

Department of Health and Human Services
DEPARTMENTAL APPEALS BOARD
Appellate Division

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In the Case of:)	
Lutheran Home at Trinity)	
Oaks,)	DATE: August 30, 2007
)	
Petitioner,)	Civil Remedies CR1428
)	App. Div. Docket No. A-06-72
)	
- v. -)	Decision No. 2111
)	
Centers for Medicare &)	
Medicaid Services.)	
_____)	

FINAL DECISION ON REVIEW OF
ADMINISTRATIVE LAW JUDGE DECISION

Lutheran Home at Trinity Oaks (Lutheran), a North Carolina skilled nursing facility (SNF), appealed a March 23, 2006 "amended decision" by Administrative Law Judge (ALJ) Carolyn Cozad Hughes, Lutheran Home at Trinity Oaks, DAB CR1428 (2006) (ALJ Decision). Lutheran had requested (and received) an ALJ hearing to contest a \$5,000 civil money penalty (CMP) imposed by the Centers for Medicare & Medicaid Services (CMS). In her decision, the ALJ concluded that: (1) on February 14, 2003, Lutheran was not in substantial compliance with a Medicare requirement that obligates SNFs to keep the resident environment as free of accident hazards as is possible; (2) CMS's determination that Lutheran's noncompliance on February 14, 2003 had created a situation of "immediate jeopardy" was not "clearly erroneous"; and (3) the amount of the CMP imposed for the noncompliance was reasonable.

Lutheran contends that these conclusions are not supported by substantial evidence or are based on errors of law. Lutheran also raises various issues regarding the ALJ's conduct of the evidentiary hearing. We find no merit in any of Lutheran's contentions and affirm the ALJ Decision in its entirety.

Legal Background

To participate in the Medicare program, a SNF must comply with the requirements for participation found in 42 C.F.R. Part 483, subpart B. 42 C.F.R. §§ 483.1, 488.3. Compliance with these participation requirements is verified by surveys conducted by state health agencies. 42 C.F.R. Part 488, subpart E.

CMS may impose enforcement remedies, including a CMP, against a SNF that is found not to be in "substantial compliance" with Medicare participation requirements. 42 C.F.R. §§ 488.402(c), 488.406. CMS's regulations (and we) use the term "noncompliance" to refer to "any deficiency that causes a facility not to be in substantial compliance." 42 C.F.R. § 488.301.

CMS determines the amount of a CMP based in part on the "seriousness" of the SNF's noncompliance. See 42 C.F.R. §§ 488.438(f)(3), 488.404. The level of seriousness is determined by considering the noncompliance's scope (whether it is isolated, constitutes a pattern, or is widespread) and severity (the degree or magnitude of harm - or potential harm - to resident health and safety resulting from the noncompliance). 42 C.F.R. § 488.404. The most serious deficiency is one that creates "immediate jeopardy," which is defined as "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.

The regulations authorize "per day" CMPs in the range of \$3,050-\$10,000 for a deficiency constituting immediate jeopardy, and in the range of \$50-\$3,000 for a deficiency that does not constitute immediate jeopardy but that either causes actual harm or creates the potential for more than minimal harm. 42 C.F.R. § 488.438(a)(1).

The Medicare participation requirement at issue in this appeal is 42 C.F.R. § 483.25(h)(1), which requires a SNF to "ensure that . . . [t]he resident environment remains as free of accident hazards as possible." In Maine Veterans' Home - Scarborough, DAB No. 1975 (2005), we held that -

[t]he standard in section 483.25(h)(1) . . . 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. . . . Where a facility alleges (or shows) that it did not know that a hazard existed, the facility cannot prevail if it could have reasonably foreseen that an endangering condition existed either generally or for a particular resident or residents.

DAB No. 1975, at 7 (footnote omitted).

Case Background¹

A May 2003 survey by the North Carolina Department of Health and Human Services (state survey agency) found that Lutheran had a number of deficiencies. CMS Exs. 1, 31 ¶ 1. One of the deficiencies concerned a February 14, 2003 incident in which a resident, known here as Resident 1, wrapped the elastic band of a "hand roll" (an orthotic device) around her middle left finger, cutting off its blood supply. CMS Ex. 1, at 18-19. The finger later developed gangrene and had to be amputated. Id. at 20. Based on its findings related to this incident, the state survey agency concluded that Lutheran was not in substantial compliance with 42 U.S.C. § 483.25(h)(1) on February 14, 2003, and that this noncompliance had created a situation of immediate jeopardy on that day. Id. at 18; CMS Ex. 2, at 1.

CMS concurred with the survey findings and imposed two CMPs: (1) a \$5,000 per-day CMP for the immediate jeopardy situation involving Resident 1; and (2) a \$250 per day CMP (effective May 22, 2003) based on other deficiency findings from the May 2003 survey. CMS Ex. 2, at 2.

Lutheran appealed these enforcement remedies by requesting an ALJ hearing. After the parties submitted documentary evidence and written direct testimony, the ALJ commenced an in-person hearing, during which the parties cross-examined some of each other's witnesses.

Before the ALJ decided the case, the parties settled all issues relating to the \$250 per day CMP. Thus, the ALJ Decision addresses only issues relating to the \$5,000 CMP, which, as

¹ 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.

indicated, CMS imposed based on its finding of immediate jeopardy-level noncompliance involving Resident 1.

The ALJ Decision

In her March 23, 2006 amended decision, the ALJ found the following relevant facts, which are essentially undisputed. Resident 1 was admitted to Lutheran in July 2000 after suffering a stroke that left her partially paralyzed on her left side. ALJ Decision at 4. She was anxious, displayed repetitive physical movements, and had memory problems associated with dementia. Id.

Resident 1 also had "contractures" (a tightening of muscles, tendons, or ligaments that inhibits normal functioning) in her left hand, a side effect of her paralysis. ALJ Decision at 5; see also CMS Ex. 27, ¶ 7. To mitigate the contractures and the associated risk of skin breakdown, the nursing staff gave Resident 1 a hand roll to hold in her left hand. ALJ Decision at 5. The hand roll was "homemade," having been made by church volunteers. Id. It was a cylindrical roll of terry cloth with an elastic strap sewn on both ends. Id. The elastic strap, whose purpose was to keep the hand roll properly positioned in the hand, was one-half inch wide and was "old and loose." Id. at 5 n.5. "Because the elastic on [Resident 1's] hand roll was old and loose, it folded over itself in places. In those places, it was effectively only one-quarter to one-half inch wide." Id.

On the night of February 13, 2003, Resident 1 went to bed with the hand roll positioned correctly in her left hand. ALJ Decision at 6. However, at 7:30 a.m. the next day –

a nurse aide noticed that the elastic band from [Resident 1's] hand roll was wrapped around the resident's left middle finger. Her finger was dark purple to the first knuckle. Ann Miller, a registered nurse and the night shift supervisor, removed the hand roll. The finger was swollen, purple with bruising, warm to the touch, with a blood blister appearing and the fingernail dark. Over the next several days, its condition deteriorated, became necrotic, and the finger was amputated on February 17, 2003.

Id. (citations omitted). Immediately after the incident, the nursing staff "removed all hand rolls with elastic straps and/or cut the straps[.]" Id. at 8.

The ALJ found that "February 14 was not the first time staff found the hand roll's elastic strap wrapped around [Resident 1's]

finger or fingers." ALJ Decision at 7. The ALJ found, for example, that "[a]pproximately two weeks prior to the incident, RN Patti Blue found the elastic wrapped around [Resident 1's] fingers, and was concerned enough to ask a second RN, Trudy Fry, to assess the problem." Id. at 11. "Yet, neither of these professionals reported the incident or took any additional action," the ALJ found. Id.

The ALJ also found that Resident 1 retained "significant dexterity with her right hand and fingers," and that "[f]acility investigators reported that 'many staff' felt she was capable of wrapping the strap around her finger." ALJ Decision at 6. Dr. Cecil Farrington, Resident 1's attending physician and Lutheran's medical director, stated that there was "no question" in his mind that Resident 1 "retained enough dexterity in her right hand to manipulate the hand roll strap around her finger." P. Ex. 24, at 2 (cited on page 7 of the ALJ Decision).

Based on these and other findings, the ALJ concluded that –

before the February 14 incident, [Lutheran's] staff understood that [Resident 1] was capable of wrapping the elastic band from her hand roll around her fingers, and, in fact, multiple staff members actually observed the elastic wrapped around her fingers. And the facility absolutely had to have known that wrapping an elastic band around the fingers of an individual in [Resident 1's] condition put her at risk of serious injury.

* * *

Here, the facility "could have reasonably foreseen that an endangering condition existed." Its resolution would have been very simple: purchase an inexpensive – and safe – device made by a company specializing in the manufacture of such medical devices. The facility's failure to do so violated 42 C.F.R. § 483.25(h)(1).

Id. at 10-11, 13 (citations omitted) (quoting Maine – Veterans' Home Scarborough).

The ALJ further concluded that CMS's determination that Lutheran's noncompliance with section 483.25(h)(1) had created a situation of "immediate jeopardy" was not clearly erroneous. ALJ Decision at 14. Finally, she concluded that the CMP imposed by CMS (\$5,000 per day for the single day of noncompliance) was reasonable. Id. at 14-15.

Standard of Review

We review a disputed finding of fact to determine whether the finding is supported by substantial evidence, and a disputed conclusion of law to determine whether it is erroneous. Guidelines for Appellate Review of Decisions of Administrative Law Judges Affecting a Provider's Participation in the Medicare and Medicaid Programs, <http://www.hhs.gov/dab/guidelines/prov.html>; Golden Age Nursing & Rehabilitation Center, DAB No. 2026 (2006).

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). Under the substantial evidence standard, the 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. Universal Camera Corp. v. NLRB, 340 U.S. 474, 488 (1951).

Discussion

In this appeal, Lutheran contends that the ALJ's conclusion that it was not in substantial compliance with section 483.25(h)(1) should be reversed because Resident 1's use of the hand roll was not (in its view) a "reasonably foreseeable hazard." Lutheran Br. at 1-5. According to Lutheran, the accident on February 14, 2003 was a "freak, apparently completely unprecedented accident." Id. at 1, 30. Furthermore, says Lutheran, the ALJ "completely misread and misinterpreted" the evidence in concluding that its staff "was on notice of some specific hazard" to Resident 1. Id. at 2, 44. Lutheran also contends that CMS's immediate jeopardy determination was clearly erroneous. Id. at 51. In addition, Lutheran urges us to reduce the CMP amount. Id. at 54. Finally, Lutheran objects to the ALJ's use of written direct testimony in this case and raises other issues regarding the conduct of the in-person hearing. Id. at 2-3, 29-30.

We address each of these issues below.

1. *Substantial evidence supports the ALJ's conclusion that Lutheran was not in substantial compliance with 42 C.F.R. § 483.25(h)(1) on February 14, 2003.*

As we have said in many prior decisions, section 483.25(h)(1) requires a SNF to take all appropriate steps to remove or

otherwise protect residents from conditions that pose a known or foreseeable risk of accidental harm.² Maine Veterans' Home – Scarborough. CMS makes a prima facie case of noncompliance with section 483.25(h)(1) if it presents evidence "that a potentially dangerous condition existed in the facility which was identified or foreseeable but was not removed and that the facility did not take appropriate steps to protect residents from that danger." Alden Town Manor Rehabilitation & HCC, DAB No. 2054, at 8 (2005).

Here, the ALJ concluded that, prior to February 14, 2003, Lutheran knew or reasonably should have foreseen that Resident 1's use of the homemade hand roll "put her at risk of serious injury" but took no steps to minimize or eliminate that risk until after her accident. ALJ Decision at 10-13. For the following reasons, we decline to disturb that conclusion.

There is substantial evidence that the hand roll's elastic strap, while arguably not inherently dangerous under other circumstances, posed an accident hazard to Resident 1.³ The circumstances of the February 14, 2003 incident make this plain. They show that Resident 1 had the ability to wrap the hand roll's elastic strap around one or more fingers of her left hand, a maneuver likely to constrict the flow of blood to those extremities. Dr. Dale Strasser, a specialist in geriatric medicine with considerable experience in treating elderly stroke patients, testified that this particular behavior posed a risk of injury because Resident 1 could not sense (or fully sense) discomfort or pain in the left hand, making it less likely that she would feel the need to protect herself by removing the elastic band with her good (right) hand or alerting staff to the problem. CMS Ex. 27, ¶ 14. Dr. Strasser further testified that Resident 1's circulatory system was already compromised by peripheral vascular disease, making her particularly susceptible to serious injury from blood flow constriction. *Id.*, ¶ 15. Dr. Strasser testified that an elastic strap wrapped around the

² A facility's duty to eliminate or protect residents from accident hazards is an element of its general duty to provide care and services necessary for residents to attain or maintain their "highest practicable . . . physical or mental well being[.]" 42 C.F.R. § 483.25; Estes Nursing Facility Civic Center, DAB No. 2000, at 6 (2005).

³ We note that while Lutheran argues that elastic straps and rubber bands "are not inherently dangerous," it concedes that they "obviously can cause injury." Lutheran Br. at 12.

finger of a person with Resident 1's circulatory problems could cause injury within minutes. Tr. 41-42.

Substantial evidence also supports the ALJ's finding that Lutheran could have removed the hazard (and thus prevented the injury to Resident 1) by purchasing a "safe" hand roll "made by a company specializing in the manufacture of such medical devices." ALJ Decision at 13. Dr. Strasser testified that the accident hazard "could have easily been removed if the nursing home had simply purchased any number of available medical devices that are normally used to help hand contractures." CMS Ex. 27, ¶ 19. Lutheran does not challenge Dr. Strasser's testimony on this point.

What is chiefly in dispute in this appeal is the ALJ's finding that Lutheran knew or should have known of the hazard prior to Resident 1's February 14, 2003 accident. Lutheran contends that there is no evidence that the nursing staff did recognize or should have recognized the hazard prior to that date, and that the accident was "unforeseeable as a matter of law." Lutheran Br. at 4, 15. We disagree. There is substantial evidence that Lutheran's nursing staff actually comprehended the hazard prior to February 14, 2003 and that, in any event, the hazard was reasonably foreseeable before that date.

There is, first of all, evidence that some of the nursing staff were aware that Resident 1 was capable of wrapping the elastic strap around her fingers. In written statements given during Lutheran's post-accident investigation, two CNAs, Catoe and Woodson, indicated that they had personally seen the elastic strap of the hand roll wrapped around or "caught" on Resident 1's finger or fingers. P. Ex. 12, at 3; P. Ex. 13, at 13. CNA Catoe stated:

On one occasion I personally witnessed [Resident 1] while trying to fix her hand roll in her hand twisting it so that it was caught on her finger. After the period of time that has passed I could not tell you on what day this happened or on what finger it was on. Upon seeing this fixed the hand roll myself. [Resident 1] had said to me many times that she could not fix it on her own. . . .

P. Ex. 12, at 3.⁴ CNA Woodson stated:

I . . . have seen [Resident 1] twist the hand roll around her fingers once. I also hear a report, she was playing with it. The elastic strap was wrapped around her fingers so I took it and straight it out.

P. Ex. 13, at 13.⁵ The ALJ noted that, "[a]lthough neither CNA was able to specify when she observed the problem with the hand roll, the facility removed all hand rolls with elastic straps and/or cut the straps immediately after the February 14 incident, so the CNAs' observations plainly occurred prior to February 14." ALJ Decision at 8. Lutheran does not dispute that inference or the veracity of the CNAs' recollections.

In addition, the Statement of Deficiencies reported that Nurse Miller, the third shift nursing supervisor, had told surveyors in a 7:35 a.m. interview on May 21, 2003 that she had overheard two nurses talking about Resident 1's ability to twist the elastic strap of the hand roll around her fingers.⁶ CMS Ex. 1, at 21-22. According to the Statement of Deficiencies, Miller told surveyors during the 7:35 a.m. interview that the conversation she had overheard related to a period prior to February 14, 2003. Id.

⁴ Along with the copy of CNA Catoe's signed written statement, Lutheran submitted what appear to be another person's comments about the incident described by Catoe. P. Ex. 12, at 4. The author of these comments is not specified, and CNA Catoe did not in any way (such as by a signature) affirm that the comments accurately reflected her statements or recollection. Thus, the comments were entitled to little or no weight, although they are consistent with CNA Catoe's signed statement that Resident 1 had managed to get the hand roll "caught" on her fingers (the unsigned comments specify her middle and ring fingers).

⁵ CNA Woodson also signed a document containing what appear to be her answers to three questions about the incident in which she saw the hand roll's elastic strap wrapped around Resident 1's fingers. P. Ex. 12, at 6. With respect to that incident, Woodson indicated that the hand roll was not positioned "tightly" in Resident 1's hands. Id. Woodson also indicated that she did not report the incident to anyone. Id. Neither of these answers is inconsistent with the substance of Woodson's handwritten statement.

⁶ Nurse Miller is identified in the Statement of Deficiencies as "Staff #2." CMS Ex. 1, at 21; CMS Ex. 28, ¶ 13.

Miller was interviewed a second time on May 21, 2003, at 3:45 p.m., in front of Lutheran's administrator and nursing director. Id. at 22. During the second interview, Miller reiterated the story she had earlier told – namely, that she had overheard two nurses talk about Resident 1 wrapping the elastic strap of the hand roll around her fingers prior to February 14, 2003. Id.

The Statement of Deficiencies further indicated that Nurse Fry, a staff nurse, had told surveyors in a May 21, 2003 telephone interview that "several weeks to a month" before February 14, 2003, Nurse Blue, a shift supervisor, had called Fry into Resident 1's room shortly after Fry's shift had ended in order to show Fry that Resident 1 had wrapped the elastic strap of the hand roll around her fingers.⁷ CMS Ex. 1, at 22. Fry told surveyors that she did not document this incident in Resident 1's clinical records because her shift had ended and because she thought that Blue would do so. Id.

Nurse Fry provided another account of this incident in a handwritten statement given during Lutheran's post-accident investigation:

One morning, 1st shift nurse, Patti Blue, RN asked me to go with her to check [Resident 1's] hand. She stated the resident had wrapped the elastic band around her fingers. Went into [the room]. Resident was dressing, sitting [up] in her [wheelchair] eating breakfast. I talked with resident about how her breakfast was while I looked at all 10 fingers. No problem was noted to any of them. No bruising. No redness. No swelling. No [complaints of] pain or any problems with her fingers or hands. When we left the room, the resident continued to eat. Patti had said she just wanted a second nurse to look at it. Stated CNA had found it when she got her [up] [and] had removed the hand roll with the elastic band. I had told Patti [that] she, [Resident 1] had not had it wrapped long because 3rd shift CNA's had been in there frequently during the night, assisting her due to her cutting her call light on.

P. Ex. 12, at 2.

⁷ Fry and Miller are identified in the Statement of Deficiencies as "Staff #3" and "Staff #4" respectively. CMS Ex. 1, at 22; CMS Ex. 28, ¶ 13.

Dr. Strasser testified that providing care to stroke patients is an interdisciplinary process. CMS Ex. 27, ¶ 9. He testified that the initial placement of a medical device "is usually done by an occupational or physical therapist," that the "facility's nursing staff and the nurse assistants are responsible for checking the device is properly positioned and not adversely affecting the patient," and that it is "incumbent upon the [nursing] staff to promptly notify the occupational therapist, physical therapist or the physician" if the staff notices that a medical device poses a potential safety concern. Id., ¶¶ 9-11. Dr. Strasser also testified that the pre-February 14, 2003 incident described by Nurse Fry "should have been reported to the occupational therapist, physical therapist or the physician," and that "[a]lthough the resident's fingers were not injured that morning, this incident put the staff on notice that the strap could get wrapped around the resident's fingers and injure her." Id., ¶ 12. Dr. Strasser testified that it "was particularly important to report any incident of wrapping or twisting of the elastic band around one or more of the [resident's] fingers because she was particularly susceptible to this type of injury," being "insensate in her left hand." Id., ¶ 14. In addition, Dr. Stasser testified:

No matter if a facility uses a homemade medical device or one that is purchased, the facility staff must report any incidents that indicate that the device may pose a risk to a resident. Any incident where the strap was observed to be twisted around the finger or fingers of this resident is the type of incident that should [have] been brought to the attention of the physical or occupational therapists.

Id. at 7. Finally, Dr. Strasser testified: "It is my professional medical opinion that the care provided to Resident 1 by Lutheran Home at Trinity Oaks . . . was below the applicable standard of care. It is also my opinion that the poor care the resident received caused her to suffer serious harm in the form of an amputated finger." Id., ¶ 4.

In our view, the evidence just described is adequate to support the ALJ's findings that: (1) Lutheran's nursing staff was aware, prior to February 14, 2003, that Resident 1 was capable of wrapping or twisting the elastic strap of the homemade hand roll around one or more of her fingers and had in fact done so, perhaps multiple times; and (2) Lutheran knew or should have known prior to February 14, 2003 that Resident 1's ability to twist or wrap the hand roll's elastic strap around her fingers had the potential to harm her. As indicated, the record shows

that, prior to February 14, 2003, at least four members of the nursing staff – Fry, Blue, Catoe, and Woodson – had actually seen or heard reports about the elastic strap of the hand roll being wrapped or twisted around one or more of Resident 1's fingers. In one such instance, two nurses – Fry and Blue – took the trouble to investigate whether Resident 1's hand or fingers had been injured. The fact that these nurses performed such an examination supports an inference that they understood that Resident 1's manipulation of the elastic strap was potentially dangerous.

In "Prefiled Direct Testimony," Nurse Fry stated that "[a]pproximately two weeks before the Resident's accident . . . Nurse Blue asked me to look at the Resident's hand, as Nurse Blue apparently had found part of the hand roll wrapped around the top of the Resident's hand." CMS Ex. 30, at 1-2 (emphasis added).⁸ Nurse Fry then stated (in the same prefiled testimony) that she was unaware "of any occasion before February 14, 2003 when Resident #1 maneuvered her hand roll or strap into a position that was hazardous." Id. at 2.

The ALJ concluded that, despite what she termed "obfuscation," Nurse Fry's prefiled testimony confirmed her earlier written statement (P. Ex. 12, at 2) and her verbal statement to the surveyor. ALJ Decision at 8-9. The ALJ noted that "[n]o one has suggested that any 'part of the hand roll' other than the elastic strap could possibly have wrapped itself around any part of the resident's hand." Id. at 9. She also found that the term "top of the Resident's hand" referred to Resident 1's fingers since "no one has suggested that the strap could have been any place other than around the fingers." Id. The ALJ also found that since Lutheran had prepared the written statement, if Nurse Fry meant to say that, "contrary to her earlier statements, some part of the hand roll other than the strap was wrapped around some part of [Resident 1's] hand other than her fingers, she should specifically have said so." Id. at 9 n.12. We find no reason to disturb these findings, which the ALJ made based on a careful weighing of the evidence.

⁸ Lutheran originally submitted (as Petitioner's Exhibit 23) Nurse Fry's testimony to "clarify" statements attributed to her by the surveyor but subsequently withdrew the testimony, claiming that it could not locate Fry and make her available for cross-examination. See Oct. 5, 2005 order summarizing prehearing conference. Without objection from Lutheran, CMS subsequently submitted Fry's written testimony as CMS Ex. 30. See Oct. 14, 2005 letter from CMS to Crystina Hong (Civil Remedies Div.).

We certainly do not read Nurse Fry's prefiled testimony as a disavowal of her awareness, from the incident involving Nurse Blue, that Resident 1 had maneuvered the elastic strap around her fingers prior to February 14, 2003. At most, the testimony constitutes a denial that Nurse Fry understood that the maneuvering posed a hazard to Resident 1. However, Nurse Fry's lack of such understanding is not material, since even if her testimony is credited, the ALJ reasonably concluded that "Nurse Blue was concerned enough about potential injury to seek a second nurse assessment [from Nurse Fry]." ALJ Decision at 11-12. It is reasonable to infer from the circumstances that Nurse Blue would not have initiated an examination of Resident 1 had she (Blue) thought that the wrapping of the hand roll's elastic strap around Resident 1's fingers posed no risk of injury. In our view, the evidence of Nurse Blue's concern about potential injury is, in itself, sufficient to support the ALJ's finding that "the facility absolutely had to have known that wrapping an elastic band around the fingers of an individual in [Resident 1's] condition put her at risk of serious injury." Id. at 11. The ALJ cited other evidence to support that finding. She correctly noted that when the CNAs found Resident 1 with the elastic strap wrapped around her fingers prior to the accident, they did not leave the strap in place but instead removed it. ALJ Decision at 11 (citing Tr. at 8 (CMS's Opening Statement)); see also P. Ex. 12, at 3; P. Ex. 13, at 13.

Furthermore, as we have indicated, CMS was not required to prove that Lutheran actually comprehended the hazard prior to February 14, 2003. Lutheran failed to satisfy section 483.25(h)(1) if its employees had reason to know of an accident hazard but failed to comprehend and act upon it. Estes Nursing Facility Civic Center, DAB No. 2000, at 7 n.5 (2005) (indicating that a SNF must take reasonable steps to protect residents from "foreseeable accident hazards"). Dr. Strasser testified that, prior to February 14, 2003, Nurse Fry and Nurse Blue had reason to know that the hand roll strap posed a risk of harm to Resident 1 given the circumstances of the incident reported by Nurse Fry, the diminished sensation in Resident 1's left hand, and her overall susceptibility to injury from constricted blood flow. That testimony – and the undisputed facts relating to the incident in question and Resident 1's medical condition – are substantial evidence that the hazard to Resident 1's hand or fingers was reasonably foreseeable prior to February 14, 2003.

Lutheran contends that Dr. Strasser's "ultimate conclusions regarding foreseeability of the hazard plainly should have been discounted because of his fundamental misunderstanding of the record[.]" Lutheran Br. at 18 n.14. According to Lutheran, Dr.

Strasser testified that his conclusions and opinions "were based on his understanding or belief that there had been numerous pre-accident reports and events" involving Resident 1's misuse of the hand roll's elastic strap. Id. Lutheran contends that Dr. Strasser "obviously compressed statements petitioners' staff obtained after the accident" with the pre-accident communication between Nurses Blue and Fry. Id.

We find no merit to these contentions, in part because Dr. Strasser made it clear in his direct testimony and on cross-examination that, irrespective of observations or reports from other employees, Nurses Fry and Blue should have recognized the potential hazard prior to the accident and reported it to Resident 1's occupational therapist or physician. CMS Ex. 27, ¶ 6; Tr. at 66-67. Moreover, we disagree that Dr. Strasser fundamentally misunderstood the record. He recollected at the hearing that his "mental picture" of the record included the account of the pre-accident examination of Resident 1's hand by Nurses Fry and Blue, as well as "reports from some CNAs on finding her, observing the patient with the strap around her hand." Tr. at 21-22. This is an essentially accurate description of the evidence.

Lutheran contends that Nurse Miller's testimony undercuts the ALJ's conclusions and was improperly rejected by the ALJ. Lutheran Br. at 23-28, 50. Noting that Miller had "refused to concede that staff should have reported that [Resident 1] had earlier [prior to February 14, 2003] wrapped the elastic around her finger," the ALJ characterized Miller's testimony as "evasive." ALJ Decision at 13. Lutheran asserts that, during redirect examination, the ALJ "badgered" Miller "to get her to agree to a conclusion that the ALJ already had reached," and that Miller "actually was doing her best to answer the [ALJ's] questions." Lutheran Br. at 24, 28. Lutheran asserts that "it is unfair and inappropriate to conclude that Nurse Miller was being evasive, or to infer that this testimony is evidence of some systemic breakdown by Petitioner." Id. at 28.

The ALJ's characterization of Miller's testimony as "evasive" is, in essence, a finding about Miller's credibility. We do not disturb an ALJ's credibility finding unless it is clearly erroneous. Lakeridge Villa Health Care Center, DAB No. 1988, at 19 n.14 (2005); Community Skilled Nursing Centre, DAB No. 1987 (2005).

We have carefully examined the substance of Nurse Miller's testimony, especially the testimony she gave during Lutheran's redirect examination. On their face, Nurse Miller's statements

appear equivocal. While Nurse Miller asserted that Resident 1's wrapping of the hand roll's elastic strap around her fingers was not a dangerous or potentially dangerous situation, she testified that this situation was "something to be on the lookout for." Tr. at 147. In the nursing home context, where maintaining a patient's health and safety is of paramount concern, one would expect a nurse or CNA to be "on the lookout for" conditions that pose some threat to health or safety. Given Miller's apparent equivocation, and giving due regard to the ALJ's ability to observe the witness's demeanor, we cannot say that the ALJ erred at all, much less clearly erred, in discounting Miller's testimony. In addition, we reject Lutheran's contention that the ALJ acted improperly in questioning Miller. The ALJ undoubtedly examined Miller closely and pressed her on key issues, but we see no evidence of "badgering" or coercive questioning. Finally, we see no indication that the ALJ treated Miller's testimony as evidence of "some systemic breakdown."

Lutheran contends that the ALJ improperly disregarded evidence that Nurse Blue had denied that the incident involving her and Nurse Fry had occurred. Lutheran Br. at 21-23. The Statement of Deficiencies states that Blue told surveyors in a telephone interview that, to the best of her knowledge, Resident 1 had never wrapped the hand roll's elastic band around her fingers prior to February 14, 2003. CMS Ex. 1, at 22-23. In addition, Lutheran produced a handwritten statement from Nurse Blue that she had "never personally witnessed [Resident 1] wrapping hand roll around fingers [and] do not know of other incidents." P. Ex. 13, at 4.

The ALJ did not disregard these statements but determined that the weight of the evidence "belie[d] Nurse Blue's denials." ALJ Decision at 9. The record supports that assessment. When confronted during the survey with Blue's apparent failure to recollect the pre-February 14th incident involving Resident 1, Nurse Fry insisted (in front of Lutheran's administrator and nursing director) that the incident had occurred. CMS Ex. 1, at 23. In addition, Nurse Miller corroborated Nurse Fry's account in a written statement: "I was told by Patti Blue, after the incident on the morning of 2-14-03 that 1-2 weeks before, Resident 1 had wrapped the elastic around all four fingers and they were red, but O.K. after the elastic and hand-roll were removed." CMS Ex. 7, at 2. At the hearing, Miller confirmed that this conversation with Blue had indeed occurred. Tr. at 141. The ALJ noted other evidence (a written statement from CNA Graham) tending to undermine Nurse Blue's denials, and the ALJ also observed that Lutheran had failed to produce Blue as a witness, even though she was still an employee at the time. ALJ

Decision at 9-10. These circumstances are more than adequate to justify the ALJ's refusal to credit Nurse Blue's denials.⁹

Lutheran complains that the ALJ unfairly criticized the testimony of facility administrator Mathis, as "incredible." Lutheran Br. at 28-30. Mathis testified: "So far as I am aware, no nurse or other employee told any surveyor that she had seen or was aware of any instance in which the Resident had wrapped the strap of her hand roll around her hand on any occasion before February 14, 2003, and no nurse or anyone else ever made such a statement to me during my investigation, or at any other time." P. Ex. 21, ¶ 11 (emphasis added). Mathis further testified that the surveyors "misunderstood or misstated their interviews by staff persons" to reach the conclusion the nursing staff was aware that Resident 1 had a history of wrapping the strap of her hand roll around her finger. *Id.*, ¶ 10.

The ALJ had ample reason to reject Mathis's testimony. First, Ms. Mathis identified no facts or evidence to support her claim that surveyors misstated or misunderstood statements given during employee interviews, and we see no evidence of material discrepancies. Second, in statements provided during the survey, during Lutheran's post-accident investigation, or during this administrative proceeding, three employees – Fry, Catoe, and Woodson – indicated that, prior to February 14, 2003, they had personally witnessed, learned about, or reported incidents in which Resident 1 had wrapped the elastic strap of the hand roll around her hand or fingers. CMS Ex. 1, at 22-23; P. Ex. 12, at 2-3; P. Ex. 13, at 13; P. Ex. CMS Ex. 30, at 1-2. Even if Mathis was not aware of this evidence during the survey or post-accident investigation, that fact would not, in itself, be a sufficient reason to reject the statements as untruthful or inaccurate.¹⁰

Lutheran contends that the ALJ should have credited testimony by Dr. Farrington, Resident 1's attending physician, that the homemade hand roll used by Resident 1 was not inappropriate or

⁹ Lutheran complains that it "*did* offer to produce Nurse Blue at the hearing for cross-examination, and both the Court and CMS declined the invitation." Lutheran Br. at 21 (emphasis added). This assertion is no help to Lutheran because it failed to submit written direct testimony from Blue.

¹⁰ We do not see how Ms. Mathis could have been unaware of at least some of these statements since they were taken in preparation for informal dispute resolution (IDR) "under the supervision of Ms. Mathis." Tr. at 57; Lutheran Ex. 12.

hazardous. Lutheran Br. at 53. However, Dr. Farrington gave no such testimony. He testified that there was "nothing wrong with securing a hand roll in place with a comfortable strap" and "nothing wrong with using a 'home made' hand roll[.]" P. Ex. 24. But Dr. Farrington made these statements without any specific reference to Resident 1 and without indicating whether it was safe for Resident 1 under the circumstances to use a hand roll with an elastic strap that the ALJ found (and that Lutheran does not dispute) "was old and loose" and "folded over itself in places."¹¹ ALJ Decision at 5 n.5.

Lutheran contends that the hazard identified by the ALJ was "bizarre" and "unforeseeable" because "no one ever had been warned of – or even had heard of – any accident like the one suffered by Resident #1." Lutheran Br. at 2, 4, 15-16, 30, 44. We reject Lutheran's suggestion that a hazard is unforeseeable simply because the facility had not witnessed or heard about an accident or injury stemming from the hazard. In deciding whether a particular hazard was foreseeable, one identifies the circumstances that were apparent or should have been apparent to the facility and then evaluates whether those circumstances – which can often be unique – were such that the facility could reasonably have anticipated the possibility of harm to the resident. Taking the circumstances here – a stroke patient with no or altered sensation of pain or discomfort in her left hand, an ability to manipulate objects with her right hand, peripheral

¹¹ Dr. Farrington's testimony on this subject is as follows:

I am aware that the government criticizes the use of a "home made" hand roll that includes an elastic band to keep it in place. I disagree with this criticism. I have many patients with contracted hands, and it is common for nursing facilities (or the patients themselves) to place rolled towels or wash cloths in hands as a comfortable means to minimize contractures. I see nothing wrong with securing a hand roll in place with a comfortable strap, as nurses cannot monitor any resident enough to make sure that she never drops or misplaces a hand roll. I understand that these specific hand rolls were sewn by volunteers, but I am aware that there are similar or identical products sold commercially, and I see nothing wrong with using a 'home made' item such as this as a handroll."

P. Ex. 24, at 2-3.

vascular disease leaving her vulnerable to injury from constricted blood flow, a hand roll with a loose elastic strap, and Resident 1's demonstrated ability to wrap an elastic strap around the fingers of her left hand and corresponding inability to extricate her hand or fingers once they had become wrapped in the elastic – it does not require any stretch of the imagination to foresee that Resident 1's use of the hand roll had the potential to cause serious injury to her hand or fingers.

We also reject Lutheran's suggestion that a SNF should be deemed compliant with section 483.25(h)(1) unless CMS proves that the SNF could have foreseen the precise manner in which exposure to a foreseeable hazard has caused injury. Section 483.25(h)(1) does not require a SNF to safeguard residents against particular types or categories of "accidents" or injuries. Instead, it requires a SNF to minimize or eliminate "hazards" that may lead or contribute to accidental injury. The hazard in this case was Resident 1's use of a hand roll with an elastic strap loose enough to allow Resident 1 to wrap it around her fingers and restrict blood flow. As we have discussed, substantial evidence supports the ALJ's finding that Lutheran's nursing staff knew or should known of that hazard prior to February 14, 2003. Such evidence would have justified a finding of noncompliance even if Resident 1 had not been injured. Cf. Josephine Sunset Home, DAB No. 1908 (2004) (rejecting the proposition that an accident cannot be considered foreseeable unless it previously "occurred to the same person in the precise manner," and further stating that "[f]or a risk to be foreseeable, it need not have been made obvious by having already materialized").

Lutheran claims that the ALJ "quote[d] – and misquote[d] – bits and pieces from a very large record that, taken as a whole, plainly does not support" her conclusion. Lutheran Br. at 16. Lutheran further contends that the record –

contains no direct evidence of any problem or hazard whatsoever relating to the hand roll or its strap *prior* to the Resident's accident, and Judge Hughes' references to various witness statements confuse the record. The record actually contains three separate sets of witness statements, taken at different times under different circumstances. Judge Hughes conflated selected excerpts from these statements to create a picture of nurses and administrators who were indifferent to "earlier incidents" involving hazards associated with the Resident's hand roll.

Id.

We disagree with Lutheran's suggestion that the ALJ cherry-picked or misrepresented the record in order to support a plainly erroneous result. In our view, the ALJ Decision shows that the ALJ carefully weighed the evidence and drew reasonable conclusions from it. As Lutheran admits, the record contains a number of witness statements that support the ALJ's findings. Lutheran has not shown that the timing of those statements, or the circumstances in which they were made, undermine their reliability. The statements were all evidence upon which the ALJ was entitled to rely.

Lutheran's appeal briefs contain various other contentions that touch upon the ALJ's analysis of the compliance issue. We have considered them all but conclude that they are either meritless or would not materially affect the outcome of the appeal.

2. *The ALJ committed no error in concluding that CMS's immediate jeopardy determination was not clearly erroneous.*

The ALJ affirmed CMS's determination that Lutheran's noncompliance on February 14, 2003 placed Resident 1 in "immediate jeopardy," finding it not clearly erroneous. ALJ Decision at 14. Noting that "immediate jeopardy" is defined in the regulations to include a situation in which a facility's noncompliance has "caused, or is likely to cause, serious injury," the ALJ found that Resident 1 "unquestionably suffered serious injury as a result of the facility's noncompliance." *Id.* (emphasis added).

Lutheran contends that CMS had the evidentiary burden of proving the elements of immediate jeopardy. Lutheran Br. at 51-52. The Board has rejected this argument, finding it inconsistent with 42 C.F.R. § 498.60(c)(2), which provides, "CMS's determination as to the level of noncompliance [which includes immediate jeopardy] . . . must be upheld unless it is clearly erroneous." Daughters of Miriam Center, DAB No. 2067, at 7 (2007); Liberty Commons Nursing & Rehab Center v. Johnston, DAB No. 2031 (2006), *aff'd*, Liberty Commons Nursing and Rehab Center - Johnston v. Leavitt, 2007 WL 2088703 (4th Cir. 2007) (slip copy). In the cited cases, the Board held that section 498.60(c)(2) in effect requires the ALJ and the Board "to presume that CMS's determination of immediate jeopardy is correct unless the SNF demonstrates that the determination is clearly erroneous." Daughters of Miriam Center at 7; Liberty Commons, DAB No. 2031, at 18-19. Reviewing our Liberty Commons decision, the Fourth Circuit specifically rejected the argument, made by Lutheran here, that placing on the nursing home the burden of proving that CMS's determination of

immediate jeopardy was clearly erroneous rather than requiring the Secretary to again establish immediate jeopardy during the appeals process somehow offended the Administrative Procedure Act and due process. The court stated:

This argument ignores the relevant regulation, which explicitly sets forth the burden of proof with respect to the level of noncompliance: "CMS's determination as to the level of noncompliance . . . must be upheld unless it is clearly erroneous." See 42 C.F.R. § 498.60 (2006). In light of the clear instructions in this regulation, which the Board unquestionably followed, we construe Liberty's argument here to be either that (1) HHS lacks statutory authority to have issued this regulation, or (2) the regulation is unconstitutional. Neither is the case.

2007 WL 2088703 at *4.

The ALJ properly concluded that Lutheran had not carried its burden of proving that CMS's determination of immediate jeopardy, which the ALJ upheld, was clearly erroneous. Lutheran does not dispute that Resident 1 suffered a "serious injury" - gangrene requiring the amputation of her left middle finger - caused by the resident's wrapping an elastic band twice around the finger. However, Lutheran suggests that this serious injury was not the result of any noncompliance on its part. Lutheran Br. at 3, 52. This suggestion is entirely unfounded. As discussed, Lutheran's noncompliance was its failure to provide Resident 1 with a safe alternative to the homemade hand roll with a loose elastic strap or to ensure by other means that she did not manipulate the loose elastic strap around her fingers.¹² Resident 1's injury occurred precisely because she was able to manipulate the strap of the homemade hand roll in this way. Thus, it is reasonable to conclude that the injury would have been avoided had Lutheran complied with section 483.25(h)(1), either by providing Resident 1 with a non-hazardous hand roll or by taking other precautions to ensure that she could manipulate the homemade hand roll's

¹² According to Lutheran, it is "speculative" to claim that Resident 1 could have been given a safer hand roll. Lutheran Br. at 53. However, CMS introduced evidence that alternative, commercially produced models without loose elastic straps were available. CMS Ex. 29, ¶¶ 10-12. None of Lutheran's witnesses denied that alternatives were available, and Dr. Farrington admitted that he was "aware that there are similar or identical products sold commercially." P. Ex. 24, at 3.

loose elastic strap around her fingers. Because compliance with section 483.25(h)(1) would have removed the very condition – Resident 1's ability to manipulate the elastic strap – that resulted in Resident 1's injury, CMS's determination that Lutheran's noncompliance had "caused" the injury was not clearly erroneous, and the ALJ properly upheld that determination.¹³

3. *Lutheran has alleged no basis to disturb the ALJ's conclusion that the CMP amount was reasonable.*

During an ALJ hearing, a SNF may contend that the amount of the CMP imposed by CMS is unreasonable. Capitol Hill Community Rehabilitation and Specialty Care Center, DAB No. 1629 (1997). In evaluating whether the amount of the CMP is reasonable, an ALJ may consider only those factors specified by the regulations, including the seriousness (scope and severity) of the noncompliance and the facility's degree of culpability. 42 C.F.R. §§ 488.438(e)(3), 488.438(f).

Here, the ALJ found that Lutheran's noncompliance was "very serious" and that its nursing staff was "culpable" given its actual, pre-accident knowledge of Resident 1's "vulnerability." ALJ Decision at 14-15. The ALJ further observed that the \$5,000 per-day CMP imposed by CMS was at the lower end of the applicable penalty range (\$3,050-\$10,000). *Id.* For these reasons, the ALJ found that the amount of the CMP – \$5,000 for the single day of immediate jeopardy – was reasonable.

Lutheran now contends:

CMS has offered no evidence that any possible noncompliance . . . is so serious under the criteria set forth in 42 C.F.R. § 488.404 and 438(f) to justify a significant CMP. Thus, even if the [Board] sustains some deficiency, Petitioner contends that it caused no "actual harm" to anyone, and that a CMP in excess of \$50 per day is unwarranted.

Lutheran Br. at 54 (emphasis added). Given that the mandatory minimum CMP for noncompliance at the immediate jeopardy level is \$3,050 per day, see 42 C.F.R. § 488.438(a)(1)(i), Lutheran's request that we reduce the per-day CMP to no more than \$50 apparently assumes that CMS's immediate jeopardy determination is

¹³ Even if Lutheran's noncompliance had not caused actual serious harm, it certainly presented the likelihood of same, given the resident's vulnerability to this type of harm.

clearly erroneous. But, as we just discussed, the ALJ properly determined that CMS's immediate jeopardy determination was not clearly erroneous. Thus, the remaining issue regarding the penalty amount is whether a \$5,000 per day CMP is unreasonable for this immediate jeopardy-level noncompliance. Lutheran does not contend that \$5,000 per day is unreasonable based on the relevant regulatory factors, nor does it even mention the ALJ's culpability finding. Furthermore, in light of our discussion in the previous section, we reject Lutheran's assertion that the noncompliance did not cause actual harm. For these reasons, we find no basis for disturbing the ALJ's conclusion that the amount of the CMP was reasonable.

4. *The ALJ committed no error in requiring written direct testimony or in conducting the in-person hearing.*

Lutheran asserts that this case "poses significant questions about the ad hoc procedures some judges now are using in nursing home cases, and whether those procedures effectively vitiate a petitioner's right to a full and fair hearing to contest what are believed to be inaccurate or inappropriate charges." Lutheran Br. at 2. This assertion refers to the practice by some ALJs of requiring a party to submit the direct testimony of its witnesses in writing, while giving each party the opportunity to cross-examine the opposing party's witnesses in person. Lutheran contends that "[w]hile this procedure may or may not have some theoretical merit, the effect of so limiting direct testimony may be effectively to convert the hearing into a summary proceeding." *Id.* at 3. Lutheran further contends:

Written testimony can be useful where a witness offers evidence on complex or technical medical or financial issues But written testimony is not well suited for most fact witnesses (it typically is drafted by counsel (on both sides) and can be (and is) crafted to distort the proceeding.) Moreover, subjecting fact witnesses – typically nurses and surveyors – only to cross-examination prepared in advance by counsel likewise distorts the record. And CMS can – and, as this record shows, does – distort the record by simply deciding not to cross-examine a petitioner's fact or expert witnesses. When CMS makes such a tactical decision, Judge Hughes does not permit the witness to appear at all, thereby depriving the petitioner of the opportunity to articulate its defense through the mouths of its employees and representatives; as a result of this (common) CMS tactic, petitioner's counsel know that they often must try to make their

case via cross-examination of surveyors, which is cumbersome at best; tries the patience of judges; and often is not particularly enlightening.

Id. at 3 n.2 (emphasis added). Lutheran suggests that CMS's decision not to cross-examine certain of Lutheran's fact witnesses was problematic because, says Lutheran, the outcome "turn[ed] largely on criticisms of . . . employees' motivations and credibility that have been drawn primarily from the written record, and that are, at best, unwarranted." Id. at 3. In other words, Lutheran suggests that the ALJ's decision is flawed to the extent that it is based on credibility evaluations of Lutheran witnesses whom CMS chose not to cross-examine and thus did not testify before the ALJ in person.

Lutheran further complains that the ALJ "continually interrupted [its] examination of CMS['s] witnesses with comments and observations about Petitioner's evidence – and the ultimate factual issues – *before any of Petitioner's witnesses even testified.*" Lutheran Br. at 29 n.17 (italics added). In addition, Lutheran notes that, at one point in the hearing, the ALJ commented: "'why are we spending all this time questioning about it when I'm going to look at documents and I'm going to decide who knew what when.'" Id. (quoting Tr. at 62). Lutheran asserts that its attorney "continually protested Judge Hughes' statements, and continually indicated that contrary testimony by Petitioner's witnesses would be forthcoming." Id. But no such testimony occurred, says Lutheran, because CMS did not cross-examine any of the facility's witnesses (except Nurse Miller).

In light of these criticisms, Lutheran urges us "to review the use of written direct testimony in general and to articulate strict limits on the use of the procedure in nursing home appeals." Lutheran Br. at 3 n.2. In addition, Lutheran asks us to remand this case to the ALJ "for a full and fair hearing of all the evidence, including complete witness testimony," in the event we decide not to reverse the ALJ's findings and conclusions. Id. at 54.

We find no evidence that Lutheran was deprived of a fair hearing by the ALJ's use of written direct testimony or any of the other procedures (or the ALJ's conduct) that Lutheran challenges. The Board has previously reviewed and approved the use of written direct testimony, so long as the right to effective cross examination is protected. See Vandalia Park, DAB No. 1940 (2004). Lutheran had the opportunity to cross-examine any of the witnesses for whom CMS submitted written direct examination and, in fact, chose to cross-examine two of those witnesses. We find

no basis for Lutheran's assertion that requiring the parties to submit direct testimony in writing before the hearing prevented it from presenting its case "through the mouth of its employees and representatives." Lutheran was free to present its case through written direct testimony of any competent employee or other witness and, in fact, submitted such testimony for seven witnesses. Furthermore, the ALJ's Initial Pre-hearing Order states:

A party must exchange as a proposed exhibit the complete written direct testimony of any proposed witness. Generally, I will accept that witness' written direct testimony as a statement in lieu of in-person testimony. [emphasis added]

The word "generally," indicates to us that the order does not foreclose a party's moving for permission to present a particular witness's direct testimony in-person if the party feels that is necessary to assure a fair hearing. We find no evidence that Lutheran moved for leave to present any direct testimony in-person. The ALJ's order also does not preclude rebuttal testimony, which presumably could be given by any witness qualified to present such testimony, without regard to whether the witness has or has not given direct testimony in writing. There is no evidence that Lutheran sought to present rebuttal witnesses. Even now, in this appeal, Lutheran has failed to specify what witnesses it would have called to testify in person had it been given the chance to do so and how their testimony might have changed the outcome.

We also reject Lutheran's vague criticism of the manner in which the ALJ conducted the hearing. Although the ALJ at times commented on the evidence, none of her commentary indicated that she had prejudged the case or was unreceptive to the submission of rebuttal testimony. We see no indication that the ALJ did anything to impair Lutheran's presentation of evidence. Moreover, Lutheran has not identified any instance in which its attorney made a record objection to the ALJ's comments or behavior.¹⁴ As for the ALJ's comment that she was going to "look at documents" to decide "who knew what when," it was made during the examination of Dr. Strasser, who was not a fact witness. In our view, the comment correctly acknowledged that undisputed

¹⁴ The hearing transcript includes a couple of terse exchanges between Lutheran's counsel and the ALJ. See, e.g., Tr. at 64-65. However, counsel did not register an objection for the record based on any of these exchanges.

documentary evidence was the source of many or most of the relevant historical facts, including the sequence of events. We do not interpret the ALJ's comment as indicating an intention to ignore pertinent testimonial evidence, and Lutheran has not pointed to any instance in which the ALJ failed to consider or weigh testimonial evidence that would have materially affected the outcome of this case.¹⁵

Finally, we reject Lutheran's implicit assertion that the ALJ Decision was based primarily on flawed or unsupported credibility findings. As discussed earlier, the ALJ gave valid, sufficient reasons for the weight she assigned to particular pieces of evidence, including the testimony of witnesses. Moreover, Lutheran has failed to demonstrate that a particular credibility finding would, if found to be unwarranted, affect the case's outcome.

¹⁵ In fact, the ALJ admitted and considered all of the "Prefiled Direct Testimony" submitted by Lutheran (Lutheran Exhibits 21-22, 24-27) even though, contrary to an instruction in the Initial Pre-Hearing Order, none of that "testimony" was made under oath or penalty of perjury (or even purports to tell the truth), except for Ann Miller's testimony, which was incorporated by reference in the oath she took when testifying in person. Tr. 133. (The ALJ also admitted and considered the Prefiled Direct Testimony of Trudy Fry, initially submitted by Lutheran and then withdrawn but ultimately submitted by CMS as a Statement In Lieu of Testimony. See CMS Ex. 30. CMS submitted its witnesses' written direct testimony as declarations under penalty of perjury.) Lutheran had the signatures on the written testimony of its witnesses notarized after CMS moved to strike the testimony for noncompliance with the ALJ's Initial Pre-hearing Order. However, notarization of signatures does not constitute an oath that the testimony is true or certification that the testimony is made under penalty of perjury. The record does not reveal why the ALJ denied CMS's motion to strike (which was also based on late filing of the testimony), and that issue has not been raised on appeal. Accordingly, we have considered all testimony admitted to the record as if it were sworn or certified, including testimony that was not actually submitted in that form. Nonetheless, we find it curious that on appeal Lutheran engages in lengthy criticism of the process below and thinly veiled insinuations of unfair treatment by the ALJ, when under her Initial Pre-hearing Order, the ALJ could have refused to consider the unsworn, uncertified Prefiled Direct Testimony but did not do so.

Conclusion

For the reasons discussed, we affirm the ALJ Decision in its entirety.

_____/s/
Leslie A. Sussan

_____/s/
Constance B. Tobias

_____/s/
Sheila Ann Hegy
Presiding Board Member