Department of Health and Human Services

DEPARTMENTAL APPEALS BOARD

Appellate Division

In the Case of:	DATE: November 26, 2008
The Windsor Place,	
Petitioner,	Civil Remedies CR1775 App. Div. Docket No. A-08-110
- v. -	Decision No. 2209
Centers for Medicare & Medicaid Services.	

FINAL DECISION AND PARTIAL REMAND ON REVIEW OF ADMINISTRATIVE LAW JUDGE DECISION

The Windsor Place (Windsor, Petitioner) requested review of the decision of Administrative Law Judge (ALJ) Keith W. Sickendick in The Windsor Place, DAB CR1775 (2008) (ALJ Decision). The ALJ sustained the determination of the Centers for Medicare & Medicaid Services (CMS) that Windsor was not in substantial compliance with five requirements for participation in the Medicare and Medicaid programs and imposed the following remedies: a civil money penalty (CMP) of $350 per day effective September 24, 2004 through October 27, 2004, and $150 per day effective October 28, 2004 through December 21, 2004; the denial of payment for new admissions (DPNA) effective October 27, 2004 through December 21, 2004; and withdrawal of Windsor's authority to conduct a Nurse Aide Training and Competency Evaluation Program effective October 12, 2004 through October 11, 2006.

On appeal, Windsor disputed the ALJ's noncompliance determination for each of the five participation requirements sustained by the ALJ and moved to introduce new evidence on its compliance with one of those requirements. For the reasons discussed below, we remand the appeal of that issue to the ALJ to consider the new evidence and the amount of the CMP imposed with respect to that issue. We sustain the remainder of the ALJ Decision.

Applicable Legal Authority

The applicable legal authority is set out at pages 8-11 of the ALJ Decision and referenced as relevant in our analysis below.

Standard of Review

Our standard of review on a disputed conclusion of law is whether the ALJ decision is erroneous. 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. Guidelines - Appellate Review of Decisions of Administrative Law Judges Affecting A Provider's Participation In the Medicare and Medicaid Programs, http://www.hhs.gov/dab/guidelines/prov.html, (Guidelines); Batavia Nursing and Convalescent Inn, DAB No. 1911, at 7 (2004), aff'd, Batavia Nursing & Convalescent Ctr. v. Thompson, 143 F. App'x 664 (6th Cir. 2005); Hillman Rehabilitation Center, DAB No. 1611, at 6 (1997), aff'd, Hillman Rehabilitation Ctr. v. U.S. Dep't of Health and Human Servs., No. 98-3789 (GEB) at 21-38 (D.N.J. May 13, 1999).

Case Background[1]

Windsor is a nursing facility in Columbus, Mississippi that is authorized to participate in the Medicare and Medicaid programs. The Mississippi State Department of Health (the State agency) completed surveys of Windsor on September 24, 2004, October 22 and 28, 2004, and December 21, 2004. Based on the survey ending September 24, 2004, CMS determined that as of September 24, Windsor was not in substantial compliance with the following requirements for participation at Part 483 of 42 C.F.R., for which CMS designates "tag" numbers in its State Operations Manual (SOM):

- 42 C.F.R. § 483.10(f)(1) (Tag F165), that a facility protect and promote resident's rights to voice grievances without discrimination or reprisal;

- 483.20(b)(2)(ii) (Tag F274), that a facility complete a comprehensive assessment of a resident within 14 calendar days "after the facility determines, or should have determined, that there

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[1] The following background information is drawn from the ALJ Decision and the record before the ALJ and summarized here for the convenience of the reader, but should not be treated as new findings.

has been a significant change in the resident's physical or mental condition";

- 483.25(a)(3) (Tag F312), that a resident who is unable to carry out activities of daily living receives the necessary services to maintain good nutrition, grooming, and personal and oral hygiene; and

- 483.25(c) (Tag F314), that a resident who enters the facility without pressure sores does not develop pressure sores unless the individual's clinical condition demonstrates that they were unavoidable and that a resident having pressure sores receives necessary treatment and services to promote healing, prevent infection and prevent new sores from developing.

CMS Exs. 1, 2.

Based on the survey ending October 22, 2004, CMS determined that Windsor's noncompliance with 42 C.F.R. § 483.10(f)(1) (Tag F165) continued at an increased level of scope and severity. CMS Exs. 3, 6. The ALJ held that CMS failed to make a prima facie showing that Windsor was not in substantial compliance with this requirement with respect to this or the prior survey, and CMS did not appeal that determination. ALJ Decision at 6, 16, 17-18.

Based on the survey ending October 28, 2004, CMS determined that Windsor had remedied the other deficiencies found during the September 24 survey as of October 27, and that as of October 28, Windsor was not in substantial compliance with the following additional requirements:

- 42 C.F.R. § 483.10(n) (Tag F176), that an individual resident may self-administer drugs if the interdisciplinary team has determined that this practice is safe;

- 42 C.F.R. § 483.13(a) (Tag F221), that the resident has the right to be free from any physical or chemical restraints imposed for purposes of discipline or convenience, and not required to treat the resident's medical symptoms; and

- 42 C.F.R. § 483.35(h)(2) (Tag F371), that a facility store, prepare, distribute and serve food under sanitary conditions.[2]

CMS Exs. 21, 57; P. Ex. 60A. The ALJ held that Windsor was in substantial compliance with section 483.35(h)(2) (Tag F371), and CMS did not appeal that determination. ALJ Decision at 34-35.

The survey of December 22, 2004 determined that Windsor had remedied the deficiencies found during the October 28 survey as of December 21, 2004. CMS Ex. 67.

CMS imposed a CMP of $350 per day effective September 24 through October 21, 2004, $550 per day effective October 22 through October 27, 2004, and $150 per day effective October 28 through December 21, 2004. Because the ALJ reversed the deficiency determined in the October 22, 2004 to have increased in scope and severity, he reduced the CMP effective October 22 through 27, 2004 from $550 to $350 per day. Although Windsor disputes CMS's and the ALJ's determinations as to the duration of the deficiencies, it does not specifically challenge the amount of the CMP. CMS also imposed, and the ALJ sustained, a DPNA effective October 27, 2004 through December 21, 2004, and withdrawal of Windsor's authority to conduct a Nurse Aide Training and Competency Evaluation Program (NATCEP) effective October 12, 2004 through October 11, 2006.

We first address Windsor's appeal of the deficiencies that concern the development of pressure ulcers by a specific resident (Resident 14). We then address the remaining deficiency findings upheld by the ALJ in the order in which they are listed above.

Discussion

I. We sustain the ALJ's deficiency determinations for Tags F176, F274, F312, and F314.

A. 483.20(b)(2)(ii) (Tag F274)

i. Significant change

Section 483.20 requires that a facility "must conduct initially and periodically a comprehensive, accurate, standardized, reproducible assessment of each resident's functional capacity." Generally, the facility must conduct that assessment within 14

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[2] The current citation for this requirement is section 483.25(i)(2). The Tag number remains F371.

calendar days after a resident's admission, at least annually thereafter, and, as relevant here,

> [w]ithin 14 calendar days after the facility determines, or should have determined, that there has been a significant change in the resident's physical or mental condition. (For purposes of this section, a "significant change" means a major decline or improvement in the resident's status that will not normally resolve itself without further intervention by staff or by implementing standard disease-related clinical interventions, that has an impact on more than one area of the resident's health status, and requires interdisciplinary review or revision of the care plan, or both.)

42 C.F.R. § 483.20(b)(2)(ii).

The following facts found by the ALJ are undisputed. Resident 14 had resided at Windsor since 2002 and had diagnoses including Alzheimer's disease, dementia other than Alzheimer's, organic brain syndrome, a seizure disorder, a history of cardiovascular accident (CVA), dysphagia (difficulty swallowing), and aphasia (inability to speak). She was totally dependent upon staff for activities of daily living and mobility and was fed by feeding tube. She was at risk for pressure ulcers due to impaired bed mobility and incontinence. Resident 14 had no pressure ulcers noted at the time that Windsor completed an annual comprehensive assessment on February 3, 2004. Blistered areas were noted on her buttocks on February 12, 2004, and on February 17, she was noted to have two Stage II pressure ulcers, one on each buttock. On February 27, 2004, she had two pressure ulcers on her left heel; on March 1, both left heel ulcers were noted to be Stage II. By March 8, 2004, the Stage II ulcer on the resident's left buttock had worsened to Stage III and was one centimeter by one centimeter and 0.8 centimeters deep with moderate drainage. By March 15, 2004, the Stage II ulcer on the right buttock had worsened to Stage IV and was six by five centimeters and six centimeters deep with tunneling. ALJ Decision at 19, 24, citing P. Ex. 23, at 1, 2, 24, 58, 59, 71-73. No new assessment of Resident 14 was undertaken from the beginning of the development of pressure ulcers until a significant change assessment was completed on April 29, 2004. Id. at 18, citing CMS Ex. 2, at 7-9 (Sept. 24 2004 Statement of Deficiencies (SOD)); see also P.

Request for Review (RR) at 10.[3] Windsor did not identify the significant change that prompted that assessment.

The ALJ analyzed whether a significant change requiring a new comprehensive assessment occurred earlier than April 29, 2004 based on his breakdown of the elements by which the regulation describes what constitutes a "significant change," as follows:

> 1. A major decline or major improvement in the resident's status;
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> 2. That will not normally resolve itself without
> - further intervention by staff or
> - by implementing standard disease-related clinical interventions;
>
> 3. That has an impact on more than one area of the resident's health status, and;
>
> 4. That requires interdisciplinary review or revision of the care plan, or both.

ALJ Decision at 20-21, citing 42 C.F.R. § 483.20(b)(2)(ii).[4]

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[3] We use this abbreviation to distinguish Windsor's request for review of the ALJ Decision from its brief before the ALJ (P. Br.), which we also cite.

[4] Both parties framed their arguments on appeal around this analysis of the regulatory language. We conclude, for the reasons explained below, that the ALJ's findings were supported by substantial evidence and that he made no error in concluding that all four of the elements which he set out were present in this case. Our decision does not imply that this analysis is the only possible view of the regulatory definition. An alternative reading might be that the regulation requires (1) a "major decline or major improvement" that (2)(A) "will not normally resolve itself" by itself or by standard clinical interventions OR (2)(B) impacts "more than one area of the resident's health status" AND requires interdisciplinary care planning OR (2)(C) both (2)(A) and (2)(B) are present. The difference is that only two elements are required, i.e. the major change plus one of the three other factors. The factors are that the change be refractory to ordinary care measures or cut across multiple health needs so that interdisciplinary coordination is essential or both. Since we agree with the ALJ that all of the factors were present, we need not determine the correct reading of the regulation here.

The ALJ rejected Windsor's contention that the regulation required showing a change in more than one area of the resident's health status. He reasoned instead that the first element required only a single change "which can be either a major decline or a major improvement in the resident's status" and concluded that the resident's development of pressure sores in February 2004 where none existed before was a major decline. ALJ Decision at 21.

Based on this construction of the regulation, the ALJ concluded that the development of pressure sores by a resident who had previously not had any and the rapid worsening of those sores constituted a major decline in the resident's health status, thus meeting the first element. Id. The ALJ pointed in this regard to CMS's guidance for this deficiency tag in the SOM, which specifically identifies "[e]mergence of a pressure ulcer at Stage II or higher, when no ulcers were previously present at Stage II or higher" as a significant change requiring a new comprehensive assessment. Id. at 20, citing P. Ex. 35, at 2 (SOM, App. PP, Tag F274).

He found that the second element was present because Windsor failed to present evidence that the sores would resolve on their own or by routine clinical treatment, especially given that they in fact worsened significantly. ALJ Decision at 21.

He further found that this major decline impacted two or more areas of the resident's health status as required by element three. Id. at 21-22. He reasoned that "impact" on multiple areas of health status did not imply a requirement that major changes have actually occurred in multiple areas. Id. He concluded that the worsening pressure sores did impact more than the obvious area of skin integrity. Specifically, he found that in addition to the obvious impact on Resident 14's skin integrity, such severe pressure sores can be expected to affect a resident's nutritional needs, to create potential for pain,[5] and to require likely adjustments in other treatments or assessment of other areas such as sleep and emotional well-being. Id. He further found that Windsor's own documentation demonstrated an awareness that "the development of pressure sores impacted more

[5] The ALJ disagreed with Windsor that nurses notes observing no distress during the relevant time period undercut the likelihood that the ulcers caused pain on the grounds that the resident's ability to communicate and be understood was limited, and that the nurses notes indicate that, at least on May 10, 2004, the resident's daughter expressed concern about signs that the resident was indeed suffering pain. ALJ Decision at 21, n.13, citing P. Ex. 23, at 105, 310.

than one area of the resident's health, including her skin integrity and nutritional needs." Id. at 22, citing P. Ex. 23, at 271, 274-75, 479 (records showing, inter alia, that Windsor consulted its dietician and dietary manager in February 2004 for nutritional recommendations relative to addressing the resident's pressure sores, and nevertheless failed to conduct a comprehensive assessment).

On the fourth element, the ALJ concluded that Resident 14's situation was indisputably serious and required "the interdisciplinary team to determine the cause, including all contributing factors, and then develop interventions to address the prevention of additional ulcers and the treatment of existing ulcers." ALJ Decision at 22.

Ultimately, the ALJ concluded that Resident 14's development of worsening pressure sores in February and March met all of the regulatory elements to constitute a significant change in the resident's physical condition requiring Windsor to conduct a comprehensive assessment well before April 29, 2004.

On appeal, Windsor disputes the ALJ's finding that the development of pressure ulcers had an impact on more than one area of the resident's health status. Windsor also argues that the ALJ's finding is inconsistent with the SOM which, according to Windsor, advises a significant change reassessment when there are two or more listed "areas of decline," only one of which was present here. SOM, App. PP, at F274. Windsor also argues that the ALJ's findings of impact on more than one health area were not supported by substantial evidence. Windsor argues that the pressure ulcers should not be considered to have impacted the resident's nutritional status in the absence of any substantial weight loss or gain. Windsor also argues that the ALJ's finding of pain as an impact relied on the relative's expression of concern on May 29, 2004 *after* Windsor had completed a significant change reassessment on April 29.

We do not agree with Windsor that the development of pressure ulcers of such severity as these had no impact on any areas of the resident's health status other than her skin integrity. As the ALJ pointed out, Windsor provided "no evidence that the development of the pressure sores did not impact multiple areas of the resident's health status." ALJ Decision at 22. On the contrary, the ALJ found, "the nursing notes and dietary progress notes presented by Petitioner clearly show that Petitioner's staff recognized that the development of pressure sores impacted more than one area of the resident's health, including her skin integrity and nutritional needs. Id. at 22, citing P. Ex. 23, at 271, 274-75, 479. In addition, we agree

with the ALJ that the fact that the worsening ulcers triggered a consultation with Windsor's dietary staff evidences Windsor's awareness that such pressure sores implicate impact on nutritional needs.[6]

The ALJ's finding that the ulcers likely caused the resident pain is also reasonable, given the descriptions of her wounds and of Stage III and IV pressure ulcers generally. By March 15, 2004, when one of the two pressure ulcers on the resident's buttocks was documented at Stage IV, it was six by five centimeters and six centimeters deep with tunneling. P. Ex. 23, at 2. The SOM guidance on pressure ulcers defines a Stage IV pressure ulcer as "[f]ull thickness skin loss with extensive destruction, tissue necrosis, or damage to muscle, bone, or supporting structures (e.g., tendon, joint capsule)." App. PP, Tag F314. By March 8, the pressure ulcer on the other buttock had progressed to Stage III, or "[f]ull thickness skin loss involving damage to, or necrosis of, subcutaneous tissue that may extend down to, but not through, underlying fascia. The ulcer presents clinically as a deep crater with or without undermining of adjacent tissue." Id.; P. Ex. 23, at 1. (The obvious severity of the pressure ulcers that afflicted Resident 14 reinforces the correctness of the finding that the resident had experienced a major decline in her health status.)

Furthermore, the ALJ provided adequate reasons for discounting nurses notes indicating that the resident did not appear to be in distress as proof of the absence of pain. The relevance of the note documenting the relative's observations of signs of discomfort is not as proof that the resident was in pain on the specific date noted but as evidence that the resident might well be experiencing the likely pain of the pressure ulcers even when the nurses did not themselves note distress.

We are not persuaded by Windsor's contention that documentation of only one of ten "areas of decline" listed in the SOM for tag F274 (i.e., the "[e]mergence of a pressure ulcer at Stage II or higher, when no ulcers were previously present at Stage II or higher") somehow bars a finding that the pressure ulcers afflicting this resident had an impact on more than one area of

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[6] This awareness of the connection between pressure sores and nutrition is consistent with discussions in the SOM about the need for interdisciplinary development of nutritional goals for residents with pressure sores to consider adequacy of protein intake (regarding tag F314) and about the "hypermetabolic state" produced by pressure sores and other wounds in order to meet energy and protein needs to promote healing (regarding tag F325 on nutrition).

her health status. The preamble to the rulemaking for section 483.20(b)(2)(ii) addressing when a "significant change" assessment is required indicates that the ten "areas of decline" are not an exclusive list of the significant changes in a resident's condition to which the facility must respond by conducting a comprehensive assessment within 14 days. The preamble does state that "[a] significant change reassessment is probably indicated if decline or improvement is consistently noted in two or more of areas of decline" and lists ten "areas of decline," one of which is "[e]mergence of an unplanned weight loss problem (5 percent change in 30 days or 10 percent change in 180 days)." 62 Fed. Reg. 67,196-97 (Dec. 23, 1997). Yet, immediately preceding this language, the preamble indicates that a five-pound weight loss that does not resolve after two weeks could, in certain circumstances and in the presence of other symptoms, trigger a significant change assessment, without addressing whether the five-pound loss constitutes a 5% change in the resident's weight or specifically requiring the presence of the other listed "areas of decline."[7] The most reasonable understanding of the discussion in context is that the presence of two of the listed areas would generally in itself establish a significant change, but that another major improvement or decline that in itself meets the other regulatory elements (such as not being resolved by ordinary care) may also constitute a significant change. Thus, we conclude that the fact that Resident 14 realized "no substantial weight loss" until she lost eleven pounds during May 2004 does not preclude the ALJ's conclusion that the pressure sores impacted more than one area of her health status. P. RR at 11, citing P. Br. at 24.

Windsor did not dispute the ALJ's finding that it presented no evidence suggesting that the resident's ulcers, which Windsor did not dispute were worsening during February and March 2004, would resolve without staff intervention or by application of some

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[7] The preamble states:

> An example of a condition that will normally resolve itself without intervention by staff is a resident's 5 pound weight loss, which would trigger a significant change reassessment under the old definition. However, if a resident had the flu and experienced nausea and diarrhea for a week, a 5 pound weight loss may be an expected outcome. If the resident did not become dehydrated and started to regain weight after the symptoms subsided, a comprehensive assessment would not be required. Generally, if the condition has not resolved at the end of approximately 2 weeks, staff should begin a comprehensive assessment.

standard disease-related clinical interventions. ALJ Decision at 21. Windsor asserts that "R14's ulcers were treated and stabilized," but this statement applies only to the two pressure ulcers on the resident's heel, which were reported to have healed on April 5 and 12. P. RR at 11; P. Ex. 23, at 58-59. Windsor's own "decubiti reports" indicate that the buttock ulcers, though substantially smaller, were still present and described as still at Stages III and IV as of May 18, 2004, the date of the last entries. P. Ex. 23, at 1-2.

We thus find no error in the ALJ's conclusion that the Windsor was not in substantial compliance with the regulation. ALJ Decision at 16.

ii. Date of substantial compliance

Windsor also argues that it abated any noncompliance with section 483.20(b)(2)(ii) by October 21, 2004 and not October 28, as CMS determined. Windsor points to the October 22, 2004 survey, which cited it only for continued noncompliance with 42 C.F.R. § 483.10(f)(1) at an increased level of scope and severity, as proof that it had corrected any prior deficiencies. Windsor's position is that the October 22, 2004 survey was effectively a revisit survey with respect to the deficiencies identified during the survey ending September 24, 2004, rather than a more limited complaint survey focused on investigating a specific issue. Windsor quotes in support of this view statements in CMS's brief that the October 22, 2004 survey was performed by "'virtually the same survey team members'" as the September 24 survey and found "only 'one uncorrected area of noncompliance from the September 2004 survey.'" P. RR at 12, quoting CMS Br. at 2. Windsor also points to a statement in the ALJ Decision that Windsor "was in violation of 42 C.F.R. §§ 483.20(b)(2)(ii), 483.25(a)(3), and/or 483.25(c) from September 24, 2004 through October 21, 2004" as showing that the ALJ agreed with its argument.[8] ALJ Decision at 36.

The record does not support Windsor's argument. CMS's letter of December 2, 2004 reporting the deficiency found in the October 22, 2004 survey plainly described as the visit as "another complaint investigation survey." CMS Ex. 6, at 1. As a matter of logic, moreover, we note that CMS's action of increasing the CMP imposed on Windsor in response to the finding of a deficiency

[8] Windsor makes these same arguments with respect to the noncompliance periods for the two other deficiency findings from the September 24, 2004 survey that the ALJ sustained. Our discussion here applies to those two deficiency findings as well.

in the October 22 survey would be unlikely had that survey found that all the other deficiencies identified in the September 24 survey had been corrected. Furthermore, the determination of the October 28, 2004 survey that the deficiencies cited in the prior complaint surveys had been corrected would have been pointless had the deficiencies from the September 24 survey already been found to have been corrected as a result of the October 22 survey. As far as the ALJ statement that Windsor quotes, the decision elsewhere throughout its analysis and findings makes clear that the ALJ determined that Windsor was in violation of the regulations through October 27, 2004. ALJ Decision at 7, 15-16, 36-37. We conclude that the use in one statement of October 21 instead of October 27 was a clerical error.

Windsor's argument is also inconsistent with its own Plan of Correction (POC) for this deficiency finding, which set a completion date of October 25, 2004 for the measures that Windsor committed to take in response to the survey findings. P. Ex. 29, at 19. Windsor does not explain how it could have come into substantial compliance earlier than this date, and does not address when or how it actually completed the POC measures. The Board "has long rejected as contrary to the goals of the program the notions underlying" the argument that a facility "can belatedly claim to have achieved substantial compliance at a date earlier than it even alleged [in its POC] that it had done so or that CMS must prove continuing noncompliance on each day for which remedies are imposed." Cal Turner Extended Care Pavilion, DAB No. 2030, at 18 (2006). Under section 488.454(a), "alternative remedies" such as per-day CMPs continue to accrue until "[t]he facility has achieved substantial compliance, as determined by CMS or the State based upon a revisit or after an examination of credible written evidence that it can verify without an on-site visit." Windsor, as explained, has not shown that CMS determined it to be in substantial compliance prior to October 27. CMS Ex. 57. The facility has the burden of proving any claim that it achieved substantial compliance on a date earlier than that determined by CMS. Kenton Healthcare, LLC, DAB No. 2186, at 24-25 (2008). Windsor has not shown any basis to find that it achieved substantial compliance any earlier than CMS determined.

Based on this analysis, we sustain the ALJ's challenged Findings of Fact 6 through 11 and Conclusions of Law 3 and 5.

B. 42 C.F.R. § 483.25)(c) (Tag F314)

This provision on pressures ulcers[9] is part of the general requirement at section 483.25 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." 42 C.F.R. § 483.25. The relevant subsection states:

> (c) Pressure sores. Based on the comprehensive assessment of a resident, the facility must ensure that–
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> (1) A resident who enters the facility without pressure sores does not develop pressure sores unless the individual's clinical condition demonstrates that they were unavoidable; and
>
> (2) A resident having pressure sores receives necessary treatment and services to promote healing, prevent infection and prevent new sores from developing.

The Board has held that this regulation imposes a duty on facilities to "go beyond merely what seems reasonable to, instead, always furnish what is necessary to prevent new sores unless clinically unavoidable, and to treat existing ones as needed." Woodland Village Nursing Center, DAB No. 2172, at 13 (2008), citing Koester Pavilion, DAB No. 1750, at 32 (2000).

The ALJ recounted the course of the development of pressure ulcers by Resident 14, who was known to be at risk for pressure ulcers due to impaired bed mobility and incontinence but had no pressure ulcers at the time that Windsor completed an annual comprehensive assessment on February 3, 2004. The ALJ then found that, once Resident 14's ulcers developed, the facility did take steps to treat them such as consulting the resident's physician and registered dietician and implementing and monitoring the interventions they ordered, and that the ulcers improved by May

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[9] "Although the regulatory language refers to pressure sores, the nomenclature widely accepted presently refers to pressure ulcers, and the guidance provided in this document will refer to pressure ulcers." SOM, App. PP, at F314. In this decision, the two terms are interchangeable.

18, 2004.[10] ALJ Decision at 24-25, citing P. Exs. 23, 72. Neither party disputes these findings.

The ALJ also found, however, that during January and February 2004, prior to the development of the pressure ulcers, Windsor did not follow its own care plan measures to prevent the development of ulcers, despite having previously assessed Resident 14 to be at risk for pressure sores and having developed a care plan to prevent pressure sores. The ALJ specifically found that Windsor --

> offered no records or other evidence to show Resident 14 was being turned as planned, that she was being checked for incontinence as planned, that she was being assessed by a nurse as planned, or that lotion was being applied, all as planned for the prevention of ulcers from the time of her admission. Following its plan of care for pressure sores may have been all the more important given that the resident had an indwelling catheter that leaked and her health was compromised by the UTI [urinary tract infection].

ALJ Decision at 25.

Windsor provides no reason to reverse the ALJ's finding, because almost all of the records it cites of measures it took related to pressure ulcers (pressure relieving devices, whirlpool baths, good skin care, nutritional supplements, routine turning and positioning) apply to the period ***after*** the resident developed blistered areas and then pressure ulcers several days later. P. Reply at 5-6, citing P. Ex. 23, at 271-85, 287-89, 292-95, 471, 479-81. Indeed, the "matrix of evidence" that Windsor provided to the ALJ summarizing the care given to Resident 14 for pressure sores spans only the period of February 14, 2004 to April 12, 2004. P. Br. at 28. Windsor cites no evidence that it took preventative measures prior to the resident's development of blisters and then pressure ulcers beginning about February 12, 2004, despite the fact that, as Windsor acknowledges, the resident was incontinent, immobile, and at risk for pressure ulcers. ALJ Decision at 25; P. RR at 14. Windsor failed to support its assertion that it "provided **more** than routine preventative care and took **all** possible measures to prevent and

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[10] As noted above, the Stages III and IV pressure ulcers on the resident's buttocks were substantially smaller but still present as of May 18, 2004, the last entry date in the decubiti reports. On May 20, the resident was discharged to a different facility. P. Ex. 72, at 40.

treat" the resident's pressure sores. P. Reply at 5 (emphasis in original).

As such, Windsor's additional argument that the pressure ulcers "were simply unavoidable" is unavailing. P. Reply at 6. The overarching requirement of section 483.25 that a facility provide "necessary care and services" to attain or maintain the highest practicable physical well-being places a heavy burden on Windsor to establish that the development of pressure sores was unavoidable in this dependent, at-risk resident. That burden is not met where, as here, the facility cannot show that it took appropriate steps to prevent their development. "Clinically unavoidable" means not just that pressure ulcers were unsurprising given the clinical condition of the resident, but that they could not be prevented even though appropriate preventive measures were taken in light of the clinical risks. Thus, the Board has held that "a pressure sore can be considered unavoidable only if routine preventive care is provided." Harmony Court, DAB No. 1968, at 11 (2005), aff'd, Harmony Court v. Leavitt, 188 F. App'x 438 (6th Cir. 2006), citing Livingston Care Center, DAB No. 1871, at 11, n.4 (2003), aff'd, Livingston Care Ctr. v. U.S. Dep't of Health & Human Servs., 388 F.3d 168 (6th Cir. 2004), citing SOM, App. PP.

Windsor sought to rely on nurses notes recording that a physician told the resident's daughter on February 23, 2004 that even 24-hour-a-day care could not guarantee that the resident would not experience skin breakdown given that the natural process of aging, late effects of old CVA, advanced dementia and her state of immobility. See ALJ Decision at 25-26 and record citations therein. The ALJ gave that statement little weight, however, because Windsor did not present the physician as a witness, precluding any opportunity to explore the basis for the reported physician's opinions made in a significantly different context than at a hearing under oath. Windsor also pointed on appeal to another recorded note of a physician's opinion "that a hospital could do nothing more for R14 than [the care] Windsor was providing." P. RR at 14-15, citing P. Ex. 23, at 206. This statement was made after the resident had developed four pressure ulcers, so the ALJ could reasonably read it as referring to the care being provided to treat the ulcers. There is no indication that this recorded opinion in any way addressed the care that Windsor had provided (or had failed to provide) *before* the pressure sores developed. The Board generally defers to an ALJ's determination of the weight to be attributed to the evidence before him. Edgemont Healthcare, DAB No. 2202, at 10 (2008); Pacific Regency Arvin, DAB No. 1823, at 22 (2002). Windsor has not provided any persuasive reason to disturb ALJ's decision to discount the physician's statements recorded in nurses notes.

We thus sustain the ALJ's challenged Findings of Fact 12 - 15 and Conclusions of Law 4 and 6. ALJ Decision at 5, 7.

C. 483.25(a)(3) (Tag F312)

The regulation requires that "[a] resident who is unable to carry out activities of daily living receives the necessary services to maintain good nutrition, grooming, and personal and oral hygiene." The ALJ sustained CMS's determination that Windsor failed to substantially comply with the regulation based on the report of the September 24, 2004 survey stating that call bells of four residents were inaccessible at specific times and dates.[11]

The ALJ concluded that the purpose of the regulation is that a facility ensure that the care needs of its residents are met, which, in the case of residents who cannot meet their own care needs, requires that there be a system by which residents can summon staff. ALJ Decision at 27. He found that Windsor did not deny that the call bells were not accessible as the surveyor observed and that Windsor presented no evidence that it had some other system in place for residents who required care to summon staff for assistance, and that Windsor therefore violated this requirement of the regulation. Id.

On appeal, Windsor asserts that it provided evidence disputing the surveyor's observations. P. RR at 16, citing P. Br. at 25-27. Windsor however cited no evidence that contradicts the specific observations and statements recorded in the SOD as to the three residents properly before us.[12]

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[11] The ALJ also determined that CMS had failed to make a prima facie showing of a violation of the regulation for a fifth resident whose call bell went unanswered for 12 minutes, as CMS presented no evidence of any applicable standard by which the ALJ could judge whether 12 minutes was too long. ALJ Decision at 26. CMS has not appealed that holding.

[12] An Informal Dispute Resolution (IDR) recommended deletion of the reference under this tag to room 213, where one of the four residents with respect to whom the ALJ concluded that Windsor was not in substantial compliance with the regulation was observed, and the Director of the State agency accepted the IDR panel's recommendation. P. Ex. 29, at 11-13, CMS Ex. 6 (letter from CMS to Windsor, Dec. 2, 2004). The regulations state that if a provider is "successful, during the informal dispute resolution process, at demonstrating that deficiencies should not

(continued...)

The SOD reports that on the morning of September 16, 2004, the resident in room 210, who had right hemiparesis, was observed with her side rails up with the call bell attached to the bed sheet above her right shoulder, and that the resident stated "I can't reach it" when she was interviewed while attempting to use the call bell. CMS Ex. 2, at 10-11. Windsor denies none of this, and does not dispute that this resident or the other residents cited in the SOD were unable to carry out activities of daily living. Instead, Windsor argues that this resident's call bell was actually attached to her right side so that she could better reach it with her left hand, because her right hemiparesis made it impossible for her to reach a call light with her right hand. P. RR at 16. Windsor cited no evidence indicating that the resident could use her left hand to operate a call bell that was located above her right shoulder as described. Absent some evidentiary support for Windsor's assertion, the ALJ could reasonably infer that an individual whose right side is immobilized by hemiparesis cannot easily reach across her body to access objects above her right shoulder.

The SOD further states that in room 302 on the morning of September 16, 2004, the call bell was seen on the floor under the head of the bed, behind the bedside table and the oxygen concentrator, and a CNA (certified nurse aid or assistant) confirmed that the call bell was out of reach of the resident who was sitting up in a wheelchair near the foot of the bed. CMS Ex. 2, at 11. The SOD further states that in room 404, shortly

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[12](...continued)
have been cited, the deficiencies are removed from the statement of deficiencies and any enforcement actions imposed solely as a result of those cited deficiencies are rescinded." 42 C.F.R. § 488.331(c). They also state that CMS's findings of noncompliance take precedence when "CMS finds that a . . . facility has not achieved substantial compliance; and . . . [t]he State finds that a . . . facility is in substantial compliance with the participation requirements." 42 C.F.R. § 488.452(a)(2). Given the absence of any statement from CMS either disavowing the State agency action described in CMS's letter or disagreeing with Windsor's assertion before the ALJ and the Board that the IDR deleted the example of this resident, we conclude that this example is not properly part of CMS's case, and amend one of the ALJ's findings of fact accordingly. That does not alter our result, as there remain findings regarding three other examples supporting the noncompliance finding. Indeed, the letter from CMS states that despite the removal of this example, the deficient practice remained as cited. P. Ex. 29, at 11-13; CMS Ex. 6.

before noon on September 14, 2004, a call bell was seen on the floor beneath the call light indicator, out of the reach of the resident, and a CNA confirmed that the call bell was out of the reach of the resident who was sitting near the door in a wheelchair. Id. Again, Windsor does not dispute these observations, but argues that room 302 was equipped with an additional call bell that the resident could have accessed using the wheelchair, and that the resident in room 404 did not need the call light near the bed because he was near the door and could have yelled for help. Windsor cited no evidence establishing that the other call bell in room 302 was accessible, or that any of these residents' rooms were sufficiently close to nurses stations that their calls for assistance would have been heard. Thus, although the ALJ did not discuss each resident individually, his observation that Windsor did not deny that the call bells were not accessible as the surveyor observed was correct.

Windsor also argues that in any event a resident's inability to access call bells does not in itself demonstrate a violation of the cited regulation. The ALJ rejected this argument because he found a "common sense relationship or nexus between the accessibility of call bells" and a facility's obligation to ensure that a resident "who, for example, cannot toilet him or herself receives assistance with toileting and associated personal care," as well as assistance in obtaining food, drink, grooming and hygiene-related services. ALJ Decision at 27. For residents who cannot meet their own care needs, he observed, there must be a system by which staff can be summoned, and Windsor presented no evidence of any other system besides its call bells for residents who required care to summon staff for assistance. Id. The ALJ found that the evidence did not show that Windsor had a system in addition to a call bell system by which residents in need of assistance with activities of daily living or in case of emergency could summon staff. Id. at 5.

We agree. While it is true that the cited provision does not specifically mention call bells, or identify any of methods a facility must use to ensure that necessary services are provided to assist with activities of daily living, the regulation does set out the required outcome, i.e. that each resident receive whatever services are needed to "maintain good nutrition, grooming, and personal and oral hygiene." 42 C.F.R. § 483.25(a)(3). Having chosen to use call bells to provide residents a way to communicate the need for assistance in one of these activities, the facility must see to it that the call bells are used in an effective manner or that it had some other effective means by which residents could summon assistance or by

which the facility could ensure that it attended to their needs. Windsor did not do that.

Given the absence of a reliable means for these residents to summon such needed assistance, Windsor's argument that CMS did not prove that the residents in question actually displayed poor nutrition, grooming, or personal or oral hygiene is not relevant. Just as we have observed that the occurrence of an accident is not a prerequisite to finding that a facility failed to provide adequate supervision and assistance devices to prevent accidents (section 483.25(h)(2)), we conclude that CMS or the State agency need not wait until a resident suffers the effects of inadequate nutrition, grooming or hygiene before citing a deficiency for failure to provide the services necessary to prevent that result. See, e.g., Clermont Nursing and Convalescent Center, DAB No. 1923, at 21-22 (2004), aff'd Clermont Nursing & Convalescent Ctr. v. Leavitt, 142 F. App'x 900 (6th Cir. 2005) (citations omitted) (an accident is not a prerequisite to a deficiency finding under section 483.25(h)(2)).

Accordingly, we modify the ALJ's Finding of Fact 16 ("[c]all bells were not accessible to four residents during the period September 14 through 16, 2004") to read as follows:

> 16. Call bells were not accessible to three residents during the period September 14 through 16, 2004.

We sustain challenged Findings of Fact 17 and 18 and Conclusions of Law 7 and 8. ALJ Decision at 5, 7.

D. 42 C.F.R. § 483.10(n) (Tag F176)

Section 483.10(n), "Self-Administration of Drugs," states that an individual resident may self-administer drugs if the interdisciplinary team has determined that this practice is safe. The ALJ determined that Windsor was not in substantial compliance with this requirement based on the assertions in the SOD for the October 28 survey that at about 5:00 p.m on October 25, a surveyor, in the presence of the medication administration nurse, observed two bottles of medications described as glaucoma eye drops on Resident 22's bedside table, but that the resident's file did not contain either a physician order for either medication or an assessment that the resident was safe to self-administer the medications. ALJ Decision at 28, citing CMS Ex. 21, at 1, and P. Ex. 46, at 1. The ALJ found that only on October 28, 2004 did Windsor assess the resident for this purpose. ALJ Decision at 29. That assessment determined that he was unable to demonstrate the ability to safely store medication in his room. Id., citing P. Ex. 51, at 3. The ALJ found that

Windsor's staff had knowledge of the prescription eye drops at least as of when the nurse was in the resident's room with the surveyor, and also that both medications were potentially harmful, based on warnings in the manufacturers' product guide of the harm that could attend their improper use or handling. ALJ Decision at 28.

On appeal, Windsor does not dispute that no interdisciplinary team determined that the resident could safely administer the medications as required by the regulation. Windsor nevertheless argues that it was not deficient because it had no knowledge that the resident possessed the medications until their discovery during the survey. Windsor cites Carehouse Convalescent Hospital, DAB No. 1799 (2001), which recognized that the facility could not conduct an interdisciplinary assessment of self-administered medications (in that case, over-the-counter cough syrup) where it was unaware of their presence. Windsor's lack of knowledge prior to the surveyor's observation is irrelevant because noncompliance is cited only from the time of that observation, and Windsor does not assert that its ignorance of the medications continued thereafter.[13]

Windsor next argues that it abated any noncompliance with this regulation by October 28, 2004, when it conducted an assessment of Resident 22 and determined that he was not capable of, among other things, demonstrating secure storage of his medications in his room and, Windsor reports, agreed to surrender the medication for storage in the medication cart. P. RR at 20-21. Windsor's argument does not show that it came into compliance any earlier than the date CMS determined based on the survey on December 21, 2004. Windsor addresses only measures that it took with respect to this individual resident, but not any of the measures which it committed in its POC to take to ensure it was in compliance with the requirement. Those measures included providing in-services

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[13] The facts here are in any event readily distinguishable from Carehouse, where the ALJ discounted as unverified hearsay an SOD allegation that a resident told a surveyor that facility staff was aware that the resident had a bottle of cough syrup. The resident's account, even if credited, did not demonstrate how long the facility had known about the cough syrup, and the surveyor testified that two staff members, when asked, had denied knowledge of the presence of the bottle of cough syrup. Here, Windsor has not disputed the SOD allegation that the medication administration nurse was present to see that the resident had the eye drops on his bedside table, and has not shown that it acted on that knowledge prior to October 28, 2004 to either remove the medications or do an assessment.

for its clinical staff on the policy for storage and self-administration of medications, conducting environmental audits for resident safety with observation for self-administration at bedside, and auditing bedside medication storage weekly until 100% compliance was met. CMS Ex. 21, at 1-2. The POC does not assert that the completion date for these measures was any earlier than December 8, 2004. Id.

The Board has held that a facility's noncompliance is what must be corrected, not merely the failure with respect to a particular resident, and that "[t]here is no requirement that the duration of a remedy coincide with particular events that form the evidence of lack of substantial compliance." Sheridan Health Care Center, DAB No. 2178, at 43 (2008), citing Regency Gardens Nursing Center, DAB No. 1858, at 21 (2002). Thus, "a facility's noncompliance is deemed to be corrected or removed only when the incidents of noncompliance have ceased and the facility has implemented appropriate measures to ensure that similar incidents will not recur." Id., citing Florence Park Care Center, DAB No. 1931, at 30 (2004), citing Lake City Extended Care Center, DAB No. 1658, at 14 (1998). As noted earlier, the Board has long rejected arguments such as that raised by Windsor here, that CMS is obliged to prove continuing noncompliance on each day for which remedies are imposed or to find substantial compliance where the facility has not completed all steps in its POC or otherwise demonstrated it has in fact achieved substantial compliance. See, e.g., Cal Turner Extended Care Pavilion at 18. Windsor cites no evidence showing that it completed all actions required by its POC by the claimed date of December 8, 2004, let alone any credible written evidence of what corrective actions it took by October 28, 2004. Furthermore, those POC measures, such as in-service training and facility-wide audit, bear a clear relationship to preventing repetition of the self-administration deficiency found during the survey on October 25. We conclude that Windsor has not met its burden to prove that it came back into substantial compliance sooner than December 21, 2004, the date that CMS determined based on the revisit survey on December 22.

Thus, we sustain the challenged Findings of Fact 19-23 and Conclusion of Law 9. ALJ Decision at 5-6, 7.

II. We remand the appeal of the findings regarding under 42 C.F.R. § 483.13(a) (Tag F221).

Section 483.13(a) states that "[t]he resident has the right to be free from any physical or chemical restraints imposed for purposes of discipline or convenience, and not required to treat the resident's medical symptoms." The October 28, 2008 SOD

alleges, as relevant here, that Windsor "failed to fully inform resident and/or responsible party, appropriately assess, document and care plan the use of restraints" for four residents for whom, it is not disputed, the facility used either side rails (Residents 1, 5, 7) or a "roll belt" (Resident 19).[14] CMS Ex. 21, at 4-6.

The SOD also made specific allegations for each resident that we do not reproduce because many were not pursued by CMS or not sustained by the ALJ.[15] The essence of the relevant resident-specific allegations is that for each resident, Windsor failed to take at least some of the steps its policy requires for restraints to be used. See CMS Pre-Hearing Br. at 8-9; CMS Post-Hearing Reply at 2 (unnumbered). Windsor's policy requires that the resident assessment show that alternative or less restrictive measures will not provide the appropriate outcome, that a physician's order be obtained, and that the resident and/or resident's responsible party be educated on various aspects of restraint use. CMS Ex. 58. Additionally, the ALJ cited the SOM as explaining that, prior to using restraints, a facility must determine the specific medical symptom that necessitates their use, how the restraints effectively treat the symptoms, how the resident's safety is protected, and how the resident will be assisted in attaining or maintaining the highest level of well-being. ALJ Decision at 30, citing SOM, App. PP, Tag 221 (P. Ex. 34, at 2-3). The medical symptoms that warrant the use of restraints must be documented in the resident's medical record,

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[14] The ALJ concluded that CMS provided no support for an allegation of noncompliance for a fifth resident and had therefore withdrawn the allegation, and CMS did not appeal that determination. ALJ Decision at 30, n.15.

[15] For example, regarding Resident 1, the SOD states, among other things, that there was "no consent, no documentation where the use of restraints had been discussed with the resident or the responsible party, no documentation on the care plan and no documentation of the use of restraint on the Resident Care Instructions for [CNAs]." CMS Ex. 21, at 4. The ALJ found that "[c]ontrary to the allegations of the SOD," there was evidence that the side rails were listed in the care plan and that the resident and a family member were invited to attend and attended the care plan conference, and an inference could reasonably be drawn that the care plan was discussed during the conference. ALJ Decision at 31-32. The SOD also alleged that there was a "lack of documentation on the Hourly Restraint Checklist," but the ALJ did not address this allegation because CMS did not pursue it. CMS Ex. 21, at 4.

ongoing assessments and care plans. Id. Thus, a physician's order alone is not sufficient to warrant the use of the restraint. Id.

The ALJ held that it was not possible to conclude that Windsor's use of the restraint in each instance was medically necessary under the terms of Windsor's policy because Windsor's evidence did not show that Windsor had counseled each resident (or the resident's responsible party) regarding the use of the restraints, including the right to refuse them, as required by Windsor's policy (and the SOM), or that Windsor had considered whether less restrictive means than restraints could have addressed each resident's medical condition (for example, Resident 1's risk for falls). ALJ Decision at 31-34. Windsor had cited care plans for each resident listing restraints (such as double side rails while in bed) among the approaches Windsor adopted to address problems such as a risk for falls (Residents 1, 5, 7, 19); impaired gait (Residents 1, 19); decreased safety awareness (Resident 1); decreased endurance and ambulation ability (Resident 5); and confusion (Resident 7). P. Pre-Hearing Br. at 26-29; P. Br., App. C; CMS Ex. 51, at 25; P. Ex. 53, at 2; P. Ex. 54, at 8; CMS Ex. 55, at 9. Windsor also cited care plan conference attendance sheets indicating the presence of the resident and/or a family member. CMS Ex. 51, at 32-33; P. Ex. 53, at 3; P. Ex. 54, at 7; P. Ex. 57, at 4. The ALJ, like CMS, did not disagree that these exhibits showed that the resident or a family member had attended care plan conferences involving the use of restraints. The ALJ found, however, that the presence of the resident or family member at the care plan conference, and "the inference that the care plan was discussed during the conference," are not sufficient to show that Windsor's staff advised the resident or responsible party of the right to refuse restraints or considered and rejected less restrictive methods. ALJ Decision at 32. He also found that neither this evidence nor the physician's orders for restraints showed that Windsor had considered whether each resident's medical condition could have been accommodated by less restrictive means, "for example the use of alarms or a low bed to minimize or eliminate the risk for falls." Id.

Before the Board, Windsor moved to submit new evidence on the ground that Windsor was not apprised until CMS's post-hearing briefing and the ALJ Decision that the care plans and documentation of resident (or relative) attendance at care plan conferences at which restraint use was addressed were not sufficient to show that Windsor had actually considered less restrictive alternatives and counseled the residents in accordance with its policy. With its motion, Windsor submitted affidavits of two employees, its Assistant Director of Nursing

and a social service designee at the time of the survey, attesting that they were familiar with Residents 7 and 19 and Residents 1, 5, and 19, respectively. The affidavits, completed in August 2008, describe how Windsor staff had considered and rejected less restrictive alternatives to restraints for each resident and had, during the conferences, explained to the residents the reason that the facility advised the use of restraints and the residents' right to refuse them. The affidavits further state that this was the facility's practice any time that the use of restraints such as bed rails was recommended. The social service designee additionally reports that she attended care plan meetings with Resident 5 and Resident 19 at which restraint use was discussed, and the Assistant Director of Nursing attests that she attended a care plan meeting at which the restraint use was discussed with Resident 19.

Regulations governing Board review of ALJ decisions in this type of case state that the Board may admit evidence in addition to that introduced before the ALJ "if the Board considers that the additional evidence is relevant and material to an issue before it." 42 C.F.R. § 498.86. In considering whether to admit additional evidence, the Board considers whether the proponent of the new evidence has shown good cause for not producing it during the ALJ proceeding. See Guidelines.

CMS argues that the evidence is not relevant or material because it is prejudicial and unlikely to affect the ALJ's determination. We disagree that the evidence is not relevant and material. CMS summarizes its argument before the ALJ as "Windsor failed to implement all of the components of its protocol for the use of physical restraints" (those components being "at least an assessment of need, a physician's order and proper education about the restraint for the resident or responsible party"). CMS Reply to Motion at 2, citing CMS Pre-Hearing Br. at 8, CMS Br. at 17-21. The affidavits directly address that argument. CMS does not explain why the new evidence would not have affected the ALJ's determination that Windsor's evidence did not establish that it had complied with its restraint policy.

CMS also argues that the affidavits are prejudicial at this stage of the proceedings because CMS has not had an opportunity to cross examine these witnesses. The two employees completed the affidavits in August 2008, relatively recently in the context of this case, and there is no basis to find that the affiants would not be available for cross examination, should the ALJ decide upon remand to reconvene the hearing. That the new evidence is proffered at the Board review stage does not, by itself, demonstrate prejudice sufficient to deny its admission. Even where prejudice may exist, new evidence may be admitted where it

impacts a material issue and any prejudice may be cured, for example by remanding to provide opportunities for cross-examination and/or additional briefing.

Finally, CMS argues that Windsor has not shown good cause for not having presented this evidence earlier. Both in the SOD and in its filings before the hearing, CMS focused on allegations that restraints were not included in the residents' care plans and that residents and/or family members were not provided information about restraint usage. At the hearing and in its documentary evidence, Windsor provided evidence, which the ALJ credited, that the facility did care plan for the restraints and included residents/relatives in the care planning process. ALJ Decision at 31-34. At the hearing, the surveyor stated that she had not taken into consideration the presence of Resident 1 and the resident's family at the care plan meeting when the use of restraints was discussed, and agreed that if the care plan was read at the meeting, then the use of side rails and their risks and benefits were discussed. Tr. at 197-98. Only in its post-hearing briefing did CMS argue that evidence of care plan meetings and resident/relative participation did not suffice to demonstrate compliance without proof of the content of the meetings including documented discussion of alternatives to restraints and of the residents' right to refuse. There was thus a reasonable basis for Windsor's belief that the evidence it presented before the ALJ adequately responded to the allegations without requiring the testimony now proffered.

Accordingly, in the interests of justice and of compiling a complete record to support sound decision making, we admit the two affidavits. We remand the appeal of this deficiency finding to the ALJ to consider the new evidence and to take whatever actions he deems necessary to develop the record. The proceeding on remand shall be limited to this deficiency and any resulting reconsideration of the reasonableness of the amount of the CMP should the new evidence result in altering the ALJ's findings and conclusions about this deficiency finding.

III. We sustain the remedies imposed for the deficiencies sustained above, and remand the determination of the remedy relative to the finding of noncompliance under 42 C.F.R. § 483.13(a) (Tag F221).

CMS may impose remedies including a CMP and a DPNA for the days on which the facility is not in substantial compliance. 42 C.F.R. §§ 488.402(a), 488.404, 488.406 and 488.408, 488.417(a). They continue until either the facility achieves substantial compliance or its provider agreement is terminated. 42 C.F.R. §§ 488.454(a). Neither the ALJ nor the Board may review the

choice of remedies or the factors considered by CMS in making that selection, once we have determined that noncompliance existed as basis for an enforcement remedy. 42 C.F.R. §§ 488.408(g), 498.3(d)(14).

Windsor's only arguments against the $350 per-day CMP were that it was always in substantial compliance with the cited participation requirements or, at least, attained substantial compliance earlier than alleged. For reasons discussed earlier, that argument is unavailing, and provides no basis to reduce the CMP amounts, which is at the lower end of the range ($50 - $3,000 per day) that CMS may impose for deficiencies that do not rise to the level of immediate jeopardy. 42 C.F.R. § 488.438(a). Similarly, other than disputing the noncompliance and its duration, Windsor does not challenge the ALJ's determination that cancellation of Windsor's authority to conduct a NATCEP was required by the law, and we uphold that determination without further discussion. ALJ Decision at 36, 37, citing 42 C.F.R. §§ 483.151, 483.152.

However, the ALJ sustained the imposition of a CMP of $150 per day effective October 28, 2004 through December 21, 2004 based on his having sustained two of the noncompliance findings identified in the October 28, 2004 survey. As we remand the appeal of one of those noncompliance findings to the ALJ, it would be premature to set the final amount of the CMP for that period. We therefore, as noted, remand to the ALJ the determination of the CMP amount effective October 28, 2004 through December 21, 2004 based on his ruling on the remanded noncompliance finding.

Regarding the DPNA, which ran from October 27 through December 21, 2004, Windsor argues that the DPNA could not begin earlier than 15 days after CMS's December 14, 2004 notice imposing a DPNA for the deficiencies found during the October 28, 2004 survey. P. Ex. 60A; see 42 C.F.R. § 488.402(f)(4) (notice of remedies other than CMPs or state monitoring "must be given at least 15 calendar days before the effective date of the enforcement action" when there is no immediate jeopardy). That argument is premised on Windsor's claim that the October 22, 2004 survey found that Windsor had corrected the deficiencies noted during the September 24 survey, for which CMS first imposed the DPNA by letter dated October 12, 2004. CMS Ex. 1, at 1. As we reject that claim, as well as Windsor's arguments about the length of the periods of noncompliance, we have no basis to reverse or reduce the DPNA.

We thus modify the ALJ's Conclusion of Law number 17 imposing the CMP amounts for the entire period of deficiencies to read as follows:

17. A CMP of $350 per day for the 34 days from September 24, 2004 through October 27, 2004 is reasonable.

We sustain his Conclusions of Law 18 and 19, that the DPNA was reasonable and that withdrawal of Windsor's authority to conduct a NATCEP was required. ALJ Decision at 8.

Conclusion

Based on the above analysis, we remand to the ALJ the appeal of the deficiency finding under 42 C.F.R. § 483.13(a) (Tag F221) for further proceedings consistent with our decision and to determine the amount of the CMP effective October 28, 2004 through December 21, 2004. We sustain the remainder of the ALJ Decision.

/s/
Judith A. Ballard

/s/
Constance B. Tobias

/s/
Leslie A. Sussan
Presiding Board Member