

[PUBLISH]

IN THE UNITED STATES COURT OF APPEALS

FOR THE ELEVENTH CIRCUIT

No. 07-12404

FILED U.S. COURT OF APPEALS ELEVENTH CIRCUIT October 22, 2008 THOMAS K. KAHN CLERK

Agency No. A-60-50-

EMERALD SHORES HEALTH CARE ASSOCIATES, LLC,
d.b.a. EMERALD SHORES HEALTH & REHABILITATION
CENTER,

Petitioner,

versus

UNITED STATES DEPARTMENT OF
HEALTH AND HUMAN SERVICES,
CENTERS FOR MEDICARE & MEDICAID SERVICES,

Respondent.

Petition for Review of a Decision of the
Department of Health & Human Services

(October 22, 2008)

Before BIRCH, DUBINA and HILL, Circuit Judges.

BIRCH, Circuit Judge:

Emerald Shores Health Care Associates, LLC, petitions for review of a decision by the Departmental Appeals Board (“DAB”) for the United States Department of Health and Human Services (“DHHS”) imposing a civil monetary penalty (“CMP”) for violating 42 C.F.R. § 483.70(h)(4). Emerald Shores argues that the DAB did not have substantial evidence to support its decision that Emerald Shores was not in substantial compliance with the regulation. After review, we grant the petition, VACATE the DAB’s decision, and REMAND for further proceedings consistent with this decision.

I. BACKGROUND

A. Regulatory Framework

Petitioner Emerald Shores is a skilled nursing facility in Calloway, Florida that participates in both Medicare and Medicaid. Such facilities must meet a number of statutory and regulatory guidelines. See generally 42 U.S.C. § 1395i-3 (2003); 42 C.F.R. Part 483 (2008). In order to ensure that these requirements are fulfilled, the Centers for Medicare and Medicaid Services (“CMS”), a division of DHHS, enters into agreements with state agencies to help monitor and enforce compliance. See 42 U.S.C. § 1395aa; 42 C.F.R. § 488.10(a)(1). In Florida, the applicable state department is the Agency for Health Care Administration (“AHCA”).

As part of its responsibilities to CMS, AHCA must conduct regular surveys of each licensed facility at least every fifteen months. See 42 C.F.R. § 488.308(a). It also must perform special surveys whenever complaints are brought, including follow-up visits to monitor facilities that are attempting to correct previously-noted deficiencies. See id. §§ 488.308(e)(2), 488.332(b)(1). Surveyors record their findings on CMS Form 2567, identifying all deficiencies by an agency-assigned “tag” number. In addition, Form 2567 provides space for them to note the scope and severity of the problem, the regulation being violated, and any specific findings to support the citation.

CMS uses these surveys as a basis for potential disciplinary action, selecting remedies appropriate to the scope and severity of the particular deficiency. See 42 C.F.R. § 488.408(a). A facility would be in “substantial compliance” if “individual deficiencies pose no greater risk to resident health or safety than the potential for causing minimum harm.” Id. § 488.301. Either CMS or the state can impose a civil monetary penalty (“CMP”) for each day a facility is not in substantial compliance. See 42 U.S.C. § 1395i-3(h)(2)(B)(ii); 42 C.F.R. § 488.430(a). The maximum penalty is \$10,000 per day of noncompliance, with the permissible range depending on the severity of the deficiencies. See 42 C.F.R. § 488.438(a). The regulations permit a penalty between \$3050 and \$10,000 per day if the deficiencies constitute “immediate jeopardy” and between \$50 and \$3000 if they cause actual

harm or have the potential to cause more than minimal harm. See id. “Immediate jeopardy” exists if a deficiency “has caused or is likely to cause, serious injury, harm, impairment, or death to a resident.” Id. § 488.301. In determining the appropriate penalty amount, CMS can consider such factors as the scope and severity of the deficiency, the degree of culpability and the facility’s past history of noncompliance. See id. §§ 488.404, 488.438(f). In addition, noncompliant facilities are required to develop a “plan of correction” to remedy these deficiencies. See id. § 488.401.

A Medicare provider can appeal a decision to impose a CMP to an administrative law judge (“ALJ”) pursuant to 42 C.F.R. § 498.40. At the hearing before the ALJ, CMS must put forward a prima facie case of noncompliance. See Cross Creek Health Care Ctr., D.A.B. No. 1665 (1998). Once this showing is made, the provider bears the burden of persuasion, which can be met by proving, by a preponderance of the evidence, substantial compliance with the regulation. See id. Both parties have the right to have the DAB review the ALJ’s decision pursuant to 42 C.F.R. § 498.80. The DAB determines whether the ALJ’s conclusions of law were erroneous and his findings of fact were supported by substantial evidence in the record. See id. In CMP cases, a facility can seek judicial review of the DAB’s decision with the appropriate circuit of the United States Court of Appeals. See 42 U.S.C. § 1320a-7a(e).

B. CMS Investigation and Response

On 7 July 2004, a bedridden resident of Emerald Shores ("Resident #1") was stung by fire ants approximately forty times.¹ AHCA received a complaint about this incident, resulting in a survey of the facility on 16 July. The survey team identified two deficiencies in its survey: failure to "maintain an effective pest control program," in violation of 42 C.F.R. § 483.70(h)(4), and failure to "develop and implement written policies and procedures that prohibit mistreatment, neglect, and abuse of residents and misappropriation of resident property," in violation of 42 C.F.R. § 483.13(c). Based on these findings, CMS determined that Emerald Shores's situation constituted "immediate jeopardy." Both before and after this finding, Emerald Shores began implementing a plan of correction.² On 28 July, AHCA performed a follow-up survey and deemed Emerald Shores to be in substantial compliance. After AHCA made this finding, CMS imposed a CMP of \$120,000 for the total violations, amounting to \$10,000 for each day between 16 July and 27 July, the period in which Emerald Shores was in immediate jeopardy.

¹ The AHCA survey report refers to the residents by number rather than name, as does the ALJ. We will use the same scheme for the sake of consistency.

² The record is rather unclear about what Emerald Shores's pest control program entailed both before and after 16 July as well as when any changes were proposed and implemented. Emerald Shores's plan of correction discusses various actions already taken or soon to be taken during this time frame, including an enhanced integrated pest management (IPM) program, additional barrier treatment, implementation of a monthly maintenance plan, regular inspections of rooms and building exteriors, and staff training programs.

C. Administrative Review Process

Emerald Shores sought administrative review of the CMP, filing claims at both the federal and state level. It successfully challenged the survey results in the state administrative review process, with the AHCA determining that it had been in compliance during the period in question. CMS did not rescind its penalties, however, so Emerald Shores then filed a request for hearing with the DHHS.

On review, the ALJ determined that Emerald Shores had no punishable violations on or after 16 July and thus rejected the CMP based on the survey findings from that date. His review focused on whether Emerald Shores had done “all that it reasonably could be expected to do to prevent ant infestation and to protect its residents against ant stings.” He noted that CMS had not prescribed any particular pest control program for nursing homes and had given little guidance as to how it would assess such a program. To fill this gap, the ALJ attempted to identify key elements that could constitute an effective program. He looked to the testimony of Dr. Michael Merchant, an entomology professor called by CMS as an expert witness, for guidance in determining what the relevant elements would be. In his written declaration, Dr. Merchant described an integrated pest management program (IPM) as “one of the best plans of attack to eradicate fire ants” and identified a number of ways in which Emerald Shores’s pest control program was deficient. R6 at 714–15. The ALJ synthesized Dr. Merchant’s recommendations

into three elements: extensive surveillance of the grounds and buildings; effective documentation of problems to aid in coordinating ant control; and an effective eradication program.³ Based on the record, he found Emerald Shores to have met all three requirements by 16 July, which thus put it in substantial compliance with the regulations.⁴

CMS requested that the DAB review the ALJ's decision. After examining the record, the DAB reversed the ALJ's findings with respect to the effective pest control program requirement.⁵ The DAB determined that there was not substantial evidence in the record to support the ALJ's decision. It based this conclusion on Emerald Shores's failure to show that CMS's immediate jeopardy finding was clearly erroneous. In assessing the effectiveness of the pest control program, the DAB did not require Emerald Shores to have adopted any particular method but emphasized that "[e]vidence of significant numbers of ants and other pests" would indicate "lack of any effective program," whether or not it involved IPM. R2 at 21

³ Importantly, though, the ALJ did not require that a facility meet these criteria to be compliant. See R2 at 6 (refusing to "find[] that a facility which fails to implement the system described by Dr. Merchant to control fire ant infestation is necessarily out of compliance with 42 C.F.R. § 483.70(h)(4)).

⁴ In addition to finding substantial compliance with the "effective pest control" requirement, the ALJ also found substantial compliance with two other regulations, 42 C.F.R. §§ 483.13(c) & 483.10(b)(7)(iii)-(iv), which deal with policies and procedures regarding resident abuse and neglect.

⁵ The DAB upheld the ALJ's findings of substantial compliance with 42 C.F.R. §§ 483.13(c) & 483.10(b)(7)(iii)-(iv). These decisions were not part of the petition for review.

n.5 (emphasis in original). Examining the record, the DAB found evidence of “numerous ant sightings” during the period in question, in sharp contrast to the ALJ’s identification of “two areas of ant activity.” Id. at 8, 23. Under the DAB’s standard, this constituted sufficient evidence to overturn the ALJ’s findings on that point. In addition, the DAB noted that the ALJ had not considered evidence that Emerald Shores had failed to implement essential parts of its IPM program until 28 July, most notably a “full barrier treatment.” Id. at 25–28. Since the DAB had not accepted all of the bases for CMS’s proposed CMP, it reduced the amount to \$8500 per day (\$102,000 overall). The DAB found this amount, which was in the upper range for “immediate jeopardy” penalties, appropriate due to the “ongoing inadequacy” of the pest control program, the increased risk of harm to the residents, and the actual harm that resulted. Id. at 42–43. Emerald Shores subsequently petitioned us for review of the DAB’s decision.

II. DISCUSSION

In its petition for review, Emerald Shores contests the DAB’s determinations that there was not substantial evidence to support the ALJ’s findings and that its deficiency constituted “immediate jeopardy.” In reviewing the imposition of a CMP, we are statutorily required to treat as conclusive all findings of fact made by the DAB, so long as they are supported by substantial evidence. See 42 U.S.C. § 1320-7a(e). Substantial evidence “means such relevant evidence as a reasonable

mind might accept as adequate to support a conclusion.” Richardson v. Perales, 402 U.S. 389, 401, 91 S. Ct. 1420, 1427 (1971). We have no statutory guidance regarding the appropriate standard for reviewing legal conclusions, however. In similar reviews of administrative actions we have reviewed such conclusions de novo, focusing on whether the correct legal standards were applied and refusing to presume the validity of any legal conclusions. See Black Diamond Coal Mining Co. v. Director, Office of Workers’ Comp. Programs, United States Dep’t of Labor, 95 F.3d 1079, 1082 (11th Cir. 1996) (involving claim for disability benefits due to black lung); Davis v. Shalala, 985 F.2d 528, 531 (11th Cir. 1993) (reviewing determination of Social Security benefits). We find this standard appropriate, particularly since the DAB and ALJ were not acting as policymakers, which means we do not accord their legal interpretations the same degree of deference we would an administrative agency’s. See Black Diamond, 95 F.3d at 1082.

Long-term care facilities participating in Medicare and Medicaid must “[m]aintain an effective pest control program so that the facility is free of pests and rodents.” 42 C.F.R. § 483.70(h)(4). Our review of the DAB’s decision thus involves two separate inquiries: what would constitute an “effective” program and whether there is substantial evidence supporting a determination that Emerald Shores failed to meet this standard. CMS and DHHS do not require facilities to adopt any particular program and have offered very little guidance about the

standards for assessing effectiveness. In the absence of any detailed elaboration of the regulatory requirements, we think it appropriate to assess the DAB's evidence of noncompliance in light of what Emerald Shores would have reasonably expected it was required to do. In making this evaluation, we find it relevant to consider DAB decisions and official CMS/DHHS publications as well as those agencies' past interactions with and directions to Emerald Shores.

The record includes only one government document discussing the "effective pest control" requirement in any detail — CMS's guidebook for surveyors of long term care facilities. The guide describes an "effective pest control program" as "measures to eradicate and contain common household pests," including ants. R6 at 682. Additionally, it advises surveyors that "[e]vidence of pest infestation in a particular space is an indicator of noncompliance." Id. However, the guidebook provides no standards for determining how many such observations would be sufficient for a finding of noncompliance or even what would constitute an "infestation."

Apart from this handbook, the remaining agency-related discussions of the provision all appear in administrative decisions. Prior to 16 July 2004, the date of Emerald Shores's alleged violation, only two decisions, one by the ALJ and one by

the DAB, discuss pest control programs in depth.⁶ In the former instance, Western Care Management Corp., D.A.B. No. CR1020 (2003), the ALJ determined that the existing pest control program was ineffective, though he did not articulate any clear standard of effectiveness. Instead, he based his decision on evidence showing a pattern of repeated incidents over multiple months in which ants were found in residents' beds and even in one resident's mouth.⁷ See Western Care Mgmt. Corp., D.A.B. No. CR1020 (2003). In addition, he emphasized that the facility had not been diligent in responding to previous complaints lodged by residents.⁸ See id. In the latter matter, Price Hill Nursing Home, D.A.B. No. 1781 (2001), the DAB found the nursing home's pest control system deficient but did not explicitly articulate the standard it used to make this determination, noting only that the facility had not put forth any evidence to show substantial compliance. In addition, it commented that an effective pest control system should account for seasonal

⁶ Though DHHS cites other DAB decisions in its brief, they all occurred after the relevant events here. See, e.g., Lake Mary Health Care, D.A.B. No. 2081 (2007). Emerald Shores cannot reasonably be held liable based on subsequent interpretations of the provision. Additionally, federal and state courts appear not to have ever addressed the regulation, though a Texas court briefly discussed a similarly-worded state law provision in a 2008 case. See Omaha Healthcare Ctr., LLC v. Johnson, 246 S.W.3d 278, 286 (Tex. App. 2008). That court determined that the statute-in-question did not set forth any "specialized standard" but rather required "only that there be a [pest control] program." Id.

⁷ The ALJ did not specify whether they were fire ants.

⁸ The DAB affirmed the ALJ's decision but did not elaborate on the "pest control" issue. See Western Care Mgmt. Corp., D.A.B. No. 1921 (2004).

variations in pest level. See Price Hill Nursing Home, D.A.B. No. 1781 (2001).

The DAB did make clear, however, that it did not expect nursing homes to have to eliminate every single pest in order to comply. See id.

Based on these decisions and official guidance, Emerald Shores could have reasonably expected that the effectiveness of its pest control system would be evaluated on something less than a strict liability standard, though exactly how much less would have been unclear. Price Hill and Western Care indicate that noncompliance would not be assumed based on the presence of a single pest but that it might occur if a facility failed to respond to repeated past infestations which had occasioned patient complaints. Further, the guidebook shows that a finding of noncompliance could be based, at least in part, on the presence of some undefined number of pest infestations at the facility.

Perhaps even more importantly, CMS had not previously cited Emerald Shores for any pest control-related penalties — even though there had been past incidents involving ants on the premises — nor had it ever suggested any changes to Emerald Shores’s pest control program. The most illustrative example of this was the response to an August 2003 incident in which a resident was stung by fire ants.⁹ This incident was reported to the AHCA, which investigated the complaint

⁹ The ALJ’s mention of a July 2003 biting incident appears to reference the same event and likely reflects a misstatement in a hearing transcript. Both parties described the event as occurring in August 2003.

and found Emerald Shores not to be in violation of the regulations. Additionally, CMS and DHHS never informed Emerald Shores that its pest control program was ineffective prior to the 16 July survey nor did they recommend that it adopt any specific programs to make it effective. It was also only after 7 July that Emerald Shores's pest control providers first suggested areas for improvement, including enhanced barrier treatment and monthly maintenance of the treatment. Emerald Shores adopted these recommendations soon afterward, putting in barrier treatments on 9, 16 and 21 July and purchasing a monthly maintenance plan on 23 July. Based on this history, it seems reasonable to conclude that Emerald Shores was not on notice prior to 7 July (and perhaps even thereafter) that it was not in substantial compliance with the effective pest control requirement.

Similarly, Emerald Shores was reasonable in assuming compliance based on its history of pest infestations. The July 2004 survey team based its finding of noncompliance on incidents reported by four individuals. One was the 7 July 2004 biting of Resident #1 which initiated the inquiry. A different resident ("Resident #2") claimed to have been bitten by ants about two months prior to the 7 July 2004 incident, though the nursing assistant could not see any bites and the resident did not report the incident to anyone else, including his son. The surveyors also noted that family members of Resident #2 and Resident #5, who were roommates, had

seen ants in their relatives' room in late June.¹⁰ Of these four events, only Resident #1's biting was reported to Emerald Shores supervisors, though Resident #5's spouse informed a maintenance worker, who subsequently sprayed the room. In addition to these pre-survey problems, the DAB noted that there were a number of observed sightings of ants or ant mounds in the period between 16 July and 27 July.

Overall, this amount of infestation does not appear to be of the same pervasive, extended nature as that which occurred in Western Care, nor was Emerald Shores's response as inadequate as that of Price Hill. Western Care had repeated, documented infestations over a period of months to which the facility failed to respond. See Western Care Mgmt. Corp., D.A.B. No. CR1020. Emerald Shores, on the other hand, appeared to have only a few sporadic problems prior to July 2004. Based on the evidence presented, the facility was first put on notice of a possible deficiency by the 7 July occurrence, since none of the earlier problems were reported to it, apart from the August 2003 incident for which it had been cleared. Further, once Emerald Shores learned of the problem, it began to implement changes even before the 16 July survey occurred. This stands in sharp

¹⁰ These appear to represent a single infestation, since both family members mention that they observed the ants around the same time, three weeks earlier. Apparently Resident #2 left a peanut butter sandwich on a bedside table overnight, which attracted ants. Assuming that the dates given by Resident #2 are correct, this event was likely distinct from the earlier biting incident, which Resident #2 said occurred two months prior to the interview.

contrast to Price Hill, which only took action once the surveyors noticed a problem. See Price Hill, D.A.B. 1781 (noting that “Price Hill removed bugs from the food storage area only after the surveyors pointed them out”). Though there were still ants present at Emerald Shores after 16 July, these were likely attributable more to the difficulties in attempting to determine how to combat a theretofore unknown problem rather than to any punishable failure to respond on Emerald Shores’s part.

Based on all of these factors, we conclude that the DAB’s decision was not supported by substantial evidence in the record. The DAB relies on two factors in its decision: the presence of substantial numbers of ants after 16 July and the failure to implement critical parts of its IPM program by 16 July. Though we do not disagree with these factual determinations, we find them legally insufficient to merit a finding of noncompliance with 42 C.F.R. § 483.70(h)(4), particularly considering the lack of guidance given to Emerald Shores prior to 16 July. In the absence of any mandatory, or even suggested, standards for establishing a pest control program, it is unreasonable to expect Emerald Shores to know that CMS would view its plan as not in substantial compliance with the statute. We find it particularly noteworthy that AHCA had previously found Emerald Shores’s pest control program compliant, even after the August 2003 incident, and that, despite

this finding, Emerald Shores purchased a barrier treatment soon after, thus enhancing its already-compliant program.

As we previously noted, both the continued presence of ants and the implementation of further protective measures should be viewed in light of the fact that Emerald Shores had only recently become aware of the problem and was trying to implement solutions with little to no assistance from CMS. Though the DAB disavowed the use of a strict liability standard, it seemed to evaluate Emerald Shores's response in just such a light. For instance, it considered the fact that Emerald Shores had not fully completed every part of its revised pest control plan by 16 July as de facto evidence of a deficiency, even though the facility had already taken steps to rectify the problem and would be clearly compliant soon after. In making this determination, the DAB focused on whether Emerald Shores had implemented by 16 July the elements of a successful IPM program, as described by Dr. Merchant and synthesized by the ALJ. However, this emphasis would seem to run counter to the DAB's assertion that Emerald Shores did not have to follow this conception of IPM to have an effective program. Though the ALJ found, and Emerald Shores asserts, that the implemented pest control program met Dr. Merchant's standards by 16 July, we do not consider this finding necessary to prove compliance, especially given the context in which Emerald Shores was operating prior to that date and its actions thereafter.

We agree with the DAB that Emerald Shores did not have the ideal pest control program at the time of the 16 July survey. However, we find that the program it had in place substantially complied with the requirements of the regulation, at least insofar as Emerald Shores would have reasonably understood them at the time. Assessing whether a pest control program is “effective” will almost always involve some degree of subjectivity due to the inherent vagueness of quantifying and qualifying “effectiveness.” This difficulty is further compounded by the average nursing home administrator’s lack of expertise in pest control methods, which makes such an individual reliant on the advice and assistance of professional exterminators. If CMS had provided a more objective and particularized concept, then we would be more inclined to affirm a finding of noncompliance. In the absence of such advice and the failure to produce any evidence that Emerald Shores did not implement a recommended pest control measure within a reasonable time frame, we find that the DAB’s conclusions not to have sufficient evidentiary support.¹¹

III. CONCLUSION

Emerald Shores petitions for review of a DAB decision to impose a CMP for failing to maintain an effective pest control program. Though there was evidence

¹¹ Since we make this conclusion, we need not address whether the situation constituted “immediate jeopardy.”

of fire ant problems at Emerald Shores, we find the facility's response reasonable and sufficient based on the then-current understanding of effectiveness; thus the DAB's decision was not supported by substantial evidence. Accordingly, we grant Emerald Shores's petition for review and VACATE the DAB's decision and REMAND for proceedings consistent with this opinion.