In the
United States Court of Appeals
For the Seventh Circuit

No. 01-4088

FAIRFAX NURSING HOME,
INCORPORATED,

Petitioner,

v.

UNITED STATES DEPARTMENT
OF HEALTH & HUMAN SERVICES,

Respondent.

Petition for Review of a Final Decision of the
Department of Health and Human Services
Department Appeals Board, Appellate Division.
DAB No. 1794

ARGUED MAY 29, 2002—DECIDED AUGUST 15, 2002

Before RIPPLE, DIANE P. WOOD and EVANS, *Circuit Judges*.

RIPPLE, *Circuit Judge*. Fairfax Nursing Home is a skilled nursing facility participating in Medicare and Medicaid. Fairfax was assessed a civil monetary penalty ("CMP") by the Center for Medicare and Medicaid Services ("CMS") because of its failure to comply substantially with Medicare regulations governing the care of respirator-dependent nursing home residents. Fairfax appealed to the Department Appeals Board of the Department of Health and

Human Services ("HHS"); after a hearing before an Administrative Law Judge, both the ALJ and the Appellate Division affirmed the CMP. Pursuant to 42 U.S.C. §§ 1320a-7a(e) and 13951-3(h)(2)(B)(ii), Fairfax appeals that decision to this court. Fairfax argues that the Department Appeals Board ("DAB") erroneously placed the burden of proof on Fairfax and that the ALJ applied the incorrect legal standard in determining that Fairfax had violated HHS regulations. For the reasons set forth in the following opinion, we affirm the decision of the Appeals Board.

I

BACKGROUND

A. Facts

Fairfax is a skilled nursing facility ("SNF"), *see* 42 U.S.C. § 1395i-3(a); 42 C.F.R. § 488.301, participating in Medicare and Medicaid (collectively "Medicare") as a provider. Regulation of SNFs is committed to the Center for Medicare and Medicare Services, formerly known as the Health Care Financing Administration ("HCFA"),[1] and to state agencies with whom the Secretary of Health and Human Services has contracted. *See* 42 U.S.C. § 1395aa(a). The primary method of regulation is by unannounced surveys of SNFs, conducted in this case by surveyors of the Illinois Department of Public Health ("IDPH"). *See* 42

[1] We shall refer to this agency by its present name, CMS, because it has been more than one year since the name change was implemented. *See* 66 Fed. Reg. 35,437 (July 5, 2001). However, in some places, when quoting from the record or the decisions of the ALJ and the Appellate Division, the agency is referred to as HCFA.

U.S.C. § 1395i-3(g). These surveys are conducted at least once every 15 months. *See id.* § 1395i-3(g)(2)(A)(iii). If the state survey finds violations of Medicare regulations, the state may recommend penalties to CMS. The civil monetary penalty imposed here was based on an IDPH recommendation.

CMS imposed the penalty because of series of failures in Fairfax's care of ventilator-dependent residents. On December 20, 1996, R10, a ventilator-dependent resident at Fairfax, suffered respiratory distress and required emergency care.[2] Respiratory therapists administered oxygen directly to R10, and one therapist turned off R10's ventilator because the alarm was sounding. Once R10 was stabilized, the therapists left, but neglected to turn the ventilator back on. As a result, R10 died. Prompted by this incident, Fairfax began to develop a policy for the care of ventilator-dependent residents. That policy was completed in February 1997 and was implemented in early March of that year. The policy provided that once the resident was stabilized following an episode of respiratory distress:

> the nurse will check the resident & chart Q 15 minutes X 4 (for a total of 1 hr.) encompassing the following: vital signs/respiratory status oxygen stats [saturation] /lung sounds/vent settings/level of consciousness/ odor color and consistency of secretions & comfort level of the resident.

Admin. R., App. A at 517.

On March 2, 1997, R126 was observed to have a low oxygen saturation level, an elevated pulse and temperature, and to be breathing rapidly. These signs indicated that the

---

[2] All residents are denoted by number to respect their privacy.

resident was having respiratory difficulties. R126's physician was called; he ordered a chest x-ray and gave several other instructions. However, contrary to Fairfax's policy, R126's medical chart did not reflect whether these orders were carried out. R126 died shortly thereafter.

On March 5, 1997, R127 was found with low oxygen saturation and mottled extremities. Fairfax staff failed to make a complete assessment, took no vital signs, made no follow-up assessments and did not notify a physician. On March 7, R127 was found cyanotic and required five minutes of ambu-bagging. Nurses charted four follow-up notes, but only observed R127's color and oxygen saturation and took no other vital signs. Also on March 7, during the 7 a.m. to 3 p.m. shift, three episodes of respiratory distress were noted, each of which required ambu-bagging. No physician was called. On March 10, R127's skin was observed turning blue, but there was no record of treatment for respiratory distress and no vital signs or assessments were charted. On March 21, R127 had another episode, this time with mottled legs, shaking and a dangerously low oxygen saturation. The physician was present; R127 was ambu-bagged and administered Valium. There was no complete assessment and no follow-up. On March 25, R127 was found to have a severe infection and died on March 27.

On March 23, 1997, R83 was found nonresponsive with low oxygen saturation, low blood pressure, an elevated pulse rate and a low respiratory rate. R83 was ambu-bagged, and the treating physician was called. The first noted follow-up was an hour later and 2-1/2 hours passed before R83 was monitored again.

On April 2, 1997, a state surveyor observed a Fairfax employee fail to use sterile procedures while perform-

ing tracheostomy care on R6 and R11. The same employee also neglected to hyper-oxygenate the residents before or after suctioning the tracheostomy.[3]

On April 3, 1997, R68 became cyanotic, with low oxygen saturation, which required ambu-bagging and an increase in the amount of oxygen given through the ventilator. The records for R68 failed to note R68's vital signs, and the record did not reflect whether R68 oxygen saturation level ever returned to a normal level. On April 4, R68 was not sufficiently stable to permit a routine tracheostomy change.

After a survey on April 8, 1997, IDPH surveyors determined that Fairfax's actions and omissions posed "immediate jeopardy" to the health and safety of its residents. Specifically, Fairfax had violated 42 C.F.R. § 483.25(k), which pertains in part to the special care of ventilator-dependent residents. CMS concurred and notified Fairfax by a letter dated May 7, 1997, that CMS was imposing a CMP of $3,050 per day for a 105-day period, from December 20, 1996, through April 3, 1997, during which Fairfax was not in substantial compliance with HHS regulations governing the care of ventilator-dependent residents. CMS also assessed a penalty for a period of noncompliance running from April 4, 1997, through May 14, 1997. The total penalty for this latter period was $2,050, and Fairfax did not challenge it.

---

[3] Hyper-oxygenation refers to "giv[ing] the patient or resident more air prior to suctioning, because when you introduce the suction catheter that's attached to the suction machine and you're actually drawing out both secretions and air, and when you hyper-oxygenate a patient or resident you're giving them air to . . . help them through the process." Admin. R., App. A at 294. This procedure should be followed both before and after suctioning. *See id.* at 295.

B. Administrative Law Judge's Decision

Fairfax appealed the CMP to the HHS Department Appeals Board ("DAB"), which reviews the imposition of CMPs pursuant to a provider's right of review under 42 C.F.R. § 498.5. The DAB assigned the case to an administrative law judge who held a hearing in late May and early June 2000. Applying an earlier DAB Appellate Division decision, *Hillman Rehabilitation Center v. United States*, DAB No. 1611 (1997), the ALJ required that CMS make out a prima facie case for the imposition of the CMP, but assigned the ultimate burden of proof to Fairfax. Thus, Fairfax had to prove, by a preponderance of the evidence, that it was substantially compliant with the applicable regulations. The ALJ affirmed CMS' initial determination to impose a CMP of approximately $320,000 on Fairfax. In doing so, the ALJ found that a state of immediate jeopardy prevailed at Fairfax from December 20, 1996, until April 3, 1997, due to Fairfax's violations of 42 C.F.R. § 483.25(k).

The ALJ discussed each of the violations found by the state surveyors, beginning with the death of R10. R10 died, in part, the ALJ concluded, because Fairfax did not have in place a policy for the monitoring of ventilator-dependent residents following an episode of respiratory distress. This lack of a policy and later failures to comply with the new policy posed severe risk to the health and well-being of the patients. The ALJ found that all but one of the surveyors' reported violations constituted a risk to patients at the immediate jeopardy level. The ALJ emphasized the repeated monitoring failures and the threat those failures posed to the residents. The ALJ found that "there is not only a prima facie case of noncompliance here, but the preponderance of the evidence is that Petitioner was not complying substantially" with the regulations governing the proper care of vent-dependent residents. Admin. R.

at 24. Finally, the ALJ found that the amount of the CMP was reasonable.

C. Department Appeals Board, Appellate Division Decision

Fairfax appealed the ALJ's decision to the DAB Appellate Division. Fairfax argued that the ALJ erred following the Appellate Division's earlier ruling in *Hillman* and assigning the ultimate burden of proof to Fairfax. It further contended that the ALJ applied the wrong legal standard, linked together unrelated incidents and that the amount of the CMP was punitive, rather than remedial.

With respect to the burden of proof, CMS submitted that Fairfax had waived the issue by not raising it before the ALJ. The Appellate Division took note of this objection, but decided the issue on the merits. The Appellate Division first concluded that the burden of proof was irrelevant because the evidence was not in equipoise. The Appellate Division nevertheless reaffirmed *Hillman* and rejected Fairfax's argument. The Appellate Division also rejected Fairfax's other arguments, determining that the ALJ applied the proper legal standard, that the ALJ's decision was supported by substantial evidence and that the amount of the CMP was reasonable. Fairfax appeals. We have jurisdiction under 42 U.S.C. § 1395i-3(h)(2)(B)(ii) and 42 U.S.C. § 1320a-7a(e).

II

DISCUSSION

We must now determine whether substantial evidence supports CMS' conclusion that a state of immediate jeop-

ardy prevailed at Fairfax from December 20, 1996, until April 4, 1997.[4]

---

[4] In *Hillman Rehabilitation Center v. United States*, DAB No. 1611 (1997), *available at* 1997 WL 123708, the Appellate Division of the HHS Department Appeals Board held that in termination hearings before an ALJ, the sanctioned facility bears the burden of persuasion once HHS has made a prima facie showing to justify the CMP. *See Hillman*, at 1; Appellant's App. 1. This rule was extended to civil monetary penalty cases by *Cross Creek Health Care Center v. HCFA*, DAB No. 1665 (1998), *available at* 1998 WL 479291. Fairfax argues that the *Hillman* rule violates the Administrative Procedure Act in two ways.

HHS argues that Fairfax waived its objection to HHS' assignment of the burden of proof to Fairfax by failing to raise the issue before the ALJ. Fairfax did raise the issue on appeal to the DAB Appellate Division. Under the statute governing our review, a party must raise an issue before "the Secretary" in order to preserve the issue. *See* 42 U.S.C. § 1320a-7a(e). Nevertheless, we think raising the issue on appeal within the DAB is sufficient to preserve it for our review. Further, the Appellate Division itself did not rely on waiver and resolved the merits of Fairfax's appeal.

Fairfax submits that the Secretary was required to promulgate this rule by notice-and-comment rulemaking and that such a rule could not be adopted by adjudication. Second, Fairfax argues that *Hillman* violates APA § 7(c), which places the burden of proof on the "proponent of a rule or order." 5 U.S.C. § 556(d).

We believe that several reasons militate against our addressing this issue at this time. First, the issue does not affect the outcome in this case. By its own terms, the rule in *Hillman* is operative only when the evidence is in equipoise, and, as our discussion in the text indicates, the evidence in this case certainly cannot be characterized as in equipoise. Secondly, we believe that this issue ought to be addressed with great prudence

(continued...)

A.

We first address Fairfax's argument that the ALJ employed the incorrect legal standard. The regulations set up two basic categories of conduct for which CMPs may be imposed. *See* 42 C.F.R. §§ 488.408, 488.438. The upper range, permitting CMPs of $3,050 per day to $10,000 per day, is reserved for deficiencies that constitute immediate jeopardy to a resident or, under some circumstances, repeated deficiencies. *See id.* § 488.438(a)(i). By contrast, the lower range of CMPs, which begin at $50 per day and run to $3,000 per day, is reserved for "deficiencies that do not constitute immediate jeopardy, but either caused actual harm or have the potential for causing more than minimal harm." *See id.* § 488.438(a)(ii). "Immediate jeopardy" is defined 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." *Id.* § 488.301.

Fairfax emphasizes the ALJ's use of the term "potential" to describe the probability of harm in several of the ALJ's findings. It submits that the ALJ's use of this terminology establishes that the deficiencies in question were deserving of "lower range" penalties. We take each in turn.

---

[4] (...continued)
and caution. The Appellate Division has not addressed the application of this rule to civil monetary penalties in any comprehensive manner. Premature adjudication on our part will not be helpful in achieving accuracy or clarity in this important area of administrative practice. Definitive adjudication on our part is best reached after that administrative body has had the opportunity to set forth in more plenary fashion than it has in this case the justification for this rule.

Finding 1(b):

> Petitioner failed to carry out the treating physician's orders and failed to properly document R126's medical charts. This had the potential for serious injury, harm, impairment, or death to the resident and constitutes immediate jeopardy.

Admin. R. at 8. Fairfax contends that potential for serious harm is insufficient to constitute immediate jeopardy, which requires that the provider's omission be likely to cause serious harm or death. However, in the discussion below this finding, the ALJ found that "Petitioner was woefully inadequate in the treatment and care of R126. . . . Such conduct caused or was likely to cause serious injury, harm, impairment or death to the resident." *Id.* at 9. The ALJ found that "[t]he record presents a picture of a lackadaisical staff, rather than a staff aggressively treating a pneumonia that was further aggravating the resident's already compromised health." *Id.* at 10. The ALJ clearly was aware of the proper standard for immediate jeopardy and applied it correctly.

Finding 1(c) addressed Fairfax's failure to monitor R127 after R127's episodes of respiratory distress. The ALJ found that this monitoring failure "had the potential for serious injury, harm, impairment, or death to the resident and constitutes immediate jeopardy." Admin. R. at 11. Fairfax argues that this is an indication of the ALJ's application of a lower standard than immediate jeopardy as defined in the regulations. Again, the ALJ's discussion of this finding demonstrates that he was well aware of the proper standard and applied it correctly. The ALJ devoted four pages of his opinion to discussing the treatment of R127, and addressed the specific risks posed to the resident by Fairfax's failure to monitor R127 after several respiratory episodes in close succession. He closes his anal-

ysis with a finding that the failures of the staff to assess properly and monitor the patient, as well as the failure to call the treating physician, "exposed the resident to risk of serious injury, harm, impairment, or death." *Id.* at 16.

The other findings of the ALJ that are questioned by Fairfax, when read in context, likewise make clear that the lapses were of a severe nature.

Finding 1(d) discussed Fairfax's failure to monitor R83 and R68, which "had the potential for serious injury, harm, impairment, or death to the resident and constitutes immediate jeopardy." Admin. R. at 16. In finding 1(e), which addressed Fairfax's failure to ensure that R6 and R11 received proper tracheostomy care, the ALJ concluded that "[t]his had the potential for serious injury, harm, impairment, or death to the residents and constitutes immediate jeopardy." *Id.* at 18. Fairfax again cites the ALJ's failure to use the precise terminology of 42 C.F.R. § 388.301 as evidence that he applied the wrong standard. Close attention to the body of the opinion, once again, reveals that the ALJ both understood the term's meaning and applied it correctly.

In finding 1(c), the ALJ had already discussed the risks posed by Fairfax's failure to monitor residents following an episode of respiratory distress, so there was no need to repeat that discussion in finding 1(d), which dealt with the same issue. The ALJ's conclusion with respect to R83 makes manifestly clear that there was no misunderstanding of the applicable standard: "That R83 survived Petitioner's incompetent care and treatment does not excuse the fact that he was placed at risk of serious injury, harm, impairment, or death." Admin. R. at 17. With respect to R68, the ALJ remarked in a similar vein: "Ms. Daniels testified that it was 'pretty lucky' that nothing serious happened to R68, because, in a matter of minutes, brain dam-

age could be sustained from lack of oxygen. Petitioner's duty to provide appropriate respiratory care to its ventilator-dependent residents cannot be a matter of chance." *Id.* at 17-18 (citation omitted). Under finding 1(d), the ALJ did point out Fairfax's violation of its guidelines and its monitoring errors. The conclusion is inescapable that the monitoring failures described in finding 1(d) could lead to the same dire consequences the ALJ chronicled in finding 1(c). The same is true with respect to finding 1(e). In similar language, the ALJ concluded that patients R6 and R11 were "placed at serious risk of injury, harm, impairment or death" from the "deficient tracheostomy" care that they received. *Id.* at 20.

As the members of the Appellate Division noted, a fair reading of the ALJ's opinion also makes clear that he focused not simply on the situation of each individual patient, but also on the entire state of readiness in the facility during the time in question. Fairly read, his "bottom line" is that a respiratory patient in Fairfax during the time in question was in continuous jeopardy of serious injury or death because of the systemic incapacity of the facility to render the necessary care to sustain life and avoid serious injury. The record is replete with references to the danger of infection to vent-dependent residents living in nursing homes. The death of R10 was the beginning of a series of events that document all too graphically the finding of the ALJ.

Finally, we note that the ALJ carefully and correctly delineated the entire regulatory scheme before he embarked on his analysis of the individual situations of the patients. This manifestation of his understanding of the distinctions that he is now accused of misunderstanding and misapplying supports further the Appellate Division's estimation—and ours—that he both understood the law and properly applied it.

B.

We also believe that the HHS' decision is supported by substantial evidence. The state surveyors documented numerous instances of Fairfax's failure to care adequately for its respirator-dependent residents. The common thread running through most of these omissions is Fairfax's repeated lack of follow-up and monitoring after a resident experienced respiratory distress. Beginning with the death of R10, and continuing throughout the period in question, Fairfax did not ensure that, once a resident had an episode, that resident was examined at regular intervals in the time immediately following the incident. The record firmly supports HHS' determination that a state of immediate jeopardy to resident health existed at Fairfax from December 20, 1996, until April 3, 1997.

Conclusion

The Board's decision was supported by substantial evidence and, therefore, it is affirmed.

AFFIRMED

A true Copy:

Teste:

_____

Clerk of the United States Court of Appeals for the Seventh Circuit