United States Court of Appeals
FOR THE EIGHTH CIRCUIT

No. 10-3628

Greenbrier Nursing and Rehabilitation Center,	*	
Petitioner,	*	
v.	*	Petition for Review of an Order of the Department of Health & Human Services.
U.S. Department of Health & Human Services, Centers for Medicare & Medicaid Services,	*	
Respondent.	*	

Submitted: November 15, 2011
Filed: July 17, 2012

Before SMITH, COLLOTON, and GRUENDER, Circuit Judges.

COLLOTON, Circuit Judge.

Greenbrier Nursing and Rehabilitation Center ("Greenbrier"), a skilled nursing facility in Greenbrier, Arkansas, petitions for review of a civil money penalty imposed by the Secretary of the Department of Health and Human Services for noncompliance with Medicare participation requirements. We deny the petition for review.

I.

Skilled nursing facilities must comply with comprehensive health care regulations to remain eligible for reimbursement under the federal Medicare program. 42 U.S.C. § 1395i-3(d)(4). The program is administered by the Centers for Medicare and Medicaid Services ("CMS") in the Department of Health and Human Services ("HHS"). *Saint Marys Hosp. of Rochester, Minn. v. Leavitt*, 535 F.3d 802, 803 n.1 (8th Cir. 2008). State agencies typically monitor a facility's compliance under an agreement between CMS and the State. *See* 42 U.S.C. § 1395aa(a). Unannounced inspections, known as "surveys," are the chief mechanism for monitoring compliance. *See id.* § 1395i-3(g). Instances of noncompliance discovered during these surveys are reported back to CMS. 42 C.F.R. § 488.11. In Arkansas, these surveys are conducted by the Office of Long Term Care of the Arkansas Department of Health and Human Services. *See Grace Healthcare of Benton v. U.S. Dep't of Health & Human Servs.*, 603 F.3d 412, 415 (8th Cir. 2009).

In February 2009, the state agency surveyed Greenbrier. During the survey, the agency reviewed the medical records of Resident #5, a 78-year-old woman with hypertension and a history of strokes and cancer. Resident #5 was taking the medication Coumadin to help prevent blood clots that could cause another stroke. Coumadin increases a patient's propensity to bleed, however, so serious bleeding is a major risk associated with the drug. According to an expert presented by CMS during the administrative proceedings, health professionals typically conduct monthly testing, known as PT/INR testing, to monitor how quickly a patient's blood clots. Patients on the drug are also monitored for easy bruising or other signs of increased propensity to bleed.

Nurses administered a PT/INR test to Resident #5 on October 31, 2008, and later faxed the lab results to her physician. They received no response from the doctor. Almost two months later, on December 27, 2008, a nurse noticed that

Resident #5 had small bruises on her left thigh. On January 11, 2009, a nurse noticed more extensive bruising under Resident #5's armpit. Eight days later, when Resident #5 picked at a scab until it began to bleed, her vital signs worsened, and she was taken to the emergency room. At the hospital, a PT/INR test revealed abnormally high levels. This test on January 19 was Resident #5's first PT/INR test since October 31 of the previous year.

The state agency determined that Greenbrier failed to comply substantially with three regulations: 42 C.F.R. §§ 483.25, 483.25(j), and 483.60(c). Section 483.25 requires facilities to "provide the necessary care and services to attain or maintain the highest practicable physical, mental, and psychological well-being" of their residents. HHS has interpreted this regulation to require facilities to meet professional standards of care. *Sheridan Health Care Ctr. v. Ctrs. for Medicare & Medicaid Servs.*, D.A.B. No. 2178, at 15 (2008). Section 483.25(j) requires the facility to "provide each resident with sufficient fluid intake to maintain proper hydration and health." And § 483.60(c) requires that each resident's drug regimen "be reviewed at least once a month by a licensed pharmacist" and that the pharmacist "report any irregularities to the attending physician."

CMS may impose civil money penalties for a facility's failure to demonstrate substantial compliance with the governing regulations. 42 U.S.C. § 1395i-3(h)(2)(B)(ii). Penalties between $3,050 and $10,000 per day are imposed for deficiencies constituting "immediate jeopardy," 42 C.F.R. § 488.438(a)(1)(i), which is defined in 42 C.F.R. § 488.301 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." When a deficiency does not constitute immediate jeopardy, but either caused actual harm or has the potential for more than minimal harm, then the penalties range from $50 to $3,000 per day. *Id*. § 488.438(a)(1)(ii). When penalties are imposed for an "instance of noncompliance," rather than on a per-day basis, the penalties range from $1,000 to

$10,000 per instance. *Id.* § 488.438(a)(2). Where more than one type of penalty is permissible, CMS selects the appropriate remedy after considering a list of factors specified by regulation. *Id*. §§ 488.404, 488.408(b).

CMS adopted the state agency's report. CMS concluded that Greenbrier was not in compliance with § 483.25 because it failed to meet professional standards when treating residents on Coumadin, and that this deficiency posed "immediate jeopardy." The agency further determined that Greenbrier failed to comply with § 483.60(c), as its pharmacist had failed to identify and report the facility's lack of PT/INR testing. And CMS concluded that Greenbrier failed to monitor the fluid intake of multiple residents who were at risk for dehydration, as required by § 483.25(j). In a letter dated February 23, 2009, CMS imposed a per-instance penalty of $7,000 for the violation. CMS later revised the penalty, imposing a penalty of $5,500 per day for 24 days (January 11 through February 3, 2009) and $600 per day for 26 days (February 4 through March 1, 2009).

Before the Secretary may impose a civil money penalty, she must give the facility written notice and an opportunity for a hearing on the record. 42 U.S.C. § 1320a-7a(c)(2). A facility is entitled to a formal evidentiary hearing before an administrative law judge ("ALJ"), 42 C.F.R. § 498.60, and either party may seek review of the ALJ's decision by the HHS Departmental Appeals Board ("DAB"). *Id.* § 498.80. The DAB's decision on a civil money penalty is the final decision of the Secretary and is subject to judicial review in a United States Court of Appeals pursuant to 42 U.S.C. § 1320a-7a(e). *See* 42 C.F.R. § 498.90(a), (c)(1); *see also Sunbridge Care & Rehab. for Pembroke v. Leavitt*, 340 F. App'x 929, 932 (4th Cir. 2009) (per curiam); *S. Valley Health Care Ctr. v. Health Care Fin. Auth.*, 223 F.3d 1221, 1223 (10th Cir. 2000).

Greenbrier sought review of CMS's determination by an ALJ. Greenbrier challenged the agency's finding of noncompliance with § 483.25, but did not dispute

the other findings of noncompliance under §§ 483.25(j) and 483.60(c). The ALJ upheld the CMS determinations. The ALJ concluded that Greenbrier's handling of patients on Coumadin was deficient, because the facility failed to test Resident #5 monthly, failed to "observe and react to signs of Coumadin toxicity," and failed to anticipate and consider problems resulting from the interaction of Coumadin with other drugs. The ALJ also found that CMS's determination of immediate jeopardy was not clearly erroneous, because Greenbrier "was in no position to protect . . . residents who received Coumadin from experiencing possible Coumadin toxicity," and that this deficiency "caused a likelihood of severe injury, harm, impairment, or death for all of them." The ALJ set aside one day of immediate-jeopardy penalty for February 3, 2009, but otherwise determined that the penalty assessed against Greenbrier was reasonable.

Greenbrier then appealed the ALJ's determination to the DAB. By regulation, the DAB reviews disputed issues of law *de novo* (*i.e.*, to determine whether the initial decision is "erroneous") and disputed findings of fact under a substantial evidence standard. 42 C.F.R. § 1005.21(h). On appeal, the facility argued (1) that it was in substantial compliance with 42 C.F.R. §483.25, (2) that the deficiency did not rise to the level of immediate jeopardy, and (3) that the agency failed to give Greenbrier adequate notice that its noncompliance with 42 C.F.R. §§ 483.25(j) and 483.60(c) would serve as a basis for imposing penalties against the facility. The DAB upheld the ALJ decision in its entirety.

Greenbrier now seeks review of the civil money penalty, pursuant to the judicial review provision of 42 U.S.C. § 1320a-7a(e). The facility challenges CMS's determination of noncompliance with 42 C.F.R. §483.25, the finding of immediate jeopardy, and the reasonableness of the penalty imposed. Greenbrier also argues that placing the burden of proof on the facility to show compliance conflicts with the Administrative Procedure Act, 5 U.S.C. § 556(d).

II.

A.

Greenbrier first contends that HHS erred in finding that Greenbrier was not in substantial compliance with 42 C.F.R. § 483.25. The facility argues that it was error for the agency to conclude that Resident #5's doctor had ordered monthly PT/INR tests, and that the ALJ and DAB erroneously held the facility's nurses to the standard of medical doctors. When evaluating CMS's determination that a facility failed to show substantial compliance, we review for substantial evidence on the administrative record as a whole. *Grace Healthcare*, 603 F.3d at 418. Substantial evidence is "such relevant evidence as a reasonable mind might accept as adequate to support a conclusion." *Horras v. Leavitt*, 495 F.3d 894, 900 (8th Cir. 2007).

The DAB determined that the facility was out of compliance for failing to meet the professional standard of care when it did not perform monthly PT/INR testing on Resident #5. The Board concluded that Resident #5's physician (also the medical director of the facility) expected the professionally recognized standard for monthly testing to be applied, and that the resident's care plan called for monthly testing. Alternatively, the DAB determined that the nursing staff did not meet the professional nursing standard of care when it made no inquiry of the physician about timely PT/INR testing. We conclude that these findings are supported by substantial evidence.

Resident #5's Overall Plan of Care included an entry stating "LAB PER PHY: MONIT PT/INR AT LEAST MONTHLY," and also included a handwritten note next to this entry stating "per phy." It was reasonable for the DAB to read these entries as reflecting an expectation by the physician that the facility would monitor the resident's PT/INR levels on a monthly basis. This is the most natural interpretation of the wording. "Per," as in "per physician," means "as indicated by," "as directed or

stated in," or "according to." *Webster's Third New International Dictionary* 1674 (2002). The action "indicated" or "directed" by the physician was to monitor PT/INR "at least monthly." Even if, as the physician told the state surveyor, he did not do standing or routine orders for PT/INR, because "the PT needs to be managed, not just looked at," the record still supports the Board's finding that the physician wanted the facility to conform to the standard of monthly testing. The care plan called for monthly testing, "per phy[sician]," and the physician also told the state surveyor that a patient taking a stable dose of Coumadin should have PT/INR monitored once a month. A.R. 390.

The DAB's alternative conclusion is supported by the affidavit of a qualified expert in the field of internal medicine and geriatrics, Dr. Lori Jacobs, M.D. She averred that even without a direct order from a physician for monthly PT/INR testing, "the nurses would be expected to know that the INR testing should be done so that they enquire about an order if it is not" received. The DAB's finding of noncompliance thus did not impose on the nurses the standard of care for physicians. It recognized, rather, that the professional standard of care for nurses called for timely inquiry about PT/INR monitoring if a physician did not give direction within a month of the last test. The Board previously concluded that CMS regulations hold long-term care facilities and their employees to standards of care separate from those applicable to physicians, *see Maysville Nursing & Rehab. Facility v. Ctrs. for Medicare & Medicaid Servs.*, D.A.B. No. 2317, at 7 (2010), and Greenbrier does not dispute this basic proposition. It was reasonable for the agency to conclude that the standard of care did not allow the staff to send a facsimile to the doctor and then wait indefinitely for a response that may never come. The DAB's conclusion that the nurses failed to comply with the professional standard of care *for nurses* in the case of Resident #5 is supported by substantial evidence.

B.

Greenbrier next claims that any noncompliance with 42 C.F.R. § 483.25 did not rise to the level of immediate jeopardy. The standard of review on this question is murky. The ALJ must uphold CMS's determination as to the level of noncompliance (including immediate jeopardy) "unless it is clearly erroneous," 42 C.F.R. § 498.60(c)(2), and the DAB says that the facility bears the burden to show clear error. *Woodstock Care Ctr. v. Health Care Fin. Admin.*, D.A.B. No. 1726, at *6 (2000); *see Liberty Commons Nursing & Rehab. Ctr.-Alamance v. Leavitt*, 285 F. App'x 37, 41-42 (4th Cir. 2008) (per curiam). The DAB in this case found "no error" in the ALJ's conclusion that CMS's determination was not "clearly erroneous," and we are directed by statute to treat the Secretary's "findings of fact" as conclusive if they are supported by substantial evidence on the record as a whole. 42 U.S.C. § 1320a-7a(e); *Horras*, 495 F.3d at 899-900. If these standards of review are combined, then the scope of judicial review would be very limited—*i.e.*, whether there is *substantial evidence on the record as a whole* to support the ALJ's conclusion that the facility did not establish that CMS made a *clear error* in finding immediate jeopardy. At oral argument, however, the attorney for the government equivocated when asked whether the court should apply two layers of deference to the CMS determination. As we agree with the DAB that CMS's determination was not clearly erroneous, it is unnecessary to decide whether judicial review is even more circumscribed. *Cf. Liberty Commons*, 285 F. App'x at 43 ("We are required to uphold this [immediate jeopardy] determination unless we find it to be clearly erroneous.").

An immediate jeopardy finding is warranted when "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." 42 C.F.R. § 488.301. Greenbrier attacks the CMS finding on the ground that the facility's actions, including its failure to monitor PT/INR, did not cause Resident #5 to develop Coumadin toxicity. The DAB concluded, however, that there was no need for CMS

to establish definitively that Resident #5's condition was caused by the failures of the facility staff to administer proper Coumadin therapy. Rather, the Board found it sufficient that Greenbrier "failed to have adequate systems in place to monitor and protect [Resident #5] from experiencing Coumadin toxicity, because the absence of such systems exposed [Resident #5] (and other residents receiving Coumadin) to likely serious injury or harm such as the bleeding and anemia [Resident #5] actually suffered."

We agree with the DAB's conclusion. The administrative record included ample evidence about the serious risks associated with Coumadin therapy, and the importance of monthly testing and monitoring. It was not necessary to establish specifically that Greenbrier's noncompliance caused harm to Resident #5. That the facility lacked an adequate system for ensuring that patients taking Coumadin would be monitored appropriately was sufficient to justify a conclusion that the facility's noncompliance was "*likely to cause* . . . serious injury or harm" to residents of the facility, whether or not the harm suffered by Resident #5 was caused by the noncompliance. Dr. Jacobs averred that Coumadin therapy requires monitoring, as Coumadin has extensive drug interactions and the propensity to cause serious bleeding. We therefore conclude that the DAB did not err in upholding CMS's determination of immediate jeopardy.

C.

Greenbrier next asserts that the civil money penalties imposed by Greenbrier were unreasonable. Before it may raise an objection to the penalties in this court, however, Greenbrier is required to present the same complaint to the DAB. The Board is empowered to make a final determination for the Secretary on civil money penalties. 42 C.F.R. §§ 498.90(a)(1), (c)(1); *cf. Boone Cnty. Hosp v. Ctrs. for Medicare & Medicaid Servs.*, D.A.B. No. CR2526, at 16 n.11 (2012). The judicial review statute states that "[n]o objection that has not been urged before the Secretary

shall be considered by the court, unless the failure or neglect to urge such objection shall be excused because of extraordinary circumstances." 42 U.S.C. § 1320a-7a(e). Thus, if a party fails to raise an objection before the DAB, then judicial review of that objection is barred in the absence of extraordinary circumstances. *See Woelke & Romero Framing, Inc. v. NLRB*, 456 U.S. 645, 665 (1982) (applying comparable statutory language that governs judicial review of the National Labor Relations Board); *Golden Living Ctr.-Riverchase v. U.S. Dep't of Health & Human Servs.*, 429 F. App'x 895, 896 n.2 (11th Cir. 2011) (per curiam).

Two of Greenbrier's present objections to the monetary penalty were not raised before the Board. The facility complains that there is no foundation in the record for the agency's selection of January 11, 2009, as the start date for calculating monetary penalties, but this objection was not raised with the DAB. Greenbrier also did not raise with the DAB its present objection that the Secretary was required to impose a per-instance penalty, rather than a per-day penalty. Accordingly, judicial review of these objections is barred by § 1320a-7a(e).

Greenbrier did argue before the DAB that CMS failed to give the facility notice that noncompliance with 42 C.F.R. §§ 483.25(j) and 483.60(c) was a partial basis for the monetary penalty. CMS gives notice of penalties by sending a written notice that includes the nature of the facility's noncompliance. 42 C.F.R. § 488.434. Greenbrier says the agency never notified the facility that the monetary penalties would be based on all three instances of noncompliance, rather than the breach of § 483.25 and the professional standard of care alone.

We agree with the DAB that Greenbrier received adequate notice. The agency's first letter to Greenbrier, dated February 23, 2009, asserted that the facility was not in substantial compliance with three requirements, including § 483.25(j) (Hydration) and § 483.60(c) (Drug Regimen Review). The letter stated that remedies were imposed because of Greenbrier's failure to comply substantially with

"requirements" for participation in the Medicare and Medicaid programs. It is true that the February 23 letter stated that the per-instance monetary penalty was imposed for the deficiency under § 483.25 for failure to meet standards of professional care. But when the agency revised the penalties in a second letter dated March 12, 2009, it wrote that the per-day amounts were based on several considerations, including "the seriousness and pervasiveness of the deficiencies." The first letter already notified Greenbrier that the "deficiencies" include noncompliance with §§ 483.25(j) and 483.60(c). The agency was not obliged to restate the specific requirements in its second letter. CMS, moreover, did clarify in its prehearing brief before the ALJ that all three deficiencies were a basis for the penalties, so Greenbrier had ample opportunity to respond even if there were ambiguity in the March 12 letter. *See Livingston Care Ctr. v. U.S. Dep't of Health & Human Servs.*, 388 F.3d 168, 176 (6th Cir. 2004).

D.

Greenbrier's final claim is that the agency's burden-shifting framework contravenes the Administrative Procedure Act. Once CMS makes a *prima facie* showing of noncompliance, the facility bears the burden of persuasion to prove by a preponderance of the evidence that it was in substantial compliance with federal regulations. *See Cross Creek Health Care Ctr. v. Health Care Fin. Admin.*, D.A.B. No. 1665 (1998); *Hillman Rehab. Ctr. v. Health Care Fin. Admin.*, D.A.B. No. 1611, at *4-13 (1997). Greenbrier argues that this procedure conflicts with the Administrative Procedure Act, which provides that "[e]xcept as otherwise provided by statute, the proponent of a rule or order has the burden of proof" in an administrative proceeding. *See* 5 U.S.C. § 556(d). We find it unnecessary to address this legal issue, because the agency's allocation of the burden makes a difference only when the evidence is in equipoise. *Hillman Rehab. Ctr.*, D.A.B. No. 1611, at *5 n.7. As the record here contains substantial evidence of Greenbrier's noncompliance, the agency's procedural framework is immaterial to the outcome. *See SunBridge*, 340 F.

App'x at 933; *Fairfax Nursing Home, Inc. v. U.S. Dep't of Health & Human Servs.*, 300 F.3d 835, 840 n.4 (7th Cir. 2002).

* * *

For the foregoing reasons, the petition for review is denied.