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No. 10-3465

UNITED STATES COURT OF APPEALS
FOR THE SIXTH CIRCUIT

LIFE CARE CENTER TULLAHOMA, Petitioner, v. SECRETARY OF THE UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES; UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES; CENTERS FOR MEDICARE & MEDICAID SERVICES, Respondents.	)	ON APPEAL FROM THE DEPARTMENT OF HEALTH & HUMAN SERVICES

Before: GILMAN and KETHLEDGE, Circuit Judges; and LUDINGTON, District Judge*

KETHLEDGE, Circuit Judge. The Secretary of Health and Human Services sanctioned Life Care Center for breaching several regulations while treating Life Care's nursing-home residents. Life Care now brings a substantial-evidence challenge to the Secretary's decision. We affirm.

I.

In 2007, a state agency inspected Life Care's facility on behalf of the Secretary to evaluate Life Care's compliance with Medicare regulations governing treatment of its residents. *See* 42 U.S.C. § 1395i-3(g). The agency determined that Life Care was noncompliant with 13 regulations

*The Honorable Thomas L. Ludington, United States District Judge for the Eastern District of Michigan, sitting by designation.

and that some "deficiencies" placed residents in "immediate jeopardy"—the gravest seriousness rating, carrying a fine between $3,050 and $10,000 per day. *See Claiborne-Hughes Health Ctr. v. Sebelius*, 609 F.3d 839, 841–42 (6th Cir. 2010). On November 30, 2007, the Centers for Medicare & Medicaid Services (part of HHS) acted on those findings and penalized Life Care $6,550 per day starting on June 25, 2007 and continuing until "the jeopardy [was] removed."

Life Care appealed to an administrative law judge. *See* 42 C.F.R. § 498.40. On appeal, CMS pressed violations of five of the 13 cited regulations, contending that it need sustain only a portion of the charges to support its penalty. The ALJ upheld the fine. Life Care appealed to the Departmental Appeals Board, which affirmed, but reduced the penalty to $4,550 per day. Life Care petitions for our review under 42 U.S.C. §§ 1395i-3(h)(2)(B)(ii), 1320a-7a(e).

II.

Life Care challenges the Board's decision to penalize Life Care for noncompliance with five regulations. We review the underlying factual determinations for substantial evidence in the record as a whole. *Claiborne*, 609 F.3d at 843. We consider "whatever in the record fairly detracts from the weight of the evidence," but we do not decide evidentiary conflicts or witness credibility. *Id.*

A.

The Board first upheld the ALJ's conclusion that Life Care violated 42 C.F.R. § 483.10(b)(11). That regulation requires Life Care to "consult with the resident's physician" immediately after a resident suffers a "significant change" in "physical, mental, or psychosocial status." *See Claiborne*, 609 F.3d at 844. A change is "significant" when "there is a chance that

physician intervention is needed." *Id.* Here, the Board concluded that Life Care failed this duty while treating four residents.

The first was Resident 56, whose elevated potassium levels aggravated her heart problems. At 1:55 a.m. one morning, Resident 56 awoke short of breath with an abnormal 45-beats-per-minute heart rate. At 3 a.m., test results revealed elevated potassium; 25 minutes later, the staff faxed the test results to the doctor. Only at 6 a.m. did the staff call the doctor, who ordered Resident 56 taken to the emergency room.

The other episodes involved diabetic residents. In one episode, Resident 18's blood sugar dropped to 20 mg/dl. She was convulsing and had cold and clammy skin. In another, Resident 27's blood sugar was 32 mg/dl. She was twitching, lethargic, mumbling, and staring blankly. In still another, Resident 27's blood sugar was 40 mg/dl. She was groggy and unable to walk. And in a final episode, Resident 40's blood-sugar was 28 mg/dl. She was cool and clammy, sweaty, and slow to react. Each of these residents was in danger: CMS's expert witness, Dr. Schmitt, testified that blood-sugar levels below 60 mg/dl can cause seizures, coma, and death. In each episode, Life Care's nurses failed to consult a doctor immediately and instead administered care themselves.

Life Care disputes the Board's conclusion that these residents suffered the "significant change" necessary to trigger the duty to consult under § 483.10(b)(11). The Board determined that a "significant change" meant having a blood-sugar level "significantly below 60 mg/dl" while displaying "additional signs or symptoms of" low blood sugar. But Life Care insists the Board failed to identify a regulation prescribing this standard and instead derived the standard from Life Care's own internal procedural documents. And those documents—particularly one titled "Life Care

Centers of America, Inc., Diabetic Care," which Life Care insists is its official protocol—purportedly require physician consultation only where a resident experiencing low blood sugar fails to respond to treatment from the nurse.

But the Board need not point to a specific regulation to show that a symptomatic drop in blood sugar below 60 mg/dl is a significant change. Whether a change is significant depends on the evidence in the record. *Cf. Clairborne*, 609 F.3d at 844 (holding that a change was "significant" because that conclusion "follow[ed] logically" from the evidence in the record). And here both expert testimony and Life Care's protocols amply support the Board's standard for significance. *Cf. id.* at 847 (holding that facility's own practices established the meaning of "sufficient fluid" under the Medicare regulation). First, CMS's Dr. Schmitt testified that episodes in which blood sugar drops below 60 mg/dl are dangerous. He added that, while drops below 60 mg/dl may not always require doctor consultation, consultation is necessary where a resident shows symptoms. Second, Life Care's Dr. Standridge acknowledged that Life Care's own procedures required consultation if "the patient is exhibiting serious symptoms of high or low blood sugar." Third, the doctor's orders for each of these three residents instructed nurses to notify the doctor if the resident's blood sugar dropped below 60 mg/dl. And a document called "Hyperglycemia & Hypoglycemia"—the document Life Care gave investigators when they asked for Life Care's hypoglycemia policy and procedure—says that nurses must "immediately" notify a doctor when "any resident who receives insulin exhibits altered behavior or mental/physical state."

Life Care further contends that its nurses did consult doctors or nurse practitioners in some instances. It says someone informed a nurse practitioner about one of Resident 27's episodes

because the nurse practitioner's contemporaneous notes about the episode say, "[B]lood sugar bottomed out last night." Life Care also reads Resident 18's records to indicate that the attending nurse called the doctor immediately after Resident 18's episode, not that she waited 30 minutes to contact a doctor (as the Board interpreted them). But neither contention is convincing. The nurse practitioner's notes for Resident 27's episode do not indicate that the attending nurse consulted with the nurse practitioner "immediately," as the regulation requires. *See Claiborne*, 609 F.3d at 844. And the nurse's notes for Resident 18's episode are best read to say the nurse waited 30 minutes to contact a doctor: The notes proceed almost entirely chronologically, starting with the 7:15 p.m. discovery of the resident convulsing and continuing through a note that the resident's blood sugar had risen at 7:45. Only after that 7:45 note does the nurse say she "notified the physician on call." Reading this note to mean the nurse waited until 7:45 to call the doctor is all the more plausible given Life Care's view that its nurses should only contact doctors when ailing diabetic patients are unresponsive to treatment. The Board thus justifiably concluded that Life Care breached § 483.10(b)(11) when its nurses failed to immediately consult a doctor about these residents' cardiovascular and diabetic episodes.

B.

The Board also concluded that Life Care failed to provide services that met professional standards of quality, in violation of 42 C.F.R. § 483.20(k)(3). For support, the Board cited nurses' decisions to treat Residents 18, 27, 40, and 56 themselves rather than immediately consult a doctor—even though the doctors' orders for Residents 18, 27, and 40 required consultation when their blood sugar dropped below 60 mg/dl. Dr. Schmitt testified that the nurses' decisions to go-it-

alone breached the applicable standard because nurses are supposed to work under the supervision of doctors and within "the bounds of physicians' orders." Nurses also testified that "nursing standards of practice" require following doctors' orders. *See In re Georgian Court Nursing Ctr. v. CMS*, DAB No. 1866 (2003). These were hardly technical infractions: Dr. Schmitt testified that Residents 27 and 40 were "exposed . . . to very serious risk of harm."

Life Care argues that the Board should have considered materials like textbooks and professional publications to establish the standard of care. It says that CMS's interpretive guide to § 483.20(k) proposes exactly that. But those guidelines say only that these materials are "possible" sources. Thus, the Board permissibly relied on expert testimony in identifying the standard of care in this case. *See In re Claiborne-Hughes v. CMS*, DAB No. 2223 (2008), *aff'd* 609 F.3d 839 (6th Cir. 2010).

Life Care responds that the Board failed to adequately consider testimony by Life Care's own experts. In fact, Life Care says, the Board went so far as to affirm the ALJ's conclusion that Life Care's expert was not credible—even though the expert testified only through written remarks. But the Board did extensively consider Life Care's expert testimony. We cannot now re-weigh the disagreements among the experts. As for the assertion that the Board could not adequately assess the expert's credibility based only on the expert's written remarks, Life Care points to no supporting authority. *See Hollimon v. Shelby Cnty. Gov't*, 325 F. App'x 406, 412 (6th Cir. 2009); *Buckanaga v. Sisseton Indep. Sch. Dist.*, 804 F.2d 469, 474 (8th Cir. 1986).

C.

Next, the Board concluded that the conduct leading to violations of the immediate-consultation and professional-standards regulations also breached 42 C.F.R. § 483.25. That rule requires facilities to "provide the necessary care and services to attain or maintain [residents'] highest practicable" state of well-being. *Id.* The Board says Life Care's failure to follow its own protocols breached this requirement. *See In re The Laurels at Forest Glenn*, DAB No. 2182 (2008).

Life Care objects that the regulation also requires proof that the affected residents actually failed to achieve their "highest practicable" state of well-being. But the regulation does not require the Secretary to show that Life Care caused "actual harm" to residents' well-being. *See Lakeridge Villa Health Care Ctr. v Leavitt*, 202 F. App'x 903, 909 (6th Cir. 2002); *cf. Harmony Court v. Leavitt*, 188 F. App'x 438, 440–41 (6th Cir. 2006). Instead, as the Board noted, the regulation required the Secretary to show only that Life Care failed to provide the "necessary care and services."

Life Care further contends that this catchall regulation's requirements—in addition to the related professional-standards requirements—are too "general" because they impose "ad hoc, unpublished, and unknowable standards." Life Care insists that the Eleventh Circuit refuses to enforce these case-by-case standards, and so should this court. But the case Life Care cites—*Emerald Shores Health Care Assocs. v. U.S. Dep't of Health & Human Servs.*, 545 F.3d 1292 (11th Cir 2008)—did not rule so broadly. There, the court held that because nurses were not experts in pest control, it would leniently evaluate the facility's compliance with a regulation that required "effective pest control" without further guidance. *Id.* at 1300. The regulations governing nursing standards of care at issue here, however, are more familiar terrain.

If Life Care means to argue that enforcing the Medicare regulations without exhaustive detail violates due process, we disagree. Outside the First Amendment, we evaluate a law's clarity according to whether an average person would expect it to apply under the facts of the case at hand. *See United States v. Mazurie*, 419 U.S. 544, 550–53 (1975). For this reason, we look for the meaning of regulatory standards on a case-by-case basis, examining particular facilities' own protocols and how a facility ought to have "logically" understood the regulations to apply in particular circumstances. *See, e.g.*, *Claiborne*, 609 F.3d at 844, 846; *Barbourville Nursing Home v. U.S. Dep't of Health & Human Servs.*, 174 F. App'x 932, 944 (6th Cir. 2006). Thus, the Board justifiably concluded that Life Care failed to provide necessary care and services.

D.

The Board also concluded that the facility failed to "ensure" that two of its residents were "free of any significant medication errors." 42 C.F.R. § 483.25(m)(2). First, Resident 48 arrived at Life Care's facility with a hospital discharge order prescribing 200 mg of Tegretol per day. Life Care's nurses instead administered twice that amount daily between August 2 and September 13, 2007. Second, Resident 18 arrived at Life Care with a hospital transfer order that, according to the Board, was ambiguous as to how much diabetes medicine Resident 18 should receive. Without seeking clarification—a professional error, according to one of the nurses who inspected the facility—Life Care's nurse transcribed the instructions to require administering the larger of the two doses listed on the transfer form. Resident 18's treating doctor later prepared a discharge summary revealing that this dosage was incorrect.

Life Care challenges both conclusions. As for Resident 48, Life Care denies that substantial

evidence shows that the overdose was "significant." It notes that its expert, Dr. Standridge, testified that Tegretol was not dangerous at just 400 mg per day, and CMS's Dr. Schmitt conceded that the dosage was not fatal. But while 400 mg per day may not have been fatal, substantial evidence still supports the conclusion that the mistake was "significant." An error is significant if it has the "potential" to cause harm, and even a "single medication error can be significant." *Life Care Ctr. of Elizabethton*, DAB No. 2367 (2011); *In re Ocean Springs Nursing Ctr. v. CMS*, DAB No. 2212 (2008). And the Board measures significance according to whether an error involving the drug "could result in serious consequences," whether the resident could have easily recovered from the error, and whether there is evidence the error occurred more than once. *Life Care Ctr. of Elizabethton*, DAB No. 2367 (2011). Here, the Board heard testimony that a Tegretol overdose could have serious consequences: An inspector testified that it is a dangerous drug, and Dr. Schmitt also said that, while 400 mg per day would not be fatal, it could still interact with other drugs. Worse still, Life Care repeated the error for 43 days. When a nurse practitioner learned of the overdose she became "very angry" and ordered lab testing immediately.

As for Resident 18, Life Care says it got the dose right. It interprets Resident 18's hospital transfer form as requiring the higher dosage that Life Care's nurse transcribed, citing testimony by Dr. Standridge for support. Without reweighing competing expert testimony, however, we agree that substantial evidence supports the Board's conclusion that the transfer form was ambiguous. The order has two sections listing medications. The first, for medications Resident 18 was taking prior to hospitalization, lists 55 units of diabetes medicine in the morning and 40 at night. Check marks appear next to both. The second, for "current active medication," lists 20 units of diabetes medicine

in the morning and 10 at night. As before, check marks or slashes appear next to both. A registered nurse testified that this form required Life Care to administer the lower dose, and she was neither obviously wrong nor obviously right. (Life Care asserts that the nurse based this opinion entirely on a discharge summary drafted after the patient arrived at Life Care's facility, but the nurse specifically said otherwise on cross-examination.) Given the transfer form's ambiguity, testimony that professional standards require nurses to seek clarification where a transfer form is ambiguous, and instructions on the transfer form stating the same, the Board justifiably concluded that Life Care failed to ensure that Resident 18 was free from significant medication errors. *See* 42 C.F.R. § 483.25(m)(2).

Life Care also says that a nurse practitioner reduced Resident 18's afternoon dosage from 40 units to 30 units days after Resident 18 moved to Life Care's facility, eliminating any error. But even assuming the nurse's intervention stopped continuation of Life Care's original error, substantial evidence still supports the conclusion that the facility originally failed to ensure the correct dosage.

E.

Life Care also disputes the Board's conclusion that the facility violated 42 U.S.C. § 483.75, which requires that a facility be "administered in a manner that enables it to use its resources effectively and efficiently" to help its residents attain their "highest practicable" state of well-being. Life Care argues that the Secretary's rationale—that the other violations listed above demonstrated a systemic failure to comply with orders and protocols—overlooks a requirement that there be a proven "nexus" between the other breaches and the facility's administration. But there is no such requirement. *See Asbury Ctr. at Johnson City v. U.S. Dep't of Health & Human Servs.*, 77 F. App'x

853, 857 (6th Cir. 2003). The Secretary need show only that conduct supporting breaches of other regulations also supports an "infer[ence]" that a facility's problems were "systemic." *See In re Britthaven, Inc. v. CMS*, DAB No. 2018 (2006). And the similarity among the nurses' mistakes in this case supports just such an inference.

F.

Life Care next disputes the conclusion that its noncompliance placed its residents in "immediate jeopardy," warranting a hefty fine. *See* 42 C.F.R. § 488.301; *Clairborne,* 609 F.3d at 841–42. It says that CMS did not offer "*any* evidence" to support an immediate-jeopardy designation, particularly evidence of actual harm to residents.

But an immediate-jeopardy designation does not require evidence of actual harm. *See Lakeridge*, 202 F. App'x at 908. Rather, it requires evidence that the facility's noncompliance with "one or more" of the regulations is "likely" to cause "serious injury, harm, impairment, or death to a resident." *See* 42 C.F.R. § 488.301; *Innsbruck Healthcare Ctr. v. CMS*, DAB No. 1948 (2004). And the record here includes evidence that one or more of Life Care's deficiencies was likely to cause harm. For example, Dr. Schmitt testified that Life Care's nurses exposed Residents 27 and 40 "to very serious risks of harm" when the nurses failed to consult a doctor about the residents' dangerously low blood-sugar levels. He explained that doctors could not make adjustments to the residents' food and medicine or establish a monitoring schedule for the patients in order to avoid the problem. Dr. Schmitt further testified that Resident 48's Tegretol overdose, and the nurses' failure to notify a doctor about Resident 56's elevated potassium levels, exposed those residents to a high likelihood of serious harm—"cardiac arrest," in Resident 56's case. Finally, one of the nurses who

inspected the facility testified that Resident 18 likely suffered hypoglycemic episodes resulting from her receipt of more diabetes medication than her doctor prescribed. Thus, substantial evidence supports the Board's conclusion that Life Care's non-compliance placed residents in immediate jeopardy.

G.

Life Care also challenges the size of the penalty, which turns on the facility's history of noncompliance, the facility's financial condition, the facility's culpability, and the "scope and severity of the deficiencies and the relationship of one deficiency to the other deficiencies." *See* 42 C.F.R. §§ 488.404, 488.438(f); *Lakeridge*, 202 F. App'x at 911. Life Care argues that CMS offered "no evidence" relating to these factors and that the Board did not consider them when upholding the penalty. It adds that the Board failed to say whether it considered deficiencies that CMS did not press before the ALJ.

But the Board did review evidence relevant to these factors. It began by evaluating the "severity" and "scope" of the deficiencies. As for severity, the Board rejected the ALJ's view that the facility "tolerated a state of anarchy." It said the "anarchy" label was "overblown" largely because the ALJ applied it after impermissibly relying on instances of noncompliance that CMS chose not to pursue before the ALJ. As for the scope of the deficiencies, the Board concluded that noncompliance was widespread because nurses failed to follow the "basic" nursing obligation to act under a doctor's supervision in five cases. The Board added that the medication errors further highlighted the staff's inattentiveness to doctors' orders.

The Board also said Life Care was "culpable," meaning it was guilty of "neglect,

indifference, or disregard for resident care, comfort, or safety." *See* 42 C.F.R. § 488.438(f)(4). For support, the Board cited several episodes: the hours-long delay in notifying Resident 56's doctor about her elevated potassium levels, the failure to record Resident 18's diabetes prescription correctly, and the "lack of diligence" in complying with doctors' orders.

Life Care also contends that the Board failed to consider whether the penalty served a "remedial purpose." But the regulations forbid the Secretary from considering any factor other than those listed in § 488.438(f). *See* 42 C.F.R. § 488.438(e)(3). And the regulation itself serves a remedial purpose, so the Board need not consider whether a particular penalty is remedial. *See In re Kenton Healthcare, LLC v. CMS*, DAB No. 2186 (2008). We therefore reject Life Care's challenge to the penalty.

III.

A.

Life Care also argues that the Board committed several legal errors. First, Life Care contends that the Board applied the wrong standard of review when reviewing the ALJ's decision and that the ALJ applied the wrong standard of review when reviewing CMS's decision. Life Care insists that the standard of review for both is "substantial evidence in the record, taken as a whole." Yet both the Board and the ALJ purportedly conducted "de novo" review by adopting reasons their inferiors did not give to conclude that Life Care was noncompliant. For example, Life Care notes that the ALJ interpreted the "significant change" regulation to require doctor consultation every time a resident's blood sugar fell below 60 mg/dl. But the Board rejected this holding and concluded that the regulation required doctor consultation only when a resident's blood sugar dropped

"significantly" below 60 mg/dl and the patient also exhibited symptoms. Life Care contends regular substantial-evidence review required the Board to remand for reconsideration rather than adopt its own definition of a "significant change."

This contention has many problems. First, ALJs are authorized to conduct a de novo review. *See In re Beechwood Sanitarium v. CMS*, DAB No. 1906 (2004). Second, the case Life Care cites as holding that the Board applies de novo review says no such thing; it says ALJs apply de novo review. *See In re Britthaven of Chapel Hill*, DAB No. 2284 (2009). Third, the Board's decision in this case explicitly states that it reviewed the ALJ's findings of fact for substantial evidence in the record as a whole. Finally, we know of no authority requiring either the ALJ or the Board to choose between adopting their reviewees' decisions wholesale or remanding for reconsideration. Life Care cites only *Citizens to Preserve Overton Park, Inc. v. Volpe*, which held that a court's review of an agency's decision should be based on the administrative record rather than litigation affidavits—not that an agency's own internal review process must incorporate Life Care's proposed take-it-or-leave-it approach. *See* 401 U.S. 402, 419–20 (1971). Moreover, the Medicare regulations allow ALJs and the Board to do much more than depart from their reviewees' reasoning: ALJs are authorized to consider new issues, and the Board is authorized to accept new evidence. 42 C.F.R. §§ 498.56, 498.86.

B.

Next, Life Care argues that the Secretary has misallocated the burden of proof. The Board has held that, once CMS makes a prima facie showing that a nursing home is noncompliant with a regulation, the nursing home must then demonstrate compliance by a preponderance of the evidence.

See Hillman Rehab. Ctr. v. HCFA, DAB No. 1611 (1997). The Board has also held that nursing homes bear the burden of demonstrating that the agency's immediate-jeopardy determination is "clearly erroneous." *See Owensboro Place & Rehab. Ctr.*, DAB No. 2397 (2011). Life Care says that these rules violate the Administrative Procedures Act, which places the burden of proof on the "proponent of the rule or order" unless "otherwise provided by statute." *See* 5 U.S.C. § 556(d); *Sanctuary at Whispering Meadows v. Thompson*, 151 F. App'x 386, 388–89 (6th Cir. 2005).

But we need decide only who should bear the burden of proof under the APA if shifting the burden would have changed the outcome below. *See Lakeridge*, 202 F. App'x at 906–07. And the preponderance of the evidence did show that Life Care was noncompliant. Similarly, the evidence that at least one of Life Care's deficiencies placed residents in immediate jeopardy shows that the immediate-jeopardy designation was not clearly erroneous.

C.

Finally, Life Care argues that the Secretary should have evaluated and dismissed the eight deficiencies that CMS chose not to press before the ALJ, citing *Grace Healthcare of Benton v. U.S. Department of Health & Human Services* for support. 589 F.3d 926 (8th Cir. 2009). There, the court held that "all findings of immediate jeopardy that are appealed should either be upheld or reversed" or otherwise "expunged from the agency's public records." *Id.* at 935. But the *Grace Healthcare* panel later amended its original opinion to eliminate the order to expunge the deficiencies from the public record. *See Grace Healthcare of Benton v. U.S. Dep't of Health & Human Servs.*, 603 F.3d 412, 423 (8th Cir. 2009). More to the point, we rejected Life Care's argument in *Claiborne*, 609 F.3d at 847.

Life Care insists that *Claiborne* is distinguishable because that court refused to order the Secretary to evaluate the unpressed deficiencies only because those that CMS *did* press were enough to support the penalty by themselves. Yet here the Board specifically declined to uphold the penalty on the basis of the other eight deficiencies. Indeed, it reduced the size of the penalty for that reason.

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The Board's decision is affirmed.