UNPUBLISHED

UNITED STATES COURT OF APPEALS
FOR THE FOURTH CIRCUIT

No. 11-1817

UNIVERSAL HEALTHCARE/KING,

Petitioner,

v.

KATHLEEN SEBELIUS, Secretary of the United States Department of Health and Human Services; UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES,

Respondents.

On Petition for Review of an Order of the United States Department of Health and Human Services. (A-11-38)

Argued: September 19, 2012 Decided: December 14, 2012

Before NIEMEYER and DIAZ, Circuit Judges, and Max O. COGBURN, Jr., United States District Judge for the Western District of North Carolina, sitting by designation.

Petition for review denied by unpublished opinion. Judge Cogburn wrote the opinion, in which Judge Niemeyer and Judge Diaz joined.

ARGUED: Joseph L. Bianculli, HEALTH CARE LAWYERS, PLC, Arlington, Virginia, for Petitioner. Adam C. Jed, UNITED STATES DEPARTMENT OF JUSTICE, Washington, D.C., for Respondents. **ON BRIEF:** William B. Schultz, Acting General Counsel, Dana J. Petti, Chief Counsel, Region IV, Elizabeth C. Benton, Assistant Regional Counsel, DEPARTMENT OF HEALTH AND HUMAN SERVICES, Atlanta, Georgia; Tony West, Assistant Attorney General, Michael

S. Raab, Helen L. Gilbert, UNITED STATES DEPARTMENT OF JUSTICE, Washington, D.C., for Respondents.

Unpublished opinions are not binding precedent in this circuit.

COGBURN, District Judge:

Universal Healthcare/King ("Universal") challenges a civil monetary penalty ("CMP") imposed by the Centers for Medicare & Medicaid Services ("CMS") for violations of the Medicare and Medicaid statutes and regulations. The challenged CMP was sustained by an administrative law judge ("ALJ") and affirmed by the Departmental Appeals Board ("DAB") of the U.S. Department of Health and Human Services. Because we find no error in the DAB's decision, we deny Universal's petition for review.

I.

Universal is a Medicare nursing facility located in King, North Carolina. Nursing facilities participating in the Medicare Program must comply with federal "Long Term Care Requirements of Participation" as set forth in 42 C.F.R. Part 483, which implements provisions of 42 U.S.C. §§ 1395i-3(b)-(e). Those regulations establish numerous clinical, operational, and other responsibilities for participating nursing facilities as well as provide a number of rights for facility residents. Id. Compliance with these regulations is evaluated via periodic inspections or "surveys," which are usually conducted, as in this matter, by a State Survey Agency ("SSA") acting under contract as the agent of Respondent Secretary of the U.S. Department of Health and Human Services. In September 2009, an

SSA conducted a survey at Universal's facility in King, which revealed that Universal had violated several of the regulations. Based on those findings, CMS imposed per diem CMPs on Universal for the period of March 21 through September 27, 2009, in the amount of $3050 per day, totaling $587,950.

The regulations are enforced by the Secretary as provided by 42 U.S.C. § 1395i-3(h). That statute authorizes the imposition of various sanctions tied to the "severity" and "scope" of noncompliance, which are in turn measured by the actual or potential impact of the noncompliance on nursing facility residents. Id. Among the sanctions available to the Secretary are two types of CMPs: a "per diem" CMP, which may be imposed "for the number of days a facility is not in substantial compliance" with the regulations; and a "per instance" CMP, which may be imposed for "past noncompliance" corrected prior to a survey. Significantly, per diem CMPs can accrue in an amount of up to $10,000 per day, and may "continue until [t]he facility has achieved substantial compliance[.]" 42 C.F.R. § 488.454(a)(1). On the other hand, per instance CMPs are limited to a cap of $10,000 per survey. 42 C.F.R. §§ 488.430, 488.438.

Supporting its imposition of a per diem CMP, CMS found that Universal committed violations of 42 C.F.R. § 483.25(l), which requires proper monitoring of prescription drugs given to

residents, § 483.75(j)(1), which regulates provision of laboratory services for residents, and § 483.20(d), which sets patient recordkeeping requirements. These violations stemmed largely from a series of serious errors committed by petitioner's staff in caring for "Resident #1," a 78-year-old woman who ultimately died in March 2009. It is undisputed that it was the death of Resident #1 which spurred the survey. Universal contends that the ALJ, the Board, and ultimately the Secretary erred in upholding the duration of CMS's per diem CMPs by failing to consider its evidence that its self-implemented corrective measures had returned the facility to "substantial compliance" in April 2009, long before the September survey.

II.

A.

On February 10, 2009, Universal's nurses noted swelling in Resident #1's right lower leg, and reported such condition to the patient's physician, who ordered a Doppler test, which disclosed a blood clot. Based on the presence of the blood clot, the physician ordered 10 mg of Coumadin daily and Lovenox (both anti-coagulant drugs), as well as daily Prothrombin Time and International Normalized Ratio tests ("PT/INR"). The tests are used to monitor the effectiveness of anticoagulant therapy,

a highly risky treatment process that requires close monitoring and a detailed care plan.

As the record establishes and petitioner concedes, the facility badly mishandled Resident #1's anticoagulant therapy care plan. Initially, petitioner's staff failed to perform the daily PT/INR tests as ordered and, when such test was eventually performed, the results indicated an elevated level of Coumadin. The patient's doctor was notified and over the next month he made a series of adjustments to the patient's medications.

After the patient's March 10 PT/INR test showed a "critical[ly] high" Coumadin level, her physician altered her regimen of medication and then ordered another PT/INR test two days later. That test, on March 12, again showed somewhat high results, but the physician ordered the Coumadin to be resumed at 6 mg/day and that another PT/INR test be conducted on March 21. Unfortunately, the nurse who took the March 21 order entered it on the resident's Medication Administration Record ("MAR") in a confusing manner, resulting in neither the lab's technician nor petitioner's nurse conducting a PT/INR test on that day. On March 23, such error was caught by a nurse and blood was drawn for the lab work.[1]

[1] It is undisputed that a MAR is prepared each month for each resident, listing on the left side of the form all medications the resident is to receive, with a series of boxes (Continued)

On March 24, the lab reported that the late sample was too small to test, so a nurse attempted to draw blood again; however, the patient refused to allow the draw. While a patient has a right to refuse treatment, 42 C.F.R. § 483.10(d)(3), the nurse did not immediately inform a supervisor or the resident's physician, as required. During the last attempt to obtain consent, a nurse noted unusual bruising around the resident's breast and shoulder area, injuries which could be signs of Coumadin overdose. This nurse did, however, report the bruising and refusal to allow a blood draw to the patient's physician, who then ordered the resident to be sent to a hospital for evaluation. In the late afternoon of March 24, a PT/INR test indicated a very high Coumadin level. Later that evening, the hospital administered a small dose of Vitamin K (the antidote for Coumadin overdose), but the resident's family thereafter declined further treatment or medical intervention, and the resident died on March 25, 2009.

B.

After Resident #1's death, Universal's staff reviewed her record and its lab policies to determine what, if anything, its

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corresponding to dates and times that a nurse initials when he or she administers the medication. Nurses use the patient's MAR each day, and an order for a lab test on a particular day is ordinarily noted in the box for that day.

nurses had done wrong. That review unearthed Resident #1's missed and delayed lab tests and the fact that she had refused blood draws several times on March 24 before the nurses informed the physician. In response, on March 26 and 27, Universal's Director of Nursing provided in-service training to all licensed nurses regarding the necessity of immediately notifying a supervisor or the Director of Nursing of any instance in which any ordered lab tests--especially PT/INRs--could not be obtained for any reason, including resident refusal. The Director of Nursing also revised Universal's protocol for posting physician orders for future lab tests to assure that a certain date was marked on each resident's Medication Administration Record.

Based on the Director of Nursing's findings, Universal's Administrator also contacted a nurse consultant to expand the investigation. That nurse audited the facility's lab procedures, as well as the medical records of every resident receiving anticoagulant therapy, and found no other errors. Nevertheless, Universal's managers decided to revise its Laboratory Procedure Policy to clarify all lines of communication, and to create a simplified reporting and tracking form for anticoagulant lab tests. All of these reports and findings, including the results of the investigations and the revised protocols, were addressed at a Quality Assessment and Assurance Committee Meeting on April 1, 2009, by Universal's

managers, Director of Nursing, and Resident #1's physician. Petitioner's clinical staff presented, and the QAA Committee approved, the new protocols at that time.

On April 3, 2009, petitioner's Director of Nursing began training nurses on the new lab, documentation, and reporting protocols, which was completed on April 7, 2009. No errors involving any lab tests occurred thereafter and the SSA found and cited none during the six-month interim until the September 2009 survey.

C.

The SSA's September 2009 survey cited Universal for the deficiencies relating to the care of Resident #1. Following the survey and at the SSA's direction, Universal developed a comprehensive "Plan of Correction," which it formally implemented on September 28, 2009. Universal contends that at no point during the survey did the team critique its internal investigation into Resident #1's death or its April 2009 corrective action. Further, Universal contends that the survey team did not find any new errors since the implementation of the April measures.

The survey team recommended to CMS that it only impose a $10,000 per instance CMP for past noncompliance. CMS rejected that recommendation, however, determining that petitioner was noncompliant for the entire period from March 21 (the date of

the missed PT/INR) through September 27, 2009 (the day before Universal implemented its comprehensive Plan of Correction). Accordingly, it imposed a CMP in the amount of $3050 per day for each day of noncompliance, totaling $587,950.

Universal requested review of this sanction by an ALJ, and offered statements of several witnesses that Universal's April 2009 lab protocol and its implementation was fully consistent with all pertinent professional and regulatory standards, and that Universal had resumed compliance with the cited regulations by no later than April 7, 2009. Defending its penalties, CMS argued before the ALJ that Universal's April corrective actions had failed to adequately address its deficiencies.

Agreeing with CMS, the ALJ determined that Universal's April 2009 corrective measures were too narrowly focused on "only one element of petitioner's noncompliance," and failed to "address the totality of the noncompliance." J.A. 16, 14. The ALJ explained that while the April measures did address the problem of petitioner's failure to perform physician-ordered testing, they failed to address other problems, "such as the failure of the staff to plan for the care of residents receiving anticoagulants or the failure [to report abnormal test results to physicians]." J.A. 16. "For that reason," the ALJ explained, "they are inadequate proof that Petitioner self-corrected its deficiencies by April 7, 2009." Id. at 14.

Ultimately finding that petitioner had not implemented comprehensive corrective actions addressing the entire range of deficiencies until it formalized the Plan of Correction on September 28, 2009, the ALJ affirmed CMS's determinations as to the duration of petitioner's noncompliance, and held that CMS's penalties were reasonable. J.A. 15, 17. The Board sustained this determination, which became the final action of the Secretary.

III.

Universal raises two challenges to the Secretary's imposition of the per diem CMP. First, Universal contends that the Secretary failed to consider its proffered evidence of resumed compliance with the Secretary's regulations as of April 7, 2009. Second, Universal contends that the final decision of the Secretary should be reversed and remanded because she failed to apply the correct legal standard in allocating the burden of proof, arguing that the ALJ's determination as to the duration of Universal's noncompliance was based only on a "presumption," which is inconsistent with applicable law. We address each contention.

A.

Under 42 U.S.C. § 1320a-7a(e), "[t]he findings of the Secretary with respect to questions of fact, if supported by

substantial evidence on the record considered as a whole, shall be conclusive." Id. Substantial evidence means "such relevant evidence as a reasonable mind might accept as adequate to support a conclusion." Richardson v. Perales, 402 U.S. 389, 401 (1971). "When the question before the court is whether an agency has properly interpreted and applied its own regulation, the reviewing court must give the agency's interpretation 'substantial deference.'" Md. Gen. Hosp. v. Thompson, 308 F.3d 340, 343 (4th Cir. 2002).

1.

Despite Universal's argument that the Secretary failed to consider its evidence of resumed compliance, we cannot say that the Secretary's decision to uphold the imposition of a per diem CMP is unsupported by substantial evidence.

As a condition of participation in the Medicare program, certified nursing facilities must meet a variety of requirements to ensure the safety of the residents under their care. Under 42 C.F.R. § 483.25(l)(1), a facility must ensure that "[e]ach resident's drug regimen" is free from drugs given "[i]n excessive dose," "[f]or excessive duration," "[w]ithout adequate monitoring," "[i]n the presence of adverse consequences which indicate the dose should be reduced or discontinued," or "[a]ny combinations" thereof. Under 42 C.F.R. § 483.75(j)(1), each facility must provide or obtain laboratory services that are

timely and that meet quality requirements. Under the DAB's interpretation of the regulations, once a facility is determined to be out of compliance, it need not be "affirmatively" shown "that noncompliance exists on each day that a remedy is in effect after the first day of noncompliance." In re Texan Nursing & Rehab. of Amarillo, LLC, DAB No. 2323, at 20 (July 2, 2010) (internal quotation marks omitted); 42 C.F.R. §§ 488.440(a)(1), 488.454(a)(1).

While Universal presented some evidence to the contrary, the Secretary had before her substantial evidence that petitioner failed to satisfy these requirements until on or about September 28, 2009. The regulations require that a skilled nursing facility "have systems in place" to ensure careful monitoring for, inter alia, "any unusual bleeding or symptoms of bleeding"; to "anticipate and plan for [the] risk" of bleeding; and to ensure "gentle handling," for example "in transfers to avoid bumps." J.A. 31-32, 35. Review of the administrative record reveals that the Secretary had before her statements from an experienced pharmacist and surveyor, as well as petitioner's own pharmacist consultant, that, at the time of the survey, Universal still lacked adequate systems to ensure that residents taking Coumadin were monitored closely for possible subtle signs of Coumadin toxicity. Further, the record contains evidence that in September 2009 Universal had yet to

implement systems to protect patients from possible trauma, such as bruising, which is dangerous to a person with impaired clotting.

In addition, the regulations require that a nursing facility have a system in place to ensure that labs are drawn when ordered, drawn correctly, processed correctly, and that the results are reported to doctors. Although Universal submitted evidence to the Secretary in support of its argument that it satisfied this requirement by April 7 by implementing a new lab protocol, such argument assumes that PT/INR tests alone are sufficient under the regulations to detect "adverse consequences" or an "excessive dose" of Coumadin. See 42 C.F.R. § 483.25(l)(1). Universal did not, however, make such argument in the course of the administrative proceeding and has not shown any exceptional circumstance warranting its consideration for the first time on appeal. 42 U.S.C. § 1320a-7a(c). Moreover, substantial evidence supports the Secretary's conclusion that adequate systems for monitoring residents on anticoagulant therapy require not only lab tests, but also protocols for monitoring and observation of residents by direct caregivers. The Secretary had ample evidence that petitioner did not return to substantial compliance with these standards until September 28, 2009, when it implemented the Plan of Correction. By way of example, the Secretary had evidence before her that before the

survey Universal did not have any system in place for ensuring that special instructions for Coumadin were placed in care plans or that subtle signs of injury were recorded.

Moreover, the Secretary had before her substantial evidence that, despite the April measures, Universal continued to lack an effective system for ensuring that labs were properly drawn and results reported. Even during the September survey, Universal's own consulting pharmacist expressed concern that she was unable to obtain or review information about labs and that she periodically discovered labs had been missed. Likewise, the Secretary's conclusion that there was a systematic failure based on petitioner's failure to "anticipate and plan for [the] risk" of bleeding, to "monitor[] for adverse drug reactions or overdoses," "to instruct staff" on touching and handling residents on Coumadin, and "to detect the errors that rank and file care givers were committing," J.A. 31-32, 37 (internal quotation marks omitted), is supported by substantial evidence. All in all, the final decision of the Secretary is supported by substantial evidence.

2.

Finally, Universal contends that the Secretary's decision should be reversed and remanded because she failed to apply the correct legal standard in allocating the burden of proof. Universal contends that the Secretary's conclusion that

petitioner did not achieve compliance until September 2009 was based only on a presumption, which is inconsistent with applicable law.

We will not reach the merits of this contention inasmuch as Universal failed to raise such argument before the Secretary below.[2] As "[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), and no exceptional circumstance has been suggested, we will not consider the merits of this contention. Woelke & Romero Framing, Inc. v. NLRB, 456 U.S. 645, 665 (1982); United States v. L. A. Tucker Truck Lines, Inc., 344 U.S. 33, 36-37 (1952).

IV.

In sum, we conclude that the Secretary's imposition of a per diem CMP of $587,950 was supported by substantial evidence. Universal's petition for review is therefore

DENIED.

[2] While Universal's procedural default on this contention prevents consideration of the merits of such argument on appeal, we note that Universal explicitly acknowledged that once it had been determined to be deficient in its care of Resident #1, there was a "presumption of continuing noncompliance." J.A. 85. Indeed, Universal argued before the Secretary that the applicable presumption was rebuttable. Id.; accord J.A. 46.