. Elsewhere, she testified that the Medical Director "thought that [a dermatology consult] would be something we should pursue" (*id*. *a*t 277) and that by the beginning of March other nurse(s) on R3's unit had talked to the treating physician about sending R3 for a dermatology consult (*id*. at 276-279). For the following reasons, we find that this apparently conflicting testimony does not show that the staff sought appropriate care for R3 or effectively involved the Medical Director in securing appropriate care for R3.

- Grand Oaks points to no documents that would tend to corroborate the DON's testimony on this point, such as notes from a QA meeting or entries in R3's record reflecting staff consultation with the Medical Director or treating physician about a dermatology consult for R3.

- The nursing notes record staff contacts with the doctor's office about R3's rash on March 9, 11, and 13 but make no mention of a dermatology referral request or a QA meeting discussion. CMS Ex. 8 at 15, 13, 12. In contrast, on March 17, a nursing note does record a discussion with the doctor's office "regarding QA meeting" but this discussion did not involve R3's rash. *Id*. at 10.

- The surveyor testified that she saw nothing in the records indicating that, prior to March 28th, the "issue of [R3's] itching rash" had been raised with the Medical Director. Tr. at 141. Also, her notes indicate that the Medical Director told the surveyor that he could not remember being contacted about R3 during the March 8 QA meeting. CMS Ex. 7, at 3.

Therefore, we conclude that the ALJ's determination that Grand Oaks failed to provide necessary care and services to enable R3 to attain or maintain his highest practicable physical, mental, and psychosocial well-being, as required by section 483.25, is supported by substantial evidence in the record as a whole and free of legal error.

2. The ALJ's determination that Grand Oaks was not in substantial compliance with 42 C.F.R. § 483.65 (infection control) is supported by substantial evidence in the record as a whole and free of legal error.

Scabies is an infectious condition which is "spread by skin to skin contact with the infected area, or through contact with bedding, clothing, privacy curtains and some furniture." CMS Ex. 9, at 1.
Section 483.65 of 42 C.F.R. sets forth requirements for "Infection Control" and provides in pertinent part:

> The 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.
>
> (a) *Infection control program*. The facility must establish an infection control program under which it (1) Investigates, controls, and prevents infections in the facility; (2) Decides what procedures, such as isolation, should be applied to an individual resident; and (3) Maintains a record of incidents and corrective actions related to infections.
>
> (b) *Preventing spread of infection*. (1) When the infection control program determines that a resident needs isolation to prevent the spread of infection, the facility must isolate the resident.

The SOD alleged that Grand Oaks was not in substantial compliance with section 483.65 because it failed to –

> --[r]espond to [R3's] rash, ruling out the cause and initiating effective treatment in a timely manner [and]
>
> --[i]nstitute infection control measures per facility policy once [R3] was diagnosed with scabies.

CMS Ex. 4, at 21; *see also* CMS Ex. 9 (Grand Oaks' infection control policy for scabies).

The ALJ's finding that Grand Oaks was not in substantial compliance with section 483.65 is supported by the following evidence.

First, as discussed in the prior section, Grand Oaks did not take timely steps to rule out an infectious condition such as scabies as the cause of R3's rash and to initiate effective treatment where (1) for weeks the attending physician was re-prescribing treatments that had previously failed, and (2) the facility knew that R3, who was "scratching his brains out" (CMS Ex. 4, at 14), was constantly wandering about his unit and was frequently lying down in other residents' beds. By failing to expeditiously determine the cause of R3's skin condition, Grand Oaks allowed other residents and staff to be exposed to an

infectious condition for almost a two-month period and thereby failed to "help prevent the . . . transmission of disease and infection" as required by section 483.65.[5]

Second, after R3's diagnosis, Grand Oaks failed to fully implement its scabies policy or comply with section 483.65 in the following ways:

- Grand Oaks' scabies policy required the facility to keep "[a]ffected residents . . . on Contact Isolation until twenty-four hours (24) hours after the last treatment." CMS Ex. 9, at 4-6. The nursing notes document that R3's behavioral pattern was to wander constantly, often in and out of residents' rooms (CMS 8, at 6, 9, 11, 15, 16, 19-21, 31) and to sleep in chairs in Grand Oaks' dining room (*id*. at 14, 16). Two CNAs also told the surveyors that R3 regularly got in other residents' beds to sleep; one of the CNAs said this would happen "at least twice per shift on average." CMS Ex. 4, at 35-36. The record does not show that the facility was able to change R3's behavior after he was diagnosed with scabies. The first day of his treatment (March 29), the nursing notes state "is on isolation precaution for scabies and is noncompliant. Wanders thru the halls and is very difficult to redirect back into room." CMS Ex. 8, at 32. Between March 29 and April 5 (his planned final treatment), the nursing notes state that he continued to wander about the facility "as usual" (*id*.) and that this is "the norm for this resident" (*id*. at 32-33). The surveyor testified that she found no documentation indicating that the staff had been able to successfully isolate R3 by redirecting his wandering. Tr. at 148-149. Further, the surveyor cited a nursing note indicating that R3 was easily redirected "but must have cont[inuous one-to-one] care," (CMS Ex. 8, at 9), and testified there was no documentation (or claim here) that Grand Oaks used one-to-one supervision to isolate R3 during his scabies treatment (Tr. at 148-149).[6]

- Section 483.65(a)(2) requires facilities to "[m]aintain a record of incidents and corrective actions related to infections." However, the surveyor testified she found no documentation showing that Grand Oaks "took precautions with regard to the living environment of the other residents in the facility" in response to R3's diagnosis of scabies and concluded that Grand Oaks had failed to take such precautions. Tr. at 148; CMS Ex. 4, at 24.

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[5] We note that one of Grand Oaks' owners submitted an affidavit stating that, upon R3's diagnosis, the DON and the state health monitor examined every resident in R3's unit and "no other residents were found to have scabies." However, Grand Oaks' scabies policy states that the "incubation period [for scabies] can be 2-6 weeks before onset of itching for persons with no previous exposure." CMS Ex. 9, at 3. Therefore, an examination at the end of March or beginning of April would not identify residents who had already contracted scabies but were not yet exhibiting symptoms.

[6] The treating physician initially prescribed a final treatment of Elimite to be applied April 5. CMS Ex. 8, at 86. On April 16, the physician ordered that R3 be retreated for scabies with two additional applications of Elimite. CMS Exs. 8, at 36; 4, at 33. On April 30, the treating physician ordered an oral medication for scabies for R3. CMS Exs. 8, at 92-93; 4, at 33-34. Again, Grand Oaks points to no documentation that it ensured contact isolation of R3 during these later treatment periods or followed the other requirements of its policy discussed above.

- Although Grand Oaks' scabies policy set forth requirements about laundry and sanitizing the residential environment, Grand Oaks points to no documentation (or other evidence) showing that it complied with the following requirements in its scabies policy: conducting daily skin examinations of the two residents living in the room with R3; effecting special containment and laundering of four of R3's outfits and sealing his remaining clothes for 14 days; cleaning and disinfecting the shower room after R3 was treated; vacuuming fabric furniture in R3's room and wrapping the furniture in plastic bags for two weeks; and conducting special cleaning protocols in R3's room for specific days in his treatment cycle. CMS Ex. 9, at 4-6.

- Grand Oaks' scabies policy also required it to provide "personal protective equipment," such as gloves, to staff. *Id*. at 4. The surveyor reported that a CNA responsible for R3's care told her that, while gloves were supposed to be used when working with R3, sometimes gloves were not available. CMS Ex. 4, at 36; *see also* Tr. at 147.

The only evidence we see that arguably supports Grand Oaks' position that it implemented these aspects of its scabies policy is the following non-specific testimony. Its temporary manager testified that "I believe we did follow all the [infection control] procedures" and that "we did a cleaning" in March "when we [the temporary management] first got to the facility" and one on May 1. Tr. at 249. He also testified that "[w]e cleaned a whole unit down, we followed all the procedures that we -- the QA process that we should have." Tr. at 226. The DON testified "I didn't see any issues with infection control." Tr. at 280. The director of admissions/co-owner submitted an affidavit stating that, when R3 was diagnosed with scabies, the DON and a state health monitor examined every resident in R3's unit and "no other residents were found to have scabies"; that "Grand Oaks maintained its infection control program . . . to the best of its ability" by "continually redirecting [R3] back to his room"; that "all linens were washed at an outside facility"; and that R3's "unit was thoroughly disinfected along with the rest of the facility." P. Ex. 13, at 2-3. This nonspecific testimony is not persuasive in light of the surveyors' contrary findings, the nursing notes stating that R3 wandered about the unit as "as usual," and in the absence of any "record of . . . corrective actions related to infections" as required by section 483.65(a)(3).

On appeal to the Board, Grand Oaks also asserts it was in substantial compliance with section 483.65 because "no other persons (residents or staff) [were] infected" with scabies, which establishes that "the facility's nursing staff fully accomplished their task." P. Reply at 2.

Grand Oaks' allegation that other residents did not have scabies is not grounds for reversing the ALJ Decision for the following reasons.

First, CMS is not required to show that noncompliance has resulted in actual harm to residents. *See* 42 C.F.R. §§ 488.301; 488.404. Therefore, the alleged fact that no other residents contracted scabies would not require the ALJ to infer that Grand Oaks was in compliance with section 483.65. Further, given the evidence in the record indicating that Grand Oaks failed to implement its scabies policy and the absence of required documentation about implementation, inferring that Grand Oaks fully implemented its scabies policy would be unreasonable even if there had been no additional cases of scabies.

Second, there is substantial evidence in the record as a whole indicating that other residents had actually contracted scabies as of the May 1 survey. The evidence is as follows:

- The surveyor performed skin audits of seven residents in which she found that these residents (one of whom was R3's roommate (Tr. at 151)) had raised red pin-point bumps characteristic of a scabies rash and similar to R3's rash, and some of these residents told the surveyor that they itched. CMS Ex. 4, at 37-44.[7]

- The DON testified that the symptoms exhibited by these residents were consistent with conditions other than scabies, such as poor circulation. Tr. at 274-275. However, Grand Oaks' witnesses did not directly dispute the surveyor's descriptions of the skin condition of these residents or deny that the symptoms the surveyor described were also consistent with scabies.[8] Moreover, although other staff members were present during these examinations, Grand Oaks did not call them as witnesses to rebut the surveyor's recorded observations. *See* CMS Ex. 4, at 37-42.

- The temporary manager testified that he believed no residents other than R3 had scabies as of May 1. Tr. at 236. He gave no basis for his belief. He also stated

[7] Grand Oaks objects that the ALJ improperly relied on the surveyor's "diagnosis" of scabies as to the seven other residents and that nurses are not qualified to make such a diagnosis. RR at 2. This argument is without merit. The ALJ did not find the surveyor had diagnosed the other residents as having scabies. Rather, he found that the surveyor's skin audits "had revealed rashes similar to [R3's] on May 1, 2008." ALJ Decision at 8. Moreover, as the ALJ noted, "no biopsies were conducted to determine if the additional residents had scabies." *Id*. Grand Oaks was free to conduct such biopsies had it seen fit to do so.

[8] As to diagnosis of scabies, Grand Oaks' scabies policy advises:

> Diagnosis may be established by recovering the mite from its burrow and identifying it microscopically. Failure to identify scrapings as positive does not necessarily indicate a negative diagnosis. It is very difficult to obtain a positive scraping because only one or two mites may cause multiple lesions. Often diagnosis is made from signs and symptoms and treatment followed without scrapings.

CMS Ex. 9, at 4. Elsewhere, the policy advises: "Should scrapings be ordered, contact the lab. (Note: Negative scrapings are not significant. Treatment should be administered if symptoms are present.)" *Id*. at 5.

> that, after the seven residents' physicians were contacted about the surveyor's observations, they ordered the residents to be treated for scabies. *Id.* at 229-231.

- Indeed, the surveyors were told on May 2 that Grand Oaks had conducted its own survey of all residents in the facility, contacted the Medical Director, and the Medical Director had recommended "the entire resident population be given prophylaxis treatment for scabies." CMS Ex. 4, at 46.

We recognize that facilities may sometimes take actions that they regard as uncalled for to establish that they have returned to substantial compliance. We find it unlikely, however, that a medical director would order an entire nursing home population to be treated for scabies if he did not believe there was a medical basis for such an order, i.e., that scabies remained present in the facility and posed a threat to the resident population.

Therefore, we conclude that the ALJ's determination that Grand Oaks failed to maintain an infection control program designed to provide a safe environment and to help prevent the development and transmission of disease, as required by section 483.65, is supported by substantial evidence in the record as a whole and free of legal error.

3. CMS was authorized to terminate Grand Oaks' provider agreement.

CMS may terminate a facility's provider agreement 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).

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). A facility may not appeal CMS's choice of remedy. 42 C.F.R. § 488.408(g)(2).

Here we uphold the ALJ's conclusion that Grand Oaks was not in substantial compliance with two participation requirements. Thus, CMS has the discretion to terminate a facility for such noncompliance, and its choice of the remedy of termination is not reviewable by the ALJ or this Board.

4. Grand Oaks' other arguments do not provide a basis for reversing the ALJ decision.

Grand Oaks makes other arguments related to the temporary manager and the alleged prejudice and bad faith of the state agency and the surveyors. These arguments do not provide a basis for reversing the ALJ Decision.

First, Grand Oaks argues that the state agency and the temporary manager were responsible for managing the facility between March 8, 2008 and May 5, 2008 and are responsible if the facility was not in substantial compliance as of those dates. RR at 3-4. Presumably, Grand Oaks is asserting that, for this reason, CMS should not terminate its provider agreement.

We reject this argument as contrary to the purpose of the Act. Temporary managers are authorized by section 1819(h)(2)(B)(iii) of the Act. It provides:

> In consultation with the State, the Secretary may appoint temporary management to oversee the operation of the facility and to assure the health and safety of the facility's residents, where there is a need for temporary management while –
>
> * * *
>
> (II) improvements are made in order to bring the facility into compliance with [federal participation requirements].

CMS appoints temporary managers where it believes the facility's management "lacks the capacity to bring the facility into compliance." 59 Fed. Reg. 56,116, at 56,189 (1994). In promulgating the final rule providing for appointment of a temporary manager, the Secretary gave the following response to a comment about managers' ultimate performances.

> *Comment*: One commenter asked that providers be allowed a time period to demonstrate an ability to correct deficiencies if, because of a temporary manager's incompetence, deficiencies have not been corrected timely.
>
> *Response*: A temporary manager's failure to correct facility deficiencies does not absolve a facility of its responsibility for generating corrections to those deficiencies, and if deficiencies are not corrected or the immediate jeopardy is not removed timely, the facility will be terminated. [CMS] and the State are not required to provide facilities with additional time to come back into substantial compliance, but we are obligated to ensure that Medicare beneficiaries and Medicaid recipients receive the quality care to which they are entitled.

59 Fed. Reg. 56,189. CMS appoints a temporary manager when it has a basis to believe that he/she is better able to return a facility to substantial compliance than the existing management. To allow facilities to avoid or delay termination because a temporary manager ultimately fails to achieve substantial compliance would subvert the Act's goal of encouraging facilities to maintain substantial compliance in the first place or to return to substantial compliance as quickly as possible, and, if they cannot do so, protecting Medicare and Medicaid recipients by terminating the provider agreement.

Second, Grand Oaks asserts that its temporary manager testified that the facility was in substantial compliance on May 1. RR at 3. While Grand Oaks does not cite a particular page of the transcript, we do see where the temporary manager characterized as "accurate" an email of July 8, 2008 from his attorney which represented that, in the temporary manager's opinion, the facility "was in substantial compliance on May 1, 2008." Tr. at 227-228, *citing* P. Ex. 6.[9]

Neither the temporary manager's opinion as to substantial compliance or the surveyors' contrary opinions are dispositive here. The authority for deciding substantial compliance lay with the ALJ. *Meadowbrook Manor – Naperville*, DAB No. 2173, at 15 (2008); *see* Tr. at 228 (The ALJ stated "It's a de novo hearing . . . and at risk of repeating myself, I have to decide based on the evidence here whether or not the facility was in compliance.").

Third, Grand Oaks alleges prejudice and bad faith on the part of the state agency and CMS and asserts that each surveyor looked at the facility on the basis of "I must find something wrong." RR at 3.

These allegations are not a basis for reversing the ALJ Decision. The purpose of an ALJ hearing is to give a facility an opportunity to show, before an impartial tribunal, that the facts on which the surveyors based their determination of noncompliance are not as the surveyors depicted them or do not otherwise support that noncompliance determination. Thus, allegations of surveyor bias in an ALJ de novo review are immaterial "where objective evidence [such as a facilities' own records] establishes noncompliance . . . ." *Jewish Home of Eastern Pennsylvania*, DAB No. 2255, at 14-15 (2009); *aff'd, Jewish Home of Eastern Pa. v. Centers for Medicare and Medicaid Services*, No. A-09-3006 (3rd Cir. Feb. 11, 2011), *citing Canal Medical Laboratory*, DAB No. 2041, at 6 (2006). In such cases, an ALJ's de novo evaluation of the objective evidence would correct any alleged bias in a surveyor's evaluation of that evidence. Here, the facility's records were sufficient to show that Grand Oaks was not in substantial compliance with at least two participation requirements on May 1, 2008.

[9] We note that, when the DON was asked whether she believed that Grand Oaks was in substantial compliance on April 30, 2008, she replied: "I felt the facility had made great strides in improving the professionalism of the nurses and how they perform their duties. The residents were happy. They were well fed and well cared for, and they wished to remain there. I guess that's the best I can say." Tr. at 282.

Conclusion

For the reasons stated above, we affirm the ALJ Decision.

_____/s/_____
Stephen M. Godek

_____/s/_____
Leslie A. Sussan

_____/s/_____
Judith A. Ballard
Presiding Board Member