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UNITED STATES COURT OF APPEALS

FOR THE SIXTH CIRCUIT

GOLDEN LIVING CENTER - FRANKFORT, *Petitioner*,	
v.	No. 10-3200
SECRETARY OF HEALTH AND HUMAN SERVICES; UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES, *Respondents.*	

On Appeal from the Department of Health And Human Services Departmental Appeals Board.
No. A-09-130.

Argued: April 27, 2011

Decided and Filed: August 31, 2011

Before: COLE and STRANCH, Circuit Judges; ZATKOFF, District Judge.[*]

COUNSEL

ARGUED: Joseph L. Bianculli, HEALTH CARE LAWYERS, PLC, Arlington, Virginia, for Petitioner. Erin S. Shear, OFFICE OF THE GENERAL COUNSEL, DEPARTMENT OF HEALTH AND HUMAN SERVICES, Atlanta, Georgia, for Respondents. **ON BRIEF:** Joseph L. Bianculli, HEALTH CARE LAWYERS, PLC, Arlington, Virginia, for Petitioner. Erin S. Shear, OFFICE OF THE GENERAL COUNSEL, DEPARTMENT OF HEALTH AND HUMAN SERVICES, Atlanta, Georgia, for Respondents.

[*]The Honorable Lawrence P. Zatkoff, United States District Judge for the Eastern District of Michigan, sitting by designation.

OPINION

JANE B. STRANCH, Circuit Judge. Resident 1 ("R1") arrived at Golden Living Center ("Golden") on December 7, 2007 with complex ailments, but oriented, able to feed herself and able to speak. During 18 days in Golden's facility, R1 was sent to the hospital twice with serious medical complications. Following a complaint and investigation, Golden was found to have failed to maintain substantial compliance with federal regulations in its treatment of R1 and appealed the resulting civil money penalty. Both an administrative law judge and the Departmental Appeals Board affirmed the penalty. We **AFFIRM**.

I. BACKGROUND

Golden Living Center, a Medicare/Medicaid certified skilled nursing facility ("Facility") admitted 66-year-old R1 to its facility after she was discharged from a week-long stay in the hospital. R1 had been diagnosed with a number of conditions including hypotension, chronic kidney disease and gout. Upon R1's arrival, Golden prepared an initial care plan. Although she was at risk for dehydration, R1 was capable of handling fluids; Golden's dietician determined R1 required 2170 mls of fluids daily to maintain proper hydration and health. Golden's records, however, show R1 consumed as little as 10% of the recommended amount some days and she never consumed more than 45% of the recommended amount.

On December 12, 2007, Nurse Practitioner Susan Payton ("Payton"), who was principally responsible for management of R1 at Golden, detected in R1 abnormal lung sounds. Payton ordered a chest x-ray and laboratory tests. The x-ray confirmed that R1 had pneumonia. Although Payton ordered Golden's staff to "push fluids," R1's fluid input remained substantially below the amount recommended by Golden's dietician. On December 14, Payton asked about the lab tests and eventually learned they had not been administered.

Meanwhile, R1 was taken to the hospital on December 15, where she was diagnosed with hyperkalemia, a condition resulting from critically high potassium levels. R1 was given medication to reduce her potassium levels and returned to Golden on December 16. The lab tests Payton had requested on December 12 were finally obtained on December 17, after R1's return from the hospital. On December 18, merely two days after R1 returned to Golden with critically high potassium levels, Golden resumed administering R1 potassium supplements.

R1's condition continued to worsen and on December 25, she had a temperature of 100.7, was slow to arouse, her speech was difficult to understand, and she refused her morning meal and medications. That same day, after only 18 days at Golden, R1 was again transferred to the hospital. She was treated for acute dehydration, acute renal failure, hyperkalemia, sepsis, and pneumonia. Following her hospital stay, R1 was transferred to another facility. On December 28, 2007, Golden completed R1's amended care plan.

On January 30, 2008, a state survey agency completed an extended survey of Golden in response to a complaint. The agency concluded Golden was not in substantial compliance with five requirements under federal law and the noncompliance created immediate jeopardy with respect to a resident's health and safety. Based on the agency's conclusions, the Center for Medicare and Medicaid Services ("CMS") imposed a civil money penalty in the amount of $3,750 per day from December 15, 2007 through January 28, 2008 and $100 per day from January 29, 2008 through March 2. After a revisit by the agency, CMS concluded that Golden removed the immediate jeopardy on January 30, 2008, but determined Golden did not achieve substantial compliance with all federal requirements until March 3. The total penalty was $172,150.

At Golden's request, a hearing was held before an Administrative Law Judge ("ALJ") on February 18, 2009. Considering her ailments and medical history, the ALJ found R1's condition was stable upon admittance and no evidence suggested she was dehydrated or experiencing any other nutritional problems. The ALJ required the parties

to submit written declarations by their witnesses, who could be cross-examined at the hearing. Golden cross-examined Dr. Jeffrey Fink, who testified for CMS over the telephone and surveyor Andrea Willhite, who testified in person. CMS cross-examined Golden's witnesses, Nurse Payton and Dr. Michael Yao.

The ALJ found that Golden was not in substantial compliance with federal regulations. She also concluded that CMS's determination of immediate jeopardy and its finding that Golden did not obtain substantial compliance until March 3, 2008 were not clearly erroneous. The ALJ reasoned that the duration of the penalty was reasonable because risk to other residents persisted until Golden reached substantial compliance.[1] Golden appealed to the Departmental Appeals Board ("Appeals Board" or "DAB)") on December 31, 2009. The Appeals Board affirmed, concluding that substantial evidence supported the ALJ's factual findings and her determination that immediate jeopardy existed was not clearly erroneous.

Golden's appeal challenges the legal standard applied by the ALJ and Appeals Board and contends substantial evidence in the record as a whole does not support a finding of noncompliance with federal regulations.

II. DISCUSSION

A. Regulatory Landscape

Federal regulations impose significant requirements on Facilities that choose to participate in Medicare and Medicaid. *See* 42 U.S.C. § 1395i-3; 42 C.F.R. § 483.1 *et seq.* Those pertinent here include requirements that: (a) the facility provide each resident with sufficient fluid intake, 42 C.F.R. § 483.25(j); (b) the facility provide or obtain laboratory services to meet the needs of the residents, § 483.75(j)(1); (c) the facility develop an individualized comprehensive care plan,§ 483.20(k)(1); and (d) the facility provide each resident with the necessary care and services to attain or maintain

[1]The ALJ noted that Golden waived argument to the reasonableness of the penalty itself by not arguing it in its pre-hearing brief or objecting to the ALJ's conclusion as to waiver of the issue.

the highest practicable well-being, in accordance with the comprehensive assessment and plan of care, § 483.25.

The Secretary of the Department of Health and Human Services ("Secretary") may impose penalties on providers that do not achieve substantial compliance with the regulations. *See* 42 C.F.R. § 488.301 (substantial compliance is a "level of compliance with the requirements of participation such that any identified deficiencies pose no greater risk to resident health or safety than the potential for causing minimal harm."). To assess compliance, the Secretary contracts with state agencies to conduct inspections known as surveys. During the surveys, the agency records any instances of noncompliance, or "deficiencies," it discovers and notes their severity. §§ 488.10, 488.404(b).

The severity categories range from noncompliance that causes "[n]o actual harm with a potential for minimum harm," to noncompliance that causes "immediate jeopardy to resident health or safety." § 488.404(b). The appropriate penalty is split into two ranges depending on the severity of non-compliance. When immediate jeopardy is present, the daily penalty may range from $3,050–$10,000. § 488.438(a)(1)(i). When there is no immediate jeopardy but the deficiencies have either caused actual harm or have the potential for more than minimum harm, the daily penalty may range from $50–$3,000. § 488.438(a)(1)(ii).

The burden is on the facility to prove it has resumed complying with the program requirements. *Owensboro Place & Rehab. Ctr. v. Ctrs. for Medicare and Medicaid Servs.*, DAB No. CR2286, at 8 (2010). The Appeals Board has held that § 498.60(c)(2) "places the burden on the [skilled nursing facility]—a heavy burden, in fact—to upset CMS's finding regarding the level of noncompliance." *Liberty Commons Nursing & Rehab Ctr. v. Ctrs. for Medicare & Medicaid Servs. (CMS)*, DAB No. 2031, at 18 (2006) (emphasis omitted).

B. Standard of Review

This Court has jurisdiction to review imposition of penalties pursuant to 42 U.S.C. § 1320a-7a(e). *Woodstock Care Ctr. v. Thompson*, 363 F.3d 583, 588 (6th Cir. 2003). The standard this Court applies is highly deferential with respect to both issues of law and fact. *Woodstock*, 363 F.3d at 588. "Judicial review of decisions under 42 U.S.C. § 1320a-7a(e) is limited to determining whether the findings are supported by substantial evidence and whether the proper legal standards were employed." *MeadowWood Nursing Home v. United States Dep't of Health & Human Servs.*, 364 F.3d 786, 788 (6th Cir. 2004). Courts may only overturn the Secretary's decision if it is arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with the law. *St. Francis Health Care Ctr. v. Shalala*, 205 F.3d 937, 943 (6th Cir. 2000).

The findings of the Secretary, with respect to questions of fact, are conclusive if supported by substantial evidence on the record considered as a whole. Upon review, this Court examines the record as a whole and takes into account whatever in the record fairly detracts from the weight of the evidence below. *Claiborne-Hughes Health Ctr. v. Sebelius*, 609 F.3d 839, 843 (6th Cir. 2010); *Universal Camera Corp. v. NLRB*, 340 U.S. 474, 488 (1951). This Court does not "consider the case de novo, nor resolve conflicts in the evidence, nor decide questions of credibility." *Myers v. Sec'y of Health & Human Servs.*, 893 F.2d 840, 842 (6th Cir. 1990); *see also Allentown Mack Sales & Serv., Inc. v. NLRB*, 522 U.S. 359, 377 (1998) (substantial evidence review "gives the agency the benefit of the doubt, since it requires not the degree of evidence which satisfies the *court* that the requisite fact exists, but merely the degree which *could* satisfy a reasonable factfinder."); *Key v. Callahan*, 109 F.3d 270, 273 (6th Cir. 1997) (This Court defers to the agency "even if there is substantial evidence in the record that would have supported an opposite conclusion, so long as substantial evidence supports the conclusion reached by the ALJ.").

C. Legal Standard Applied Below

Golden raises two objections to the legal standard applied by the ALJ and Appeals Board. First, Golden argues that by requiring submission of written direct testimony, the ALJ violated Golden's rights under the Confrontation Clause. The Confrontation Clause of the Sixth Amendment guarantees a criminal defendant an opportunity for cross examination. *See Melendez-Diaz v. Massachusetts*, 129 S.Ct. 2527, 2531 (2009). Golden has not shown that the Confrontation Clause applies to this case.[2] Moreover, the ALJ required the parties to present the witnesses for cross-examination at the hearing, a method approved by the Appeals Board. *See Laurels at Forest Glenn v. Ctrs. for Medicare & Medicaid Servs.*, DAB No. 2182, at 9 (2008) (the Appeals Board "previously reviewed and approved the use of written direct testimony, so long as the right to effective cross examination is protected and no prejudice is alleged and shown"). Golden does not explain how this procedure denied effective cross examination nor does Golden establish any prejudice.

In its second objection to the legal standard, Golden argues that the ALJ and Appeals Board disregarded Golden's evidence and applied an improper subjective *de novo* standard of review. We disagree. The ALJ's decision considered Golden's evidence, including Payton's testimony, Dr. Yao's testimony, and a number of Golden's exhibits. In fact, much of Golden's own evidence supported a finding of violations: Dr. Quarles's medical forms failed to mention R1's fluid complexities; Golden's fluid intake exhibit showed that Golden failed to provide R1 with sufficient fluids (*id.* at 6); and, Dr. Yao's testimony supported a finding that the labs were not timely (*id.* at 11). Ultimately the ALJ weighed Golden's evidence against that submitted by CMS and concluded that Golden violated four Medicare participation requirements.[3]

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[2] Golden contends that issues raised at oral argument before the Supreme Court, in a case in which the Court issued no written decision, expands Confrontation Clause rights to the civil context. *See Briscoe v. Virginia*, 130 S.Ct. 1316 (2010) (vacating judgment of the Supreme Court of Virginia and remanding in light of *Melendez-Diaz*). We do not find this argument persuasive.

[3] Golden claims the ALJ was required to defer to its "medical experts," Nurse Practitioner Payton and Dr. Yao, in reviewing the evidence. However, the "long line of case law" Golden contends supports this deference arises in the context of the "treating physician rule" in Social Security disability regulation.

Like the ALJ, the Appeals Board articulated the correct standard of review. The Board stated that it reviews a disputed finding of fact to determine whether the finding is supported by substantial evidence in the record as a whole, and a disputed conclusion of law to determine whether it is erroneous. The Board also noted that it is not to reweigh the evidence or substitute its own evaluation, but is to determine whether the findings reached by the ALJ are supported by substantial evidence viewed in the context of the entire record. *id*. at 26. After considering Golden's arguments, the Appeals Board applied the correct standard and appropriately concluded that substantial evidence on the record as a whole supported the ALJ's findings.

D. Substantial Evidence Review

Substantial evidence exists on the record as a whole to support the ALJ's finding that Golden was not in compliance with the hydration requirement of 42 C.F.R. § 483.25(j), the requirement to provide proper laboratory services under § 483.75(j)(1), the requirement to create a comprehensive care plan under § 483.20(k), and the requirement to provide necessary care and services under § 483.25. We address each separately.

1. Hydration Requirement

Federal law requires a facility to "provide each resident with sufficient fluid intake to maintain proper hydration and health." 42 C.F.R. § 483.25(j). *See Woodland Village Nursing Ctr. v. Ctrs. for Medicare & Medicaid Servs.*, DAB No. 2053 (2006) ("whether [the facility] provided the amount of fluids recommended by the resident's dietician can be critical" on the issue of adequate hydration). The record supports a determination that Golden failed to properly monitor and maintain fluid levels for R1.

See 20 C.F.R. § 404.1527(d)(2) (requiring the ALJ give greater deference to the opinions of treating physicians in the social security context); *see also Rogers v. Comm'r of Soc. Sec.*, 486 F.3d 234, 242 (6th Cir. 2007). This rule has no applicability to nursing facility enforcement cases. Indeed, it makes little sense to apply the treating physician rule in this context where the actions of the treating physician are at issue.

Soon after R1 arrived at Golden, the facility's dietician determined R1 needed 2170 mls of fluid each day. Golden's records, however, show R1 never received the recommended amounts of fluids; on many days, she only received 10% of the recommended amount. Even after Payton directed Golden's staff to "push fluids," R1's fluid intake did not increase. R1's extreme dehydration upon arrival at the hospital on December 15 is strong evidence that Golden did not properly manage R1's fluids.

Golden emphasizes the complexity of R1's condition and the fact that R1 was at risk for hydration overload as a basis for its failure to comply with the dietician's recommended fluid intake. However, Golden points to no evidence in the record showing that it made a care plan decision or provided staff instruction to reduce the fluid level ordered for R1 based on any of her physical problems. In fact, evidence in the record supports the ALJ's conclusion that Golden's staff, including its attending physician, were not sufficiently apprised of R1's conditions to appropriately consider them in their care-taking decisions. Though trained to be alert to hydration issues, L.P.N. Atha did not recall R1 having any problems with hydration and Nurse Payton could not recall if she was notified about the resident's hydration (*id.* at 663). Evidence in the record also shows that Golden never properly recorded R1's fluid intake and output and, thus, failed to monitor her to assure sufficient fluid intake to maintain proper hydration and health. Substantial evidence in the record as a whole therefore supports the determination that Golden violated § 483.25(j).

2. Laboratory Services

Nursing facilities must "provide or obtain laboratory services to meet the needs of its residents. The facility is responsible for the quality and timeliness of these services." 42 C.F.R. § 483.75(j)(1). The parties agree that the lab tests Payton ordered on December 12, 2007 were not completed in a timely manner though Golden contends the ALJ exaggerated the impact of the delayed test. Evidence in the record shows timely lab tests could have revealed R1's high potassium levels and thereby enabled timely treatment of R1 and prevention of R1's hyperkalemia. Thus, substantial evidence in the

record as a whole supports the ALJ's finding that Golden did not provide the laboratory services necessary to meet R1's needs.

3. Comprehensive Care Plan

Within 14 days of a patient's admission, Facilities must develop a comprehensive assessment. 42 C.F.R. § 483.20(b)(2)(i). Within seven days after this assessment is completed, the facility must develop a care plan for the resident. 42 C.F.R. § 483.20(k)(1) (the care plan must "include[] measurable objectives and timetables to meet a resident's medical, nursing, mental and psychosocial needs that are identified in the comprehensive assessment"). Under part (i) of this provision, the care plan must describe, "[t]he services that are to be furnished to attain or maintain the resident's highest practicable physical, mental, and psychosocial well-being as required under § 483.25." § 483.20(k)(1)(i). Moreover, the Facility must ensure that "services arranged by the facility meet professional standards of quality." § 483.20(k)(3)(i).

Both care plans developed by Golden were not specific to R1's needs. The December 7, 2007 initial plan stated the intervention to address R1's risk for dehydration was "detection and intervention through next review." The subsequent care plan aimed to "encourage fluids as tolerated" but did not specify how much fluid to provide. *Id.* at 1582. Moreover, the December 28 care plan did not address R1's extremely high potassium levels. Because the care plans did not address a number of R1's specific needs nor provide measurable objectives, there is substantial evidence in the record to support a finding of violation of the requirement to provide a comprehensive care plan for each resident.

Golden's initial brief does not address the issue of professional standards of quality for the care plan. Therefore the issue is waived. *See Marks v. Newcourt Credit Grp., Inc.*, 342 F.3d 444, 462 (6th Cir. 2003).[4]

[4]In any event, a reasonable mind could find the failure to address R1's fluid complications and hyperkalemia sufficient to conclude Golden violated the provision to create a comprehensive care plan.

4. Necessary Care and Services

Pursuant to 42 C.F.R. § 483.25,

> Each resident must receive and the facility must 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.

Golden's treatment of R1's hyperkalemia supports a finding that Golden failed to provide necessary care and services. Merely two days after the hospital diagnosed R1 with hyperkalemia, critically high potassium levels, Golden's staff resumed administration of potassium pills to R1 and R1 was diagnosed with hyperkalemia again when she was admitted to the hospital on December 25, 2007. Evidence in the record shows R1's potassium levels were not monitored after her admission to the emergency room on December 15. A Golden employee conceded that the hyerkalemia "just got missed." (*id.* at 1588) The CMS expert opined that excessive potassium administration can lead to complications in patients with R1's level of kidney function. This and other evidence in the record supporting the violations described above constitutes substantial evidence that Golden did not provide R1 with the necessary care and services to satisfy this regulation. *See* 42 C.F.R. § 488.404(c)(1) (one of the factors to be considered in assessing a fine is "the relationship of the one deficiency to other deficiencies resulting in noncompliance"); *Lakeridge Villa Health Care Ctr. v. Leavitt*, 202 F. App'x 903, 909 (6th Cir. 2006) ("A single act can easily violate more than one provision[.]").

E. Immediate Jeopardy

Noncompliance rises to the level of "immediate jeopardy" when it "has caused, or is likely to cause, serious injury, harm, impairment, or death to a resident." 42 C.F.R. § 488.301. CMS's determination as to the level of noncompliance is upheld unless clearly erroneous. § 498.60(c)(2).

In this case, a seriously ill resident received a small portion of the fluids she required, her fluid intake and output were not properly recorded, and she quickly

developed severe dehydration and other medical complications. Lab tests that could have identified the resident's high potassium levels were not completed in a timely manner. Two days after the resident was diagnosed with dangerously high potassium levels, Golden resumed administering potassium pills. All the while Golden's staff members, including its attending physician, were not adequately apprised of the resident's condition or of her specific monitoring and treatment needs. These facts support a finding that Golden's noncompliance was likely to cause harm and indeed did harm R1.[5] CMS's finding of immediate jeopardy, therefore, was not clearly erroneous.

F. Duration of Penalties

Golden did not contest the Appeal Board's decision regarding the duration of noncompliance in its initial brief. *See Sanborn v. Parker*, 629 F.3d 554, 579 (6th Cir. 2010) (arguments raised for the first time in a reply brief are waived). However, without arguing it was waived, Respondent fully briefed the issue and Golden responded in its Reply Brief. Because both parties fully briefed the duration issue, we will address it.

This Court may only reverse the duration of noncompliance if it is left with a definite and firm conviction that the Secretary committed a clear judgment error in reaching its conclusion after weighing the relevant factors. *United States v. Haywood*, 280 F.3d 715, 720 (6th Cir. 2002).

Golden does not contend the violations ended at some other point; instead, Golden argues that failure to provide appropriate care for a single resident during her 18-day stay cannot support an 80-day duration of noncompliance.[6] However, the burden

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[5] A finding of immediate jeopardy under 42 C.F.R. § 488.301 does not require that the facility's actions actually harm the resident, rather, a likelihood that serious harm, injury, or death will result is sufficient. *See Spring Meadows Health Care Ctr. v. Ctrs. for Medicare & Medicaid Servs.*, DAB No. CR1063 (2003) ("[A] finding of immediate jeopardy does not hinge on a showing of a direct causal relationship between the facility's failure and the serious injury or death of a resident.").

[6] Golden argues that beginning the sanction on December 15 is arbitrary because it does not coincide with a particular event. This argument lacks merit because the Appeals Board has consistently held, "[t]he noncompliance—the failure to meet the participation requirement—is what constitutes the deficiency, not any particular event that was used as evidence of the deficiency." *Regency Gardens Nursing Ctr. v. Ctrs. for Medicare & Medicaid Servs.*, DAB No. 1858, at 21 (2002); *see also Windsor Place v. Ctrs. for Medicare & Medicaid Servs.*, DAB No. 2209, at 20 (2008).

is upon the facility to prove it has resumed compliance and Golden has not shown that it fully complied at an earlier date. Moreover, Golden's treatment of R1 is indicative of its practices in general and sheds light on the risk to all Golden residents resulting from poor recording of ailments, improperly executed lab requests, and inadequate care plans.

Given the severity of the violations described above, the fact that these violations likely affected Golden's other residents, and the necessity to revisit the facility to confirm compliance, there is adequate support for the Secretary's decision. This Court finds no clear judgment error in the duration of the penalty.

III. CONCLUSION

The ALJ and Appeals Board applied the correct legal standard. Substantial evidence in the record supports each violation found by the ALJ and affirmed by the Appeals Board. Moreover, CMS's findings of immediate jeopardy were not clearly erroneous, and CMS did not clearly err in setting the penalties' duration. Therefore, we **AFFIRM**.