Department of Health and Human Services

DEPARTMENTAL APPEALS BOARD

Appellate Division

In the Case of:) DATE: April 23, 2008
Woodland Village Nursing Center,)))
Petitioner,) Civil Remedies CR1668) App. Div. Docket No. A-08-32)
) Decision No. 2172
- v)
Centers for Medicare & Medicaid Services.))

FINAL DECISION ON REVIEW OF ADMINISTRATIVE LAW JUDGE DECISION

Woodland Village Nursing Center (Woodland) appealed the October 6, 2007 decision of Administrative Law Judge (ALJ) Keith W. Sickendick upholding the imposition by the Centers for Medicare & Medicaid Services (CMS) of a total civil money penalty (CMP) of \$20,050 and a denial of payment for new admissions (DPNA). <u>Woodland Village Nursing Center</u>, DAB CR1668 (2007)(ALJ Decision). These remedies were based on findings that Woodland was not in substantial compliance with program participation requirements based on surveys of its facility completed on January 24, 2003 (January survey) and March 12, 2003 (March revisit).

For the reasons explained below, we conclude that substantial evidence in the record as a whole supported the ALJ's findings on the five regulatory requirements at issue on appeal and that no error was shown in the ALJ's legal conclusion that Woodland was not in substantial compliance. Therefore, we affirm the ALJ's holding that CMS had a legal basis to impose remedies and sustain the remedies imposed.

Relevant background

Woodland is a dually-participating (Medicare and Medicaid) facility located in Diamondhead, Mississippi. The January survey found that Woodland was not in substantial compliance with program requirements. As a result, CMS notified Woodland that a CMP of \$350 per day would be imposed effective January 24, 2003 and lasting until Woodland achieved substantial compliance, a DPNA would be imposed effective March 10, 2003 until Woodland achieved substantial compliance, and that Woodland would be terminated until it came into substantial compliance prior to July 24, 2003. ALJ Decision at 1-2. A revisit survey was completed on March 12, 2003 (March survey) which again found deficiencies and resulted in CMS notifying Woodland that the remedies would continue. Id. at 2. Ultimately, CMS sought to impose a CMP of \$350 per day from January 24 to March 11, 2003 and a reduced CMP of \$50 per day from March 12 to May 22, 2003, and a DPNA from March 10 to May 22, 2003.

The January survey resulted in deficiency findings under twelve different regulatory requirements, cited as "tags." CMS Ex. 1. The March revisit resulted in deficiency findings under four tags. After an informal dispute resolution, the state agency recommended that three of the four cited tags from the March revisit be deleted, but CMS rejected that recommendation.² ALJ Decision at 8.

² CMS did agree to reduce the scope and severity level of the fourth tag (Tag F 224) from "G" to "D" on the matrix used by CMS in the State Operations Manual (SOM). CMS Ex. 25, at 1; SOM, section 7400E. The effect was that CMS asserted that the deficiency was an isolated occurrence and presented no actual harm but had the potential for more than minimal harm (D), as opposed to having caused actual harm (G).

¹ The ALJ explained that the date on which Woodland came into substantial compliance was not documented on the record, but CMS did not request that he impose any CMP after May 22, 2003 and that he also applied that end date for the DPNA. ALJ Decision at 2, n.1. Neither party objects on appeal to the ALJ's action. The ALJ also noted that Woodland appealed each survey and its associated remedies separately, but both cases were consolidated. <u>Id.</u> at 2.

The present appeal followed.

ALJ Decision

The ALJ held an in-person hearing and issued his decision on October 6, 2007.

The ALJ declined, for reasons of judicial economy, to make any findings as to the following tags cited in the January survey: Tag F 364, Tag F 366 and Tag F 371 (all relating to subsections of 42 C.F.R. § 483.35) and Tag F 252 (relating to 42 C.F.R. § 483.15(h)(1)). ALJ Decision at 9. He sustained the noncompliance findings for the following tags from the January survey:

- Tags K 028 and K 038 (42 C.F.R. § 483.70(a)(1) involving life safety code violations);
- Tag F 309 (42 C.F.R. § 483.25 involving quality of care);
- Tag F 314 (42 C.F.R. § 483.25(c) involving pressure sores);
- Tag F 323 (42 C.F.R. § 483.25(h)(1) involving accident hazards); and
- Tag F 324 (42 C.F.R. § 483.25(h)(2) involving inadequate supervision to prevent accidents).

<u>Id.</u> at 9, 12, 14, 22, 24. The ALJ sustained one noncompliance finding from the March revisit for the following tag:

• Tag F 314 (42 C.F.R. § 483.25(c) - involving pressure sores).

<u>Id.</u> at 14.³

Based on these conclusions, the ALJ found that CMS had a basis to impose remedies on Woodland.

The ALJ then turned to Woodland's challenges to the reasonableness of the CMPs. He noted that Woodland challenged

³ The ALJ also concluded that the following deficiency findings were not supported on the record before him: Tag F 280 (42 C.F.R. § 483.20(k)(2)) (January survey); Tag F 224 (42 C.F.R. § 483.13(c)) (March revisit); Tag F 327 (42 C.F.R. § 483.25(j)) (March revisit); and Tag F 502 (42 C.F.R. § 483.75(j)) (March revisit). ALJ Decision at 10, 30, 32, 33. CMS did not appeal the ALJ's determinations overturning these deficiency findings, and we therefore do not discuss them further.

the existence of the deficiencies but did not argue that, if the deficiencies were found to be substantiated, substantial compliance was achieved earlier than the dates alleged by CMS. ALJ Decision at 34. Therefore, the ALJ concluded that the duration of the CMPs was not at issue. The ALJ noted that he had no authority under the regulations to reduce the \$50 per day CMP, since that was the lowest authorized amount for a per day CMP. Id., citing 42 C.F.R. § 488.438(a)(ii) and (e). Finally, he found that the amount of the \$350 per day CMP was reasonable, particularly in light of the actual harm to multiple residents and the culpability demonstrated. Id. at 35.

<u>Applicable law</u>

The federal statute and regulations provide for surveys to evaluate the compliance of skilled nursing facilities with the requirements for participation in the Medicare and Medicaid programs and to impose remedies when a facility is found not to comply substantially. Sections 1819 and 1919 of the Social Security Act; 42 C.F.R. Parts 483, 488, and 498.⁴ "Substantial compliance" is defined as "a level of compliance with the requirements of participation such that any identified deficiencies pose no greater risk to resident health and safety than the potential for causing minimal harm." 42 C.F.R. § 488.301. "Noncompliance" means "any deficiency that causes a facility to not be in substantial compliance." Id.

Life safety code requirements for fire safety are incorporated into the federal regulations by 42 C.F.R. § 483.70(a)(1)(tags K 028 and K 038).

"Quality of care" requirements reflect the overarching regulatory objective that "[e]ach 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(tag 309). Among the required measures to that end, a facility must treat any existing pressure sores and prevent any new ones, except when clinically unavoidable. 42 C.F.R. § 483.25(c)(tag 314).

⁴ The current version of the Social Security Act can be found at <u>www.ssa.gov/OP Home/ssact/comp-ssa.htm</u>. Each section of the Act on that website contains a reference to the corresponding United States Code chapter and section. Also, a cross reference table for the Act and the United States Code can be found at 42 U.S.C.A. Ch. 7, Disp Table.

Further, a facility must ensure that the "resident environment remains as free of accident hazards as is possible[.]" 42 C.F.R. § 483.25(h)(1)(tag F323). A facility must also ensure that "[e]ach resident receives adequate supervision and assistance devices to prevent accidents." 42 C.F.R. § 483.25(h)(2)(tag F324).

Where, as here, no immediate jeopardy is alleged, a CMP may be imposed within a range from \$50 to \$3,000 per day covering the time a facility is not in substantial compliance. 42 C.F.R. § 488.438(a)(1)(ii).

Board precedent has established that a facility must prove by the preponderance of the evidence that it is in substantial compliance. <u>Batavia Nursing and Convalescent Center</u>, DAB No. 1904 (2004), <u>aff'd Batavia Nursing & Convalescent Ctr. v.</u> <u>Thompson</u>, 129 Fed. Appx. 181 (6th Cir. 2005). In order to put the facility to its proof, CMS must initially present a prima facie case of noncompliance with Medicare participation requirements. Once CMS has presented prima facie evidence as to any material disputed facts, the burden of proof shifts to the facility to show at the hearing that it is more likely than not that the facility was in substantial compliance.

Standard of review

Our standard of review on a disputed finding of fact is whether the ALJ decision is supported by substantial evidence on the record as a whole. Our standard of review on a disputed conclusion of law is whether the ALJ decision is erroneous. <u>Guidelines for Appellate Review of Decisions of Administrative</u> <u>Law Judges Affecting a Provider's Participation in the Medicare</u> <u>and Medicaid Programs</u>, www.hhs.gov/dab/guidelines/prov.html.

Substantial evidence is "more than a mere scintilla. It means such relevant evidence as a reasonable mind might accept as adequate to support a conclusion." <u>Richardson v. Perales</u>, 402 U.S. 389, 401 (1971), <u>quoting Consolidated Edison Co. v. NLRB</u>, 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. <u>Universal Camera Corp. v. NLRB</u>, 340 U.S. 474, 488 (1951).

<u>Analysis</u>

Woodland challenges the ALJ's conclusions that it was not in substantial compliance with the participation requirements

represented by the five tags in January and one tag in March for which the ALJ upheld CMS's deficiency findings. Woodland argues in each case that the ALJ's determinations were not based on substantial evidence in the record. We address each tag in turn below.

Woodland requests, if we do not overturn each deficiency finding, that "the scope and severity level of each deficiency be appropriately reduced, the amount of the CMPs be likewise reduced, and the DPNA reversed." Woodland Br. at 22. We discuss these requests after our discussion of the individual tags.

1. Substantial evidence in the record as a whole supports the ALJ's conclusion that Woodland was not in substantial compliance with Tags K 028 and K 038 at the January survey.

These tags were cited based on allegations that Woodland failed in two respects to meet the requirements of the Life Safety Code (LSC) of the National Fire Protection Association, 1985 edition, which is incorporated into the regulatory participation requirements by 42 C.F.R. § 483.70(a)(1) (Tag K 038). CMS Ex. 21, at 2-3. The ALJ heard testimony from Robert Trigg, LSC Inspector, that (1) a section of a smoke barrier door did not close properly, which defeated the purpose of containing smoke, and (2) an exit door could not be opened even with 15 pounds of pressure as required. ALJ Decision at 9, citing Tr. at 68-77, 86-88, 92-96. Based on the record and testimony, the ALJ concluded Woodland was not in substantial compliance with section 483.70(a)(1) at the January survey (and noted that no deficiency was cited in this area for the March survey). ALJ Decision at 10.

On appeal, Woodland does not dispute the underlying factual allegations about the malfunctioning of both doors. Instead, Woodland contends that CMS failed to show that the deficiencies presented any more than a potential for causing minimal harm and hence argues that they should not be a basis for finding a lack of substantial compliance. Woodland Br. at 5-7. According to Woodland, the ALJ used an "improper strict liability standard" because he relied on Inspector Trigg's testimony in other regards as "`both credible and unrebutted'," but "ignored" Inspector Trigg's "opinion that these deficiencies created a potential for just minimal harm." Id. at 6, citing ALJ Decision at 9 and Tr. at 81, 92, 95-96.

The ALJ did not ignore Inspector Trigg's testimony. Instead, the ALJ focused on what Inspector Trigg testified about what harm could result from having a set of smoke barrier doors fail and an

exit that could not be opened with reasonable effort. ALJ Decision at 9. Thus, Inspector Trigg explained that the major cause of death in fires is not burning but smoke inhalation and that preventing smoke inhalation involved creating smoke-tight compartments which allow occupants to be moved to another section of the building without necessarily being forced out of doors, a significant consideration with elderly residents. Tr. at 63, 68-70; <u>see also</u> Tr. at 93 ("Smoke kills people, not fire."). He also explained that every corridor of more than 30 feet in length must have an exit door which must be able to open with 15 or less pounds of pressure so as to make it easier to get out of the building "to the outside air" and not to create a "dead-end." Tr. at 72, 76.

The ALJ recognized that Inspector Trigg's testimony included statements minimizing the degree of danger created by the factual findings, i.e, describing them as "minor," and stating that the deficiency under Tag K 028 was "scoped" as minimal harm and the deficiency cited under Tag K 038 created a potential for minimal Tr. at 81, 92, 95. The ALJ concluded, however, that this harm. testimony reflected Inspector Trigg's "lack of familiarity or confusion" about the terms used in the CMS scope and severity matrix, i.e., the distinction between a potential for minimal harm and a potential for more than minimal harm. ALJ Decision at 9. The ALJ's determination not to rely on Inspector Trigg's testimony opining scope and severity level was explicitly based on the ALJ's assessment that the witness lacked clarity or expertise about the scope and severity levels, not on any assessment that the witness was not believable. Thus, the ALJ made no adverse finding about Inspector Trigg's credibility that might discount the witness's testimony about other matters as to which he had expertise, such as fire safety and the requirements of the Life Safety Code.

In general, as an appellate body, we do not disturb an ALJ's assessment about the relative credibility of testimony by witnesses who appear in person at the hearing absent a compelling reason to do so. Thus, the Board has held that --

[a] reviewing panel does not have the opportunity to evaluate the credibility of a witness by listening in person to the witness's testimony or observing the witness's demeanor. The evaluation of the credibility of a witness is properly left to the hearing officer. . . Thus, we defer to the ALJ's evaluations of the credibility of the witnesses who appeared before him in this matter.

South Valley Health Care Center, DAB No. 1691, at 32 (1999); see also Evergreene Nursing Center, DAB No. 2069, at 37 (2007). In this situation, the ALJ's perception that the witness did not lack credibility but rather was confusing various levels of scope and severity is buttressed by a reading of the witness's testimony in context. Thus, for example, where he refers to deficiency findings as presenting a potential for minimal harm, he also refers to them as "scoped minimal for a D." Tr. at 96; see also Tr. at 68. Yet, a "D" on the scope and severity matrix is defined as a situation presenting the potential for more than minimal harm. He also testified that the possibility of smoke entering a compartment created a potential for harm more significant than minimal harm in that fire and smoke travel fast and could outrace nursing home residents. Tr. at 93. In addition to these apparent contradictions, Inspector Trigg evidenced confusion when he was asked his understanding of the term "substantial compliance" and responded that "if it doesn't have an immediate threat to life and the preservation of life it's in substantial compliance." Tr. at 78-79. This misstates the meaning of substantial compliance as defined in the regulations quoted earlier. Inspector Trigg's evident lack of clarity about the applicable legal standards is not surprising in light of his testimony that his job does not include determining the scope and severity level to be assigned to findings. Tr. at 82 ("I don't grade or scope"); see also Tr. at 89 ("My people above me make [the scope and severity] decisions, I don't have any opinion on that, sir.").

It was thus reasonable for the ALJ to rely on Inspector Trigg's testimony in the areas of fire safety in which Mr. Trigg claimed competence while not deferring to Mr. Trigg in the interpretation or application of the regulatory standards, as to which Mr. Trigg did not claim to have special competence. The ALJ instead applied the correct definitions of "substantial compliance" and "potential for more than minimal harm" to the factual findings about the real possibilities for harm to nursing home residents identified in the record from an exit door that could not easily be opened and a smoke barrier that would leak through.

We therefore conclude that the ALJ's findings were adequately supported and the ALJ's conclusion regarding this tag was not erroneous. 2. Substantial evidence in the record as a whole supports the ALJ's conclusion that Woodland was not in substantial compliance with Tag F 309 at the January survey.

The corresponding regulation for this tag requires that a facility provide the necessary care and services so that each resident attains or maintains "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 allegations here involved Resident 5, an 82-year-old woman with multiple diagnoses including three pressure sores and a urinary tract infection (UTI) upon her October 22, 2002 admission. See ALJ Decision at 12, and record citations therein. She was documented as having repeated UTIs after admission and her doctor ordered ten-day treatment with Ampicillin on January 9, 2003 for a UTI. <u>Id.</u> at 12-13, and record citations therein. According to the January survey statement of deficiencies (January SOD), Woodland failed to provide her with an adequate quality of care in that Woodland failed to timely perform a repeat culture and sensitivity (C&S) test which the doctor also ordered on that date. CMS Ex. 1, at 5.

Based on the record and testimony regarding Resident 5, the ALJ concluded Woodland was not in substantial compliance with 42 C.F.R. § 483.25 at the January survey (and noted that no deficiency was cited in this area for the March survey). ALJ Decision at 14.

On appeal, Woodland does not dispute the facility's delay in performing the C&S test ordered by the physician or offer any explanation or justification for the delay. Woodland asserts that the ALJ "incorrectly determined that CMS established its prima facie case" on this deficiency, but offers no supporting argument and points to no evidence to demonstrate its assertion. Woodland Br. at 7. We reject this argument without further discussion.

The remainder of Woodland's briefing on this deficiency focuses on Woodland's claim that the evidence did not show that Resident 5 "suffered any harm, even minimal harm, that she would not have suffered even with a timely-conducted C&S," because the "delay was minor." Woodland Br. at 7-8.

The ALJ rejected this argument and found that the delay in obtaining C&S results resulted in actual harm to Resident 5 given that the results showed that Ampicillin was not effective against the bacteria involved in UTI. ALJ Decision at 13. Hence, three days were lost in which other approaches were not tried to treat the Ampicillin-resistant infection. The ALJ also noted that the same organism was cultured from a pressure sore on the resident's coccyx as from her urine sample. <u>Id</u>. CMS's expert witness, Dr. Osterweil, testified that the UTI might have contributed to the infection of the pressure sore. Tr. at 390-91. The record thus contained substantial evidence to support the ALJ's finding of actual harm due to the persistence of the untreated infection and its possible spread to the pressure sore.

Woodland points to no contrary evidence, but contends that Resident 5 might nevertheless have failed to recover from the UTI even if the resistant bacteria had been identified because she was "a very sick lady, at risk for chronic UTI due to her indwelling catheter." Woodland Br. at 8. The undisputed evidence that Resident 5 had multiple illnesses including chronic UTIs while at Woodland does not justify dilatory handling of her C&S test. On the contrary, the ALJ reasonably concluded that leaving a drug-resistant infection untreated for three days in such a patient was detrimental precisely because she was so vulnerable. Indeed, her frequent need for antibiotic treatment put Woodland "on notice that this resident required special attention and increased care" in regard to UTIs. ALJ Decision at 13.

Furthermore, even if we accepted Woodland's contention that no actual harm was proven to have taken place (which we do not), the deficiency would stand on a showing of a potential for more than minimal harm. The record as a whole amply supports the presence of a potential for more than minimal harm resulting from the delay in identifying the infective organism(s), and therefore in enabling the physician to attempt more effective treatment.

We therefore conclude that the ALJ's findings were adequately supported and the ALJ's conclusion regarding this tag was not erroneous.

3. Substantial evidence in the record as a whole supports the ALJ's conclusion that Woodland was not in substantial compliance with Tag 314 at the January and March surveys.

The relevant regulation is a subsection of the quality of care regulation, the overarching requirement of which is cited in the prior section. The relevant provision applicable here states as follows:

Pressure sores. Based on the comprehensive assessment of a resident, the facility must ensure that -

(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.

42 C.F.R. § 483.25(c). In each survey, surveyors identified a resident for whom Woodland allegedly did not meet the requirements for prevention and treatment of pressure sores. We next discuss Woodland's challenges to the ALJ's conclusions about the deficiency findings under this tag from each survey in turn.

A. January survey - Resident 3

Resident 3's care plan required that she be turned every two hours and that she wear heel protectors at all times due to infected pressure sores. CMS Ex. 1, at 5-6; ALJ Decision at 16-17, and record citations therein. It is undisputed that one of the sores (on her right heel) developed after her admission to the facility. ALJ Decision at 17. During the January survey, she was observed four times on one day between 8:35 AM and 4:20 PM and three times on the next day between 8:20 AM and 3:50 PM to be lying flat on her back. CMS Ex. 1, at 6. The January SOD also alleged that Woodland "failed to apply heel protectors in accordance with the care plan" and the surveyor's review worksheet documented the absence of heel protectors during observations. Id. at 5; CMS Ex. 12, at 4-5.

The ALJ determined that the actual observations during the survey of repeated noncompliance with Resident 3's care plan outweighed the testimony by Woodland's Medical Director (who was Resident 3's treating physician) that he believed she was being turned properly because her lower back pressure sore healed. ALJ Decision at 17; Tr. at 570. The ALJ further traced the course of Resident 3's pressure sores and found that overall the record undercut Woodland's claims that the healing of some pressure sores sufficed to show compliance with physician orders and the care plan.⁵ The ALJ relied on testimony of Dr. Osterweil about

⁵ The ALJ noted that the weekly skin reports for Resident 3 show no objective changes to bilateral heel ulcers despite daily notations that progress was good, and show the presence of some inflammation characterized as a "skin rash" on (continued...)

the standard of care for pressure sore prevention and treatment, especially as to hydration, nutrition, and appropriate interventions. ALJ Decision at 21, citing Tr. at 384-401.

According to Woodland, CMS was required to show that either existing pressure sores "became worse, or became infected" or that new sores developed. Woodland Br. at 9. Woodland contends that the ALJ made no findings that existing sores became worse or became infected, but merely "guessed" that a new sore might have developed on her buttock. Id. at 9-10. Woodland disputes the ALJ's finding that the facility did not follow Resident 3's care plan. To the contrary, Woodland asserts, the extensive treatment records and clinical documents which it submitted demonstrate that Resident 3 was receiving interventions for her pressure sores and that they were healing.⁶ Id. at 10.

The ALJ correctly cited to and applied leading Board cases on pressure sores in his decision. Woodland, however, takes out of context a brief summary of the elements of a prima facie case set out by the ALJ which could be misconstrued. The ALJ states that CMS must prove that a resident either developed new pressure sores or "had one or more pressure sores that became worse, or became infected, or the resident developed additional sores, indicating that the facility did not provide treatment and

⁵(...continued)

the left buttock. ALJ Decision at 18, citing P. Ex. 6, at 356-57. The ALJ also noted that Woodland failed to offer testimony to clarify whether this skin rash was the start of a new Stage I pressure sore but states that this is his reading of the record. <u>Id</u>. (The severity of a pressure sore is designated by a stage number, from I (least severe) to IV (most severe).) On appeal, Woodland argues that the ALJ was mistaken that the skin rash was "anything more than" that. Woodland Br. at 10. We need not resolve this dispute given the direct evidence, credited by the ALJ, that the resident was not receiving even the interventions ordered by her physician and care-planned for her by the facility, and her undisputed acquisition of at least one new pressure sore while in the facility.

⁶ For many of the residents whose care is at issue in this case, Woodland submitted hundreds of pages of clinical records, the vast majority of which material is unrelated to the matters in dispute. <u>See, e.q.</u>, P. Ex. 6 passim. We have reviewed all the pages in such exhibits that were cited by the ALJ or either party on appeal, but not necessarily every other page. services to promote healing, prevent infection, and prevent new sores from developing." ALJ Decision at 15. After this showing, according to the ALJ, the burden shifts to the facility to show that the adverse outcomes were clinically unavoidable. <u>Id</u>.

The Board has explained, as the ALJ recognized, that the regulatory requirement is that each resident "must receive 'necessary treatment and services' for healing, prevention of infection, and prevention of yet more pressure sores." Clermont Nursing and Convalescent Center, DAB No. 1923, at 9 (2004) (emphasis added in DAB No. 1923). Further, the Board has explained that regulatory language on pressure sore treatment and prevention applies a particularly demanding standard, i.e., that the facility must "ensure" healing and prevention as the outcomes of that treatment and those services unless the facility can prove with clinical evidence that a negative outcome was unavoidable despite the facility having furnished all necessary Koester Pavilion, DAB No. 1750, at 30. Further, the Board care. has repeatedly held that the 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." Id. at 32; see also Josephine Sunset Home, DAB No. 1908, at 7 (2004); Meadow Wood Nursing Home, DAB No. 1841, at 21 (2002), aff'd, Meadow Wood Nursing Home v. Dep't of Health & Human Services, No. 02-4115 (6th Cir. Mar. 2, 2004). Based on this analysis of the regulation, the Board has found, as the ALJ pointed out, that observing a caregiver cleaning or dressing sores in the presence of fecal matter suffices to demonstrate a failure to provide necessary treatment and services for existing pressure sores. See ALJ Decision at 15, citing Meadow Wood at 32 and <u>Ridge Terrace</u>, DAB No. 1834, at 15-16 (2002).

To be sure, it is accurate to say, as the ALJ does, that evidence showing that a resident developed a pressure sore or that a resident's pre-existing pressure sore worsened or grew infected while under a facility's care is enough to show a deficiency in the absence of clinical evidence from the facility proving such negative outcomes to have been clinically unavoidable. It would not be accurate to conclude that a prima facie case cannot be made under this regulatory tag unless CMS proves that a new pressure sore developed or an existing one worsened. First, a pressure sore that persists without improvement for a long period of time is not healing, which is the target outcome.⁷ In order to

In the present case, CMS's expert directly addressed (continued...)

avoid a deficiency finding in that circumstance, the facility would have to show that the failure to achieve healing was clinically unavoidable, despite implementing measures to address the persistent sore, even if the sore had not actually grown even worse or become infected. Second, as Meadow Wood and Ridge Terrace illustrate, where the facility is proven to have been providing improper care or not providing care as ordered by the physician or planned for by the facility itself as necessary to protect against or treat pressure sores, CMS need not wait to see if an infection or aggravation of a sore ensues before citing a deficiency. Despite his phrasing of the summary of the elements of the case on which Woodland attempts to piggyback, the ALJ plainly understood and correctly applied these points since he stated that Woodland failed to rebut CMS's prima facie case shown by evidence that Woodland "was not complying with the orders of Resident 3's physician or its own care plan for pressure ulcers" and by Woodland's failure to show "that the development of new ulcers or the failure to resolve existing ulcers was unavoidable." ALJ Decision at 18 (emphasis added).

Therefore, Woodland's assertions that CMS failed to provide "evidence that any of [Resident 3's] previously existing pressure sores became worse or infected" and that the ALJ made no finding to that effect are irrelevant even if true (which is not clear on the record). Woodland Br. at 9. The ALJ clearly found that the claims that Resident 3's pressure sores were healing prior to the survey, rather than remaining at the same staging level, were not credible or supported. ALJ Decision at 18. In disputing whether the new rash on Resident 3's buttock amounted to a Stage I pressure sore, Woodland glosses over the undisputed fact that Resident 3 did develop a new pressure sore on her right heel. About this new sore, Woodland simply asserts without argument or record citation that its development was "clinically unavoidable." Woodland Br. at 10.

Furthermore, the various entries in Resident 3's clinical records to which Woodland points as showing its provision of necessary care cannot undercut the uncontradicted evidence that Woodland staff was not providing care as ordered when observed by the surveyor. In any case, as the ALJ noted, the detailed records submitted by the facility in themselves show gaps in treatment

⁷(...continued)

the question of what time period is appropriate to expect signs of healing and, in the absence of such signs, what sort of reconsideration or review of treatment options is called for by the applicable standards of care. Tr. at 385.

and services, such as the absence of entries showing use of heel protectors (or the notation "float heels") on weekend days throughout January 2003. ALJ Decision at 17, citing P. Ex. 6, at 354.

B. <u>March survey - Resident 6</u>⁸

The surveyors found that Resident 6 had a pressure sore on her coccyx which worsened from Stage II to Stage IV according to documentation in a physician's progress notes as of February 11, 2003. CMS Ex. 23, at 4. During February, Resident 6's albumin levels (a marker for adequate protein availability) fell and facility records did not demonstrate that Resident 6 actually received the nutrition and hydration identified as necessary given her condition. Id. at 4-6. During the survey, the resident was transferred to the hospital for care of the wound which by then was six centimeters by five centimeters in size and three centimeters deep with "foul odor and purulent drainage" and "yellow, greenish tinged slough covering the entire wound bed." Id. at 6-7.

The ALJ found that Woodland conceded in its briefing that Resident 6's existing "decubiti worsened" between January and early February 2003 after having largely "remained stable" since her admission. ALJ Decision at 19, citing P. Br. (in C-03-339) at 23-24.⁹ The ALJ concluded that this concession amounted to admitting the existence of a prima facie case, and stated that Woodland's defense was that the worsening was unavoidable despite Woodland having done all it could. ALJ Decision at 19, citing P. Br. at 24-26. The ALJ considered the opinion of Dr. Tilley, Woodland Medical Director (and Resident 6's treating physician) that nothing more could have been done for Resident 6, especially since her family would not permit a feeding tube to be reinserted. ALJ Decision at 21, and record citations therein.

⁸ The resident designated as Resident 6 in the March survey is the same individual who had been designated as Resident 5 in the January survey, where the facility was cited for inadequate care in delaying her C&S test.

⁹ Although the ALJ found this concession sufficient to make out a prima facie case, he also reviewed Resident 6's records showing that the coccyx sore was rated Stage II on admission in October 2002, worsened to Stage III by January 23, 2003, and then deteriorated to Stage IV by March 3, 2003, growing even larger by March 10, 2003. ALJ Decision at 19-20, and record citations therein.

He also considered testimony from Dr. Osterweil opining that Woodland did not provide all necessary care as the wound worsened and that several interventions could and should have been attempted by Woodland or discussed with the physician. <u>Id</u>. The ALJ noted that over the course of the relevant period some wounds healed, while others worsened and new ones developed. <u>Id</u>. at 22. Further, the ALJ reviewed the nearly 600 pages of clinical records and found only "spotty," inadequately detailed and incompletely annotated documentation of interventions planned to prevent and treat the resident's ulcers and to optimize her nutrition and hydration. ALJ Decision at 21-22; P. Ex. 8 passim.

Woodland acknowledges on appeal that Resident 6 (as well as Resident 3) developed new pressure sores while in its care and suffered worsening of existing sores. Woodland Br. at 11-12. Woodland again argues that Resident 6's complex clinical condition nevertheless made the sores unavoidable. Woodland argues that the removal of the feeding tube caused her intake to drop severely and her weight to drop from water loss, but relies on the testimony of Dr. Tilley that he felt that "we did everything possible." Tr. at 578; Woodland Br. at 12.

Dr. Tilley made that comment after reviewing the many, increasingly aggressive, wound care orders that he reported having issued as Resident 6's condition deteriorated. Tr. at 572-79. The ALJ made clear, however, that his conclusion was not based on any finding about the appropriateness of Dr. Tilley's orders but only his assessment that Woodland had not shown on the evidence before him that its staff did "all that was necessary within the parameters of Dr. Tilley's orders to prevent or resolve the resident's ulcers." ALJ Decision at 22.

The ALJ could reasonably determine that other evidence in the record overall deserved more weight in addressing that issue than Dr. Tilley's assertion that Woodland did all it could. That evidence included Dr. Osterweil's expert testimony that Woodland failed in many respects to respond in a timely and consistent fashion to the worsening status of Resident 6's severe pressure Tr. at 384, 433. Especially troubling is the fact that sores. the resident's protein status was known to be low and dropping, and she had signs of dehydration, yet many gaps were evident in documentation of her intake and output. <u>See, e.q.</u>, P. Ex. 8, at 445 and 455 (supplement administration not recorded for various shifts in January and February 2003 and no indication of how much was consumed when provided); CMS Ex. 29, at 93-107 (two versions of intake/output records).

The evidence also included other testimony by Dr. Tilley. For example, Dr. Tilley admitted that the registered dietician actually calculated the resident's protein needs incorrectly so the calculated diet would not have addressed the resident's actual needs even if it was consumed. See Tr. at 586-87. Dr. Tilley was asked whether finding gaps in treatment records for the wound care to Resident 6's coccyx ulcer on 10 out of 28 days in late February to early March 2003 would have caused him concern, and responded that "it would have caused me concern for state survey," and then agreed that "documentation is something that my office staff, you know, dropped the ball on." Tr. at 598-99. While Dr. Tilley also stated he "would bet" that the wound care nurse, Ms. Ladner, would have provided wound care every day, "with the exception of the days she didn't work," the doctor also noted that Ms. Ladner did not work on Saturdays or Sundays. Tr. at 599. Although Dr. Tilley also said he assumed other nurses provided care on those days, the ALJ could reasonably place more weight on his review of the documentation than on Dr. Tilley's assumptions.

We conclude that the ALJ's findings as to the deficiencies found in both the January and March survey concerning pressure sores were based on substantial evidence on the record as a whole. We also conclude that the ALJ's conclusions that Woodland was not in substantial compliance with the pressure sore requirements at the time of each of the surveys was not erroneous.

4. Substantial evidence in the record as a whole supports the ALJ's conclusion that Woodland was not in substantial compliance with Tag 323 at the January survey.

This tag again relates to a subsection of the quality of care regulation, which provides that a facility must "ensure that the resident environment remains as free of accident hazards as is possible." 42 C.F.R. § 483.25(h)(1). The January SOD reported that, during a tour of a shower room at the facility, two potentially hazardous items were found on the floor - a pair of scissors and a one-gallon container of "Uric Acid Eradicator." CMS Ex. 1, at 7. In addition, a "large pool" of standing water was observed "in the middle of the floor near a shower stall on the 400 Hall." Id. The surveyors reported that staff stated that water accumulated there due to a "flaw in construction" and that a group interview suggested that standing water was present at that location even when the shower was not in use. Id. at 6-7.

The ALJ stated that CMS had to show a potentially dangerous condition of which Woodland was or should have been aware in

order to shift the burden to Woodland to show substantial compliance. ALJ Decision at 23, citing <u>Alden Town Manor</u> <u>Rehabilitation & HCC</u>, DAB No. 2054 (2006). The ALJ found that Woodland failed to prove its assertion that the scissors were blunt-ended (even if the facility provided only blunt-end scissors) or that, even if these particular scissors were bluntended, that they could not cause more than minimal harm in the hands of a resident. ALJ Decision at 23-24. As to the container, the ALJ found that the uncontested evidence showed that a uric acid eliminator could be harmful if swallowed and could irritate skin or eyes. <u>Id.</u> at 23. According to the ALJ, Woodland did not show that it took reasonable steps to protect residents from that hazard or that it should not reasonably have known of the hazard. <u>Id.</u> at 24.

On appeal, Woodland contends that CMS had to prove as part of its prima facie case that Woodland or its staff had possession, control, or knowledge of the items in the bathroom, rather than Woodland having the "responsibility . . . to show it did not know of a condition's presence." Woodland Br. at 15.¹⁰ Woodland also

A facility must prevent accidents where it is possible for the facility to do so. Here, the evidence does not show that the resident's possession of a razor was an event that the facility either knew about or should have known about. Moreover, the only way in which Petitioner could have prevented this resident - or any resident from having an unauthorized razor would be by systematically searching each resident's possessions. Had Petitioner done so other issues of privacy rights and dignity no doubt would have arisen.

(continued...)

¹⁰ The only authority Woodland cites for this proposition is Carehouse Convalescent Hospital, DAB No. 1799 (2001), which Woodland describes as overturning a Tag 323 deficiency for a razor found at a resident's bedside because no evidence proved that the facility left it there and Tag 323 does not "impose a strict liability standard." Woodland Br. at 15. The cited Board decision contains no discussion of Tag 323 at all. The earlier ALJ decision in that case overturned the citation of Tag 323 where a resident had secreted a razor invisibly inside a personal box of tissues at her bedside. The ALJ's explanation undercuts rather than supports Woodland's claim that it had no responsibility for conditions openly observable in a common bath area:

argues that the condition was removed in fact, because a nurse picked up the scissors, and removal constituted substantial compliance. <u>Id</u>. According to Woodland, substantial evidence in the record viewed as a whole thus does not support the ALJ's conclusion that the regulation was violated. <u>Id</u>. at 16.

We disagree with Woodland's characterization both of the burden of proof and of the evidence of record. CMS's uncontradicted evidence established that three obvious hazards were present in an open common bathroom used by multiple residents and staff. Woodland has provided no persuasive reason that CMS must also prove that the hazards were either placed there by staff members or were actually known to be there by the staff. As the ALJ noted, in Alden Town, the Board rejected the idea that CMS had to prove that a container left accessible to residents actually contained the hazardous substance for which it was labeled. DAB No. 2054, at 7. As the Board explained, "it sufficed for CMS to show that a product which potentially was and was believed to be hazardous was left unattended within reach of extremely Id. In so holding, the Board quoted from vulnerable residents." an earlier decision articulating the standard applicable under Tag 323, as follows:

> 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 If a facility has identified and planned for condition. a hazard and then failed to follow its own plan, that may be sufficient to show a lack of compliance with the regulatory requirement. In other cases, an ALJ may need to consider the actions the facility took to identify, remove, or protect residents from the hazard. 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. 2054, at 7, <u>quoting</u> <u>Maine Veterans' Home - Scarborough</u>, DAB No. 1975 (2005) (footnote omitted).

¹⁰(...continued)

<u>Carehouse Convalescent Hospital</u>, DAB CR729, at 39 (2001), <u>rev'd</u> <u>in part and aff'd in part</u>, DAB No. 1799.

The sensibleness of this reasoning is plain in the present case. Information about the measures taken by Woodland and its staff to discover and respond to these hazards would be largely within the The facility staff, for example, could control of the facility. have testified as to their knowledge of how the scissors, uric acid eliminator, and pool of water came to be in the bathroom.¹¹ The facility could have presented evidence demonstrating a protocol to inspect the bathrooms or all common areas on some schedule that might have substantiated the unsupported assertion Woodland now makes that these "dangerous items . . . may have been left there by someone other than staff scant minutes prior to an investigation." Woodland Br. at 16. Woodland points to nothing of this sort in the record, relying only on its allegation that CMS's evidence falls short of proving the contrary propositions.

Further, Woodland emphasizes that the surveyor provided uncontradicted testimony that the staff nurse accompanying her on the inspection of the bathroom immediately picked up the scissors and put them in her pocket. Woodland Br. at 15. From this testimony, Woodland concludes that the facility actually acted promptly to remove the dangerous condition. <u>Id.</u> at 16. Even if we accepted that the nurse's reaction in front of the surveyor established that the facility responded to remove that hazard, Woodland proffers no evidence or even allegation that the uric

¹¹ The most relevant evidence the facility even offered on this point was testimony from Ms. Julie Cain, administrative supervisor, that she did not know how the one-gallon container of uric acid eradicator came to be in the bathroom and that the substance was not one that the facility provides. Tr. at 661. She did not testify as to whether any investigation was done to determine if anyone on staff could shed light on the provenance of the eradicator. She also testified that she was not aware of a problem with water on the floor at that bathroom and that a resident could have showered and created the pool without receiving assistance from a facility employee. Tr. at 662. Again, she offered no evidence that the facility determined that an independent resident had in fact showered just before the surveyor arrived at the bathroom such that staff had not had an opportunity to clean up the pool of water. In addition, the record contained conflicting evidence on how often a pool of water had recurred at that location, and it was within the province of the ALJ to determine not to give weight to Ms. Cain's denial, especially since she did not establish that she would necessarily have been aware of any recurring problem of that nature.

acid eliminator was similarly removed or that the pool of water was promptly cleaned up or that residents were otherwise protected from those hazards.

We therefore conclude that the ALJ's findings were adequately supported and the ALJ's conclusion regarding this tag was not erroneous.

5. Substantial evidence in the record as a whole supports the ALJ's conclusion that Woodland was not in substantial compliance with Tag 324 at the January survey.

The corresponding requirement for this tag, again part of the quality of care regulation, provides that a facility must ensure that "[e]ach resident receives adequate supervision and assistance devices to prevent accidents." 42 C.F.R. § 483.25(h)(2). The January SOD reported that facility records showed that, at 3:30 PM on December 28, 2002, Resident 4 was found face down on the asphalt at the bottom of stairs outside an exit door of the facility. CMS Ex. 1, at 7-8. Resident 4 was still restrained in her wheelchair and was bleeding from an injury to her head. <u>Id.</u>; <u>see also</u> ALJ Decision at 25. The resident was 92 years old and suffered from impaired decisionmaking and safety awareness, dementia, and depression, syncopal episodes, mini-strokes, and multiple other diagnoses. See ALJ Decision at 26, and citations therein to resident's clinical records in P. Ex. 7. The surveyors reported a history of falls (including another on November 16, 2002 when the resident toppled over in her wheelchair after exiting the facility) and wandering behavior with attempts to exit the facility (including two times in a single afternoon on December 1, 2002). CMS Ex. 1, at 8. The surveyors found that Resident 4 had been assessed as high risk for elopement and falls, but they concluded that Woodland did not respond to these events with reassessments, adequate care planning and implementation, or compliance with its own Wandering Resident policy to "determine the reason for wandering in an effort to reduce triggers." Id. at 9.

The ALJ stated that CMS had demonstrated that the accident which occurred was foreseeable and that, while the occurrence of an accident in itself does not prove a violation of the regulatory requirements, the evidence as a whole before the ALJ showed that Woodland had not provided Resident 4 with adequate supervision or assistive devices. ALJ Decision at 25-26, citing the regulatory standard articulated in <u>Alden Town</u> at 10-11. The ALJ noted consistent assessments in Resident 4's records of high fall risk and a wandering/elopement risk assessment dated November 18, 2002, but found nothing showing care planning and implementation

to minimize the "risk of accidents secondary to the resident's foreseeable attempts to leave the facility, i.e., elope," as opposed to fall prevention and anti-wandering interventions. ALJ Decision at 26-27, and record citations therein. The ALJ discussed in detail specific care plans and planned interventions, including checking her whereabouts, documenting and reporting any changes in mental status, and using behavior monitoring forms, from November 12, 2002-January 2, 2003 (after which Resident 4 was moved to the secured unit). Id. at 27-29, and record citations therein. Nevertheless, the ALJ concluded that Woodland did not directly address exit-seeking behavior even after the resident's repeated attempts to go out through facility Id. at 29. exit doors. The ALJ concluded that Woodland was not in substantial compliance under Tag 324 because despite "continued falls and attempted exits, the record does not show that Petitioner attempted to use interventions such as bed and chair alarms, exit alarms, or one-on-one observation," the last of which he noted had been included as a planned intervention but found "no evidence it was ever done." Id. at 29, and n.15.

Woodland contends that CMS did not make out a prima facie case. Woodland Br. at 17. Woodland acknowledges that a facility "should supervise residents in order to minimize risks," but argues that the regulations do not impose "strict liability" but instead call for "common sense balancing" of this obligation with "the right to engage in risky behavior, and the resident's right to privacy or to reject treatment and care." Id. at 18.

For this proposition, Woodland cites an ALJ decision, <u>The</u> <u>Residence at Salem Woods</u>, DAB CR1311 (2005). Woodland Br. at 18. Woodland quotes out of context language from a discussion which actually concludes that such balancing cannot justify evading the clear duty to protect the residents:

> Petitioner's argument that the resident, or in this case her daughter, had the right to dictate care and services, is no defense to the violation in this case. There is no question that resident rights are protected under the regulations. However, a facility has to balance the need to protect the resident from harm and the resident's right to engage in certain behaviors. The fact that a resident may have a right to engage in behavior, including certain risky behaviors, does not relieve the facility of the duty to care for residents in their facility and to minimize the risk for harm to a resident or other residents. There needs to be a common sense balancing of the need to supervise a resident, the right to engage in risky behavior, and the resident's

right to privacy or to reject treatment and care. <u>See</u> e.q. Tr. 186-88.

In this case, Petitioner did not supervise Resident 14 when she went outside in her wheelchair although it was clear to Petitioner that she required such supervision. Tr. 181-82. It is no defense that Resident 14's daughter insisted that Resident 14 be permitted to go outside, as Petitioner cannot simply avoid its duty to care for and protect a resident.

DAB CR1311, at 35.12

Woodland concludes that the ALJ failed to accept evidence in the record that Woodland provided adequate supervision and assistance devices but instead imposed an improper requirement that Woodland undertake specific interventions which Dr. Tilley testified had either been tried or were inappropriate for her. <u>Id.</u> at 20; Tr. at 565-69.

Woodland's assertion that CMS failed to present a prima facie case under this tag is without merit. CMS provided evidence that Resident 4 was known to be at high risk of accidents from exitseeking behavior in light of her mobility in the wheelchair and her compromised mental status, that she had a history of many falls and multiple attempts to exit the facility, and that she had previously fallen while exiting through an unlocked door. CMS presented evidence that, despite use of a wheelchair restraint and a plan for monitoring every 30 minutes, Resident 4 was able to exit the facility and sustained injuries in the December 28, 2002 fall. The fact of the accident does not alone prove that Woodland's supervision and/or assistance devices were inadequate, but the ALJ could reasonably infer from the circumstances of this accident and the other evidence before him

¹² We also note that, on appeal, the Board rejected Salem Woods' attempt to frame the ALJ's holding as imposing "strict liability," concluding that the ALJ properly understood that "the quality of care regulations under section 483.25 'hold facilities to meeting their commitments to provide care and services in accordance with the high standards to which they agreed but do not impose strict liability, i.e., they do not punish facilities for unavoidable negative outcomes or untoward events that could not reasonably have been foreseen and forestalled.' <u>Tri-County Extended Care Center</u>, DAB No. 1936, at 7 (2004)." <u>The Residence at Salem Woods</u>, DAB No. 2052, at 6, n.3 (2006).

that Resident 4's needs were not adequately addressed absent a contrary showing by Woodland. ALJ Decision at 26, 29.

In an effort to rebut the evidence supporting CMS's findings, Woodland counters that it did increase its interventions in response to Resident 4's falls and wandering behavior. Woodland Br. at 19. According to Woodland, the facility tried "any number" of the possible interventions mentioned by CMS's expert, or concluded they would not help or might be problematic, and concluded that Resident 4's falls occurred despite taking the "best and most prudent measures." Woodland Br. at 20.13 Woodland points to its adoption of side rails and belts for bed and wheelchair as restraints after a fall in September 2002 and of 30-minute monitoring after the November 16, 2002 incident in which she fell after exiting the facility. Id. at 19. Woodland also states that the care planning in November 2002 included a call for "one-on-one observation, if necessary," but fails to identify any evidence that such observation was ever actually implemented even after recorded episodes of unsafe wandering and repeated attempts to exit in December. Id. at 19-20; see ALJ Decision at 28 and record citations therein.

Woodland argues that the staff thwarted these elopement attempts so the care plan must have been followed and proven successful. Woodland Br. at 20. This is not a necessary inference.¹⁴ The record shows escalating elopement attempts after November 17, 2002 when the monitoring care plan was adopted but does not document implementation of the one-on-one observation or assessment of whether additional interventions were called for in light of the escalating risk. Woodland points to nothing in the record showing it considered or adopted any measure to address the ease with which a disoriented, wheelchair-bound resident was able to open and exit various doors to leave the facility. While Woodland argues that bed or wheelchair alarms would not have prevented Resident 4's fall down the exit stairs, Woodland never

¹³ Woodland drew the quoted language from the ALJ Decision in <u>Beechwood Sanitarium</u>, DAB CR821 (2001).

¹⁴ Woodland essentially asks us to assume that unsuccessful elopement attempts prove adequate supervision but that "successful" exits from the facility do not implicate the adequacy of supervision. We make neither assumption but look rather at whether substantial evidence in the record as a whole supports the ALJ's evaluation of whether the measures actually undertaken by Woodland adequately addressed the known risks to Resident 4.

explains why a door alarm system (such as WanderGuard) would not have been feasible and effective nor why other approaches were not considered or attempted (such as securing the doors in a way that competent individuals could operate them but residents like Resident 4 would not be able to do so or would at least be delayed so that staff would be more likely to see and respond to an attempt to exit.)

Woodland's further claim to have sensibly balanced the need to protect Resident 4 from accidents with deference to her rights to refuse treatment and to "engage in risky behavior" is unsupported factually as well as legally. Woodland identifies no relevant documented refusal of care by Resident 4 or on her behalf or choice by her or on her behalf to engage in particular risky behavior contrary to medical advice or facility policy. <u>See</u> 42 C.F.R. § 483.20(k)(1)(ii) (a care plan must document a resident's refusal of services that are otherwise required under section 483.25).

Woodland asserts that, even after it took the "most extreme measure it could" by relocating the resident to the secure unit, she continued to experience falls and her family asked that she be moved back to a regular room. Woodland Br. at 20-21. Her stay in the secure unit began on January 3, 2003. Clearly, this intervention did not respond to the November 17, 2002 incident, nor the subsequent repeated attempts to elope in December, and was not attempted until almost a week after even the December 28, The move to the secure unit "due to continued 2002 incident. attempts to exit" the facility is documented in nurse's notes. CMS Ex. 13, at 50. Woodland does not identify on appeal any documentation of the family's request to move her out of the secure unit or its resolution. A facility social services progress note, however, shows that her daughter-in-law made such a request on January 22, 2003 and was informed that the secure unit location was the "best place for saf[e]ty" for the resident and that the resident was responding better to staff and peers in that setting. Id. at 117-18; see also id. at 4. It is thus not at all clear that Woodland could not have at least tried this alternative setting at an earlier point after the continued elopement attempts and the "successful" exit from the facility on December 28, 2002 made evident that other interventions were not adequate to forestall elopement. The fact that Resident 4 still had falls in the secure unit does not undercut the evidence that her risk of elopement or of accidents from attempting to exit the facility were reduced in that safer setting.

In any case, the ALJ did not indicate that placement in a secure unit was the only option, but rather that Woodland was required to address the dangers presented by the combination of the resident's exit-seeking behavior, dementia, and mobility. Given that she had already sustained a similar fall after exiting in her wheelchair through an opened back door in November 2002, the ALJ could reasonably conclude that the facility should have made some new plan of action directed specifically at the resident's potential to suffer accidents by exiting through unsecured doors. ALJ Decision at 29. Other options included one-on-one individual supervision, use of alarm systems, and any method of controlling Resident 4's egress through open or unlocked doors.

We therefore conclude that the ALJ's findings were adequately supported and the ALJ's conclusion regarding this tag was not erroneous.

6. Woodland's other arguments are without merit.

Woodland rests its request that the CMP and DPNA should be reversed solely on the arguments rejected above that it was in substantial compliance with all of the cited tags or at least that any failings did not rise to the level of even minimal harm. Woodland Br. at 22. We have explained why we affirm the ALJ's conclusions about each of the deficiency findings. We also note that deficiency findings need not rise to the level of "minimal" actual harm but simply must, at a minimum, create the <u>potential</u> for more than minimal harm.

Woodland also requests, in the alternative, that "the scope and severity level of each deficiency be appropriately reduced, the amount of the CMPs be likewise reduced, and the DPNA reversed." Woodland Br. at 22. Under the regulations, we have no authority to reduce the scope and severity level of deficiencies where, as here, we have upheld the factual findings on which the noncompliance was found and where a successful challenge to the level of noncompliance would not affect the range of applicable CMPs or a finding of substandard quality of care resulting in loss of a nurse aide training program. 42 C.F.R. § 498.3(b)(14). Woodland has not shown that either condition obtains here to authorize us to review the scope and severity level of the deficiencies at issue. Furthermore, 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). We therefore have no authority to reverse the DPNA here. Neither we nor the ALJ may review CMS's discretion in determining to impose a CMP nor reduce a CMP to zero, where a basis to impose a CMP exists. 42 C.F.R. § 488.438(e)(1) and (2).

It is not clear if Woodland intended to seek review of the reasonableness of the amounts of the CMPs imposed even assuming we made no change in the scope and severity levels or the number of deficiencies upheld. In any case, if we reached the issue of the reasonableness of the amounts, we would make no change in the remedies imposed. As the ALJ noted, the amount of the \$50 per day CMP is the lowest authorized amount for a per day CMP, and therefore must be viewed as reasonable as a matter of law since we have found a basis for CMS to impose a remedy. ALJ Decision at 34, citing 42 C.F.R. § 488.438(a)(ii) and (e). The ALJ also found that the amount of the \$350 per day CMP was reasonable, in light of the actual harm to multiple residents and the culpability demonstrated. <u>Id.</u> at 35. Woodland has not demonstrated any error in that assessment, and we find none.

<u>Conclusion</u>

For the reasons explained above, we affirm the ALJ Decision in its entirety and sustain the remedies imposed therein.

/s/ Judith A. Ballard

/s/ Constance B. Tobias

<u>/s</u>/

Leslie A. Sussan Presiding Board Member