Department of Health and Human Services

DEPARTMENTAL APPEALS BOARD

Appellate Division

In the Case of: Laurelwood Care Center, Petitioner, - v. - Centers for Medicare & Medicaid Services.	DATE: February 17, 2009 Civil Remedies CR1796 App. Div. Docket No. A-08-123 Decision No. 2229

FINAL DECISION ON REVIEW OF
ADMINISTRATIVE LAW JUDGE DECISION

Laurelwood Care Center (Laurelwood) appealed the May 30, 2008 decision of Administrative Law Judge (ALJ) Carolyn Cozad Hughes, DAB CR1796 (2008) (ALJ Decision). The ALJ concluded Laurelwood was not in substantial compliance with Medicare participation requirements and upheld the imposition by the Centers for Medicare & Medicaid Services (CMS) of a civil money penalty (CMP) of $5,000 per day for four days of immediate jeopardy, and $100 per day for 94 days of noncompliance that was not immediate jeopardy ($29,400 total). For the reasons discussed below, we conclude that the ALJ Decision is based on substantial evidence in the record as a whole and is free of legal and procedural error.

Applicable Law

The Social Security Act (Act) establishes the requirements for nursing facilities to participate in the Medicare program and authorizes the Secretary of Health and Human Services to promulgate regulations implementing those statutory provisions.

See section 1819 of the Act.[1] The applicable regulations are found at 42 C.F.R. Parts 483, 488, and 498. In order to participate in the Medicare program, a nursing facility must maintain substantial compliance with program requirements. The Act and regulations provide for state survey agencies to evaluate the compliance of skilled nursing facilities with participation requirements and to impose remedies when a facility is found not to comply substantially. Section 1864(a) of the Act; 42 C.F.R. § 488.20. The regulations require that each facility be surveyed once every twelve months, and more often, if necessary, to ensure that identified deficiencies are corrected. Section 1819(g)(2)(A) of the Act; 42 C.F.R. §§ 488.20(a), 488.308.

A "deficiency" is defined as a nursing facility's "failure to meet a participation requirement specified in the Act or [42 C.F.R. Part 483]." "Substantial compliance" is defined as "a level of compliance with the requirements of participation such that any identified deficiencies pose no greater risk to resident health and safety than the potential for causing minimal harm." 42 C.F.R. § 488.301. "Noncompliance" means "any deficiency that causes a facility to not be in substantial compliance." Id. "Immediate jeopardy" is defined as a situation in which a provider's noncompliance "has caused, or is likely to cause, serious injury, harm, impairment, or death to a resident." 42 C.F.R. § 488.301. CMS may impose a CMP for the days on which the facility is not in substantial compliance. 42 C.F.R. §§ 488.404, 488.406 and 488.408. Where the noncompliance poses immediate jeopardy, CMS may impose a penalty in the range of $3,050 to $10,000 per day. 42 C.F.R. § 488.438(a)(1)(i).

Under the Act and regulations, CMS has the initial burden of going forward, but the facility has the ultimate burden to prove by the preponderance of the evidence that it is in substantial compliance with participation requirements. Batavia Nursing and Convalescent Center, DAB No. 1904 (2004), aff'd, Batavia Nursing & Convalescent Ctr. v. Thompson, 129 Fed.Appx. 181 (6th Cir. 2005).

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[1] The current version of the Social Security Act can be found at www.ssa.gov/OP_Home/ssact/comp-ssa.htm. Each section of the Act on that website contains a reference to the corresponding United States Code chapter and section. Also, a cross reference table for the Act and the United States Code can be found at 42 U.S.C.A. Ch. 7, Disp Table.

Factual Background[2]

Opened in 1989, Laurelwood is a 120-bed long-term care facility located in Johnstown, Pennsylvania, that is certified to participate in the Medicare program as a provider of services. P. Ex. 10, at 1-2. Laurelwood initially was equipped with "old-style beds" that had side rails with vertical rods that were approximately eight inches apart. P. Br. at 4. On August 30, 2004, the U.S. Food and Drug Administration (FDA) issued draft side rail guidelines indicating that gaps larger than 4¾ inches may pose a risk of entrapment. CMS Ex. 58. Later that year, Laurelwood began replacing the old-style beds with new ones that had narrower spaces between bars. P. Ex. 10, at 1-2; P. Br. at 4. On March 10, 2006, the FDA issued its final Guidance for Industry and FDA Staff: Hospital Bed System Dimensional and Assessment Guidance to Reduce Entrapment, which included the 4¾-inch gap guideline for side rails. CMS Ex. 58, at 13. By August 20, 2006, Laurelwood had replaced 66 of its old-style beds with newer beds that complied with the FDA's recommendation regarding the width of gaps between the side rails. P. Ex. 10, at 1-2; P. Br. at 4. Thus, on August 20, 2006, Laurelwood still had 54 old-style beds remaining. Id.

On the evening of August 20, 2006, a 64-year-old resident (R1) with a history of seizures died in his bed. CMS Ex. 10. The next day Laurelwood reported that R1 had been found dead with his left arm and head facing down caught in the right side rail. CMS Exs. 2, at 3; 10, at 2; Tr. 121. After receiving this report, surveyors from the Pennsylvania Department of Health, Division of Nursing Care Facilities surveyed the Laurelwood facility. They determined that Laurelwood had not ensured that R1's environment was as free of accident hazards as possible. CMS Ex. 2, at 3-7. Although the facility placed R1 in an old-style bed, the surveyors found that Laurelwood had not provided any documentation showing that staff had adequately assessed the potential safety hazards posed by putting him in a bed with such side rails. Id.; CMS Ex. 58, at 15, 18. The surveyors also reviewed 53 other Laurelwood residents (R2-11, R13-15, R17, R25, R27-32, R35-66) that had the old-style beds. CMS Ex. 2, at 3. Only one of these other 53 residents (i.e., resident R2) had the gaps between the side rail vertical bars covered by mattress

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[2] The information in this section is drawn from the ALJ Decision and 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.

pads. Tr. 142-144, 150. The surveyors determined that the facility had not adequately assessed for safety the use of similar side rails on the beds of these 53 other residents reviewed, and that this failure posed immediate jeopardy to resident health and safety. CMS Ex. 2, at 3-7.

Based on the survey findings contained in the Statement of Deficiencies (SOD), CMS determined that: 1) from August 22 through November 27, 2006, the facility was not in compliance with the program requirement that the resident environment remain as free of accident hazards as possible (42 C.F.R. § 483.25(h)(1)); and 2) from August 22 through 25, 2006, its noncompliance posed immediate jeopardy to resident health and safety. CMS Exs. 8 and 9. CMS imposed CMPs of $5,000 per day for four days of immediate jeopardy, and $100 per day for 94 days of substantial noncompliance that was not immediate jeopardy. Id.

The ALJ Decision

Laurelwood timely requested a hearing before an ALJ, which was conducted in Pittsburgh, Pennsylvania on November 6 and 7, 2007. The ALJ admitted CMS Exhibits 1-71 and Petitioner Exhibits 1-8 and 10-31. See Tr. at 2-3; Ruling on Petitioner's Motion to Exclude CMS's Proposed Exhibits, and Petitioner's Request for Issuance of Subpoenas (October 19, 2007).[3] In a written decision dated May 30, 2008, the ALJ ruled in favor of CMS on each of the issues before her. See ALJ Decision at 3.

Specifically, the ALJ found that Laurelwood was not in substantial compliance with 42 C.F.R. § 483.25(h)(1) (quality of care) because it routinely used side rails without adequately assessing the potential safety hazards they posed to the individual residents. Id. at 8-11. The ALJ also made findings, which were not directly challenged on appeal, that Laurelwood did not ensure that its bed systems were as safe as possible, failed to take steps to minimize the risk of entrapment whenever side rails were used, and inadequately responded to evidence of problems with the side rails. Id. at 4-8, 11-16.

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[3] The ALJ did not admit Petitioner's Exhibit 9, which consists of autopsy photographs of the deceased resident R1. ALJ Decision at 3. Even though Laurelwood does not contend that the ALJ improperly excluded this exhibit, Laurelwood relies upon this unadmitted exhibit in its brief on appeal. See P. Br. at 14, 23. In considering Laurelwood's appeal, we do not rely upon any evidence that was not admitted during the hearing.

The ALJ then concluded that CMS's determination that the facility's noncompliance posed immediate jeopardy to the residents' health and safety was not clearly erroneous. Id. at 16-17. The ALJ found that Laurelwood's routine use of bed rails without assessing their risks for each resident created the likelihood of serious injury or harm to the residents.[4] Id. at 17. More specifically, the ALJ found that Laurelwood "routinely left its vulnerable individuals in beds with widely spaced rails, without filling in any of the gaps . . . [and that] CMS's determination that such practices pose immediate jeopardy to resident safety was not clearly erroneous." Id. Finally, the ALJ concluded that the amounts of the CMPs were reasonable. Id. at 17-18.

Standard of Review

Our 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. Our standard of review on a disputed conclusion of law is whether the ALJ decision is erroneous. Guidelines for Appellate Review of Decisions of Administrative Law Judges Affecting a Provider's Participation in the Medicare and Medicaid Programs, www.hhs.gov/dab/guidelines/prov.html.

Substantial evidence is "more than a mere scintilla. It 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), quoting Consolidated Edison Co. v. NLRB, 305 U.S. 197, 229 (1938). In applying the substantial evidence standard, the Board has previously stated that:

> [T]he reviewer must examine the record as a whole and take into account whatever in the record fairly detracts from the weight of the decision below. The reviewer does not, however, reweigh the evidence or substitute his or her judgment for that of the initial decision-maker. Thus, the reviewer must not displace a "choice between two fairly conflicting views," even though a different

[4] The ALJ also stated that "compelling evidence establishes that R1 died trapped between side rails, and I find it more likely than not that Petitioner's deficiencies contributed to his death." ALJ Decision at 17. However, it appears that the ALJ did not base her finding that the deficiencies posed immediate jeopardy because of R1's death.

> choice could justifiably have been made if the matter had been before the reviewer de novo. The reviewer must, however, set aside the initial conclusions when he or she cannot conscientiously find that the evidence supporting that decision is substantial, when viewed in the light that the record in its entirety furnishes, including the body of evidence opposed to the [initial decision-maker's] view.

Golden Age Nursing & Rehabilitation Center, DAB No. 2026, at 8 (2006) (citations and internal quotations omitted).

Analysis

We first address why Laurelwood's contention that the ALJ erred in finding that it was not in substantial compliance with program requirements set forth at 42 C.F.R. § 483.25(h)(1) is without merit. We note that Laurelwood's brief conflates the issues about the factual and legal basis supporting a finding of noncompliance with the basis for finding that such noncompliance constitutes immediate jeopardy to the residents' health and safety. Laurelwood essentially repeats the same argument regarding both issues. Accordingly, we will initially address Laurelwood's argument in the context of addressing the ALJ's findings about noncompliance but refer to that discussion where appropriate in later addressing the ALJ's findings about immediate jeopardy. We address there why we find no error in the ALJ's conclusion that CMS's determination that Laurelwood's conduct created the likelihood of serious injury or harm to its residents was not clearly erroneous. Finally, we address why Laurelwood's assertions that CMS failed to provide adequate notice and an opportunity to be heard, as well as its allegation that the ALJ was biased, are without merit.[5]

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[5] We have fully considered all arguments raised on appeal and reviewed the full record, regardless of whether we have specifically addressed particular assertions or documents in this decision.

1. We sustain the ALJ's conclusion that Laurelwood failed to substantially comply with 42 C.F.R. § 483.25(h)(1), which requires that facilities ensure the resident environment remains as free of accident hazards as is possible (Tag F323).

The ALJ found that Laurelwood failed to substantially comply with program requirements set forth at 42 C.F.R. § 483.25(h)(1) because: 1) it routinely used side rails without adequately assessing the potential safety hazards they posed to the individual residents; and 2) it failed to make sure that the side rails in use were as safe as possible.[6] ALJ Decision at 4. Laurelwood argues that the ALJ is precluded from making this finding on the grounds that the ALJ had also found that the use of side rails with wide gaps did not constitute a per se violation of the standard of care. For the reasons discussed below, we find that Laurelwood's contention is without merit and that the ALJ Decision is supported by substantial evidence in the record.

A. The ALJ's finding that the wide gaps in the side rails of the old-style beds are not a per se violation of the standard of care does not preclude a finding that Laurelwood was not in substantial compliance with 42 C.F.R. § 483.25(h)(1) for not conducting adequate assessments of the safety risks and benefits for each resident.

Laurelwood argues that its alleged failure to perform side rail assessments could not form the basis of a deficiency finding given the ALJ's conclusion that "widely-spaced bed rails do not per se violate any standard of care." P. Br. at 6, 11; ALJ Decision at 12. Laurelwood further contends that the fact the survey team did not cite any of the 66 residents using "new-style beds" (i.e., with narrower gaps in the vertical bars in the side rails), conclusively shows that the noncompliance findings were limited to the spacing issue, upon which the ALJ ruled in its favor. P. Br. at 5. Thus, Laurelwood argues that the ALJ's conclusion that the side rail assessments were inadequate could not form the basis for finding that Laurelwood was not in substantial compliance with participation requirements.

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[6] Laurelwood does not challenge the second finding by the ALJ on this issue.

Facilities participating in the Medicare program must meet standards for quality of care. The applicable regulation states as an overarching requirement that:

> 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.

Specifically, in regard to preventing accidents, the regulation provides as follows:

> *Accidents.* The facility must ensure that -
>
> (1) The resident environment remains as free of accident hazards as is possible . . .

42 C.F.R. § 483.25(h)(1). The Board has previously stated that:

> The standard in section 483.25(h)(1) itself - that a facility "ensure that the environment is as free of accident hazards as possible" in order to meet the quality of care goal in section 483.25 - places a continuum of affirmative duties on a facility. A facility must determine whether any condition exists in the environment that could endanger a resident's safety. If so, the facility must remove that condition if possible, and, when not possible, it must take action to protect residents from the danger posed by that condition.

Maine Veterans' Home Scarborough, DAB No. 1975, at 5 (2005). Section 483.25(h)(1) clearly informs facilities that they must ensure that the resident environment remains as free of accident hazards as possible. Other program requirements in the regulations require nursing home facilities to engage in a comprehensive assessment of a resident's needs. See 42 C.F.R. § 483.20(b). Such an assessment necessarily includes evaluating the benefits and risks of a particular service initiated by a facility. Maine Veterans' Home Scarborough at 5. Resident safety is a basic facility responsibility. 42 C.F.R. § 483.25(h).

In Wellington Specialty Care & Rehabilitation Center, DAB CR548 (1998), an ALJ summarized the potential dangers of using side rails as follows:

> [S]ide rails can be dangerous to residents of long term care facilities. There exists a risk that some residents under certain circumstances may suffer injuries from side rails . . . on occasion, individuals have become wedged in the gaps between side rails, resulting in injuries or death to those individuals . . . The dangers posed by side rails impose on long-term care facilities a duty to assess and address the risk of using side rails.

Id. at 9. We agree with this general summary.

Beginning in 1995, the FDA issued several advisory bulletins and other alerts describing the potential dangers presented by the use of side rails. See CMS Exs. 53-62. The FDA has long recognized that gaps that exist or could be created in or between bed side rails and mattresses are potential sources of entrapment, which could be lethal. Id. For example, the FDA has stated that "side rails present an inherent safety risk, particularly when the patient is elderly or disoriented." CMS Ex. 60, at 5-6. As a result of the potential safety risks presented by side rails, the FDA has said that: "We suggest that facilities and manufacturers determine the level of risk for entrapment and take steps to mitigate the risk. Evaluating the dimensional limits of the gaps in hospital beds is one component of an overall assessment and mitigation strategy to reduce entrapment." Id. at 5.

The ALJ found that it was not disputed that "side rails can represent an accident hazard." ALJ Decision at 4; see also id. at 14; Tr. at 218, 279-80. Against this backdrop, the ALJ found that widely-spaced vertical bars in the 54 old-style beds at issue in this case "do not per se violate any standard of care." ALJ Decision at 12. Consistent with the Board's statements in Maine Veterans, regulatory requirements, and the FDA's recognition of the potential safety risk presented by side rails, the ALJ also found that "[t]he standard of care mandates that side rails be used only where an individualized resident assessment establishes that their potential benefit outweighs the risks." ALJ Decision at 5; see also CMS Exs. 53, at 6; 60, at 6-14; 65, at 6 (¶¶ 10-12); 66, at 5-6 (¶ 13); P. Ex. 5, at 1 (¶ 5). Neither party challenges these findings by the ALJ.

As noted above, however, Laurelwood contends that because the ALJ ruled that the wide side rail gaps do not in themselves violate the standard of care, the ALJ is precluded from finding that Laurelwood was not in substantial compliance with program requirements. P. Br. at 2, 6, 9, 11. According to Laurelwood, the "only issues fairly raised by the [SOD] are the 7.5 to 8 inch gaps between the vertical side rails and the failure to perform a side rail assessment before using those rails." Id. at 11. We disagree.

The surveyors found that Laurelwood failed to ensure that the residents' environment remained free of accident hazards with respect to 54 residents who were in the old-style beds with wide gaps because Laurelwood had not assessed for safety hazards. CMS Ex. 2, at 3-7. Contrary to Laurelwood's contention, moreover, the basis for the ALJ's finding of noncompliance was not the size of the gaps in the side rails per se but the continued use of the old-style beds absent adequate side rail risk-safety assessments for the 54 residents. Id. Because the main issue underpinning the finding of noncompliance in this case is not the width of the gaps in the old-stye beds in itself but the adequacy of Laurelwood's assessments, the ALJ's finding that wide rails do not automatically violate the standard of care cannot reasonably be read to preclude her from further finding that Laurelwood was not in substantial compliance with program requirements.

Moreover, the ALJ's findings are consistent with the applicable standard of care that mandates such individualized risk-safety assessments for each resident before using side rails. The ALJ's finding recognized that, while the use of side rails may present an accident hazard, their use may nevertheless be appropriate in some circumstances. For example, it may be appropriate for a facility to use side rails in order to provide mobility or support for a resident or to prevent dangerous falls. The FDA guidance also recognizes that "[n]ot all patients are at risk for an entrapment [in side rails], and not all hospital beds pose a risk of entrapment." CMS Ex. 58, at 5. According to Laurelwood's expert witness, Engineer Mark E. Bruley, C.C.E., a bed system containing side rails with wide gaps may also be made safe by eliminating the excessive gaps through the use of high density foam and foam-filled pads to mitigate entrapment hazards posed by the wide gaps between the vertical bars of side rails,

as well as any other gaps in a bed system.[7] See P. Ex. 5, at 1 (¶ 6), 2 (¶ 12). We find it was reasonable for the ALJ to conclude that determining when and how to use side rails with a particular resident requires an adequate individualized safety-risk assessment to determine if the benefits of using side rails outweigh the potential risks.

Furthermore, Laurelwood does not cite any legal authority to support its argument that an ALJ must first determine that the wide gaps in the side rails constitute an accident hazard in every circumstance before a finding of noncompliance can be made. Laurelwood has essentially raised a "straw-man" argument by attempting to take the ALJ's finding out of context to support a rationale that is not consistent with either the ALJ's ultimate finding of noncompliance or prior Board case law. Thus, we reject the contention that, before the ALJ may find noncompliance here, it is a necessary predicate for her to find that the wide gaps themselves constitute a violation of the standard of care.

Laurelwood also points out that the surveyors did not find noncompliance with regard to any of the 66 residents using new beds with smaller gaps. Laurelwood argues that the absence of negative findings as to those residents demonstrates that CMS focused solely on the width of the side rails in the old-style beds as deficient, rather than reviewing the adequacy of the assessments of all residents using side rails. P. Br. at 9. This is not persuasive. The fact that the surveyors did not cite the facility for the remaining beds does not mean that the surveyors found that those beds were within the standard of care. It only means that the deficiencies at issue were based upon the surveyors' review of 54 residents at the facility.

Even if the facility had been found in substantial compliance for care of the remaining residents using the new beds with smaller gaps, it does not change or otherwise limit the scope of the

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[7] Of the 54 residents reviewed by the survey team, only residents R1 and R2 had any pads covering the wide gaps in the vertical bars of the side rails in the old-style beds used by these residents. ALJ Decision at 14; CMS Exs. 2, at 5; 68, at 16 (¶ 48); Tr. 142-144, 150. The ALJ found, and it was not contested on appeal, that "without the padding, the side rails are simply unsafe [,] . . . pose an accident hazard and are not within the standard of care." ALJ Decision at 14. Thus, the conclusion that the wide gaps were not a per se hazard did not mean that the facility could use the old-style beds without taking steps to reduce their risks.

underlying basis of the deficiencies relating to the 54 residents who used the old-style beds with the wide gaps in the side rails without having an adequate assessment performed. It is not reasonable for us to draw any inference from the lack of a deficiency finding by surveyors regarding the remaining 66 new-style beds.

B. The ALJ's finding that Laurelwood used side rails without adequate safety-risk assessments is supported by substantial evidence in the record.

Laurelwood argues that the ALJ erred in determining that it failed to perform any side rail risk-safety assessments. Id. at 6-11. Laurelwood contends that, contrary to the ALJ's findings, "side rail screens . . . were completed for every resident cited in the survey." Id. at 7. However, Laurelwood misconstrues the actual finding made by the ALJ. The ALJ did not find that Laurelwood failed to conduct any safety assessments of the residents before using side rails. Instead, the ALJ found that Laurelwood's "use of side rails without adequate assessments jeopardized resident health and safety." ALJ Decision at 8 (emphasis added). Thus, this argument is without merit.

Regarding the assessments that had in fact been conducted by Laurelwood, the ALJ found that Laurelwood failed to assess whether the benefits of using side rails in the old-style beds outweighed any risk of using the side rails. Id. at 8-11. In response to this finding, Laurelwood contends that 42 C.F.R. § 483.20(b)(1) provides a definition of "assessment" that does not require an assessment to include evaluating the safety of the total bed system. P. Br. at 10. Laurelwood also argues that its "Initial Restraint Assessment" form sufficed as an adequate assessment for using side rails with the 54 residents.

This form is a two-page document containing, among other things, eight general "yes-no" questions regarding a resident's medical condition.[8] P. Ex. 20. However, the use of the word "restraint"

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[8] The eight questions on the restraint assessment form were:

1. Is the resident comatose, obtunded, or have fluctuations in level of consciousness?
2. Does the resident have a cognitive problem?
3. Does the resident have a history of falls?

(continued...)

in the title suggests that the actual purpose of these questions was limited to assessing whether some type of restraint should be used for a resident. None of the questions is addressed at assessing the level of risk of entrapment from use of side rails or other safety hazards. Nor does the form require assessment of the relative benefits for the resident in their use.

The evidence also indicates that Laurelwood never used its restraint assessment form to evaluate the risk of a resident becoming entrapped in the gaps between the vertical bars of the side rails. For example, the facility administrator, James Neely, told the surveyors and testified at the hearing that Laurelwood only considered whether the side rails were "enablers" or restraints and did not conduct an individualized assessment of the risks-benefits of using side rails. CMS Exs. 2, at 5-6; 68, at 23, 31; Tr. at 204. In addition, Laurelwood's Director of Nursing Terri Russo and the Corporate Quality Nurse Judy Polanz both told the surveyors that there were no assessments of side rail safety related risks conducted before using side rails for the residents, and neither individual denied making that statement. CMS Ex. 68, at 33; P. Exs. 20, at 10; 11, at 4.

The ALJ also found that the inadequacy of Laurelwood's assessment form is "well illustrated" by the circumstances involving R1. ALJ Decision at 10. It is uncontested that R1 was a 64-year-old mentally retarded man with a seizure disorder who required complete care. CMS Exs. 12, at 2; 15, at 11; P. Br. at 23. It is also uncontested that R1 was a very small man, just 4'10" and 120 pounds, and he was incapable of voluntary movement. Id. Laurelwood kept this resident in a bed with approximately eight inch gaps between the vertical rods of the side rails and with the side rails continuously in the "up" position. Tr. at 37-38,

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[8](...continued)

4. Has the resident demonstrated poor bed mobility or difficulty moving to a sitting position on the side of the bed?
5. Does the resident have difficulty with postural hypotension?
6. Is the resident on any medication, which would require increased safety precautions?
7. Is the resident currently using the side rail for positioning or support?
8. Has the resident expressed a desire to have the side rails up while in bed?

P. Ex. 20, at 12.

41. Laurelwood's Initial Restraint Assessment stated that R1 is "currently using the side rail for positioning and support."[9] P. Ex. 20, at 10. The ALJ found that this statement "is patently incorrect" because "R1 was not capable of any voluntary movement." ALJ Decision at 10. Even more illustrative of the inadequacy of the form is the fact that on the second page of that form for R1 is a space for indicating who comprised the assessment team and for writing in any notes, but it was blank. P. Ex. 20, at 11; Tr. at 255. Corporate Quality Nurse Judy Polantz testified that the blank page meant that the assessment team did not meet to assess R1. Tr. at 256; P. Ex. 20, at 11.

Laurelwood's reliance on 42 C.F.R. § 483.20(b)(1) as setting the scope of appropriate assessment for side rail safety hazards is also misplaced. That regulation addresses the comprehensive resident assessments which facilities must conduct using a state-provided instrument to document required data at specifically-defined intervals. The instrument is not intended to serve the function of evaluating the risks and benefits of any particular interventions, such as side rails.

The ALJ correctly determined that she needed to review the applicable standard of care to define what constitutes an adequate risk-safety assessment. In so doing, the ALJ relied upon the testimony of two experts from CMS - Beryl D. Goldman, Ph.D., R.N., N.H.A., and Dan Osterweil, M.D., C.M.D. Both of these experts opined, and the ALJ found, that the "Initial Restraint Assessment" form used by Laurelwood for each of the 54 residents is "insufficient as a tool for assessing the costs/benefits of side rail use." ALJ Decision at 9; CMS Exs. 65, at 2, 6-7; 66, at 3-5.

Dr. Osterweil testified during cross-examination that an individualized assessment must "take the individual as a whole

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[9] The ALJ also found that for the vast majority of the other 53 residents, Laurelwood's staff checked "yes" to question 7 on the Initial Restraint Assessment form, which asked "Is the resident currently using the side rail for positioning or support?" ALJ Decision at 7. Thus, the ALJ found that in virtually of these documents, the only justification for using the side rails was for "positioning," which clearly did not account for an individualized assessment of the resident's environment or total bed system. Id. at 7-8. The ALJ concluded that this evidence supported a conclusion that Laurelwood had a de facto policy of using bed rails. Id. at 8. Laurelwood does not challenge this finding by the ALJ on appeal.

and look for that particular individual what are the pros, what are the cons, what are the potential risks versus potential benefits of any intervention, including citing the risks even when you decided that the certain mode of action you're taken in your opinion is more beneficial." Tr. at 22-23. The assessment should also include consideration of the total bed system or sleeping environment and the resident's plan of care. See CMS Exs. 65, at 6 (¶ 10); 66, at 4-5 (¶¶ 13-16); P. Ex. 5, at 1 (¶ 5).

Both Dr. Goldman and Dr. Osterweil testified that Laurelwood failed to perform an adequate individualized risk assessment of the safety of the bed systems for the 54 residents at issue before deciding to use side rails. CMS Exs. 65, at 5-6 (¶¶ 10, 12; 66, at 5-6 (¶¶ 14-16). Dr. Goldman opined that Laurelwood's side rail assessment is not adequate because it is "just a collection of data" and does not provide "any rationale for why side rails are used or not used." Tr. at 119. In other words, Laurelwood's assessment failed "[t]o explain how this [data] impacts this particular resident and why a side rail is more of a benefit than a risk." Id. at 120. Dr. Goldman further testified without contradiction that an adequate assessment requires consideration of each resident's medical condition and the surrounding environment, including the bed system (i.e., the bed, mattress, bed rails, pads, etc.). CMS Ex. 10, at 6 (¶ 10); Tr. at 104. She also emphasized that Laurelwood's Initial Restraint Assessment form does not inquire about the resident's environment. Id.

Dr. Osterweil further explained that Laurelwood's assessment form is missing the "logic and disposition" to connect the resident's medical condition with the risks presented by a side rail restraint. Tr. at 56. In response to a question on cross-examination why he concluded that Laurelwood's assessment form was not adequate, Dr. Osterweil testified that: "There's really no rationale whether . . . [a resident] needs a rail or doesn't need a rail. It doesn't balance the other problems that [a resident] has . . . ." Tr. at 24. He further testified that the assessment form does not indicate whether a discussion by an interdisciplinary team ever took place and, if so, that a joint decision was made regarding balancing risks or benefits. He further explained that "the logic is not built in [the assessment form] and not indicated, and that leaves that assessment [form] incomplete." Tr. at 27. Dr. Osterweil concluded that Laurelwood was not "in compliance with assessing the individual and conducting the appropriate interventions." Tr. at 100.

Laurelwood contends that "Dr. Osterweil's opinion is wrong as a matter of law" because the regulations do not include any requirement for "logic." P. Br. at 10. We do not agree that an explicit requirement for "logic" must be in the regulation for an expert to testify that the applicable standard of care requires consideration of the rationale for use of side rails in order to effectively balance the anticipated benefits with the potential safety hazards. Moreover, even were we to disregard Dr. Osterweil's opinion, Laurelwood does not challenge the expert opinion of Dr. Goldman.

The ALJ also relied upon the testimony of Laurelwood's fact and expert witnesses. ALJ Decision at 9-10. Nurses Russo and Polanz testified that they agreed a facility must assess whether the benefits of using a side rail outweigh the risks to the resident safety. P. Exs. 11, at 3; 13, at 2; Tr. at 269. Laurelwood's own expert witness, Engineer Bruley, testified that "[t]here is a consensus among experts that patient safety must be determined with respect to the bed system, not merely with respect to each individual component of the bed system."[10] P. Ex. 5, at 1 (¶ 5). Engineer Bruley also testified on cross-examination that Laurelwood's form was not adequate for assessing the safety of the resident's bed system. Tr. at 272. Engineer Bruley further testified that he saw no evidence that Laurelwood's assessment form contained any articulation of the attendant risks regarding side rails for a resident with cognitive problems or any evidence of appropriate risk benefit analysis for R1 or any of the other 53 residents. Tr. at 273-74.

The ALJ reasonably concluded from this testimony, and other evidence discussed in the record, that Laurelwood failed to assess the risks related to the totality of the bed system for each resident to determine whether the benefits of using side rails outweigh the risks before using them. Therefore, we conclude that substantial evidence in the record demonstrates that Laurelwood failed to ensure the environment was as free from accident hazards as possible.

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[10] Engineer Bruley's testimony is also consistent with a statement he made in a published interview, where he emphasized that "users [of these products] should identify and address areas of potential entrapment for each resident through a comprehensive bed safety program." CMS Ex. 53, at 6.

2. The ALJ did not err in upholding CMS's determination that the deficiencies pose immediate jeopardy or in finding the amounts of the CMPs reasonable.

Laurelwood contends that the ALJ erred in finding that Laurelwood's "routine use of bed rails . . . creates the likelihood of serious injury or harm" and that "CMS's determination that such practices pose immediate jeopardy to resident safety was not clearly erroneous." P. Br. at 17 (quoting ALJ Decision at 17). This argument is premised upon Laurelwood's repeated contention that a finding of immediate jeopardy is precluded because the ALJ ruled in its favor that the wide gaps in the side rails do not per se violate the standard of care. P. Br. at 3. However, this argument, as well as its underlying premise, is without merit.

As an initial matter, Laurelwood does not accurately quote the ALJ's finding on immediate jeopardy. In the quote above, taken from its brief, Laurelwood omits the phrase "without assessing their risks."[11] This phrase is a material component of the ALJ's conclusions. For the reasons discussed in the prior section, the main issue in this case is not whether the wide gaps in side rails violated the standard of care. Nor is a finding that the width of the gaps in the rails violates the standard of care a necessary predicate to an immediate jeopardy finding here, as Laurelwood contends. Id. at 6. The issue before the ALJ was whether CMS's determination that the noncompliance (which we have upheld above) "has caused, or is likely to cause, serious injury, harm, impairment, or death to a resident" is clearly erroneous. 42 C.F.R. § 488.301. We review whether she erred in concluding that CMS's determination was not clearly erroneous.

Laurelwood simply fails to address this issue directly in its brief on appeal. We find no error in the ALJ's conclusion.

Moreover, Laurelwood does not challenge any of the factors relevant to the ALJ's evaluation of the reasonableness of the amounts of the CMPs on appeal. Instead, Laurelwood merely contends that the CMPs imposed were unwarranted because it was in substantial compliance with all participation requirements during the relevant periods. We have affirmed the ALJ's conclusion that Laurelwood was not in substantial compliance with program requirements during the relevant periods, as well as her

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[11] The full quote reads: "Petitioner's routine use of bed rails without assessing their risks creates the likelihood of serious injury or harm." ALJ Decision at 17.

conclusion that CMS's immediate jeopardy finding was not clearly erroneous.

Thus, the ALJ had an adequate legal basis to affirm the imposition of CMPs within the ranges specified in the regulations. Because Laurelwood does not otherwise challenge the reasonableness of the amount of the CMPs imposed in this case, there is no legal basis to reduce the amount of the CMPs. See e.g., The Windsor Place, DAB No. 2209 (2008).

3. Laurelwood received adequate notice of the allegations and had ample opportunity to respond.

Laurelwood contends that its due process rights have been violated because the ALJ went beyond the scope of the allegations raised in the SOD in finding that the assessments were inadequate, and it had no notice and opportunity to be heard on this issue. P. Br. at 2, 12, 16, 17. Laurelwood contends that the only issues raised in the SOD are: 1) the width of the gaps between the vertical side rails; and 2) the alleged failure to conduct an assessment before using those side rails to determine if the risks associated with the use of those side rails were outweighed by the benefits that the rails might offer to the individual resident. Id. at 5, 11, 16, 17. Based upon this characterization of the issues raised in the SOD, Laurelwood argues that it did not have notice that the adequacy of its bed rail assessments formed the basis for the finding of noncompliance in this case. We disagree.

The SOD contains language that put Laurelwood on notice that the adequacy of the bed rail assessments for each of the residents was an issue in this case. For example, the "Findings" section of the SOD contains the following entry:

> Review of "initial restraint assessment" records . . . for Residents R2-10, R13-15, R25, R27-32, R35-36 revealed that the safety hazards involved with the continued use of the side rails were not assessed for these residents.
>
> ***
>
> Review of 30 incident and accident reports . . . revealed that there were 11 incidents directly linked with the use of side rails with injuries and 19 of the incident reports that did not reflect that the use of side rails was

> reviewed as possible causes of the injuries. <u>There was no documented evidence that the side rails were reviewed as possible safety hazards for these residents.</u>

CMS Ex. 2, at 6 (emphasis added). In addition, the SOD states:

> Interview on 8/22/06 at 4:35 p.m. with the director of nursing and nurse consultant 12 revealed that <u>none of the side rails in use were assessed as potential safety hazards for these [54] residents.</u>

<u>Id.</u> (emphasis added).

The quoted language above can reasonably be read to indicate that the surveyors' concerns went beyond the mere width of the side rails. Furthermore, the SOD language points out that the surveyors' concern was with whether <u>safety hazards</u> associated with the use of these side rails for these residents were assessed. In this context, the term "safety hazard" reasonably encompasses an assessment of the entire bed system, including side rail gaps, gaps between mattress and the side rail, and gaps between the mattress and the headboard.

Our reading of the SOD as giving notice that the adequacy of risk-safety assessment was at issue is further supported by Laurelwood's response to the SOD in its plan of correction. There, Laurelwood stated that:

> A <u>side rail safety assessment</u> will be developed by 8/23/06 and completed on residents who continue to utilize side rails due to medical justification, resident request or as an aid to positioning. These assessments will be completed and indicated safety measures implemented by August 26, 2006.

<u>Id.</u> at 4 (emphasis added). Laurelwood's plan of correction demonstrates that Laurelwood understood that the adequacy of the assessments were at issue. The plan of correction indicated that it was developed and implemented by August 26, 2006, five days after the death of R1. We conclude, therefore, that Laurelwood was well aware of the nature of the concerns which it had to address long before it learned of the CMPs here. Thus, Laurelwood had adequate notice from the contents of the survey, as demonstrated by its response in the plan of correction, that

the safety assessments for each of the residents were not adequate and that this inadequacy formed the basis for the deficiencies at issue.

The record also demonstrates that Laurelwood had notice that the adequacy of its assessments was at issue from the pre-hearing pleadings, which included the testimony of one of the State surveyors and the two CMS expert witnesses. See CMS Exs. 65, 66, and 68. The written testimony of these witnesses had been provided to Laurelwood well before the hearing. Laurelwood did not object to the admission of this testimony at the hearing or in its post-hearing submission to the ALJ. The adequacy of the risk-safety assessments was also addressed by CMS in its pre-hearing brief. See Respondent's Pre-Hearing Br., at 18-19 (¶ 27). Laurelwood had an opportunity to respond to the issues and evidence raised by CMS relating to the adequacy of the assessments. We conclude that Laurelwood was not unfairly surprised that the adequacy of its assessments formed part of the basis for the findings contained in the SOD and constituted a material issue in this case.

Moreover, Laurelwood has not pointed to any legal authority for its view that CMS is strictly constrained by the allegations in the SODs. Prior Board decisions have held to the contrary. For example, in Pacific Regency Arvin, DAB No. 1823 (2002), the Board found prejudicial error when an ALJ appeared to treat the SOD as rigidly framing the scope of admissible evidence concerning any allegation relating to a cited deficiency and required formal amendment of the SOD as a prerequisite to allowing any additional supporting evidence stating:

> The [SOD] is a notice document, and is not designed to lay out every single detail in support of a finding that a violation has been committed. If the opposite were the case, there would not be much of a need for an exchange of documents or, for that matter, a hearing. This approach is consistent with the intention of the regulations governing surveys as embodied in this exchange from the preamble to the regulations:
>
>> Some commentators further suggested that the facility should be provided with full information that supports each citation and the survey agency's decisions including the underlying reason, basis or rationale for the

> findings of noncompliance with a regulatory requirement.
>
> Response: We are not accepting this suggestion because we believe that the Statement of Deficiencies and Plan of Correction (HCFA-2567) provides facilities with the specific information necessary to formulate an acceptable plan of correction. To include such detailed information regarding deficiencies in the notice of noncompliance would be duplicative and administratively burdensome.

Pacific Regency Arvin at 9-10 (quoting 59 Fed. Reg. 56,116, at 56,155 (November 10, 2004)); see also Northern Montana Care Center, DAB No. 1930, at 26 (2004) ("The statement of deficiencies does not rigidly frame the scope of evidence to be admitted concerning any allegation relating to a cited deficiency, nor does it require formal amendment to allow additional supporting evidence.").

Applying the logic in these decisions, we conclude that Laurelwood had sufficient notice of the issue about the adequacy of the risk-safety assessments both from the face of the SOD and from the pre-hearing proceedings.

4. The ALJ was not biased.

Laurelwood claims that it was denied an adequate opportunity to be heard because the ALJ was biased. P. Br. at 2, 18-19, 22. In support of this claim, Laurelwood argues that the ALJ Decision reflects her personal views based upon “extrajudicial knowledge of what constitutes an unsafe bed rail” from three sources: 1) her work in nursing homes during the 1970's (Tr. at 36-37); 2) the portrayal of bed rails with wide gaps in a Hollywood movie from the 1930's (Tr. at 36-37); and 3) the 54 bed rails at issue reminded the ALJ of the types of beds used in Romanian orphanages (Tr. at 278). P. Br. at 21. Specifically, during the first day of the hearing, the ALJ referred CMS’s expert witness to Petitioner’s Exhibit 8 and stated:

> I look at this picture which is a picture of a[n] [old-style] bed with side rails up and I have never seen side rails that look like this, and I’ve seen a lot of side rails. Even back in like – I think maybe I’ve seen side rails that look like this in a 1930s movie or something. I mean even back in the

> '70s when I was – I worked in a nursing [home,] we didn't have side rails that looked like that.

Tr. at 36-37. During the second day of the hearing, the ALJ stated:

> I was trying to think of what this [old-style bed] reminded me of because I felt like I'd seen it. And you know what it looks like? It looks like, you remember the Romanian orphans who were . . . those beds look this bed.

Tr. at 278. Laurelwood argues that these sources of extrajudicial knowledge are inadmissible and highly prejudicial because the ALJ's exposure to them caused her to have a preconceived judgement or bias toward the outcome of the case thereby depriving Laurelwood of a fair trial. P. Br. at 21.

In several prior cases, the Board has discussed the law governing challenges to ALJ decisions based on claims of bias and prejudice as follows:

> In Edward J. Petrus, Jr., M.D., and The Eye Center of Austin, DAB No. 1264 at 23-26 (1991)[aff'd sub nom., Petrus v. I.G., 966 F.2d 675 (5th Cir. 1992), cert. denied, 506 U.S. 1048 (1993)], the Board described the standard for disqualifying a judge on a charge of bias. The Supreme Court, the Board noted, has held that "[t]he alleged bias and prejudice, to be disqualifying, must stem from an extrajudicial source and result in an opinion on the merits on some other basis than what the judge learned from his participation in the case . . . ." United States v. Grinnell Corp., 384 U.S. 563, 583 (1966); see also Tynan v. United States, 376 F.2d 761 (D.C. Cir. 1967), cert. denied, 389 U.S. 845 (1967); Duffield v. Charleston Area Medical Center, 503 F.2d 512, 517 (4th Cir. 1974).

St. Anthony Hospital, DAB No. 1728, at 84 (2000), aff'd, 309 F.3d 680 (10th Cir. 2002); see also Tri-County Extended Care Center, DAB No. 2060 (2007); Madison Health Care, Inc., DAB No. 2049 (2006); Britthaven of Goldsboro, DAB No. 1960 (2005). It is not

evidence of bias that the ALJ's view of the record was not in accordance with a petitioner's views. See Meadow Wood Nursing Home, DAB No. 1841, at 10 (2002), aff'd, Meadow Wood Nursing Home v. HHS, 364 F. 3d 786 (6th Cir. 2004)("[W]eighing of testimony and evidence in the record is the essential task of an ALJ and can hardly be viewed as a demonstration of bias toward the party that does not prevail on the merits, however disappointed."). The Board has also found that "it is not evidence of bias for the ALJ to have a formed a view of the case by the close of the hearing." Madison Health Care, Inc., DAB No. 2049, at 15 (2006).

A close examination of the entire record shows no support for Laurelwood's accusations of bias against the ALJ.[12] The ALJ's comments during the hearing and in the ALJ Decision simply reflect her impressions about the evidence in the record. For an ALJ to have formed a view of the case based upon a review of the evidence does not demonstrate bias or constitute a violation of due process. See e.g., Madison Health Care, Inc. at 15. In addition, none of these statements suggest that the ALJ was unwilling to provide a fair hearing or to weigh the resulting record fairly.

The ALJ's comments, furthermore, are not prejudicial because the ALJ ruled in Laurelwood's favor on the very point as to which it questioned her objectivity, by finding "that widely-spaced bed

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[12] Laurelwood also asserts that during the pre-hearing conference, "the ALJ remarked to the effect that, 'if CMS had filed a motion for summary judgment, I would have granted it, because I do not know when the last time I saw bed rails like these.'" Pet. Br. at 19. However, there is no transcript of the pre-hearing conference or any other evidence in the record to substantiate this alleged comment. For example, the ALJ's summary of the pre-hearing conference does not contain any reference to the purported comment, and Laurelwood did not raise any objection to the ALJ's subsequent written summary of the pre-hearing conference. See ALJ Order Denying Motion To Recuse, at 1 (December 13, 2007). Moreover, in her Order, the ALJ challenged Laurelwood's assertion by stating that "I do not believe that [Laurelwood] accurately characterizes any discussion of summary judgment during the prehearing conference." Id. The ALJ further stated in her Order that during the conference, she simply asked CMS's counsel whether it would be filing a motion for summary judgment, and after CMS's counsel replied that he would not, the ALJ scheduled a hearing. On appeal, Laurelwood does not contest the ALJ's recitation of events discussed in her Order. See P. Br. at 19, 22.

rails do not per se violate any standard of care." ALJ Decision at 12; see also id., at n.10. Thus, the ALJ's observation that the widely-spaced side rails of the beds for the 54 residents reminded her of other beds with wide side rails is not relevant to the ultimate issue in the case – whether Laurelwood conducted an adequate risk-safety assessment of the side rails for each resident before deciding to use them. As previously discussed, the ALJ's findings of fact on that issue are supported by substantial evidence. Consequently, there is no result in the ALJ Decision on the merits on some basis other than what the ALJ learned from her participation in the case.[13] Laurelwood has also not shown how the outcome in the case would have been different if the ALJ had viewed its side rails as modern, rather than outdated. Thus, even if the ALJ's comments had demonstrated bias, which they did not, those comments were not prejudicial.

Finally, Laurelwood claims that it was prejudiced because the ALJ improperly converted the hearing from an adversarial type hearing into a "continental style" or inquisitory hearing. P. Br. at 2, 22-23; Tr. at 22-24. Laurelwood relies upon a purported "leading" question that the ALJ asked CMS's expert witness:

> ALJ: But if [resident R1] wanted to move his arm, he could move his arm?

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[13] On December 4, 2007, Laurelwood filed a Motion to Recuse the ALJ based upon the same arguments that it raises in this proceeding. In a ruling dated December 13, 2007, the ALJ denied the motion, stating that "[c]ommenting on the issues or the evidence presented on the record can hardly be considered 'extrajudicial.'" ALJ's Order Denying Motion To Recuse, at 2 (December 13, 2007). The ALJ also stated that "openly bringing into the proceedings references to widely-recognized images, which ultimately benefits the process by allowing the parties ample opportunity to respond[,]" does not constitute an impermissible reliance upon an extrajudicial source. Id. On January 10, 2008, Laurelwood filed a Second Motion to Recuse the ALJ and sought a factual hearing to determine whether the extrajudicial sources were "widely recognized images." This motion was denied in an Order dated January 15, 2008. On appeal before us, Laurelwood contends that the ALJ's denial of its second motion was erroneous. For the reasons discussed above, there is no indication in the record that the ALJ relied upon the alleged extrajudicial sources in reaching her decision. Thus, we conclude that there was no need for a factual hearing regarding the alleged bias, and that Laurelwood's Second Motion to Recuse the ALJ was properly denied.

> The Witness: Yeah, he could. He was not paralyzed.

Tr. at 38. Laurelwood contends that CMS did not dispute that R1 was incapable of voluntary movement such that by asking the witness a "leading" question that mischaracterized this undisputed fact, the "ALJ veered from impartial fact finder to dedicated advocate; or at the very least, a continental style inquisitor." P. Br. at 23. We find this argument to be without merit. The regulations, which require the ALJ to inquire fully into all matters at issue, implicitly authorize an ALJ to question witnesses in a non-jury administrative proceeding as the finder of fact. 42 C.F.R. § 498.60(b). Conversely, the regulation does not prohibit the ALJ from asking "leading questions" which is what Laurelwood apparently objects to.[14] The administrative proceeding is informal in nature and the federal rules of evidence do not apply. ALJs customarily ask questions of witnesses in order to ensure that the record has been fully developed. Moreover, in the portion of the transcript cited by Laurelwood as evidence supporting bias, the ALJ's question resulted in testimony by CMS's expert that Laurelwood points out was not factually correct. P. Br. at 22-23. However, the ALJ clearly did not rely upon the inaccurate testimony in her decision. Instead, the ALJ relied upon the undisputed record evidence noted by Laurelwood indicating that resident R1 was not capable of voluntary movement. See ALJ Decision at 6. Thus, we find that any misstatement by the witness that may have occurred during the questioning was corrected by the ALJ in her decision and, therefore, was not material.

For the reasons discussed above, we find that the ALJ Decision is supported by substantial evidence in the record, and the ALJ was not biased.

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[14] In that regard, we find that the ALJ's question was not "leading" because it does not suggest the answer to the witness. See McCormick § 6(b) (2006) ("A leading question is one that suggests to the witness the answer desired by the examiner.").

Conclusion

For the reasons explained above, we uphold the ALJ Decision and affirm and adopt each of the ALJ's findings of fact and conclusions of law.

/s/
Judith A. Ballard

/s/
Leslie A. Sussan

/s/
Stephen M. Godek
Presiding Board Member