Department of Health and Human Services
DEPARTMENTAL APPEALS BOARD
Appellate Division

Greenbrier Nursing and Rehabilitation Center
Docket No. A-10-60
Decision No. 2335
September 27, 2010

FINAL DECISION ON REVIEW OF ADMINISTRATIVE LAW JUDGE DECISION

Greenbrier Nursing and Rehabilitation Center (Greenbrier), an Arkansas skilled nursing facility (SNF) participating in the Medicare program, requests review of the March 29, 2010 decision of Administrative Law Judge Steven T. Kessel, *Greenbrier Nursing and Rehabilitation Center*, DAB CR2100 (2010) (ALJ Decision). The ALJ sustained CMS's imposition of civil money penalties (CMPs) based on Greenbrier's noncompliance with the SNF participation requirements at 42 C.F.R. §§ 483.25, 483.25(j), and 483.60(c) from January 11 through March 1, 2009, although he reduced the amount of the CMP to accord with his finding that the period of immediate jeopardy ended a day earlier than CMS had found. The CMPs sustained by the ALJ are $5,550 per day for January 11, 2009 through February 2, 2009 and $600 per day for February 3 through March 1, 2009.[1] We conclude that the ALJ's material findings of fact are supported by substantial evidence in the record as a whole, and that the ALJ committed no error of law. Accordingly, we affirm the ALJ Decision.

Applicable Law

Long-term care facilities participating in the Medicare and Medicaid programs are subject to the survey and enforcement procedures set out in 42 C.F.R. Part 488, subpart E, to determine if they are in substantial compliance with applicable program requirements which appear at 42 C.F.R. Part 483, subpart B. "Substantial compliance" means a level of compliance such that "any identified deficiencies pose no greater risk to resident health or safety than the potential for causing minimal harm." 42 C.F.R. § 488.301. "Noncompliance," in turn, is defined as "any deficiency that causes a facility to not be in substantial compliance." *Id.* Survey findings are reported in a Statement of Deficiencies (SOD). The SOD identifies each "deficiency" under its regulatory

[1] A heading on page 11 of the ALJ Decision says that the CMPs continued through March "11," 2009. However, based on the totality of the ALJ Decision and the record, that is clearly a typographical error. The parties do not dispute that Greenbrier's noncompliance, and the CMPs, continued only through March 1, 2009.

requirement, citing both the regulation at issue and the corresponding "tag" number used by surveyors for organizational purposes.

A long-term care facility found not to be in substantial compliance is subject to various enforcement remedies, including CMPs. 42 C.F.R. §§ 488.402(c), 488.406, 488.408. CMS has the option to impose a CMP whenever a facility is not in substantial compliance. 42 C.F.R. § 488.417(a). CMS may impose per-instance or per-day CMPs, and there are two ranges of CMPs that depend on the scope and severity of the noncompliance. 42 C.F.R. §§ 488.408(a), 488.408(d)(iii)-(iv), (e)(iii)-(iv). When CMS chooses to impose a per-day CMP, it imposes a CMP in the $50-$3,000 range for each day of noncompliance at less than the immediate jeopardy level, 42 C.F.R. § 488.408(d)(iii), and $3,050 to $10,000 per day for noncompliance at the immediate jeopardy level, 42 C.F.R. § 488.408(e)(iii). Once a facility is found not in substantial compliance, that finding continues until "[t]he facility has achieved substantial compliance, as determined by CMS or the State based upon a revisit or after an examination of credible written evidence that it can verify without an on-site visit . . . ." 42 C.F.R. § 488.454(a)(1).

Standard of Review

The Board's standard of review on a disputed conclusion of law is whether the ALJ decision is erroneous. The Board's standard of review on a disputed finding of fact is whether the ALJ decision is supported by substantial evidence on the record as a whole. *Guidelines – Appellate Review of Decisions of Administrative Law Judges Affecting a Provider's Participation in the Medicare and Medicaid Programs*, http://www.hhs.gov/dab/divisions/appellate/guidelines/prov.html; *Batavia Nursing and Convalescent Inn*, DAB No. 1911, at 7 (2004), *aff'd, Batavia Nursing & Convalescent Ctr. v. Thompson*, 143 F. App'x 664 (6th Cir. 2005).

Background[2]

A. *The survey and CMS's determinations*

The Arkansas Department of Human Services (State agency) conducted a survey at Greenbrier that ended on February 4, 2009. ALJ Decision at 2. The surveyors found that Greenbrier was not in substantial compliance with the Medicare requirements at 42 C.F.R. §§ 483.25, 483.25(j), and 483.60(c) and that the noncompliance with section 483.25 put residents in immediate jeopardy for a portion of that time. Id. Based on these findings, CMS initially imposed remedies, including a per-instance civil money penalty

[2] The information in this section is drawn from undisputed findings in the ALJ Decision as well as from the record before the ALJ, and is presented to provide a context for the discussion of the issues raised on appeal. Nothing in this section is intended to replace, modify, or supplement the ALJ's findings of fact or conclusions of law.

(CMP) of $7,500 for the immediate jeopardy level noncompliance with section 483.25. ALJ Decision at 2, n.1; CMS Ex. 1, at 2 (notice letter of February 23, 2009). CMS later revised the CMP to a $5,550 per-day CMP for the period of immediate jeopardy (January 11 through February 3, 2009) and a $600 per-day CMP for the period of continuing noncompliance (January 4 through March 1, 2009). ALJ Decision at 1 and 2, n.1; CMS Ex. 1, at 4 (notice letter of March 12, 2009). In its request for an ALJ hearing, Greenbrier challenged the alleged immediate jeopardy level noncompliance with section 483.25. Greenbrier also argued that the Departmental Appeals Board's assignment of the ultimate burden of persuasion to facilities appealing noncompliance determinations was unlawful, but the ALJ declined to address this issue. *Id.* at 3 and n.2. The parties agreed to decision on the written record and briefs. *Id.* at 2.

B. *Summary of the ALJ Findings and Conclusions*

The alleged noncompliance with section 483.25 largely involved Greenbrier's alleged failure to provide quality care to an elderly female resident, identified as Resident 5 (R. 5), who was being treated with the anti-coagulent drug Coumadin. ALJ Decision at 3, 5. Coumadin "is a medication that anticoagulates the blood, antagonizing blood proteins to slow the rate of clotting." *Id. at 3*, citing CMS Ex. 12 (declaration testimony of Laurie Jacobs, M.D.), at 3. Coumadin is used to treat diseases, such as atrial fibrillation, in which the propensity for blood clotting is increased. *Id.* A major risk of Coumadin therapy is that the risk of bleeding increases with the intensity of the therapy. *Id*. at 4. Tests known as international normalized ratio (INR) and Prothrombin Time (PT) measure blood clotting time. *Id.*, citing CMS Ex. 12, at 3-4. Generally, an INR no greater than 1.0 is considered normal, and an INR between 2.0 and 3.0 is considered an acceptable risk of bleeding when measured against the benefits the patient may receive from Coumadin therapy. *Id.*, citing CMS Ex. 12, at 4. PT/INR testing must be done regularly for a patient who is receiving Coumadin in order to assure that the patient's blood clotting time is not outside acceptable parameters. *Id.* The professionally recognized standard of care is to conduct this testing at least once every four weeks. *Id.* In addition, a patient being treated with Coumadin should be monitored physically for signs and symptoms of bleeding, such as easy bruising and visible bleeding. *Id.*

The ALJ found that the weight of the evidence amply supported CMS's allegations that Greenbrier staff failed to provide PT/INR testing to R. 5 for nearly three months; failed to comprehend the signs of Coumadin toxicity manifested by R. 5; and failed to take into account that R. 5 was receiving antibiotics that could heighten the risk of bleeding. ALJ Decision at 5. The ALJ also found that the weight of the evidence supported CMS's allegation that the reviews done by Greenbrier's pharmacist failed to note the absence of any PT/INR testing after October 2008 and failed to assess the resident's use of Coumadin in conjunction with antibiotic treatments she received. *Id.* at 5, 9. The ALJ found that as a result of these failures of care, R. 5 developed a toxic reaction to Coumadin so severe that it required emergency hospitalization in order to treat the resident's bleeding and anemia. *Id.*

Based on these findings, the ALJ concluded (1) Greenbrier was not in substantial compliance with section 483.25; (2) CMS's determination of immediate jeopardy level noncompliance with section 483.25 was not clearly erroneous; and (3) CMPs of $5,500 per day for the period January 11 through February 2, 2009, the period of immediate jeopardy, and $600 per day for the period February 3 through March 1, 2009, the period of continuing noncompliance at less than the immediate jeopardy level, were reasonable. ALJ Decision at 3, 9, 10-11. The ALJ also found that the unappealed findings of noncompliance with sections 483.25(j) and 483.60(c) were administratively final and provided an additional basis for finding that Greenbrier's noncompliance continued after February 2, 2009 and that the $600 per day CMP was reasonable. *Id*. at 3, 12-13. The ALJ's conclusion as to the duration of the immediate jeopardy level CMP incorporates his finding that CMS had no basis for imposing a CMP at that level on February 3, 2009 (as CMS originally found), because, as CMS acknowledged, the immediate jeopardy was abated on February 2, 2009.

C. *Summary of Greenbrier's arguments on appeal*

In its request for review, Greenbrier disputes the ALJ's conclusions that it was not in substantial compliance with section 483.25 at the immediate jeopardy level, challenging the findings of fact, set forth above, on which the ALJ based that conclusion. RR at 2-4, 6-11. Greenbrier also disputes the ALJ's conclusion that its noncompliance continued on and after February 3, 2009. *Id.* at 5-6. Greenbrier argues that it was error for the ALJ to base his conclusion of continuing noncompliance, in part, on the unappealed findings under sections 483.25(j) and 483.60(c). *Id.* at 12-13. Greenbrier disputes the ALJ's finding that CMS gave the facility adequate notice of its reliance on those findings. *Id.* Greenbrier also asks the Board to address the burden of proof issue the ALJ declined to address.

As discussed below, we have carefully considered Greenbrier's arguments but uphold the ALJ Decision in its entirety.

Discussion

A. *The ALJ did not err in concluding that Greenbrier did not comply with 42 C.F.R. § 483.25 when it failed to follow professionally accepted standards of care for Coumadin therapy.*

This appeal involves the quality of care requirement at 42 C.F.R. § 483.25 (tag F309). The introductory or lead-in language of that regulation states:

> 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.

Subsections of the regulation set forth specific requirements relating to particular types of care, services and resident needs. However, surveyors may cite a deficiency (using tag F309) for failure to comply with the lead-in language itself, because this language sets out the overarching requirement and congressional mandate of the quality of care provision. *Sheridan Health Care Center*, DAB No. 2178 (2008). In *Sheridan*, the Board held that the quality of care regulation implicitly imposes on facilities a duty to provide care and services that, at a minimum, meet accepted professional standards of quality "'since the regulations elsewhere require that the services provided or arranged by the facility must meet such standards.'" DAB No. 2178, at 15, quoting *Spring Meadows Health Care Center.*, DAB No. 1966, at 17 (2005) (holding that an accepted standard of clinical practice need not be specified in a regulation before it may be considered by an ALJ in assessing whether the skilled nursing facility was compliant).

1. Substantial evidence supports the ALJ's finding that Greenbrier failed to follow for R. 5's Coumadin therapy the professionally accepted standard of at least monthly PT/INR testing.

The ALJ found that the standard of care with respect to the timing of PT/INR tests for residents on Coumadin therapy is to perform those tests at least once a month. ALJ Decision at 5. The ALJ based this finding on the testimony of Dr. Jacobs, a licensed physician certified in internal medicine and geriatrics. *Id.* at 4, citing CMS Ex. 12 at 3-4; *see also id.* at 1. Greenbrier does not dispute that monthly PT/INR testing is the standard of care. Neither does Greenbrier dispute the ALJ's finding that Greenbrier did not perform a PT/INR test for R. 5 between October 31, 2008 and January 19, 2009, the date she was hospitalized, a period of nearly three months.[3] We conclude that absent an effective rebuttal by Greenbrier, these facts support the ALJ's conclusion of noncompliance with section 483.25.

In its Request for Review, Greenbrier in effect repeats the rebuttal arguments it made before the ALJ. Greenbrier argues that its failure to adhere to the professional standard of care for R. 5's PT/INR testing is not a quality of care violation because, Greenbrier asserts, the record does not support the ALJ's conclusion that R. 5's physician (who was also Greenbrier's medical director) ordered Greenbrier staff to perform a PT/INR test at least monthly. RR at 2-3. Greenbrier argues that it was merely following the physician's wishes when it made no effort to obtain an order for further testing. As support for its position, Greenbrier points to the following evidence: the absence of a standing order for PT/INR testing for R. 5; the presence of specific orders for more frequent testing for R. 5; and the physician's statement to a surveyor that he did not issue standing orders for

[3] The ALJ Decision states that the last test was October 29, 2008. ALJ Decision at 5. Although a PT/INR test was performed on October 29, 2008, the last PT/INR test, as CMS agrees, was actually done on October 31, 2008. CMS Ex. 2, at 6; CMS Response Brief (R. Br.) at 6. The ALJ's misstatement of the date is harmless since neither party disputes his finding that no testing occurred after October 2008 and that R. 5, therefore, went nearly three months without this test.

PT/INR testing. RR at 3, citing CMS Ex. 7, at 44-69, CMS Ex. 2, at 6, and CMS Ex. 4, at 39. This evidence, Greenbrier asserts, "stands in direct conflict with the ALJ's conclusion that the 'credible evidence in this case proves that the physician ordered monthly INR and PT testing be done.'" RR at 3, quoting ALJ Decision at 6.

The ALJ's conclusion is supported by substantial evidence. It is clear from the full context of his discussion of the testing issue that what the ALJ meant, and what he later stated more precisely, was that notwithstanding the absence of a formal or standing order, the record supports a conclusion that R. 5's physician expected that the professionally recognized standard for at least monthly testing, which he acknowledged to the surveyors, would be applied to R. 5. The conclusion quoted by Greenbrier followed the ALJ's lengthy discussion of the standard of care for Coumadin treatment in general and, in particular, for PT/INR testing at least once every four weeks. ALJ Decision at 4. After discussing this standard, the ALJ found that R. 5's care plan did not support Greenbrier's argument that it was merely following the physician's wishes when it did not provide at least monthly PT/INR testing. *See id.* at 6. He noted that R. 5's care plan, consistent with the professional standard, stated "LAB PER PHY: MONIT PT/INR AT LEAST MONTHLY," supplemented with an undated handwritten note stating "per phy." *Id.*; CMS Ex. 7, at 35. The ALJ also noted that the care plan "was prepared with the medical director's [also R. 5's physician] input." *Id.* The ALJ inferred from these facts that "the resident's physician ordered monthly INR and PT testing."[4] *Id.* Greenbrier disputes this inference, asserting, as it did below, that "per phy" meant that staff should await specific orders from the resident's physician about when to do the tests. RR at 2; ALJ Decision at 6.

We conclude that the ALJ's reading of R. 5's care plan is supported by its plain language. We further conclude that Greenbrier's reading is not reasonable. Under Greenbrier's reading, the words "at least monthly" have no meaning, because, absent a physician order, staff could fail to obtain PT/INR testing for R. 5 indefinitely. Greenbrier's reading also is inconsistent with its acceptance of the ALJ's finding that the professionally accepted standard of care requires at least monthly testing. As we stated above, the quality of care regulation implicitly imposes on facilities a duty to provide care and services that, at a minimum, meet accepted professional standards of quality. As construed by the ALJ, R. 5's care plan is consistent with that requirement. As construed by Greenbrier, it is not, because it would mean that the facility, which is responsible for developing care plans, with the input of the resident's physician and other staff, did not follow the professional standard for at least monthly testing and did not document any reason to alter the standard in the case of this resident.

[4] Since the ALJ was discussing whether the physician concurred with the "at least monthly" standard, we assume his omission of the phrase "at least" from some of his statements about Greenbrier's failure to meet that standard was simply inadvertent, or intended as a shorthand reference, and has no other significance. Greenbrier does not argue otherwise or even note the ALJ's omission.

We also agree with the ALJ that the physician's statement to a surveyor that he did not issue standing orders for PT/INR testing does not support a conclusion that he did not want Greenbrier to follow the professional standard and test R. 5's PT/INR at least once a month. ALJ Decision at 6. As the ALJ noted, although the physician told the surveyor he did not issue standing orders for this test, the physician agreed that PT/INR should be monitored once a month, "'if no other issues are going on.'" *Id.*, quoting CMS Ex. 4, at 39. The surveyor's interview notes indicate that the physician made this statement in response to the surveyor's question as to how frequently the PT/INR should be monitored when a patient's Coumadin dosage is stable. The ALJ concluded, correctly in our view, that the physician's statement was "an acknowledgement of what I have found, a failure to test the resident at least monthly is a violation of professionally recognized standards." *Id.* The ALJ's conclusion that R. 5's physician wanted at least monthly PT/INR testing is further supported by the physician's additional statement, during the same interview, that had he received the October 31, 2008 test results (which Greenbrier says showed Coumadin levels within normal limits – RR at 7), he "would've done a therapeutic draw in one month . . . ." CMS Ex. 4, at 39.

For the reasons stated above, we conclude that the record as a whole supports the ALJ's conclusion that regardless of whether there was a formal or standing order to that effect, R. 5's physician, consistent with the professionally recognized standard of care, wanted R. 5's PT/INR monitored no less frequently than once a month and that R. 5's care plan reflects this. The presence in the record of specific physician orders for testing more frequently than the outside boundary of that standard (four weeks) in the period leading up to October 31, 2008 does not undercut this conclusion. On the contrary, these orders show that during that period the physician consistently monitored R. 5's PT/INR within the parameters of that standard.

Even if we were to accept Greenbrier's contrary interpretation of the evidence, we would not conclude that Greenbrier complied with section 483.25 by doing nothing about scheduling a future test in the face of the physician's failure to issue a specific testing order. The regulation imposes a duty on the long-term care facility and its staff that exists regardless of how residents' physicians fulfill their professional obligations. That duty includes the obligation of facility nursing staff to meet professional nursing standards of care. *See Maysville Nursing and Rehabilitation Facility*, DAB No. 2317 (2010) (holding nurses had a professional obligation to question a physician about the absence of a timely order for PT/INR testing as part of their obligation to monitor the resident's drug treatment under section 483.25(l)). Dr. Jacobs discussed the professional obligations of long-term care nurses in her testimony.

> In a long term care facility, it is the nurses' role to administer [Coumadin], ensure that the INR is obtained according to the physicians' orders, and that the results are communicated to the physicians. In addition, it is their role to report any observations of possible bleeding associated with treatment in a prompt fashion to the physician. <u>The physician is responsible for</u>

> ordering INR testing, but if this is not done, there are several levels of oversight to ensure that it is done. First 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, secondly medications are reviewed and orders renewed no less frequently than every 30 days by the physicians, and the consultant pharmacist usually reviews the medication regimen every month, providing suggestions and oversight.

CMS Ex. 12, at 4 (emphasis added), cited in ALJ Decision at 4.

Greenbrier does not dispute that Dr. Jacobs correctly stated the professional standard of care for long-term care nurses caring for residents receiving Coumadin therapy. The system for monitoring PT/INR testing used by Greenbrier during the time at issue did not meet this standard. Under that system, a nurse would fax the results of PT/INR testing to the resident's physician (and, in the case of abnormal results, also phone them in), and the physician would return the fax to nursing staff with written comments and orders for future testing on the fax; nursing staff would implement the new orders upon receipt. RR at 4; *see also* CMS Ex. 2, at 6 (physician statement to surveyor). Greenbrier asserts that it faxed the results of the October 31, 2008 PT/INR test to R. 5's physician, but he failed to follow his usual practice of returning the fax with written instructions for new testing. RR at 4-5, citing CMS Ex. 4, at 39; *see also* CMS Ex. CMS Ex. 7, at 120 (nursing note stating results were faxed to physician). Greenbrier asserts that its nurses fulfilled their duty under section 483.25 by merely awaiting an order that never arrived. We disagree, because under the professionally accepted nursing standard of care, Greenbrier's nurses had a duty to inquire about the absence of an order, regardless of who was responsible for the absence.

Our conclusion here that staff could not comply with section 483.25 by merely waiting indefinitely for the physician to issue a new order is consistent with the Board decision in *Maysville*. The Board held Maysville responsible for the quality of the drug therapy received by its residents, rejecting the facility's argument that to do so required the facility to act in place of the resident's physician. The Board explained that although the Medicare and Medicaid Acts and section 483.75(h)(2)(i) (requiring facilities to obtain services meeting professional standards) do not require a facility to act in place of the resident's physician, they do hold the facility responsible for the health and safety of the resident. DAB No. 2317, at 8. Although *Maysville* addressed the failure to monitor Coumadin testing under subsection (l) of section 483.25 (unnecessary drugs), we see no reason why the Board should not apply the principle more generally to section 483.25, at least where, as here, the issue is the same, that is, whether the fact that a physician has sole authority to prescribe drugs insulates a facility from a finding that it has failed to properly monitor a resident's drug regimen. As we noted earlier, section 483.25 incorporates the same professional services requirements of section 483.75(h)(2)(i) on which the Board relied in *Maysville*. We conclude here, as the Board did in that case, that nursing staff could not meet their professional responsibilities or comply with section

483.25 by simply waiting in silence for another PT/INR testing order from the resident's physician even when the professionally accepted maximum 30-day testing interval had expired.

2. Substantial evidence supports the ALJ's finding that Greenbrier failed to address bruising and bleeding manifested by R. 5 as possible signs of Coumadin toxicity.

The ALJ found that although Greenbrier staff noted multiple bruises between December 27, 2008 and January 19, 2009 (the date R. 5 was hospitalized), they failed to address these developments as signs of possible Coumadin toxicity. Nursing notes document observations of bruising on December 27, 2008 (small darkened areas on left thigh) and January 11, 2009 (extensive bruising under the resident's right armpit). ALJ Decision at 7, citing CMS Ex. 7, at 121, 123. Nursing notes for January 17 and 18, 2009 again document right underarm bruising and also complaints of pain and a hard ridge. CMS Ex. 7, at 124-125. On January 19, 2009, the resident scratched a scab on her left forearm and began to bleed. *Id.* at 125. This was documented at 2:40 a.m. *Id.* R. 5's physician ordered staff to send her to the emergency room at 6:25 a.m., after a nurse documented changes in her vital signs. *Id.*

The December 27 note does not indicate that staff notified R. 5's physician of the bruising, even though the note shows that the nurse was aware that R. 5 was being treated with Coumadin and that the resident "bruises easily" as a result of that therapy. ALJ Decision at 7, citing CMS Ex. 7, at 121. Although nursing notes indicate that R. 5's physician saw her during rounds on December 31, 2008, there is no indication that staff alerted him to the bruising or that the physician himself noted it. CMS Ex. 7, at 121. Staff apparently did notify the physician after noting the extensive bruising and firm ridge in the armpit area on January 11, 2009. *Id.* at 123. However, there is no indication that staff and the physician discussed whether the bruising could be related to Coumadin or the need for a PT/INR test.

Greenbrier admits in its request for review "that there is no documented proof that a physician was notified of each instance of bruising noted in the chart . . ." but asserts that such notification is not the standard of care, that a physician need only be notified of a "significant deterioration in condition." RR at 8. The ALJ rejected this argument (calling it a "red herring") and so do we. In the first place, Greenbrier misstates the standard of care it invokes. That standard actually requires the facility to consult with (not just notify) a resident's physician when there is a "significant change," not a "significant deterioration," in the resident's status. A "significant change" is defined as "a[ny] deterioration in health, mental, or psychosocial status in either life-threatening conditions or clinical complications," not just a significant deterioration. 42 C.F.R. § 483.10(b)(11)(i)(B); *see also Senior Rehabilitation and Skilled Nursing Center*, DAB No. 2300 (2010).

Moreover, the standard Greenbrier cites is for determining whether a resident's rights have been violated not, as here, for determining whether Greenbrier "staff failed to recognize and apply the relevant standards of care for treating a patient who is receiving Coumadin." ALJ Decision at 8. Under the standard of care for Coumadin therapy, quoted above, nurses must promptly report to a resident's physician any observations of possible bleeding associated with the treatment. As the ALJ noted, the nurse who first noticed bruising on R. 5 (on December 27, 2008) expressly acknowledged that R. 5's Coumadin treatment could be causing the bruising yet did not report these bruises to R. 5's physician or take any other action to address the possibility that R. 5 was showing signs of Coumadin toxicity. ALJ Decision at 7. While staff reported a subsequent observation of bruising, the ALJ found "nothing in the resident's treatment record showing that the bruising and related problems caused the staff to reassess the resident's condition or to consider interventions that were specifically aimed at possible Coumadin toxicity." *Id*. Greenbrier points to no evidence undercutting this finding. Thus, the record supports the ALJ's conclusion that Greenbrier's staff did not recognize and apply the relevant standard of care when it failed "to assess the resident for possible Coumadin toxicity despite the fact that the resident was manifesting signs that any reasonable trained health care professional should have recognized as ominous." *Id.* at 8.

3. Substantial evidence supports the ALJ's finding that Greenbrier failed to take into account R. 5's receipt of antibiotics that could heighten the anti-clotting effects of Coumadin.

The ALJ found that in addition to not consulting with R. 5's physician as to whether her bruising could be related to Coumadin therapy, Greenbrier did not consult with him about possible adverse interactions between Coumadin and antibiotics (Levaquin and Bactrim) the physician prescribed. ALJ Decision at 5. On January 17, 2009, when notified of the bruising and hard ridge under R. 5's right arm, R. 5's physician, apparently suspecting cellulitis, prescribed Bactrim. ALJ Decision at 8, citing CMS Ex. 7, at 67, 124. The ALJ noted Dr. Jacobs' testimony that antibiotics have a known potential to heighten the effects of Coumadin and thereby increase the risk of Coumadin toxicity and bleeding. *Id*., citing CMS Ex. 12, at 2. The ALJ then found, and we agree, that there is no evidence that the facility discussed this risk with R. 5's physician, even though R. 5 was already manifesting signs of possible Coumadin toxicity (bruising) when he prescribed the Bactrim. Thus, Greenbrier once again failed to comply with professionally recognized standards of care.

Greenbrier argues that staff failure to discuss with R. 5's physician the possible adverse interaction of drugs is a non-issue because the treatment with Levaquin, the first antibiotic prescribed, ended before R. 5's last PT/INR test, and the subsequent treatment with Bactrim did not begin until the day before R. 5 was admitted to the hospital. RR at 8-9. However, this argument misses the point. As the ALJ concluded, given the recognized risk that antibiotics would heighten the anti-clotting effects of Coumadin,

Greenbrier had a duty to anticipate and plan for this risk, not simply react to any problems that developed. There is no evidence that staff did any planning or had any discussions with R. 5's physician, even though staff observed signs of possible Coumadin toxicity before the physician prescribed Bactrim. In particular, as the ALJ noted, there was no change to R. 5's care plan to address this risk, and there is no indication that the PT/INR test administered on October 31, 2008 was related to assessing the possible adverse interaction between drugs. ALJ Decision at 8.

These facts, which are not disputed by Greenbrier, constitute substantial evidence supporting the ALJ's conclusion that staff failed to take into account the risk R. 5's antibiotic treatment posed in light of her Coumadin therapy and the fact that she was already showing signs associated with the risk of Coumadin toxicity.

4. The ALJ did not err in concluding that the consulting pharmacist's failure to review or assess R. 5's Coumadin treatment was another basis for finding noncompliance with section 483.25.

As a final basis for concluding that Greenbrier was not in substantial compliance with section 483.25, the ALJ found that the weight of the evidence "strongly supports a conclusion that Petitioner's consulting pharmacist failed to provide any review or assessment to the staff concerning the administration of Coumadin to Resident #5." ALJ Decision at 9. The ALJ cited the pharmacy review forms related to R. 5's drug regimen from October through December 2008. *Id.*, citing CMS Ex. 7, at 147-49. He noted that these reviews did not mention the risks associated with taking Coumadin, by itself or in combination with antibiotics, or the absence of PT/INR testing after October 2008. *Id.*

Greenbrier does not dispute these facts or the ALJ's conclusion as to what they showed. Instead, Greenbrier argues that the ALJ committed prejudicial error by relying on these facts to find noncompliance with section 483.25 because on the statement of deficiencies, CMS cited these facts for the noncompliance with section 483.60(c), noncompliance that Greenbrier did not appeal. The Board rejected a similar argument in *Oak Lawn Pavilion, Inc.*, DAB No. 1638, at 8-12 (1997), concluding that the ALJ there did not err in finding noncompliance with the quality of care requirement based, in part, on facts cited under other unmet requirements. The Board concluded in *Oak Lawn* that the facility was not prejudiced because it had notice that CMS (then HCFA) intended to rely on these facts as part of its proof of noncompliance with the quality of care requirement. Here, Greenbrier had notice from CMS's briefs below that CMS intended to rely on the facts relating to the pharmacy consultant as part of its proof for the section 483.25 noncompliance. *See* CMS Motion for Summary Judgment at 10; CMS Closing Br. at 12. Before the ALJ, as here, Greenbrier chose not to dispute the facts relied on by CMS. *See* Petitioner's Response to CMS's Motion for Summary Judgment at 6. Furthermore, the facts regarding the pharmacy reviews are relevant to the quality of care requirement since they relate to the

professionally accepted standard of care, as articulated in Dr. Jacobs' testimony. *See* ALJ Decision at 4.

In any event, the ALJ's findings of fact regarding the pharmacy reviews are not necessary to our decision. His conclusion that Greenbrier was not in substantial compliance with section 483.25 is amply supported by any one of his findings regarding the facility's failures to (1) assure at least monthly PT/INR testing, (2) address R. 5's bruising and bleeding as a possible sign of Coumadin toxicity, and (3) take into account the possible adverse interactions between R. 5's Coumadin and her prescribed antibiotics.

B. *The ALJ did not err in concluding that CMS's immediate jeopardy determination was not clearly erroneous.*

Greenbrier disputes the ALJ's conclusion that CMS's determination that Greenbrier's noncompliance with section 483.25(h)(2) posed immediate jeopardy to R. 5 was not clearly erroneous. "Immediate jeopardy" is "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." 42 C.F.R. § 488.301. An ALJ may overturn CMS's determination of the level of noncompliance, including immediate jeopardy, only if the ALJ determines that it is "clearly erroneous." 42 C.F.R. § 498.60(c) (2). A facility has the burden of proving that CMS's determination of the level of noncompliance is "clearly erroneous," and our decisions make it clear this is a heavy burden. *See e.g., Liberty Commons Nursing & Rehab Center v. Johnston*, DAB No. 2031, at 18-19 (2006), *aff'd, Liberty Commons Nursing & Rehab Ctr.– Johnston v. Leavitt*, 241 F. App'x. 76 (4th Cir. 2007).

The ALJ concluded that Greenbrier had not shown CMS's determination to be clearly erroneous. On the contrary, he found that "[t]he failure to monitor Resident #5's use of Coumadin coupled with the other deficient practices that I have discussed created a high likelihood of severe harm or worse." ALJ Decision at 9. The ALJ noted that R. 5 "was in the process of bleeding to death when she was hospitalized . . . ." *Id.* He further concluded that R. 5's anemia "might not have occurred or might have been detected sooner had staff monitored her Coumadin use on a regular basis . . . reacted appropriately to the bruising and signs of bleeding . . . or . . . taken other steps to anticipate and plan for the risks of Coumadin." *Id.*

We find no error in the ALJ's conclusion that CMS's determination of immediate jeopardy was not clearly erroneous. It is undisputed that, when admitted to the hospital, R. 5 manifested a decreased level of consciousness and suffered from extreme anemia, likely caused by Coumadin toxicity. ALJ Decision at 9, citing CMS Ex. 7, at 125, 158-61; CMS Ex. 12, at 6. R. 5 required transfusion therapy and the administration of vitamin K, a substance used to counteract the effects of Coumadin. CMS Ex. 7, at 161; CMS Ex. 12, at 6. The ALJ reasonably concluded from these undisputed facts that "[i]t [was]

likely that [R. 5's] anemia was caused by Coumadin toxicity." ALJ Decision at 9, citing EMS Ex. 12 at 6; CMS Ex. 7 at 160-61.

Greenbrier does not dispute these facts but argues that to support its immediate jeopardy determination, CMS was required to prove that the anemia and Coumadin toxicity were caused by its staff having mishandled R. 5's Coumadin therapy. RR at 10. The ALJ properly rejected the argument that he needed to definitively determine that R. 5's condition was caused by the staff's multiple failures in connection with R. 5's Coumadin therapy. Under the definition of immediate jeopardy, it was enough to conclude, as the ALJ did, that Greenbrier failed to have adequate systems in place to monitor and protect R. 5 from experiencing Coumadin toxicity, because the absence of such systems exposed R. 5 (and other residents receiving Coumadin) to likely serious injury or harm such as the bleeding and anemia R. 5 actually suffered. ALJ Decision at 9-10.

Greenbrier asserts that its systems were adequate and that it was attentive to R. 5's changes in condition. However, we have already concluded that substantial evidence supports the ALJ's determination that Greenbrier's systems were not adequate. The facility's system of faxing PT/INR test results to the physician and awaiting instructions for future testing was not adequate since staff had no system for following up if the physician, as happened here, did not return the fax with instructions. Furthermore, Greenbrier had no system for assuring that staff caring for a resident on Coumadin therapy would recognize and consult with the resident's physician upon observing signs of possible Coumadin toxicity or the potential for adverse interactions between antibiotics and the Coumadin. An overarching problem with Greenbrier's system was that it did not reflect an adequate understanding of the professionally accepted role of nursing staff in monitoring a resident's drug regimen. These findings amply support the ALJ's conclusion that CMS's determination of immediate jeopardy was not clearly erroneous.

C. *The ALJ did not err in concluding that CMP amounts of $5,500 per day for the period January 11 through February 2, 2009 and $600 per day for the period February 3 through March 1, 2009 were reasonable.*

CMS imposed a CMP of $5,500 per day for each day of the period of immediate jeopardy level noncompliance, which CMS found was January 11 through February 3, 2009. CMS also imposed a CMP of $600 per day for each day of continuing noncompliance at less than the immediate jeopardy level, which it found was February 4 through March 1, 2009. The ALJ assessed whether these amounts were reasonable, applying, as required, the factors at 42 C.F.R. § 488.438(f)(1)-(4). The ALJ concluded that Greenbrier's noncompliance endured for the entire January 11 through March 1, 2009 period and that both per-day CMP amounts were reasonable. ALJ Decision at 10-13. However, the ALJ found that since CMS had found the immediate jeopardy to have been abated on February 2, 2009, there was no basis for continuing the CMP at the immediate jeopardy level

amount on February 3, 2009. Accordingly, the ALJ adjusted the CMP so that the $5,550 per day CMP was in effect from January 11 through February 2, 2009 and the $600 per day CMP was in effect for the period February 3 through March 1, 2009. ALJ Decision at 10-11. CMS does not dispute this adjustment. The ALJ based his finding that the noncompliance continued after February 2 on continued noncompliance with section 483.25 and noncompliance with sections 483.25(j) and 483.60(c), all at less than the immediate jeopardy level. *Id.* at 12.

On appeal, Greenbrier does not argue that the ALJ did not properly apply the factors in section 488.438(f)(1)-(4) or otherwise dispute the ALJ's findings that the $5,500 and $600 per-day CMP amounts were reasonable amounts. Greenbrier also does not dispute the ALJ's finding that the immediate jeopardy began on January 11, 2009 and continued through February 2, 2009. Accordingly, we affirm without further discussion the ALJ's findings regarding the CMP amounts and the duration of the immediate jeopardy level noncompliance.

Greenbrier's appeal of the remedies imposed is limited to the duration of the non-immediate jeopardy noncompliance period and, consequently, to the number of days it was subject to the $600 per-day CMP. Greenbrier argues that the ALJ erred in concluding that noncompliance continued on and after February 3, 2009. RR at 5. Greenbrier cites the ALJ's finding, which is undisputed, that it abated the immediate jeopardy on February 2, 2009. Greenbrier also asserts, as it did below, that it had implemented all of the measures on its plan of correction for the section 483.25 noncompliance by February 3, 2009. *Id.* In particular, Greenbrier disputes the ALJ's finding that it had not completed its in-service training by February 3, 2009. *Id.* at 5-6.

We uphold the ALJ's conclusion that although Greenbrier abated the immediate jeopardy by February 3, 2009, its noncompliance with section 483.25 continued on and after that date because Greenbrier had not completed all of the measures in its corrective action plan. Greenbrier's plan of correction identified the following as a measure necessary to correct its noncompliance with section 483.25: "in-servicing all licensed nursing staff on Signs & Symptoms of Coumadin toxicity, monitoring & ensuring R receiving Coumadin are on correct dose, & have current PT/INR lab draw orders." CMS Ex. 2, at 3. The ALJ noted Greenbrier's admission that it "had not completed in-service training of its entire professional staff by February 3, 2009." ALJ Decision at 12, citing Petitioner's Final Br. at 9. In its request for Board review, Greenbrier likewise concedes that as of February 3, 2009, "the facility had not yet in-serviced all non-routine, temporary, or PRN [as needed] staff . . ." RR at 6. Moreover, although the narrative in the plan of correction states that the in-service training "will be completed by 2/18/09" (which is later than the date Greenbrier asserts here), the "completion date" listed for all section 483.25 corrections on the plan is "3/2/09." CMS Ex. 2, at 3, 5, 12.

Greenbrier contends that the fact that some staff had not been trained by February 3, 2009 should not preclude its being found in substantial compliance on that date, since it

completed training these staff members before they began their shifts so they would not pose a risk to residents. RR at 6. This argument misses the point. The issue of whether Greenbrier can establish a compliance date earlier than March 1, 2009 does not hinge on whether it trained staff before allowing them to care for residents but, rather, whether it completed the corrective measures listed in its plan of correction by the alleged earlier date. Greenbrier admits that it did not do so. Having identified the in-service training of "all licensed nursing staff" as a measure necessary to correct its noncompliance with section 483.25, Greenbrier cannot claim that steps short of that goal "should nevertheless be accepted as adequate to require lifting the remedies imposed." *Cal Turner Extended Care Pavilion*, DAB No. 2030, at 19 (2006); *accord Meridian Nursing Center*, DAB No. 2265, at 20-21 (2009); *Lake Mary Health Care*, DAB No 2081, at 29 (2007).

Greenbrier also asserts as evidence that it achieved substantial compliance by February 3, 2009 the fact that its revised system for monitoring laboratory results was in place by that date. RR at 5. The ALJ found that implementation of the new system did not address all of Greenbrier's noncompliance. ALJ Decision at 12. As evidence, the ALJ cited Greenbrier's failure to complete in-service training by February 3, 2009 and Greenbrier's failure to "provide assurances that it had addressed with its pharmacy consultant the consultant's failure to evaluate the possible effects of Coumadin administered in combination with other medications." *Id.* In its reply brief, Greenbrier argues that the latter failure is irrelevant to whether it achieved substantial compliance with section 483.25 by February 3, 2009. Reply Br. at 3. We assume Greenbrier is referring to its earlier argument that the ALJ could not lawfully rely on the pharmacy consultant deficiency for his finding of noncompliance with section 483.25 because the surveyors did not cite the deficiency under that section but, rather, under section 483.60(c). We rejected that argument in upholding the ALJ's finding of noncompliance with section 483.25, and we reject it for the same reasons in connection with Greenbrier's argument about its continuing noncompliance.

We also note that in its plan of correction, Greenbrier itself suggested that the measures for correcting the section 483.60(c) deficiency were also relevant to correcting the section 483.25 deficiency by discussing the pharmacy consultant corrective measures in both contexts, notwithstanding the different tag numbers assigned to the respective deficiencies. *See* CMS Ex. 2, at 8, 11. In any event, the ALJ's finding with regard to the corrective measures involving the pharmacy consultant is not necessary to our decision in light of our conclusion that Greenbrier's failure to show an earlier completion date for the in-service training supports the ALJ's determination that Greenbrier's noncompliance continued through March 1, 2009.

Finally, we find no merit in Greenbrier's argument that it was unfair for the ALJ to consider its unappealed noncompliance with sections 483.25(j) and 483.60(c) when determining the duration and amount of the CMPs, because, Greenbrier alleges, CMS did not give notice that its imposition of remedies relied, in part, on that noncompliance. Petitioner relies here, as it did before the ALJ, on the fact that CMS's initial notice letter,

dated February 23, 2009, imposed a per-instance CMP for the noncompliance with section 483.25 and imposed no other CMP. RR at 13, citing CMS Ex. 1, at 2. The ALJ rejected this argument, finding that CMS's letter "explicitly refers to all of the deficiencies that were found at the February survey – and not just Petitioner's noncompliance with 42 C.F.R. § 483.25 – as a basis for imposing remedies." ALJ Decision at 13, citing CMS Ex. 1, at 1.

The ALJ's finding is supported by the record. The first paragraph of CMS's February 23, 2009 letter specifically identifies the findings of noncompliance with all three regulatory requirements and then states, "Because of your failure to substantially comply with Medicare/Medicaid participation *requirements*[,] the following remedies are imposed . . . ." CMS Ex. 1, at 1. The notice then names the remedies imposed, and these remedies include termination of Greenbrier's provider agreement and a denial of payment for new admissions (both ultimately rescinded), as well as the per-instance CMP that was subsequently changed to a per-day CMP. The fact that one of the remedies imposed in that original notice, the per-instance CMP, was specific to the section 483.25 noncompliance does not obviate the fact that CMS gave notice that it was imposing remedies based on Greenbrier's noncompliance with all three requirements. Greenbrier points to the fact that CMS's subsequent notice, on March 12, 2009, revised the per-instance CMP to a per-day CMP without stating the specific findings of noncompliance on which it based the revised remedy. However, CMS's March 12 letter revised only the CMP imposed based on the findings of noncompliance identified as the basis for imposing remedies in its original notice letter; it did not revise the findings of noncompliance. CMS was not required to restate the findings of noncompliance since it had already notified Greenbrier of those findings. Furthermore, the March 12 notice letter referred to the State agency's February 4, 2009 survey, the survey that identified and reported (on the statement of deficiencies) the findings of noncompliance on which both the original and revised CMP (and other remedies) were based. CMS Ex. 1 at 4.

In addition, as the ALJ noted, in its opening brief CMS cited all three deficiencies as a basis for the remedies, thus giving Greenbrier "a full month's notice of CMS's arguments, even assuming it had not understood the implications of the February 23, 2009 notice letter, and could have prepared a defense to them based on what CMS had contended." ALJ Decision at 13, citing CMS Prehearing Br. at 11. Greenbrier argues that it "would be patently unfair to allow CMS' Pre-hearing Brief to provide notice that CMPs were imposed for non-compliance with 42 C.F.R. §§ 483.25(j) and 483.60(c)." RR at 13. Since we have rejected the argument that CMS's notice letter did not provide adequate notice of its reliance on all of the noncompliance, we, of course, reject the premise of this final argument. Moreover, the Board has long held that CMS can amend its bases for imposing remedies during ALJ proceedings provided that the facility has adequate notice and an opportunity to present a case addressing any such amendments. *Kingsville Nursing and Rehabilitation*, DAB No. 2234, at 12 (2009). Greenbrier's prehearing brief indicates that it was well aware by the time it filed its pre-hearing brief, if not sooner, that CMS was relying on the alleged additional noncompliance. In that

brief, Greenbrier presented the same legal argument it makes here rather than mounting, at least in the alternative, a defense to those allegations. *See* Greenbrier Pre-hearing Br. at 19-20. For all of these reasons, we conclude that it was fair for the ALJ to base his decision, in part, on the additional, administratively final findings of noncompliance. In any event, since we have upheld the ALJ's conclusion that noncompliance continued under section 483.25 through March 1, 2009, the ALJ's conclusion that Greenbrier was also out of compliance with sections 483.25(j) and 483.60(c) until that date is not necessary to our decision.

D. *We find no merit in Greenbrier's argument that the Board should revisit its decisions on the burden of proof.*

In his decision, the ALJ declined to address Greenbrier's argument that the Board decisions assigning to long-term care facilities the ultimate burden of persuasion on the issue of substantial compliance are unlawful. ALJ Decision at 3, n.2, citing *Hillman Rehabilitation Center*, DAB No. 1611 (1997), *aff'd, Hillman Rehabilitation Ctr. v. U.S. Dep't of Health & Human Servs*., No. 98-3789 (GEB)(D. N.J. May 13, 1999); s*ee also Batavia Nursing and Convalescent Center*, DAB No. 1904, at 15 (2004)(applying this burden in a SNF appeal and setting out the Board's analysis), *aff'd, Batavia Nursing & Convalescent Ctr. v. Thompson*, 129 Fed. App'x 181 (6th Cir. 2005); RR at 14. The ALJ stated that he had no authority to address the issue and that it was moot "because I find to be overwhelming the evidence supporting CMS's noncompliance finding and remedy determinations." *Id.* Greenbrier asks the Board to revisit its prior decisions on this issue, citing language from a footnote in *Grace Healthcare of Benton v. U.S. Dept. of Health & Human Servs.*, 589 F.3d 926, *amended by* 603 F.3d 412 (8th Cir. 2009), which Greenbrier alleges supports its position that those decisions are inconsistent with section 556(d) of the Administrative Procedure Act (APA). RR at 14.

We reject Greenbrier's request, which cites no authority that would require us to reconsider the Board's prior decisions. In *Batavia*, the Board rejected the same APA argument made by Greenbrier, and nothing in the Eighth Circuit decision in *Grace Healthcare*, including the footnote Greenbrier cites, requires us to revisit that issue. Indeed, as Greenbrier concedes (RR at 14), the issue of whether putting the burden of ultimate persuasion on the facility is consistent with the APA was not raised or decided by the court in *Grace Healthcare*. We also agree with the ALJ that it is unnecessary to reach the issue since the evidence in this case (viewed under any evidentiary standard) overwhelmingly supports his conclusion that Greenbrier was not in substantial compliance. We find baseless Greenbrier's contention that "if the proper burden of proof were applied to the underlying facts, CMS's evidence would not be considered overwhelming." RR at 14. The material facts in this case are undisputed and, in addition to overwhelmingly supporting the ALJ's noncompliance determination, remain constant, regardless of which party is assigned the burden of going forward or the ultimate burden of persuasion.

Conclusion

For the reasons stated above, we affirm the entire ALJ Decision.

_____/s/_____
Constance B. Tobias

_____/s/_____
Leslie A. Sussan

_____/s/_____
Sheila Ann Hegy
Presiding Board Member