NOT RECOMMENDED FOR FULL-TEXT PUBLICATION
File Name: 06a0809n.06
Filed: November 3, 2006

No. 05-4194

UNITED STATES COURT OF APPEALS
FOR THE SIXTH CIRCUIT

LAKERIDGE VILLA HEALTH CARE CENTER,	)	
Petitioner-Appellant,	)	
v.	)	**ON APPEAL FROM THE DEPARTMENTAL APPEALS BOARD OF THE UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES**
MIKE LEAVITT, Secretary, United States Department of Health and Human Services; UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES,	)	
Respondent-Appellee.	)	

Before: GIBBONS and MCKEAGUE, Circuit Judges; FORESTER, District Judge.[*]

JULIA SMITH GIBBONS, Circuit Judge. Petitioner Lakeridge Villa Health Center ("Lakeridge") is an Ohio specialized nursing care facility that participates in the Medicare and Medicaid programs under an agreement with respondent, the Secretary of Health and Human Services ("Secretary"). As a participant in the federal programs, Lakeridge is required to be in substantial compliance with federal requirements for skilled nursing homes ("provider

[*] The Honorable Karl S. Forester, Senior United States District Judge for the Eastern District of Kentucky, sitting by designation.

requirements"). The Ohio Department of Health ("ODH") surveyed Lakeridge on behalf of the Centers for Medicare and Medicaid Services ("CMS") and found that Lakeridge was not in substantial compliance with several provider requirements. CMS imposed a civil monetary penalty ("CMP") against Lakeridge in the amount of $80,300. An administrative law judge ("ALJ") upheld the CMP and, on appeal, the Departmental Appeals Board of the Department of Health and Human Services ("DAB") upheld the decision of the ALJ. Lakeridge appealed the DAB decision. Because substantial evidence supports the DAB's decision, we affirm.

I.

As a skilled nursing service provider, Lakeridge receives federal payments in accordance with its provider agreement with the Secretary. 42 U.S.C. § 1395i-3. As part of the Medicare system, Lakeridge must substantially comply with provider requirements for such nursing facilities as described in the Social Security Act. 42 U.S.C. § 1395i-3(a)-(d); 42 C.F.R. §§ 483.1-483.75 (identifying provider requirements). State health agencies, acting by agreement with the Secretary, conduct surveys of participating nursing facilities to monitor their compliance with provider requirements. 42 C.F.R. § 488.305. Deficiencies identified during such surveys subject the facility to a range of enforcement actions, including the imposition of a CMP of up to $10,000 per day of violation, depending on the seriousness of the offense. 42 U.S.C. § 1395i-3(h)(2)(B)(ii). The Secretary has clarified that "deficiencies constituting immediate jeopardy" are eligible for penalties ranging between $3,050 and $10,000 per day, while "deficiencies that do not constitute immediate jeopardy, but either caused actual harm, or caused no actual harm, but have the potential for more than minimal harm" are eligible for fines ranging between $50 and $3,000 per day of violation. 42 C.F.R. § 488.438(a)(i)-(ii). CMPs begin on the date that the Secretary finds that the facility became

out of compliance and end when the facility has achieved substantial compliance. *Id.* § 488.440.

The following facts are not in dispute. On August 27, 1999, ODH, a designated reviewing state agency, completed a standard survey[1] at Lakeridge. ODH identified violations of five provider requirements of sufficient seriousness to warrant a CMP, including one violation of 42 C.F.R. § 483.25(h)(2), creating immediate jeopardy, and violations of 42 C.F.R. §§ 483.13, 483.25, 483.25(c), and 483.25(d)(2), not producing immediate jeopardy.[2] On October 8, 1999, ODH completed a revisit survey. As a result of this survey, Lakeridge was determined to be in substantial compliance with the provider requirements as of October 3, 1999. CMS imposed a fine on Lakeridge in the amount of $5,150 per day from August 23, 1999 to August 30, 1999 and $1,150 per day from August 31, 1999 until October 3, 1999, for a total of $80,300. Lakeridge timely requested a hearing, which occurred over three days before an ALJ. CMS presented testimony by four state surveyors, including three registered nurses and a registered dietician, and Lakeridge presented testimony from one licensed practical nurse in its employ. The ALJ found that Lakeridge was not in substantial compliance with respect to the asserted violations during the periods asserted and upheld CMS's imposition of a CMP. On appeal, the DAB upheld the ALJ's determination.

II.

This court's review of the DAB's imposition of a CMP is "highly deferential." *Woodstock Care Ctr. v. Thompson*, 363 F.3d 583, 588 (6th Cir. 2003). "The findings of the Secretary with

---

[1] A standard survey is "a periodic, resident-centered inspection which gathers information about the quality of service furnished in a facility to determine compliance with the requirements for participation." 42 C.F.R. § 488.301.

[2]CMS also presented evidence of a deficiency under 42 C.F.R. § 483.20(b), but the ALJ determined Lakeridge was in substantial compliance with this section.

respect to questions of fact, if supported by substantial evidence on the record considered as a whole, shall be conclusive." *Id*. (quoting 42 U.S.C. § 1320a-7a). Substantial evidence is "such relevant evidence as a reasonable mind might accept as adequate to support a conclusion." *Myers v. Sec'y of Health & Human Servs.*, 893 F.2d 840, 842 (6th Cir. 1990) (quoting *Richardson v. Perales*, 402 U.S. 389, 401 (1971)). As to questions of law, significant deference is accorded to the agency's interpretation of its own regulations, and such an interpretation will be overturned only if it is "arbitrary, capricious, an abuse of discretion or otherwise not in accordance with law." *St. Francis Health Care Ctr. v. Shalala*, 205 F.3d 937, 943 (6th Cir. 2000) (citation and quotation marks omitted). The court "do[es] not consider the case de novo, nor resolve conflicts in the evidence, nor resolve questions of credibility." *MeadowWood Nursing Home v. United States Dep't of Health & Human Servs.*, 364 F.3d 786, 788 (6th Cir. 2004) (internal citation and quotation marks omitted).

A.

Lakeridge first contends that both the ALJ and the DAB applied an incorrect standard of review in this case "by placing the burden of persuasion on the facility" under *Hillman Rehabilitation Center*, DAB No. 1611 (1997), *available at* 1997 WL 123708. *Hillman*'s burden-shifting framework applies only when the evidence is in equipoise. *Batavia Nursing & Convalescent Ctr. v. Thompson*, 143 F. App'x 664, 665 (6th Cir. 2005) (citing *Fairfax Nursing Home, Inc. v. United States Dep't of Health & Human Servs.*, 300 F.3d 835, 840 n.4 (7th Cir. 2002)). The evidence in this case is not in equipoise. As a result, *Hillman* does not apply, and the panel need not address the validity of the *Hillman* standard.[3]

[3] Counsel for Lakeridge has raised an identical challenge to *Hillman* at least five times on behalf of different clients. *See Harmony Court v. Leavitt*, No. 05-3644, 2006 WL 2188705, at *1 (6th Cir. Aug. 1, 2006); *Ivy Woods Healthcare & Rehab. Ctr. v. Thompson*, 156 F. App'x 775,

B.

Lakeridge proceeds to offer evidence purporting to counter the findings of deficiency made by the CMS and upheld by the DAB. Although we are not obliged to review every violation, we outline the findings of the DAB to demonstrate the substantial evidence supporting the imposition of the CMPs.

1. 42 C.F.R § 483.25(h)(2)

Lakeridge's most serious violation was based on 42 C.F.R. § 483.25(h)(2), which requires facilities to provide adequate supervision and assistance devices to prevent accidents. The DAB found that Lakeridge violated this regulation by attaching restraints to immovable objects in a manner warned against by the restraint manufacturer and by not supervising residents who were thus restrained. These failures created immediate jeopardy to six residents. Resident 30 has an impaired cognitive status and a history of falling out of bed, and ODH observed her attempting to get out of a bed with lowered side rails five times while restrained and unsupervised, thereby placing her at risk of suffocation. ODH observed Resident 29 attempting to remove her restraint while unsupervised, placing herself at risk of suffocation as a result, and Resident 8 attempting to get out of bed while wearing a waist restraint and unsupervised while wearing the restraint, even after the ODH surveyor informed the nursing staff of the resident's attempt to leave the bed. Resident 22, like Resident 8,

---

778 (6th Cir. 2005); *Sanctuary at Whispering Meadows v. Thompson*, 151 F. App'x 386, 388-89 (6th Cir. 2005); *Batavia Nursing & Convalescent Ctr. v. Thompson*, 143 F. App'x 664, 665 (6th Cir. 2005); *Batavia Nursing & Convalescent Ctr. v. Thompson*, 129 F. App'x 181, 183-84 (6th Cir. 2005). On each occasion, panels of this court have declined to entertain the claim for the same reasons articulated in this opinion. The briefing on behalf of Lakeridge makes no mention, however, of this argument's lack of success before the Sixth Circuit. While we are mindful of counsel's wish to preserve this issue should there be a change in the law, we believe it incumbent upon him to notify any future reviewing panels of the status of this argument in the Sixth Circuit. *See Thompson v. Parkes*, 963 F.2d 885, 888 n.1 (6th Cir. 1992).

attempted to get out of bed while restrained and unsupervised. Resident 74 was incorrectly placed in an improperly sized vest restraint, and ODH observed the resident become repeatedly suspended by the restraint while unsupervised. Finally, Resident 73 was unsupervised while wearing a pelvic restraint, contrary to the manufacturer's instructions. The ALJ and DAB both found this evidence sufficient to show immediate jeopardy to the restrained residents.

Lakeridge challenges the findings of deficiency as to each of these residents, but it does not challenge the facts underlying the ALJ's and the DAB's holdings. Instead, Lakeridge asserts that it was following a physician's instructions in each case and makes unsubstantiated assertions that its supervision was adequate. These arguments are unavailing. Not only does § 483.25(h)(2) not address the justification for the use of restraints, but the ODH surveyors' unchallenged observations of residents attempting to get out of bed and becoming suspended are sufficient evidence to support the DAB's conclusion that Lakeridge's supervision was inadequate. In addition, whether or not the supervision was adequate, Lakeridge has not addressed CMS's argument that the restraints were in some cases incorrectly sized and secured.

Lakeridge also asserts that it cannot be cited for violating § 483.25(h)(2) because no actual injury occurred; to hold otherwise, Lakeridge argues, would be to impose a strict liability standard. Neither the regulation nor this court requires that actual harm occur for an immediate jeopardy finding to be valid. *Woodstock*, 363 F.3d at 589-90; *see also* 42 C.F.R. § 488.301 (defining "immediate jeopardy" as "a situation in which the provider's noncompliance with one or more requirements of participation has caused, *or is likely to cause*, serious injury, harm, impairment, or death to a resident.") (emphasis added). This holding does not impose strict liability but rather requires a nursing facility to take reasonable care to avoid accidents. As we have noted, the question

of whether a facility's precautions are reasonable "is highly fact-bound and can only be answered on the basis of expertise in nursing home management. As such, it is a question the resolution of which we defer to the expert administrative agency, the HHS." *Woodstock*, 363 F.3d at 589. Thus, Lakeridge has provided no basis on which the panel could overrule the DAB's conclusion that Lakeridge violated 42 C.F.R. § 483.25(h)(2).

2. 42 C.F.R. § 483.13

The regulations guarantee nursing facility residents "the right to be free from any physical or chemical restraints imposed for purposes of discipline or convenience, and not required to treat the resident's medical symptoms." 42 C.F.R. § 483.13(a). The DAB found that Lakeridge violated this requirement with respect to at least four residents. Lakeridge's sole argument is that this determination is flawed because each restrained patient exhibited medical symptoms warranting the use of restraints and because restraints were used upon a doctor's orders.

This justification is unpersuasive. Even if the use of restraints on a patient is warranted for a medical purpose, that use may not exceed the bounds established by § 483.13(a). As the DAB has noted:

> Because section 483.13(a) is directed towards nursing facilities, the regulation imposes on the long-term care facility an independent obligation to ensure that the use of restraints, even with a doctor's order, meets the criteria of the regulation. Further, it imposes an independent obligation to continue to assess the impact of the use of a restraint and to consult with the doctor if the nursing facility finds that use of the restraint no longer meets the criteria of the regulation. Finally, review of a facility's compliance requires careful consideration to make sure that the facility is implementing the doctor's restraint order pursuant to its terms. Therefore, a long-term care facility cannot rely solely on a doctor's order to prove compliance with section 483.13(a) and must be able to show with other evidence as appropriate that the specific restraints applied were not imposed for discipline or convenience and were necessary to treat a medical symptom.

Cross Creek Health Care Ctr., DAB No. 1665, at 11 (1998).

The record is replete with evidence supporting the DAB's determination as to the manner in which Lakeridge personnel utilized restraints. Although Lakeridge restrained Resident 29 on the basis of a doctor's order to immobilize the resident following a hip fracture, Lakeridge did not reassess the need for restraints after the fracture healed in May 1999. The DAB also determined that two patients were in pelvic restraints to a degree not supported by a physician's orders. Resident 73 was to be released from her restraints after two hours, but was restrained for three hours during the ODH survey. Similarly, Resident 62 was restrained for four consecutive hours, even though her physician ordered that she be released after two hours.

Other than noting that each of these residents had symptoms that could support the use of restraints, Lakeridge has not contested the evidence supporting the DAB's findings for any of these residents. The undisputed evidence is sufficient to support the DAB's conclusion that Lakeridge violated § 483.13(a) because Lakeridge used restraints, at a minimum, in ways not permitted by a physician's orders. There is substantial evidence to support the DAB's conclusion that Lakeridge violated § 483.13(a).

3. 42 C.F.R. § 483.25

The DAB upheld CMS's citation of Lakeridge for violating the catchall provision, which requires that "[e]ach resident . . . receive and the facility . . . 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 ALJ determined that Lakeridge violated § 483.25 with respect to several residents by not providing care consistent with that provided for in the plan of care for each resident. Lakeridge does

not offer a challenge to the findings underlying the DAB's decision as to §483.25. Instead, it presents two arguments wholly unrelated to the evidence. It contends, first, that it is inappropriate to cite the nursing facility under the general language of § 483.25 when the violations could have been cited under a specific subsection. Second, it insists, generally, that no causal relationship exists between the care administered by Lakeridge employees and the problems suffered by the residents.

Lakeridge's first contention is without merit and exhibits a misunderstanding of the deficiency; not only has Lakeridge failed to identify a specific subsection under which failure to follow a plan of care would be appropriately addressed, but such identification would not be dispositive. A single act can easily violate more than one provision, as did Lakeridge's care for some residents who developed pressure sores as a result of Lakeridge's failure to follow a prescribed standard of care. As the DAB stated, relying on *Beechwood Sanatarium*, DAB No. 1906 (2004), "[t]he fact that CMS may have been able to cite a deficiency under another tag is irrelevant." JA 75.[4]

Lakeridge's causation argument is similarly unavailing. The issue of whether Lakeridge followed the plan of care is logically independent from the health outcome of the care actually delivered. Actual harm is not required for Lakeridge to violate the provider requirements. Nor does the mere presence of adequate plans of care suffice; the ALJ did not determine that the plans of care were insufficient but rather determined that Lakeridge failed to follow them.

4. 42 C.F.R. § 483.25(c)

Lakeridge next claims that the DAB wrongly upheld the CMP imposed for violation of

[4] In fact, the regulations anticipate this eventuality; one of the factors to be considered in assessing a fine is "the relationship of the one deficiency to other deficiencies resulting in noncompliance." 42 C.F.R. § 488.404(c)(1).

§ 483.25(c), which provides:

> Based on the comprehensive assessment of a resident, the facility must ensure that–
>
> (1) A resident who enters the facility without pressure sores does not develop pressure sores unless the individual's clinical condition demonstrates that they were unavoidable; and
>
> (2) A resident having pressure sores receives necessary treatment and services to promote healing, prevent infection and prevent new sores from developing.

42 C.F.R. § 483.25(c). CMS claims that Lakeridge violated this subsection by allowing several residents to develop pressure sores and by failing to provide necessary treatment of such sores.

The ALJ determined that Lakeridge failed to provide proper pressure sore care to four residents. This decision is supported by substantial evidence as to each of the residents. Resident 24 suffered from a pressure sore that increased in size between August 17 and August 26, 1999. The ODH surveyor noted that Resident 24 was left in a chair with no pressure-relieving device for three hours and two hours on two separate occasions. The surveyor testified that the pressure sore was exacerbated by these long periods without movement. The surveyor also noted that the sore was not dressed, in contravention of a physician's instruction, and that the wound was covered by a urine-soaked incontinence brief while not dressed. The surveyor testified that this condition also exacerbated the condition of the sore. This is sufficient evidence to support the ALJ's determination that Lakeridge failed to provide necessary care to promote healing and prevent infection of the sore. The fact that Lakeridge's plan of care included the application of an ointment to the area twice a day and that no doctor noted any sores prior to the development of the sore on August 19, 1999 does not change this conclusion. The ALJ could reasonably credit the surveyor's testimony and determine that Lakeridge was not providing necessary treatment despite the fact that Lakeridge provided some

treatment.

The ALJ's conclusions as to the other residents is similarly supported by substantial evidence. Resident 29 had a sore that increased in size, and the surveyor saw that feces were allowed to come in contact with the wound. Like Resident 24, Resident 29 was restrained in a wheelchair without a pressure-relieving device. Lakeridge defends its actions by claiming that no doctor ordered the use of a pressure-relieving device. This is an insufficient argument: Lakeridge cannot fail to take action based on its reliance on the lack of a prescribed course of action; Resident 29 had a sore, and the regulation requires Lakeridge to use a pressure-relieving device whether or not prescribed.

Resident 9 exhibited several pressure sores. Like the preceding residents, he was left in his wheelchair for an extended period without a pressure-relieving device. He was not toileted and was allowed to sit in urine. The ALJ could properly determine that Resident 9 was not provided the required standard of care to promote healing of the sores. This would be true even if the panel accepted Lakeridge's argument that the ALJ improperly relied on an abrasion of the resident's skin rather than on pressure sores. The evidence regarding the chair positioning and toileting of the resident is sufficient to support the decision.

In sum, there is substantial evidence to support the DAB's determination that Lakeridge violated § 483.25(c).

5. 42 C.F.R. § 483.25(d)(2)

Finally, Lakeridge challenges the DAB's conclusion as to its violation of § 483.25(d)(2), which requires nursing facilities to ensure that "[a] resident who is incontinent of bladder receives appropriate treatment and services to prevent urinary tract infections and to restore as much normal bladder function as possible." 42 C.F.R. § 483.25(d)(2).

As is the case for the other violations, substantial evidence supports the Secretary's conclusion that Lakeridge's care violated § 483.25(d)(2). Resident 39 is a particularly egregious example of Lakeridge's failings in this area. According to the ALJ, the resident's toileting program was insufficient because it was to be used only three to five times per week. The facility failed to provide toileting in advance of need as required by the care plan. The resident was transferred to her bed after spending two hours in her chair during dinner without being offered toileting, the resident soiled herself less than 45 minutes later, and the staff did not change the brief for an additional 45 minutes. Finally, the resident was left in a chair for three hours without an offer of toileting. Lakeridge's sole defense to this evidence is to claim that the patient refused treatment due to knee pain. CMS rightly notes, however, that this claim is based on testimony as to Resident 31, not Resident 39

The record reveals a number of similar deficiencies. Resident 31, who was left in bed wearing a wet brief, knew when she needed to use the bathroom but was unable to find help at that time. Resident 26 was not offered toileting after meals or at bedtime in violation of the plan of care. Resident 30 was left for more than an hour wearing a soiled brief and was not cleaned when the brief was changed. Resident 9 received assistance moving to the commode only upon the surveyor's prompting, and his soiled brief was replaced only after the resident successfully used the commode. This is substantial evidence to support the Secretary's finding.

C.

Finally, Lakeridge challenges the amount of the fine imposed by CMS.[5] Lakeridge, however,

[5] CMS claims that Lakeridge has not challenged the reasonableness of the CMP. Lakeridge, however, has made a sufficient argument as to this point to require review of the issue.

provides no reason why the fine is excessive. CMS imposed a fine well within the statutory range for both the immediate-jeopardy violation and the non-immediate-jeopardy violations. In imposing a CMP, CMS is required to consider (1) the facility's history of noncompliance; (2) the facility's financial condition; (3) the facility's degree of culpability; and (4) the factors listed in 42 C.F.R. § 488.404. 42 C.F.R. § 488.438(f). Section 404 allows CMS to consider the scope and severity of the deficiencies and the relationship of one deficiency to other deficiencies resulting in noncompliance.

In this case, the ALJ analyzed the fines separately for each jeopardy category. In upholding the CMP as to the immediate-jeopardy violation, the ALJ considered: (1) the severity of the violation; (2) the broad scope of the violation, which affected six separate residents; (3) Lakeridge's poor compliance history; and (4) Lakeridge's culpability, because its staff appeared indifferent to the plight of its residents. As to the violations not creating immediate jeopardy, the ALJ considered (1) scope, both as to the large numbers of affected residents and the number of separate types of violation; (2) severity, because several residents suffered actual harm from the violations; and (3) Lakeridge's prior history of violations, especially as to pressure sores. The ALJ adequately considered the required factors to satisfy any procedural reasonableness claim and reached a reasonable conclusion as to the amount of the CMP.[6]

III.

For the reasons outlined above, we affirm the decision of the Departmental Appeals Board.

---

[6] Lakeridge also argues that CMS may not assess a fine while the facility is implementing a plan of correction. Lakeridge points to no authority, however, within the statute or the applicable regulations to support the proposition that the adoption of a corrective plan by a care provider effects a stay of penalties upon the adoption and execution of a corrective plan. Rather, the regulations state that per-day civil money penalties are computed and collectible "for the number of days of noncompliance until the date the facility achieves substantial compliance . . . ." 42 C.F.R.§ 488.440(b).