Department of Health and Human Services

DEPARTMENTAL APPEALS BOARD

Appellate Division

In the Case of:	DATE: May 30, 2000
Woodstock Care Center	
Petitioner,	Civil Remedies CR623 App. Div. Docket No. A-2000-32 Decision No. 1726
- v. -	
Health Care Financing Administration.	

FINAL DECISION ON REVIEW OF ADMINISTRATIVE LAW JUDGE DECISION

Woodstock Care Center (Woodstock), appealed the November 1, 1999 decision of Administrative Law Judge (ALJ) Steven T. Kessel upholding the imposition by the Health Care Financing Administration (HCFA) of a Civil Monetary Penalty (CMP) on Woodstock in the amount of $3,050 per day for the period from March 4, 1998 through March 14, 1998. See Woodstock Care Center, DAB CR623 (1999) (ALJ Decision). Woodstock excepted to findings of fact and conclusions of law (FFCLs) to the effect that, during that period, Woodstock was not in substantial compliance with quality of care requirements set out at 42 C.F.R. § 482.25(h)(2) and that the noncompliance was at a level that constituted immediate jeopardy. Noncompliance at the immediate jeopardy level had been found in a survey in February 1998 and during follow-up monitoring in March 1998. The surveyor findings at issue centered on Woodstock's alleged failure to provide supervision to its residents at a level adequate to prevent accidents, as evidenced by repeated elopements and resident-to-resident physical attacks, often involving severely cognitively-impaired residents and, in some cases, resulting in serious injury. Woodstock challenged the ALJ's factual findings and

legal conclusions, arguing in particular that the events cited were not "accidents" and were not reasonably foreseeable or preventable. For the reasons explained in detail below, we conclude that the ALJ's factual findings were supported by substantial evidence in the record and that the ALJ properly interpreted the applicable regulatory language. Therefore, we sustain the ALJ Decision in its entirety and affirm and adopt each of the FFCLs.

Factual Background

Woodstock is a long-term care facility in Ohio that participates in the Medicare and Medicaid programs. At the relevant time, the facility housed 43 residents. Of those, 22 suffered from some form of dementia and 35 exhibited behavioral symptoms. A Woodstock employee made a complaint about the facility to the Ohio Department of Health (ODH), the State agency designated to perform surveys of such facilities. ODH surveyors initiated a complaint survey on February 17, 1998. As a result of the conditions observed, the surveyors expanded the scope of their survey to a standard survey, and ultimately an extended survey, which ended on March 4, 1998. HCFA Ex. 2, at 8. Woodstock was found out of compliance with 18 participation requirements. HCFA Ex. 2. The level of noncompliance with one of those participation requirements, marked as F Tag 324, was found to present immediate jeopardy to Woodstock's residents. Id. at 1-2, 49.

F Tag 324 assessed compliance with 42 C.F.R. § 483.25(h)(2), requiring facilities to ensure that each resident receives supervision adequate to prevent accidents. The survey report especially cited concerns about the facility's handling of repeated altercations and elopements involving severely mentally-impaired residents. HCFA Ex. 2, at 49-61. Woodstock did not dispute that certain of its residents had caused injuries (some of them quite serious) in unprovoked altercations with other disabled residents. See, e.g., Woodstock Reply Br. at 3. Woodstock further did not dispute that certain residents left the facility on a number of occasions, while rejecting HCFA's characterization of certain of these episodes as elopements. Id. The dispute at the hearing and on appeal to us centered rather on whether the concerns were properly cited under this tag number and whether Woodstock had taken reasonable steps to respond to the residents' need for supervision.

The surveyors made several follow-up visits and found additional instances of inadequate supervision of residents in hazardous situations. Finally, the surveyors determined on March 15, 1999

that the immediate jeopardy had been removed. On April 29, 1999, they found that Woodstock had achieved substantial compliance with the remaining requirements as of March 17, 1998.

Based on the survey findings, HCFA decided to impose a CMP of $3,050 per day for the period during which immediate jeopardy was found, as well as a CMP of $50 per day for March 15-16, 1998 when noncompliance at a lower level of severity was found to have persisted.[1] The total CMP amount was $33,650.

Legal Authority

Pursuant to sections 1819(a)-(d), 1861(1), and 1919(a)-(d) of the Social Security Act (Act), the Secretary has promulgated regulations at 42 C.F.R. Part 483 that contain the requirements that a facility must meet in order to qualify to participate in the Medicare and Medicaid programs. To participate in Medicare, a provider must have a provider agreement. Section 1866(a) of the Act. In addition, the Act provides for a survey and certification process, under which state survey agencies are generally responsible for certifying compliance with the requirements for participation. Sections 1819(g) and 1864 of the Act. "[C]ertification" is a "recommendation made by the State survey agency on the compliance of providers . . . with the conditions of participation . . . ." 42 C.F.R. § 488.1; see 42 C.F.R. § 488.12. Furthermore, the facility must maintain substantial compliance with the applicable requirements to continue to be eligible to participate. Under the regulations, a "State survey agency certification to HCFA that a provider . . . is no longer in compliance with the conditions of participation . . . will supersede the State survey agency's previous certification." 42 C.F.R. § 488.20(c).

Section 483.25 of the regulations sets out program requirements that a facility must meet to ensure an acceptable quality of care to residents. The opening provision describes an outcome which the facility is expected to achieve and subsidiary provisions detail specific components of that goal which facilities are to achieve. The overall requirement is as follows:

---

[1] Woodstock did not appeal the ALJ's conclusion upholding the non-immediate jeopardy CMP for March 15th and 16th embodied in FFCLs 5 and 6. ALJ Decision at 16. We therefore affirm and adopt these FFCLs without further discussion. Consequently, the amount of the CMP presently in dispute is $33,550.

> 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.

The more specific component under quality of care with which Woodstock was found out of compliance at the immediate jeopardy level reads as follows:

> (h) *Accidents.* The facility must ensure that --
>
> * * *
>
> (2) Each resident receives adequate supervision and assistance devices to prevent accidents.

42 C.F.R. § 483.25(h)(2).

"Accident" is defined in the State Operations Manual (SOM) issued by HCFA as "an unexpected, unintended event that can cause a resident bodily injury," excluding "adverse outcomes associated as a direct consequence of treatment or care (e.g., drug side effects or reactions)." SOM Appendix PP, Guidance to Surveyors, Part 2, SOP 483.25 Quality of Care (Rev. 274, June 1995) (SOM Guidance).

Long-term care facilities like Woodstock are subject to various kinds of enforcement surveys conducted by surveyors from a state survey agency to determine whether the facilities are in compliance with federal participation requirements. See 42 C.F.R. §§ 488.305, 488.307, 488.308, 488.310, 488.332. Where deficiencies are found in a survey, the state survey agency and HCFA assess the seriousness of the deficiencies on a scale that considers scope (how isolated or widespread the deficiency is) and severity (how great the harm or potential for harm the deficiency causes). 42 C.F.R. § 488.404. The findings are reported on a standard form (called a "2567") that identifies specific deficiencies and assigns "tag" numbers identifying the regulatory requirements at issue. In order to be found in "substantial compliance," a provider must have no deficiencies that pose a risk to resident health or safety greater than "the potential for causing minimal harm." 42 C.F.R. § 488.301. At the other extreme, the most serious deficiencies are those determined to constitute immediate jeopardy.

The Act and the regulations further provide a variety of remedies, including the imposition of CMPs, to enforce prompt

compliance with program requirements. See sections 1819(h) and 1919(h) of the Act; 42 C.F.R. Subpart F. The Act provides authority for HCFA to impose CMPs of up to $10,000 per day on facilities that are not in substantial compliance with Medicare and Medicaid participation requirements. Sections 1819, 1919, and 1866(b)(2) of the Act. Regulations limit the amount of CMPs imposed to amounts set at $50 increments within two ranges. 42 C.F.R. § 488.438(a). The upper range is from $3,050 to $10,000 per day and applies whenever a deficiency is found at the immediate jeopardy level. 42 C.F.R. § 488.438(a)(i). The lower range is from $50 to $3,000 per day and applies when the deficiencies found have the potential to cause more than minimal harm but do not constitute immediate jeopardy. 42 C.F.R. § 488.438(a)(ii).

The ALJ Decision

Woodstock took exception to the following four FFCLs from the ALJ Decision:

> 1. Between March 4, 1998 and March 14, 1998, Petitioner failed to take adequate measures to ensure that residents did not assault other residents and to ensure that residents were protected from assaultive behaviors of other residents. Furthermore, Petitioner failed to take adequate measures to deter residents from eloping from its facility.
>
> a. Petitioner knew that some of its residents were at risk for assaulting other residents yet did little or nothing to prevent assaults from occurring.
>
> b. Petitioner knew that some of its residents were at risk for eloping from its facility yet did little or nothing to prevent residents from eloping.
>
> 2. Beginning with March 4, 1998, and continuing through March 14, 1998, Petitioner failed to comply with the requirements of 42 C.F.R. § 483.25(h)(2) to the extent that residents of Petitioner's facility were in immediate jeopardy.
>
> 3. Petitioner's affirmative defenses are not persuasive.

> 4. A $3,050 per day CMP imposed by HCFA for the period beginning on March 4, 1998, and ending on March 14, 1998, is reasonable.

ALJ Decision at 4-15 (bold and italics removed from original) (numbered FFCLs excerpted from text of decision).

The substantive core of the ALJ's analysis is reflected by the following excerpts from the decision:

> There is strong and essentially unrebutted evidence that Petitioner allowed several of its residents to perpetrate assaults against other residents. Petitioner did little or nothing to prevent assaults and what minimal measures it took were ineffective. Moreover, the evidence establishes that Petitioner failed to supervise its residents in order to ensure against their eloping from Petitioner's facility. The consequence was that several of Petitioner's residents eloped. At least one of these residents eloped on multiple occasions.
>
> * * *
>
> As a consequence of Petitioner's failure to supervise its residents, residents were assaulted and beaten so severely that they needed hospital treatment . . . and frail, demented individuals were allowed to escape the premises of Petitioner's facility to wander unsupervised along trafficked roads.

ALJ Decision at 4, 11. The ALJ rejected Woodstock's argument that what occurred could not be considered "accidents" because the residents who assaulted other residents or eloped acted intentionally. The ALJ found that the assaults were accidents from the viewpoint of the victims and that the eloping residents were subject to injuries from accidental causes while at large, even if the elopement itself could be viewed as volitional. Id. at 14. The ALJ further found that Woodstock had failed to show that any of the impaired and demented residents involved had the mental capacity to plan or execute "volitional acts." Id. at 13.

The ALJ further concluded that--

> whether the assaults or elopements were intentional or not is irrelevant to my determination that Petitioner failed to supervise its residents adequately to prevent them from sustaining accidents. The ultimate issue here is not whether residents were assaulted or eloped, or

> whether these residents were injured as a consequence of assaults or elopements, but whether *Petitioner failed adequately to supervise residents to prevent their injury from accidental causes.* Residents who are not supervised in their daily activities are susceptible to injury, not just from assaults or from the consequences of their elopements, but from other causes as well. The evidence which shows that repeated unprovoked assaults were tolerated by Petitioner, coupled with the evidence which shows that residents were able to escape Petitioner's facility on multiple occasions, is ample evidence of a lack of supervision of these residents.

ALJ Decision at 13-14 (emphasis in original).

The ALJ's factual findings about specific residents and episodes are discussed in the analysis below.

Petitioner's arguments on appeal

Woodstock did not dispute that "instances of assaults or elopements ultimately occurred," but Woodstock excepted to the above-quoted FFCLs as based on a faulty interpretation of the relevant regulatory requirement. Woodstock Br. at 4; Woodstock Reply Br. at 2-3. Woodstock reasoned that prerequisites to any deficiency under F Tag 324 are findings that (1) an "accident" occurred, and (2) the accident could have been "practically prevented by assistive devices and/or a level of supervision that Woodstock failed to provide." Id. at 2, n.1.

Woodstock argued that the ALJ had instead improperly accepted HCFA's premises that assaults are accidents, that unprovoked assaults can be prevented, that any departure by a person who wants to and is able to leave the facility even momentarily is an elopement, and that every instance of an assault or elopement is an accident causally related to inadequate supervision (despite security measures and the highest practicable supervision having been provided). Id. at 2. Woodstock contended that intentional behavior could by definition not constitute an "accident." Woodstock Br. at 3-8. In addition, Woodstock contended that whether a particular incident was an intentional act or an accident must be evaluated from the point of view of the actor not the victim. Id. at 7.

Woodstock also took the position that mere knowledge of a risk of elopement or assault by a resident generally did not give notice to Woodstock sufficient to justify holding the facility responsible for specific unpredictable incidents since the

regulation does not provide for strict liability. Woodstock Br. at 16, 27, 33.

Woodstock also argued that, to the extent that the ALJ was correct in finding that HCFA had established a prima facie case, Woodstock's affirmative defenses were meritorious. Woodstock Br. at 4.[2] Specifically, Woodstock contended that the assaults were "unpredictable manifestations of the drug treatment of the residents' diagnoses." Id. at 4; see also id. at 22-26, 32. In addition, Woodstock argued that immediate jeopardy had not been established for several reasons:

- The elopements were isolated and presented little potential for harm. Id. at 4, 16-22.
- The elopements and assaults were not predictable or preventable by any measures within Woodstock's control that would be consistent with residents' rights. Woodstock Reply Br. at 12.
- Since the immediate jeopardy determination was lifted with no changes to Woodstock's staffing, any staffing issues must not have presented immediate jeopardy. Woodstock Br. at 31.

Finally, Woodstock attributed responsibility for the difficulties it had with certain residents to the residents' over-medication ("snowing") and mistreatment by the Federal government in their earlier placements in Veterans Administration (VA) facilities. In addition, Woodstock suggested that allegedly fraudulent information provided by the VA and State of Ohio to Woodstock caused it to accept the transfers. Woodstock Reply Br. at 6, 12, 15, 19-20.

Standard of Review and Burden of Proof

---

[2] Woodstock argued that the ALJ mischaracterized as affirmative defenses most of its arguments relating to the meaning of "accident" and the scope of a facility's duty of prevention. Woodstock Br. at 31-32; cf. HCFA Br. at 2; ALJ Decision at 13-15. We agree that these issues are properly viewed as legal interpretation questions rather than as affirmative defenses. We conclude in our analysis on the substance of Woodstock's arguments that the ALJ correctly resolved these issues in HCFA's favor. Hence, any error in characterizing them as affirmative defenses was harmless.

Our standard for review of an ALJ decision on a disputed issue of law is whether the ALJ decision is erroneous. Our standard for review of a disputed issue of fact is whether the ALJ decision as to that fact is supported by substantial evidence on the record as a whole. See, e.g., Fairview Nursing Plaza, Inc., DAB No. 1715, at 2 (2000); South Valley Health Care Center, DAB No. 1691 (1999). Where the ALJ's findings rely on his assessment of the credibility of witnesses, we give deference to that assessment on appeal. See, e.g., Oak Lawn Pavilion, Inc., DAB No. 1638 (1997). The applicable burden of proof requires HCFA to come forward with sufficient evidence to prove a prima facie case that the facility is not complying with one or more participation requirements and ultimately requires the facility to show substantial compliance, by a preponderance of the evidence, effectively rebutting any prima facie case of noncompliance established by HCFA. Hillman Rehabilitation Center, DAB No. 1611 (1997); aff'd Hillman Rehabilitation Center v. United States, No. 98-3789(GEB) (D.N.J. May 13, 1999). HCFA's determination that a deficiency constituted immediate jeopardy must be upheld unless the facility proves that the determination was clearly erroneous. 42 C.F.R. § 498.60(c)(2).

Analysis

A. Substantial evidence in the record as a whole supports the factual findings of the ALJ.

Many of Woodstock's legal arguments were premised upon factual assertions and assumptions that ignore or contradict the ALJ's findings as to the events at issue. We must therefore disentangle arguments about the proper legal standard and its application to the facts from allegations about the nature and course of the events at issue. To do so, we first consider what the evidence in the record supports concerning the events themselves. Various events cited as examples of the evidence supporting the finding of a deficiency in F Tag 324 are described in detail in the ALJ Decision, in the surveyors' reports, in the testimony, and in other record evidence. Overall, and after careful review of the entire record, we conclude that substantial evidence supports the ALJ's findings of fact with respect to the events that formed the basis for HCFA's determination of noncompliance. In many instances, the proof offered by HCFA was derived from Woodstock's own contemporaneous records and was not rebutted meaningfully at the hearing, but rather countered only by unsupported assertions in Woodstock's briefing.

In order to illustrate our reasons for affirming the ALJ's factual findings, we track the evidence concerning Woodstock's

care of two residents, denominated as Resident (R.) 3 and R. 11, upon whom Woodstock focused in its briefs. We note that we also examined all the evidence as to the other residents identified in the survey report with equal care and found analogous (or even more convincing) support for the findings made by the ALJ as to the events relating to those residents.

1. Our review of the evidence relating to R 3[3]

R. 3 was an 81-year old woman who was admitted to Woodstock on January 4, 1998. Woodstock Ex. 4, at 7. She was assessed as having advancing dementia, as being high risk for elopement, with a history of wandering, and as being unable to survive independently in the community. Id. at 1-2. On the same day as her admission, she was discovered missing and found outside the facility's grounds on a heavily-traveled rural road having ambulated with a walker "past a large unfenced pond and rubble from a burned building." ALJ Decision at 10; Tr. at 93; HCFA Ex. 2, at 57. Woodstock described this incident as a "singular, 'brief' elopement down the driveway of Woodstock" and no more than "an anecdotal episode for which Woodstock was not on prior notice." Woodstock Reply Br. at 14. In support, Woodstock asserted:

- R. 3 "never left the facility's geographic premises and displayed a level of cognition that demonstrated an understanding of the weather conditions and reasons surrounding her departure;"
- R. 3 was wearing a WanderGuard alarm at the time that went off and alerted the staff;
- a visitor held the exit door for R. 3 because R. 3 was wearing her coat and hat and because R. 3 routinely had left in the same way when she had visited her husband before her own admission; and
- R. 3 was not injured and the Medical Director was properly informed.

Woodstock Br. at 19-20. Woodstock called it mere speculation on the part of HCFA that the resident might have been inclined to swim in the pond in January or to traverse the burned-out rubble with her walker and thus endanger herself. Id. at 20. Woodstock

[3] Detailed discussion of R. 3's history can be found on pages 9-10 of the ALJ Decision.

argued instead that R. 3 was in no danger and should not really be considered to have eloped because she knew what she was doing, i.e., going home as usual. Id. at 8.

Woodstock's factual description of this episode is apparently derived primarily from testimony by the former Director of Nursing (DON) Ms. Joni DeLay (although Woodstock did not cite to specific sources for many of its factual assertions). When asked on direct examination about R. 3's departure, Ms. DeLay stated that R. 3 had regularly visited her husband in the facility before her own admission that day and that another visitor held the front door for her. Tr. at 417. According to Ms. DeLay, R. 3 then "decides to walk on out the door while it was being held open. She got about out to the parking lot, and then we got her back in." Id. Asked whether R. 3 made it down the street or to the highway, Ms. DeLay testified: "Not that I'm aware of, no." Id. Ms. DeLay further asserted that R. 3 ran no risk of injury as a result of leaving the facility and, in fact, that she was in no greater risk outside the facility than in it. Id. at 428. On cross-examination, Ms. DeLay asserted that R. 3's WanderGuard alarm went off and staff responded and retrieved her "right there at the end of the parking lot." Tr. at 437.

The nursing notes on this episode (signed by S. McNeal, R.N.) describe the events as follows: "2:30 Res missing from facility. Room to room search conducted res not in facility ....2:40 Res found oo [outside of] building. Res ambulated per walker down Park Lane to stop sign. Res. trans. to WCC [Woodstock] per car . . . ." P. Ex. 4, at 7 (abbreviations in original); see also Tr. at 89-91. The nursing notes also record that, hours after the elopement, a WanderGuard was used with R. 3. No mention occurs in the documentation of any role played by a visitor, of an alarm sounding, or of how R. 3 was dressed at the time she eloped that day.[4] The assertions that a visitor held

[4] However, two days later, the nursing notes (signed by C. Roberts, L.P.N.) record another incident at 4 a.m. in which R. 3 had been pacing all night and at "one point she dressed, got her purse, hat and coat, and went out the front door. She said she was waiting on the bus. Came back [without complaint]." P. Ex. 4, at 7. The coincidence of the description with the DON version of the admission day episode suggests the possibility that Ms. DeLay had confused or combined two different events. The absence of any documentation of R. 3's attire during her admission-day elopement casts doubt on Woodstock's flat assertion that she "was dressed properly" for the outdoors on that occasion. Cf.

(continued...)

the door open for R. 3, and that R. 3 left just because she was used to leaving after visiting were also entirely unsubstantiated. Ms. DeLay acknowledged that the nursing notes, which were supposed to be a timely and accurate record of an incident, contained no mention of staff observing R. 3's departure or responding to an alarm, and recorded that R. 3 was found on Park Lane not in the parking lot. Tr. at 436-37.

The ALJ, after having the opportunity to observe the demeanor of Ms. DeLay on the stand, did not accord weight to her version of this episode. ALJ Decision at 10. He credited instead the account of events recorded contemporaneously in the facility's records over the later-proffered account of Ms. DeLay. Id. We agree with the ALJ's evaluation of the evidence for a number of reasons. As noted, Ms. DeLay never indicated that she personally observed the discovery of R. 3's departure or where or how R. 3 was located. The facility offered no other witnesses or affidavits from among the staff who were present at or involved in the incident. Ms. DeLay provided no contemporaneous documentation of her version of the incident. Her account was internally inconsistent or vague on a number of details. For example, she described R. 3 as being promptly retrieved from the parking lot, but does not say by whom or how R. 3 was returned. The nursing notes state that R. 3 was retrieved by car. A reasonable inference is that she had wandered a significant distance.

Ms. DeLay's testimony conflicted at times with the facility's existing documentation. For example, the documentation showed that a WanderGuard was placed on this resident after the admission-day elopement and that a room-to-room search was conducted, both facts that are inconsistent with Ms. DeLay's separate claims that staff either observed the departure or was alerted immediately by R. 3's WanderGuard alarm. Woodstock offered no additional evidence to explain such discrepancies. Furthermore, Ms. DeLay had personally signed the high risk profile that identified R. 3 as high risk for elopement, among other reasons, because R. 3 was a new admission "who has a history of wandering from home or other facilities," who tended to "follow visitors out of exits," and who hovered at and opened exit doors. Woodstock Ex. 4, at 1. A community survival

---

(...continued)
Woodstock Reply Br. at 14. Further, the documentation of this second elopement episode with R. 3 undercuts Woodstock's claim that the admission-day incident was singular. Cf. Woodstock Br. at 19.

assessment, also completed at admission, showed that R. 3 was unable to give her name and address, to use money, to operate pay phones, to cross streets safely, or to be in the community unsupervised. See Woodstock Ex. 4, at 2. These records of R. 3's proclivities and disabilities undermine the credibility of Ms. DeLay's assertion that R. 3 was no more at risk outside than in the facility.[5] The ALJ could reasonably credit the facility's own documentation made at a time when litigation was not pending, above the later testimony of a former administrator who did not even claim to have directly observed the events and who may have had some motivation to minimize her responsibility and that of the facility.

2. Our review of the evidence relating to R. 11[6]

This 61-year old resident was transferred from a VA facility in September 1997 with diagnoses of organic brain syndrome and ethanol alcohol dependency. HCFA Ex. 2, at 44; HCFA Ex. 22, at 17; ALJ Decision at 12. Woodstock recorded on admission that R. 11 had a history of aggressive behavior and wandering in his charts from the VA facility. Woodstock Ex. 7, at 23. Woodstock was clearly conscious of this history, since the objectives identified in his initial behavior management plan included a goal of minimizing his maladaptive areas such as elopement and verbal and physical aggression toward peers and staff. Woodstock Ex. 7, at 1. His community survival assessment showed that, as a result of his impairments, he was incapable of being at large without supervision. HCFA Ex. 22, at 19; Woodstock Ex. 7, at 25.

Despite this advance notice, Woodstock failed to prevent numerous episodes involving R. 11 in both elopements and assaults. For example, during January 1998, R. 11 was found outside the building four times, three times in one night. HCFA Ex. 2, at

---

[5] On the other hand, there is indeed evidence in the record that R. 3 ran a significant risk of accidental injury while in the facility as well, as a result of Woodstock's lax supervision. For example, she repeatedly used a locked public restroom not equipped or intended for residents by getting a key from the nurses' station. Tr. at 415-7. The DON permitted this practice to continue (even after the survey results and during the monitoring period) because she "didn't even think about that after seeing [R. 3] so many times use it before." Tr. at 416; HCFA Ex. 12, at 1, 4.

[6] Detailed discussion of R. 11's history can be found on pages 7-9 of the ALJ Decision.

54-55. According to the nursing notes, in the early hours of January 4th, R. 11 was found after more than an hour in a roadside ditch by a cornfield. Woodstock Ex. 7, at 5; HCFA Ex. 2, at 38. Nursing notes also show that, on January 21, 1998, R. 11 fled out the back door three times and jumped over the fence twice, all between 1 a.m. and 5:30 on a "very cold" night with snow on the ground. Woodstock Ex. 7, at 12. The last time, he was located 45 minutes after he was missed, walking along the side of a road, and was brought back by car. Woodstock Ex. 7, at 12. The surveyors were informed by Woodstock staff that R. 11 was wearing no shoes when found. HCFA Ex. 2, at 39. At the time, R. 11 was being treated for a lung infection. HCFA Ex. 2, at 54. Yet, no changes were noted to his behavior plan to address these recurring elopements or their effect on his health. Tr. at 223-24.

Woodstock's records showed that R. 11 had been agitated 141 times and aggressive 134 times in February 1998 and that interventions were "essentially ineffective." HCFA Ex. 2, at 44. R. 11 was assigned a roommate with organic brain disorder whom R. 11 proceeded to assault three times in one month, once causing a head wound severe enough to require staples to close the laceration and later pulling out the staples to reopen the wound. HCFA Ex. 2, at 53; see generally ALJ Decision at 7-8 (and record citations therein) for further details. Additional violent episodes in which R. 11 threatened or struck other residents and staff members were recorded in the nursing notes. See, e.g., Woodstock Ex. 7 at 3, 8, 24-6; Tr. at 224-25.

The DON summarized the treatment Woodstock provided for R. 11's behavioral problems as follows:

> He, of course, had a behavior management program that we had set up. He had his individual care plan. He eventually was referred to psych. We have different medication -- tried different medications with him, monitored through a behavior flowsheet to see if the medication was effective or not effective, see if it needed changed, raised or lowered [sic].

Tr. at 411. R. 11's referral for psychological treatment other than medication was not made until March 1998. HCFA Ex. 2, at 45; Tr. at 240-42. No evidence was presented of re-evaluations of his care plan or additions of new services or interventions to address the aggressive behavior, other than the removal of a section restricting his access to cigarettes in February 1998. Woodstock Ex. 7, at 26; Tr. at 240.

Despite the ample concerns about R. 11 expressed in the survey statement of deficiencies, he continued to be involved in altercations during the post-survey monitoring period. HCFA Ex. 2, at 9; HCFA Ex. 11, at 6; Tr. at 239. He continued to demonstrate many warning signs of agitation and unhappiness with his placement. For example, at one point after the initial survey was completed, R. 11 was found on the floor attacking another resident and stated that he "hates this place. 'It's worse than jail.'" HCFA Ex. 11, at 6. The surveyor found this statement very unusual for a long-term care facility resident, which suggests that it should have been another marker of continued poor adjustment. See Tr. at 239-40.

Woodstock did not rebut HCFA's evidence on which the ALJ based his factual findings about R. 11, but merely argued that the events could be interpreted in a less damning light. Thus, Woodstock argued that the ALJ should have found that its plan of care for R. 11 was working because weeks passed in which he did not elope or assault anybody. Woodstock Br. at 15-19. However, the fact that dangerous episodes did not occur daily or even that Woodstock staff may have been providing supervision that was effective at times, does not counteract the clear evidence in the record as a whole that serious and recurring problems existed before and after periods in which there were no negative outcomes. Also, Woodstock pointed out that it did intervene after the assaults in that in each instance it provided one-on-one counseling with redirection and notified the resident's family. Woodstock Br. at 16; Woodstock Ex. 7, at 24-26. Furthermore, Woodstock pointed out that changes were made in R. 11's medication during the period, as well as letting him handle his own cigarettes, in an effort to reduce his aggression. Woodstock Br. at 16. Therefore, Woodstock argued that "[s]hort of being invested with psychic powers or constantly following [him] around . . . when there was no reason or utility in doing so," Woodstock could have done nothing more to prevent the assaults. We discuss below why we do not accept the premise that Woodstock could not practicably do more to prevent accidents through better supervision or assistance devices.

Further, Woodstock asserted that two out of three of R. 11's fence-climbing episodes were merely "attempted elopements" since he was successfully called back. Woodstock Br. at 18. The fact that he succeeded in the end should, according to Woodstock, be attributed to the resident's "physical condition and his desire to leave" rather than to the inadequacy of supervision. Id. However, it was Woodstock's duty to provide a level of supervision that took into account both the resident's physical capacity and his mental incapacity.

We find nothing in Woodstock's arguments to undercut either the ALJ's factual findings on the events related to R. 11, or the reasonableness of the inferences he drew from those findings.

3. Conclusion on the factual findings

The record thus contains ample evidence supporting the ALJ's finding that Woodstock knew some of its residents were at high risk for elopement or aggression and "yet did little or nothing to prevent" the resulting dangerous exposure, repeated assaults, and serious injuries. ALJ Decision at 5, 8, 11. The above examples highlight the overall pattern of evidence proffered by Woodstock. The facility presented only three witnesses: the Medical Director (Dr. John R. Evans), who testified that he was not present for any of the incidents and depended on staff reports; a pharmacy consultant (Richard Gleckler), who likewise testified that he was not present for any of the incidents and depended on staff reports; and the former DON. The DON likewise did not testify to personal observation or involvement in any of the incidents at issue. Her version of events was not corroborated, and, in fact, was often contradicted by Woodstock's own records. No eyewitnesses to any of the events were presented by Woodstock despite evidence that Woodstock's staff observed many of them (based, for example, on the nurses' notes documenting the incidents). On the other hand, the surveyors presented by HCFA were eyewitnesses to some of the episodes and/or their consequences, and reported detailed interviews with Woodstock nurses and other staff as to what had occurred. See, e.g., ALJ Decision at 5; HCFA Ex. 2, at 50-52; HCFA Ex. 3, at 2-3; Tr. at 62, 75, 238. The surveyors' testimony was generally more internally consistent than that of Woodstock's witnesses and was often corroborated by Woodstock's records.[7]

One surveyor commented that she had never encountered in her experience a facility that experienced the high number of elopements, altercations, and injuries that occurred at Woodstock during the review period. Tr. at 242. Woodstock proffered little persuasive evidence contesting the course of events as reported by the surveyors and recorded in its records. ALJ

[7] These observations apply as well to the evidence concerning additional events discussed by the ALJ in relation to two other specific residents, namely R. 17 and R. 5, whom we have not discussed in detail herein. Similar observations apply too to additional assaults documented during the monitoring period as to which the ALJ found that Woodstock had not contested the evidence. See ALJ Decision at 12.

Decision at 4-5, 12. Where Woodstock did put forward a different version of particular episodes, it did so mainly by assertions not substantiated by documentation or eyewitness testimony. Particularly lacking is evidence on the level of supervision being provided at the time the episodes occurred, such as who was responsible, what training did they have, how often were they checking on residents, and what means they used for monitoring resident behavior. While Woodstock provided evidence that some residents were wearing WanderGuards, Woodstock provided no evidence about exactly how the WanderGuards were monitored or who was available to respond if a WanderGuard triggered an alarm.

It is within the bailiwick of the ALJ to evaluate conflicting evidence and to determine what weight to accord to each piece of evidence. We find nothing to suggest that the ALJ erred in that process in arriving at a picture of Woodstock as "a facility whose residents were not closely watched" and which permitted repeated beatings and recurring dangerous situations to take place without effective counter-measures. Id. at 11. We thus sustain the ALJ's factual findings. We turn next to the legal arguments concerning applicability of the cited regulation to the facts shown.

B. The ALJ correctly interpreted the regulation in concluding that Woodstock was not in substantial compliance.

The regulation on which F Tag 324 is based requires each facility to ensure that each "resident receives adequate supervision and assistance devices to prevent accidents." 42 C.F.R. § 483.25(h)(2). The key flaw in Woodstock's arguments on appeal about how HCFA and the ALJ applied this regulation is that those arguments presuppose that a citation may properly issue under F Tag 324 only if each of the events involved is an "accident." Woodstock Br. at 3-4. We disagree with this premise. As we explain later, observations and the occurrence of events other than accidents may suffice to expose the absence of supervision adequate to prevent accidents. The ALJ correctly identified the key issue as "whether *Petitioner failed adequately to supervise residents to prevent their injury from accidental causes."* ALJ Decision at 13-14 (emphasis in original).

For purposes of this discussion, however, we first address Woodstock's reasons for denying that the events at issue constitute accidents as that term should be understood. To that end, we first discuss what the meaning of the term "accidents" is in the regulatory framework. We next consider Woodstock's assertion that these assaults and elopements were intentional rather than accidental in nature.

We then examine Woodstock's assertion that the events, if accidents, were so unforeseeable that Woodstock could not be expected to anticipate and prevent their occurrence. Next, we consider Woodstock's claim that it had exhausted all reasonably practicable means of preventing the episodes from occurring, short of intruding impermissibly on residents' rights.

After rejecting Woodstock's attacks based on its reading of the term "accidents" and its view of the nature of these events, we then explain more fully why we reject Woodstock's premise that a conclusion that these events were "accidents" is essential to finding noncompliance under F Tag 324.

Finally, we discuss why we reject Woodstock's defense that these events were unavoidable side effects of the treatment of the residents' mental illnesses.

In each of these areas, we conclude that, in finding noncompliance with F Tag 324, the ALJ correctly interpreted the regulation to hold Woodstock responsible for failing to provide supervision or assistance devices adequate to protect its residents.

1. Woodstock's arguments about the meaning of the term "accidents" are not persuasive.

Woodstock "vehemently dispute[d]" that "'accidents'" could ever include physical assaults." Woodstock Br. at 5.[8] According to Woodstock, the ALJ erred in treating such intentional acts as accidents. Woodstock implied that the ALJ took the position that criminal actions are mere accidents. Cf. Woodstock Br. at 8. In addition, Woodstock argued that voluntarily leaving a place where a person is not obligated to remain cannot be characterized as accidental. Woodstock argued that, under the ALJ's reading of

[8] This stance is in logical conflict with Woodstock's affirmative defense that the same incidents were not accidents because they were the unavoidable result of side effects from management of mental illnesses through psychotropic medication. For reasons discussed further below, we find neither argument persuasive. Whether an act is intentional can be judged only by looking at the intent of the one acting. A behavior caused directly by an illness or medication hardly seems intentional in nature. It does not follow, in any event, that such an act could not be an accident from the viewpoint of one impacted by the consequences of the behavior.

the regulation, every departure or elopement must necessarily be classified as an accident occurring to the eloping resident.

We first note that the ALJ did not hold that every departure or elopement must necessarily be classified as an accident occurring to the eloping resident. Instead, he viewed the elopements as placing the residents at risk for accidents and therefore as relevant in determining whether Woodstock was providing supervision adequate to prevent accidents. Nor did the ALJ take the absurd position that criminal acts are accidents, as Woodstock implied.

The ALJ made two key points. First, he rejected Woodstock's view that the term "accidents" excludes any event that involves an intentional act, even if the event is unintentional from the viewpoint of the person injured or put at risk. Second, he found that, in any event, the acts were not intentional from the perspective of either the actor or the victim.

a. The meaning of "accidents" in the regulation

The regulation does not define the term "accident," and it was undisputed that "accident" is not a legal term of art. Woodstock suggested that the absence of an express regulatory definition of the term might make the regulation so ambiguous as to be void for vagueness. Woodstock Br. at 5. Woodstock also turned to law dictionaries and various state tort cases to distill a legal meaning, reading "accident" as limited to events which are wholly unexplained, fortuitous, and unintentional. Woodstock Br. at 6. Woodstock argued that the ALJ had erred in determining that intent should be determined from the viewpoint of the victim, rather than the actor.

Where a regulation employs a term without a specialized legal meaning, its meaning generally should be derived from the context and purpose for which it is used and from ordinary understanding and usage. See, e.g., United States v. LaBonte, 520 U.S. 751, 757-762 (1997). Furthermore, since Woodstock itself admitted that the term has no single meaning but rather a variety of connotations depending on the context and the purpose for which it is used, we must therefore consider the term as it is used here. See Woodstock Br. at 5, n.1. A review of the state authorities mentioned by Woodstock makes clear why this approach is especially appropriate for the term "accident," which may be used in a wide range of legal contexts. See Woodstock Br. at 5-6, and cases cited therein (involving, for example, insurance coverage for intentional torts by the insured and a defense of accidental force in a criminal case). As with terms like "abuse"

or "negligence," the meaning is inextricably tied to the duties owed between parties in a specific context. See, e.g., Lee G. Balos, DAB No. 1541 (1995); Summit Health Limited, d/b/a Marina Convalescent Hospital, DAB No. 1173, at 8 (1990); Janet Wallace, L.P.N., DAB No. 1326, at 10 (1992).

Contrary to Woodstock's claims, the duty of care owed to residents by a nursing home under common or state law is unrelated to the duty of care owed by a long-term care facility to a severely-disabled resident under federal regulations. The context here is a federal regulation. The meaning of the term in the regulation cannot vary by the usage of different states, but must be derived from federal usage. For this reason, too, Woodstock's citations to definitions quoted without context from state law cases are not helpful in clarifying the meaning of "accident" in this case. Id. at 5-6.

We therefore must look instead to the ordinary sense of the word and to the federal regulatory context in which it appears.

The ordinary meaning of "accident" includes any unexpected and undesirable event, which suggests untoward events or injuries suffered by an individual who neither expected nor wished it to occur. See Webster's II New Riverside University Dictionary (1984). Black's Law Dictionary also defines the term broadly enough to encompass this understanding, notwithstanding the selective language culled from it in Woodstock's brief. Black's Law Dictionary (6th Ed.)(West's Pub. 2000)(Black's). According to Black's, "accident" encompasses an event--

> which under the circumstances is unusual and unexpected by the person to whom it happens . . .; an unusual or unexpected result attending the operation or performance of a usual or necessary act or event or as denoting a calamity, casualty, catastrophe, disaster, an undesirable or unfortunate happening; any unexpected personal injury resulting from any unlooked for mishap or occurrence; any unpleasant or unfortunate occurrence, that causes injury, loss, suffering or death; some untoward occurrence aside from the usual course of events. An event that takes place without one's foresight or expectation; an undesigned, sudden, and unexpected event. . . . Its synonyms are chance, contingency, mishap, mischance, misfortune, disaster, calamity, catastrophe.

Thus, the ALJ's reading of the term "accidents" to include events that are unintentional from the viewpoint of the resident who was or could have been injured is consistent with the plain meaning.

The ALJ's reading is also consistent with the context in which the term "accident" appears. The purpose of the quality of care requirements in section 483.25 as a whole is to assure that facilities "provide the necessary care and services to attain or maintain the highest practicable physical, mental, and psychosocial well-being." 42 C.F.R. § 483.25. HCFA thus sought to obtain certain outcomes for residents and, to that end, to require that care and services be provided by facilities as necessary to obtain those results. The specific outcome to be attained here is the "highest practicable" physical well-being of residents. 42 C.F.R. § 483.25(h)(2). The necessary care to be provided to that end is "adequate supervision and assistance devices to prevent accidents." Id. Interpreting the regulation not to apply to events that could or did cause injury to residents and that could have been prevented by supervision, merely because those events were intentional from the viewpoint of another resident or involved some intentional act, would frustrate the regulatory goal.

Woodstock offered no authority to support its contention that whether an event is an "accident" must always be determined from the viewpoint of the actor. Woodstock Br. at 7.[9] Instead, Woodstock asserted that, to inquire into whether an event was unexpected from the viewpoint of the recipient of the effect rather than the actor would "redefine the concept of free will." Id. Whether an event is accidental for a particular purpose,

---

[9] Woodstock did cite to another decision of the same ALJ for the proposition that "matters done willfully are not accidental" Woodstock Br. at 7, citing Life Care Center of Hendersonville, DAB CR542 (1998). However, a close reading of that ALJ decision leads to the opposite conclusion from that which Woodstock drew. The ALJ found that the injuries that occurred in that case were accidental rather than evidence of abuse. Id. The ALJ concluded that: "A necessary element of abuse is willfulness. There can be no abuse absent the willful infliction of harm. Accidentally inflicted injury is not abuse." Id. at 18 (emphasis in original). No allegations in that case were made under F Tag 324 so the ALJ did not address whether the facility took adequate steps to prevent the accidents. It certainly does not follow from the conclusion that abuse requires intent on the part of the actor that accidents may not include any element of human will or agency on the part of the actor.

however, logically depends on which perspective (that of the actor, the victim, or a responsible third party) is most relevant to the question presented. The relevant viewpoint depends on whose duty and liability are under consideration. None of the cases relied on by Woodstock hold that the only relevant perspective from which to consider whether an occurrence is an "accident" for all purposes is that of the person acting rather than the person acted upon, and we do not find authority for that general proposition.

Contrary to what Woodstock argued, the definition HCFA provided for use by surveyors does not support Woodstock's reading of the term "accidents." HCFA defined an "accident" as any "unexpected, unintended event that can cause a resident bodily injury," stating that it does not include "adverse outcomes associated as a direct consequence of treatment or care (e.g., drug side effects or reactions)." SOM Guidance. This definition clarifies that the term includes events that "can" cause injury and excludes events that are expected and intended as part of the care and treatment provided by the facility, even where there are adverse outcomes. Nothing in this definition specifically excludes the possibility that a cause of the event might be an intentional act by a resident. The assaults here led to events that were unexpected and unintended from both the viewpoint of the residents whose well-being was at risk and the viewpoint of the facility. Moreover, the elopements clearly put the eloping residents at risk for unexpected, unintended events that could cause bodily injury.[10]

We also reject Woodstock's attempt to support its narrow reading of "accident" by asserting that the requirements of section 483.25(h)(2) should be read in "para materia" with the preceding subsection. Woodstock Br. at 6-7. That subsection requires facilities to ensure that "the resident environment remains as free of accident hazards as possible." 42 C.F.R. § 483.25(h)(1) (emphasis added). The phrase "accident hazards" as used in this provision is defined in the SOM to mean "physical features in the nursing home environment that can endanger a resident's safety." SOM Guidance (re: F Tag 323). From that interpretation, Woodstock extrapolates that "accidents" too must refer to

---

[10] We note that establishing that an accident occurred would not alone establish that inadequate supervision or insufficient assistance devices caused or could have prevented the accident. We discuss later whether the circumstances here support an inference that Woodstock was not providing adequate supervision.

environmental mishaps, such as those events caused by frayed wires or wet floors. Woodstock Br. at 7.

"In pari materia," meaning "on the same subject," refers to a principle of statutory interpretation that means that the language used in different parts of a single statute or legislation on a related subject, where ambiguous, should generally be read in harmony to achieve the overall purpose. See Black's; see generally Sullivan v. Finkelstein, 496 U.S. 617, at 632 (1990). In the present case, the two parts of the regulatory provision expressly use different words to address different concerns. The use of two different terms would be superfluous if both referred to the same responsibility to protect residents from environmental hazards. We do not find the use of different terms ("accident" and "accident hazard") to be mere surplusage. Rather, they indicate a substantive distinction between the two subsections of section 483.25(h). The two subsections define different duties: one to provide a safe environment and the other to provide adequate supervision and assistance devices. Thus, it is reasonable that the definition of "accident" focuses on a transitory event that presents a potential for bodily injury to a resident to whom the event occurs and the accident hazard definition instead focuses on static physical features. We find no lack of harmony in this reading of the language.

Finally, we note that Woodstock did not argue that, in determining what supervision it needed to provide, it somehow relied on the narrow definition of "accidents" that it proposed here. Instead, the record as a whole indicates that Woodstock understood that its duty under the regulation encompassed the duty to take steps to protect residents from resident-to-resident assaults and from elopements. Woodstock's argument about the vagueness of the regulation, therefore, constitutes a post hoc rationalization, rather than any legitimate complaint about lack of notice.

Thus, we conclude that the ALJ correctly interpreted the meaning of the term "accident" and that Woodstock's interpretation is an unreasonable one. We turn next to whether the record supports the ALJ's finding that the acts here were not intentional.

b. Whether the acts here were intentional

The ALJ rejected Woodstock's contention that behaviors like attacking another resident or leaving the facility are volitional, intentional acts. ALJ Decision at 13. The ALJ found that, given the severely-demented state of the residents involved in this case and the facility's awareness of their proclivities

and illnesses, the departures and altercations were more likely uncontrolled behaviors rather than willed acts. ALJ Decision at 14.

We agree. As the ALJ pointed out, it is difficult to imagine a meaningful or appropriate sense in which one might consider these events intentional from the viewpoint of "actors" who are plainly described in Woodstock's records as confused, unable to function outside of a supervised setting, and displaying a range of combative and disruptive behaviors. See ALJ Decision at 13. These "actors" were known to be suffering from advanced dementia, schizophrenia, and/or organic mental disorders, as well as from the effects of various medications, all of which suggests that malice or any other intentional mental state was likely to be beyond their capacity. Id. In reality, both the "actors" and the "victims" (who were in the case of elopement the same person) have been shown by persuasive evidence in the record to have been largely incapable of forming either expectations or intentions about the likely consequences of their actions.

Moreover, these residents' mental status is relevant in determining the duty Woodstock had to provide preventive supervision, because these residents were unable to take reasonable precautions to protect themselves. Permitting these residents to wander off into potentially dangerous settings without supervision or protective precautions, when their standing care plans provided that they were not capable of managing unsupervised community release, placed them at great risk of sustaining accidental injuries. Whether or not an elopement per se constituted an accident, Woodstock cannot reasonably deny that the absence of supervision of these impaired residents as they navigated hazards outside the facility exposed them to unexpected situations that could cause bodily injury (including snow, unfenced ponds, and car traffic). Likewise, leaving aggressive, agitated residents known to be prone to violence unsupervised to wreak havoc among their peers without effective management or intervention endangered both them and the others around them in ways the residents were not capable of controlling or modifying themselves.

Woodstock is the responsible party whose actions or omissions are to be evaluated in applying the regulation. Had the injuries and dangers been the result of intentional actions by Woodstock or its agents, the issue would be one of abuse. Here, there is no such allegation. Rather, the question is whether the events at issue evidenced a lack of adequate supervision by Woodstock to prevent accidents. The ALJ correctly concluded that they did.

2. Woodstock's arguments that the events were unforeseeable events that Woodstock could not practicably prevent are not persuasive.

As noted above, Woodstock argued that a proper interpretation of the regulation requires that the accident was practically preventable by assistive devices or a level of supervision that the facility failed to provide. Woodstock Reply Br. at 2, n.1. Woodstock based this argument in part on the use of the term "practicable" in the regulation and in part on its arguments about the particular circumstances.

We first note that, while the concept of practicability is relevant in examining what duty a long-term care facility has to prevent accidents, the regulation requires that the facility "ensure" that each resident receive adequate supervision. In response to comments that a facility cannot control or be responsible for all variables surrounding the deterioration or diminished capacity of residents, HCFA elucidated the requirements as follows:

> We recognize that a facility cannot ensure that the treatment and services will result in a positive outcome since outcomes can depend on many factors, including a resident's cooperation (i.e., the right to refuse treatment), and disease processes. However, we believe that it is reasonable to require the facility to ensure that 'treatment and services' are provided, since the basic purpose for residents being in the facility is for the 'treatment and services' and that is why the Medicare or Medicaid program makes payment on the residents' behalf. We also think it is reasonable to require the facility to ensure that the resident does not deteriorate within the confines of a resident's right to refuse treatment and within the confines of recognized pathology and the normal aging process.

54 Fed. Reg. at 5,332. Thus, while the regulations do not make facilities unconditional guarantors of favorable outcomes, the quality of care provisions do impose an affirmative duty to provide services (in this case, supervision and devices to prevent accidents) designed to achieve those outcomes to the highest practicable degree.[11]

---

[11] Woodstock criticized HCFA and the ALJ for a "results-oriented" approach, but that approach is consistent with the

(continued...)

Woodstock acknowledged that its duty of care extended to protecting residents "from any danger or injury which may be *reasonably anticipated*, including danger from others under the control of the home." Woodstock Br. at 27 (italics in original)(citation omitted). Nevertheless, Woodstock asserted that it did not breach its duty here because these assaults or elopements could not be reasonably anticipated. In particular, Woodstock emphasized the lack of any provocation or pattern preceding each individual event. Id. at 9-21. Woodstock challenged the ALJ's conclusion rejecting Woodstock's claims that it did not have sufficient information to anticipate the likelihood of such hazardous situations arising with these residents. See, e.g., ALJ Decision at 5, 8, and 11. Woodstock also argued that no reasonably practicable means of preventing these events in question, short of intruding impermissibly on residents' rights, were available to Woodstock.

In this section, we explain why we reject these arguments and agree with the ALJ that Woodstock did not meet its duty under the regulation.

a. Whether Woodstock had notice of or should have reasonably anticipated such events

To support its argument that it could not have reasonably anticipated the events here, Woodstock presented several time lines tracing the treatment course of individual residents to demonstrate the absence of triggers or warning signs in their behavior or environment. Woodstock Br. at 11-16. However, we find the time lines unreliable in that they do not give a fair picture of the content of the underlying exhibits which they purport to summarize. For example, Woodstock asserted that the nursing notes on R. 11 between his assaultive behavior in mid-December 1997 and his December 26 assault showed "zero agitation." Woodstock Br. at 15, citing Woodstock Ex. 7, at 3-5. From this, Woodstock concluded that it could discern no "pattern" or "predisposition to assaultive behavior" which would trigger special precautions. Id. In fact, the notes show that, on December 20th, R. 11 threatened to beat up another resident

---

(...continued)
regulatory framework and the legislative background. Moreover, where HCFA inferred from certain results that Woodstock was not providing adequate supervision, Woodstock had an opportunity to rebut that inference with persuasive evidence that it was providing supervision that was adequate under the circumstances, but failed to do so.

despite showing no signs of aggression earlier that day. Woodstock Ex. 7, at 3. On the evening of December 22, 1997, he appeared agitated, was sensitive to being approached and struck another resident's face, even though he was not combative or threatening during earlier shifts. Id. Thus, the records for that period establish that, in the days leading up to December 26th, R. 11 had frequent disturbances interspersed with interludes of less disruptive behavior and was actively manifesting a predisposition to violent actions. Further, Woodstock's exhibits show just how dramatic some of these patterns of maladaptive behavior became. For example, an R.N. documented in medication records for R. 17 (another resident found by the ALJ to have engaged in repeated assaultive behaviors) that, during the month of December 1997, he experienced 107 episodes of verbal aggression, 25 episodes of physical aggression, and 9 episodes of combativeness with caretakers. Woodstock Ex. 8, at 37.

Despite these records, Woodstock argued that the residents' history of assaults or elopements did not suffice to provide notice to trigger any higher duty of reasonable care because the facility had no way of anticipating when or where a resident might explode. See Woodstock Br. at 29. For the same reason, Woodstock discounted the importance of the prior histories of similar problems which many of the residents brought with them on admission, as well as Woodstock's own assessments of the high risks facing the residents of precisely the sort of behavioral episodes that soon took place. See, e.g., Woodstock Exs. 4, at 1 and 7, at 23.

We find no basis for Woodstock's concept that it must somehow be provided advance warning of each adverse event in order to be responsible for taking reasonable measures to prevent injurious occurrences which it knows to be likely to take place at some point, if not at a particular time or place. As noted above, Woodstock's own assessments of the residents involved were replete with documentation warning of the propensities and manifestations that could predict eloping or aggression, and with documentation of the dangers such behaviors would present to residents with little or no ability to protect themselves or to survive outside a supervised facility.

In sum, it is inherent in the nature of accidents that the exact time and place of their occurrence is not foreseeable. Woodstock had ample reason to be aware of the likelihood of such accidents occurring and had a duty to its residents under federal law to provide appropriate care to prevent such foreseeable adverse outcomes. Having found that Woodstock did have the duty and the

notice to do whatever could be done to address the high risks, we deal next with Woodstock's claim that nothing more could practicably have been done.

b. Whether reasonably practicable means of preventing accidents, short of intruding impermissibly on residents' rights, were available to Woodstock

An undercurrent in much of Woodstock's briefing is the complaint that the impossible is being asked of it. Among the descriptions which Woodstock presented of its reading of the duty imposed upon it by HCFA (and the ALJ Decision) were the following: a duty "to act as a prison, a police force, or a guarantor of resident safety," Woodstock Br. at 5; the imposition of "strict liability," Woodstock Br. at 16, 26; and "an absolute standard . . . that even a prison cannot uphold, as assaults can happen even in the confines of a penal institution," Woodstock Br. at 29. This theme is a "straw man." The ALJ expressly stated, and we agree, that the regulatory standard does not amount to strict liability or require absolute success in an obviously difficult task. ALJ Decision at 15. The ALJ concluded, and we agree, that "an element of reasonableness is inherent in the regulation's requirements." Id. The problem is not that Woodstock's supervision fell short of an unattainable perfection but that it fell far short of what could reasonably be considered adequate supervision under the circumstances. Substantial, virtually uncontradicted, evidence throughout this record supports the ALJ in finding that Woodstock essentially made no changes in its practices long after it became clear that the measures it was using were wholly ineffective for the residents it had chosen to admit. See, e.g., ALJ Decision at 4-5, 7, 15.

The most telling evidence appears throughout the treatment records submitted by Woodstock. The main approaches Woodstock used to manage the behavioral dangers were medication, "one-on-one" talks, and redirection of maladaptive behavior. See, e.g., Woodstock Ex. 7, at 1-2. The ineffectiveness of these measures with these residents was reported multiple times, for example, in R. 11's records. See, e.g., Woodstock Ex. 7, at 11; Woodstock Ex. 8, at 37, 39 (relating to R. 17); HCFA Ex. 22, at 20 (relating to R. 11); see also Woodstock Br. at 13.

Further, we see no merit in Woodstock's complaint that HCFA and the ALJ imposed on it a "meaningless and unachievable" duty without demonstrating that any viable alternatives were available to Woodstock. Woodstock Br. at 29; Woodstock Reply Br. at 3, 7. We note that the specific manner in which the care and services

at issue are to be provided is not prescribed by the regulations. Rather, the facility is permitted to determine the means to achieve the regulatory ends (prevention of accidents), in light of its own resident mix, its own capabilities, or its preferred methodologies. This approach permeates the long-term care facility program requirements which, as a matter of policy, chose to direct attention to the important desired ends rather than impose rigid checklists of technical means, allowing facilities to meet the requirements in a variety of ways. See Omnibus Budget Reconciliation Act of 1987, Pub. L. 100-203; 54 Fed. Reg. 5,316 (1989) ("The purpose of the revisions is to focus on actual facility performance in meeting residents' needs in a safe and healthful environment, rather than on the capacity of facility to provide appropriate services."). In light of the balance struck by the law and regulations between flexibility in methods and responsibility for achieving results, Woodstock's complaint that neither HCFA nor the ALJ prescribed "concrete" means that Woodstock should have used "other than `closely supervise' residents who were already receiving the most practicable level of supervision" is unpersuasive. Woodstock Reply Br. at 7. First, it was Woodstock's job, not that of HCFA or the ALJ, to select specific effective means.[12] Second, we do not accept the bald assertions that Woodstock was already closely supervising its residents, given the factual findings already affirmed.

We simply do not accept as credible Woodstock's repeated claims that it was entirely powerless to better protect its residents

---

[12] For the same reason, Woodstock cannot attribute fault to third parties where Woodstock failed to provide the requisite level of care. For example, whether or not a visitor did hold the door open for R. 3 and thereby facilitate her admission day elopement, is irrelevant to Woodstock's duty toward R. 3. Understandably, a visitor accustomed to seeing R. 3 leave might well hold a door for her. It is quite plausible that a mentally-impaired person with a tendency to wander would act out of habit in leaving the facility and heading "home." Nevertheless, as the DON acknowledged, the facility's duty of care toward someone admitted as a resident exceeded its duty toward the same individual as a visitor to the premises. Tr. at 439-40. Among the duties owed on admission is a comprehensive assessment, which in R. 3's case revealed serious mental impairment. Id. at 140-42. The facility's documented awareness of her numerous warning signs for elopement should have triggered heightened alertness to her location and orientation during the transition period. The record does not show any action taken by the staff to forestall foreseeable episodes of the kind that occurred.

from each other and from the hazards outside the facility without incarcerating the residents. Cf. Woodstock Br. at 29. Despite the outrage expressed by Woodstock over being held to an "impossible" standard of perfect outcomes, Woodstock elsewhere made clear that it did understand the applicable standard. Compare Woodstock Reply Br. at 4-5 with Woodstock Br. at 27. Thus, Woodstock acknowledged that any facility has a duty to exercise reasonable care and that the level of care that is reasonable varies in proportion to the ability of residents to protect themselves. Woodstock Br. at 27.

Woodstock characterized the ALJ's "picture" of Woodstock as unfairly painting Woodstock as a sponsor of "a pugilistic environment reminiscent of a schoolyard bully in a playground of invalids." Woodstock Reply Br. at 4. In fact, the analogy sarcastically offered by Woodstock is much on point. A school has a somewhat similar duty of care toward dependent young persons in its charge who cannot be expected to take complete responsibility either for foresight in their behavior or self-protection from hazards around them. See, e.g., Giebink v. Fischer, 1989 WL 76875 (D. Colo. 1989) and cases cited therein. No school and no long-term care facility is able to or expected to guarantee that no untoward events will ever occur on their premises. Both are expected to take all reasonable measures to make the environment safe for those in their charge, with the appropriate level of supervision depending on the capacity and needs of the charges. It may not be reasonable to expect a school to foresee every playground quarrel but it is reasonable to expect it to watch children closely and intervene effectively when vulnerable children are repeatedly subject to harmful behavior, without shifting the blame to its vulnerable or incompetent charges. Similarly, Woodstock, having undertaken the care of vulnerable and dependent elderly residents, is responsible to provide care to protect them from harmful events that they are not themselves capable of avoiding.

Woodstock objected that any more effective measures would be expensive, impracticable or necessarily too intrusive on residents' freedom. Woodstock Br. at 29; Woodstock Reply Br. at 3. Woodstock explained that it would be impossible to wean residents off excessive psychotropic medication (i.e., chemical restraints), if its compliance were weighed by the magnitude of the injuries that "unsnowed" residents might cause because that "would lead to economic consequences so drastic that Woodstock could not afford to retain or treat them." Id. Woodstock stated that a facility that is "fenced in, has alarms, and is appropriately laid out to allow staff to monitor residents is reasonably equipped to handle elopers." Woodstock Br. at 30.

Yet, Woodstock failed to meet even these criteria which it set for itself. It arranged for the installation of the fence alarm only after the survey, and did not have the alarm fully functioning until at least March 14, 1998. See, e.g., HCFA Ex. 11, at 1, 4, 6-7, 12; HCFA Ex. 12, at 4. Woodstock contended that the malfunctions were not its fault but that of the contractor who installed the alarm and that Woodstock could not "cross-train staff to become installers and repairmen." Woodstock Br. at 30; Woodstock Reply Br. at 13. Woodstock, however, chose the alarm system and selected the contractor about whose competence Woodstock complains. Woodstock cannot reasonably evade its responsibility for the continuing danger to its residents while the alarm was not fully operative by placing the blame on its contractors. As the ALJ held, the residents remained at risk until the alarm worked effectively. ALJ Decision at 12. Absent a working alarm, Woodstock had a duty either to take other steps to prevent elopements or to provide closer supervision.

Woodstock also contended that the only practical measures that might be effective to prevent these episodes would have been unacceptably intrusive and that all less intrusive alternatives were already implemented. Woodstock Br. at 29-30. Thus, according to Woodstock, a conflict existed between the rights of residents to refuse treatment, engage in activities as they wish, and leave if they choose, and the duty imposed on the facility to control the choices and actions of the residents in order to prevent accidents. See, e.g., Woodstock Reply Br. at 12. Woodstock further argued that Federal law itself imposed these conflicting obligations on Woodstock and would have been violated had Woodstock implemented the kinds of coercive measures it read HCFA's interpretation of the accident prevention standards to require.

The ALJ rejected Woodstock's position that assaults and elopements were matters of "free will" in which these residents had a "right" to engage and from which they could not be deterred absent complete physical restraints. ALJ Decision at 14. Instead, the ALJ concluded that, while practical and legal constraints might well limit some steps the facility might take to control resident behavior, Woodstock failed to take available "reasonable steps" to protect its residents short of such Draconian measures." Id. We agree with the ALJ.

Without question, an important goal in the treatment of residents suffering from dementias and other mental and physical problems is to avoid the unnecessary use of coercive restraints to control difficult behavior. See sections 1819(c)(1)(A)(ii) and

1919(c)(1)(A)(ii) of the Act. Excessive or improper use of intrusive methods of restraint impinges on residents' dignity and well-being, and even when needed they can be emotionally and physically devastating. Cross Creek Health Care Center, DAB No. 1665 (1998); 57 Fed. Reg. 27,397 (June 19, 1992). The regulations guarantee residents the right to be free from physical or chemical restraints "imposed for purposes of discipline or convenience, and not required to treat the resident's medical symptoms." 42 C.F.R. § 483.13(a). The involuntary imposition of restraints for such purposes rather than for the benefit of the resident is proscribed by a part of the section that guarantees residents freedom from all forms of abuse. 42 C.F.R. § 483.13; see also section 1819(c)(1)(A)(ii) of the Act.

Indisputably, the regulations also safeguard the right of residents or their surrogates to make decisions about their health care and treatment. 42 C.F.R. § 483.10. Specifically, residents have "the right to refuse treatment," except those residents who have been adjudged incompetent in court whose appointed representatives may act instead on their behalf. Act, § 1819(c)(1)(A)(i) and (C); 42 C.F.R. § 483.10(b)(4). As Woodstock noted, some of the residents here became more aggressive and agitated as a result of refusing medication. Woodstock Br. at 11, 24. Yet, Woodstock felt it could not administer the medication non-consensually. The Medical Director testified that he could override a refusal when a resident "was in danger from the standpoint of himself, by himself, harm, or something," but that he considered such administration of medication to be "not a very wise thing to do." Tr. at 346. However, Woodstock pointed to nothing in the regulations that would limit its ability to take reasonable measures to avert the predictable consequences of a medication refusal by monitoring for and effectively responding to behavioral disturbances.[13]

We note the Act does not prohibit every use of chemical or physical restraints but rather recognizes the medical necessity for the use of restraints in care in certain limited circumstances. HCFA found, in implementing the limits on such protective restraints, that despite their problematic history

---

[13] Woodstock implied that it could exercise no authority to control the behavior of residents who were not legally adjudicated incompetent and did not have appointed guardians. Tr. at 423. Yet, Woodstock offered no explanation of why such adjudications were not sought for residents it had assessed, according to its own records, as so severely compromised.

which included risks of misuse and potential for severe and even fatal consequences, such restraints also provide benefits in some situations, when their use is carefully controlled. 57 Fed. Reg. 27,397-98 (June 19, 1992). The Act permits use of restraints in long-term care facility settings in emergencies, and in non-emergency situations only "to ensure the physical safety of the resident or other residents" and only with a detailed order from a physician. Section 1819(c)(1)(A)(ii) of the Act. As discussed at length above, the residents here were in serious physical danger from themselves and each other. The ALJ was not persuaded, nor are we, that Woodstock had attempted all less restrictive interventions to ensure their safety. ALJ Decision at 14. Had all such means been exhausted, however, we conclude that the provisions of the Act plainly permitted Woodstock to seek an appropriate order from the physician before standing by impotently to allow the physical injuries here.[14]

Instead, the ALJ found that, and the record supports the finding, that Woodstock presented little or no evidence that it made pro-active attempts to find more effective methods to address repeated problems as opposed to adopting a largely "passive" attitude to recurring dangerous episodes. ALJ Decision at 15. Woodstock failed to attempt different interventions that might have prevented crises from developing and instead continued to repeat the same limited repertoire of responses that had proven ineffective. ALJ Decision at 11-15. Resources such as psychological counseling, social services, and activities planning were not marshaled promptly or effectively. For example, despite his history of mental impairment, it was undisputed that R. 17 was not referred for psychological counseling or psychiatric treatment other than medications until just before he was discharged.[15] See ALJ Decision at 7. No referral was made earlier even though R. 17 arrived with a

---

[14] Notably, the SOM explicitly states that the failure to use restraints when needed may be the basis of an immediate jeopardy determination. SOM, Appendix Q, Guidelines For Determining Immediate And Serious Threat To Patient Health And Safety, SOP V, at Q-12 (Rev. 209) (SOM Appendix Q).

[15] Indeed, Woodstock disparaged the importance of making such referrals stating that it had no "duty to give [useless] psychological tests to those with organic mental diseases" nor to "try to communicate with residents who cannot reason." Woodstock Reply Br. at 11. One surveyor stated on the contrary that such residents should appropriately be referred for psychiatric evaluation and possible treatment. Tr. at 85-87, 241-42.

diagnosis of schizophrenia and during his stay had exhibited documented hallucinations, suicidal tendencies, and multiple serious assaults on peers. Tr. at 85-87; Woodstock Ex. 8, passim. The management techniques planned for his care, as with many other residents' care plans, amounted to one-on-one interactions with him by staff[16] and efforts to redirect him. Yet, as the ALJ found, "staff were not trained in the care of physically aggressive residents." ALJ Decision at 12. Consequently, the staff, as much as the residents, was fearful of the most disturbed residents and focused on avoiding dangerous confrontations with them. Tr. at 80.

The beginning point for appropriate planning and management of residents' mental and behavioral issues is the development of comprehensive assessments, with regular reviews, by the facility for each resident and the preparation of individualized behavior management plans. 42 C.F.R. § 483.20. When the Medical Director was shown copies of Woodstock's behavior management plans for the assaultive residents (including R. 11 and R. 17) during his direct examination and was asked if they were appropriate for those individuals at the time, he asked the following question: "[A]re these behavior plans that are specially designed for this patient, or are these behavior plans that comes out of a book? [sic]." Tr. at 355. The question captures the basis for the ALJ's findings that these behavior plans were not specific to each resident's issues and did not guide the staff adequately to respond to dangers arising from aggressive behaviors. ALJ Decision at 7-8.

Woodstock did not make necessary changes to its practices and environment even after the need for them had been specifically pointed out by surveyors or made obvious by events. Id. The ALJ specifically noted that his conclusion might have been different had Woodstock "reacted promptly" to the incidents as they occurred so as to prevent recurrences. ALJ Decision at 15. The argument that nothing could be done to intervene effectively in the assaults and elopements beyond essentially imprisoning residents by use of improper physical and chemical restraints is belied by the record as a whole.

Woodstock argued that the regulation "neither explicitly mentions nor implies any obligation on a skilled nursing facility to act as a prison, a police force, or a guarantor of resident safety,"

---

[16] The fact that the care plan called for such one-on-one counseling undercuts Woodstock's claim that it was predictably useless to try to talk with residents who were unable to reason.

and that nothing would have satisfied HCFA's standards short of a prison-like level of physical restraints or forced medication. Woodstock Br. at 5. We find this implausible in light of the resolution of the immediate jeopardy finding without such extreme and improper measures. The major steps taken by Woodstock to eliminate the immediate jeopardy were to provide its staff with more training (for example, in handling critical situations), to acknowledge that four of the most violent residents with dementia were beyond the facility's capacity to manage at an adequate level and transfer them to other placements, to make more appropriate room placements for remaining residents, and to get its contractor to install and fix an alarm on a perimeter fence. See generally HCFA Ex. 4. The ALJ expressed some skepticism about whether Woodstock had implemented ongoing changes to prevent assaults by new residents in the future, but clearly HCFA was not requiring the facility to do the impossible or to become an absolute guarantor that no unforeseeable mishaps would ever occur. ALJ Decision at 12.

Irreducibly hard choices exist between preserving freedom and dignity and preserving health and safety. Woodstock abdicated its responsibility to its residents to engage in the struggle to optimize both aspects of their well-being to the maximum extent practicable.

3. Proof of "accidents" is not a prerequisite to a deficiency finding under F Tag 324

As mentioned above, we do not accept the premise that it was necessary for HCFA to prove that each episode cited was itself an accident. We agree with the ALJ that the core issue is not whether the assaults or elopement were accidents, nor whether they resulted in injuries, but whether the quality of the supervision at Woodstock was such that residents were subject to the risk of injury from accidental causes in their daily activities. ALJ Decision at 12-13. The emphasis in the quality of care regulation is on ensuring the adequacy of supervision to meet the specified goal (preventing accidents). 42 C.F.R. § 483.25(h)(2). Occurrences that do not themselves constitute accidents may well be evidence that the supervision provided was not adequate to prevent accidents.

Hence, even if some or all of the particular episodes here were not "accidents," they may nevertheless support a deficiency finding when they expose the inadequacy of supervision provided to residents. A surveyor may appropriately conclude that the supervision being provided is not adequate to prevent accidents if a surveyor observes a resident left unattended in a dangerous situation, regardless of whether any accident results from that episode.[17] For example, consider a situation in which a surveyor observed a dining room left unattended during a meal, and noted certain residents there who had been documented as unable to eat safely without assistance or otherwise in need of close monitoring during meals. It would hardly be necessary to wait for one of the residents to choke to death in order to find that the facility's supervision was inadequate in a situation presenting such a high risk of accidents preventable by appropriate supervision.[18] Similarly, if the staff is unaware of the whereabouts of a resident for a period of time long enough

---

[17] A telling example of this kind did occur in this case. Woodstock did not dispute the testimony of a surveyor who observed an unsupervised resident pushing a medication cart, the loss of which had gone unnoticed by the nurse. Tr. at 108-09; HCFA Ex. 2, at 8-9. Fortunately, no accident transpired, but the supervision being provided to that resident could not have prevented a foreseeable accident that could cause serious bodily injury (such as poisoning).

[18] Further, it would not suffice as a defense to assert that there were many days on which choking did not occur or even that the dining room was sometimes well-attended.

that a high risk of untoward events is created, a surveyor may reasonably conclude that supervision was inadequate to prevent accidents, whether or not any injury occurred. The record in this case presents striking examples of situations observed during the survey or monitoring periods that give rise to an inference of a failure to adequately supervise even though they did not result in accidents.

4. Woodstock's affirmative defense that these events were not accidents because they resulted from medication side effects or underlying illnesses lacks merit.

As mentioned, the SOM provides that "adverse outcomes associated as a direct consequence of treatment or care (e.g., drug side effects or reactions)" are not considered accidents. SOM Guidance on F Tag 324 (emphasis added). We agree with the ALJ that this exception does not immunize Woodstock from responsibility for the episodes here either as a matter of fact or law. ALJ Decision at 13.

The testimony of Woodstock's pharmacist and the medication records in the record simply do not establish that any of these episodes were directly associated with reactions to particular drugs. Id. At most, they establish the possibility that altering dosages of medication for dementia patients sometimes has the potential to alter their levels of expressed hostility and agitation, in a direction and at a rate that vary from patient to patient. Tr. at 342-43, 396-401. If these reactions were foreseeable side effects, it is troubling that Woodstock's own forms for tracking drug reactions do not record them or track them as such. See, e.g., Woodstock Exs. 5, at 4, and 8, at 37-41; see also Tr. at 81-82. In any case, as the ALJ noted, if assaults and elopements were anticipated outcomes of the changes undertaken in their medication regimes, more rather than less diligence in monitoring was called for. ALJ Decision at 13.

To the extent that Woodstock (and its consulting pharmacist and Medical Director) considered such behavioral episodes to be manifestations of treatment, it was on notice that such treatment required planning for the impact of such predictable hazards not only on the patients themselves but also on other residents. Even if agitation or other behavioral manifestations result from a medication regime, injuries caused by failing to safely prepare for and manage such manifestations are no longer a direct consequence of the medication itself but a secondary consequence of poor management of the reaction. This point may be clearer when considering a necessary treatment which can cause a physical adverse reaction, such as seizures. A facility treating a

patient with such medication would not violate F Tag 324 by failing to prevent any seizures from occurring to the patient while on the medication regime. However, the case would be different if the facility repeatedly left a patient on the same medication unsupervised near unstable, frail individuals. Should the patient during seizures recurrently knock over and injure another resident, those accidents would not be a direct consequence of the original patient's treatment but rather an indirect result more proximately caused by a lack of adequate supervision or other measures to prevent accidents. Similarly, when a patient on psychotropic medication becomes assaultive repeatedly and yet is given unsupervised access to vulnerable residents, even if the medication does trigger the aggression, the impact of that behavior on other residents is not the direct consequence of the original patient's medication. If the facility fails to provide adequate supervision or other measures to prevent accidental injury to residents, as Woodstock did, its duty to its residents under the quality of care regulation has been breached.

Furthermore, Woodstock's reliance on regulations requiring it to avoid excessive or unnecessary drugs does not suffice to justify Woodstock's action of instituting drug reductions without adequately planning for management of potential reactions. See 42 C.F.R. § 483.25(l)(1). Over-medication for the purpose of making residents tractable for the convenience of the facility is indeed barred by the restrictions on chemical restraints discussed earlier. The quality of care regulations do require that residents "who use antipsychotic drugs receive gradual dose reductions, and behavioral interventions, unless clinically contraindicated, in an effort to discontinue these drugs." 42 C.F.R. § 483.25(l)(2)(ii). However, the regulations also require that a facility ensure that any resident "who displays mental or psychosocial adjustment difficulty, receives appropriate treatment or services to correct the assessed problem." 42 C.F.R. § 483.25 (f)(1). Woodstock's Medical Director agreed that medication alone is not a sufficient approach to treating such psychiatric problems. Tr. at 375-76. Woodstock's treatment of these residents, as found by the ALJ and discussed above, may have correctly aimed at reducing drugs as much as possible, but wrongly failed to substitute effective behavioral interventions or to monitor and respond to clinical contraindications. See, e.g., ALJ Decision at 13. Hence, these behaviors were not simply direct and unavoidable consequences of the appropriate provision of treatment but, rather, the result of inadequate management of treatment.

5. Conclusion on noncompliance

We conclude for the reasons explained above that the ALJ did not err in concluding that Woodstock was not in substantial compliance with 42 C.F.R. § 483.25(h)(2).

C. The determination that the deficiencies present an immediate jeopardy to residents was not clearly erroneous.

Woodstock argued that the ALJ erred in referring to "potential" and "risk" in assessing the determination that immediate jeopardy existed and therefore failed to apply the correct standard that the deficiency "has caused or is likely to cause serious harm." Woodstock Br. at 30; see 42 C.F.R. § 488.301. We, like the ALJ, must affirm a finding of immediate jeopardy unless we find that HCFA's determination was clearly erroneous. 42 C.F.R. § 498.60(c).

Indisputably, the regulation does not require any finding of actual harm to justify a determination that immediate jeopardy to residents exists. "Immediate jeopardy" is defined in the regulations as "a situation in which the provider's noncompliance with one or more requirements of participation has caused, or is likely to cause, serious injury, harm, impairment, or death to a resident." 42 C.F.R. § 488.301 (emphasis added). "Jeopardy" generally means danger, hazard, or peril. See Black's. The focus of the determination of immediate jeopardy is on how imminent the danger appears and how serious the potential consequences would be. 42 C.F.R. § 488.301; see also SOM, Appendix Q, at SOP III. The language of potential and risk is hence entirely appropriate in considering these questions.

Woodstock also argued that, because the immediate jeopardy determination for this tag was lifted at a point when there were no changes in staffing, we must conclude that the immediate jeopardy citation was "wholly unrelated to any issue concerning the number of staff at the facility." Woodstock Br. at 31. Woodstock's conclusion does not follow.

HCFA has made clear that the adequacy of staff is not a simple mathematical measurement, but rather is closely related to the needs of the particular facility and its resident population. Thus, in the preamble to the regulations on adequate staffing, HCFA stated that it prefers "not to rely on nurse-resident ratios because the number and skills of nursing staff depend on the severity of the residents' condition. The severity or case-mix of the resident population is a much better determinant of

sufficiency of nursing staff." 54 Fed. Reg. at 5,337. In addition, HCFA indicated that the facility must have sufficient nursing staff to provide nursing services "to attain or maintain the highest practicable physical, mental and psychosocial well-being of each resident." Id. This criterion is derived from the overarching quality of care standard of which adequate supervision to prevent accidents is one component. As a legal matter, staffing problems are thus clearly relevant to a finding that supervision is inadequate to maintain an aspect of quality of care but changes in staffing are not the only way to address the finding. For example, changes in the case-mix, in the level of training,[19] or in the physical environment may all impact the level of staffing required to provide adequate supervision.

By the date that immediate jeopardy was lifted, Woodstock had taken a number of such measures that the surveyors decided had lowered the danger level (such as transferring the most violent residents, providing additional in-service training, and installing a functional fence alarm).[20] It is true that Woodstock was still out of compliance with staffing requirements. It does not follow that the inadequacy of staffing and training had been irrelevant to the conditions that had presented an immediate jeopardy to residents. The staffing problem was not the sole cause of the immediate jeopardy in the area of supervision (and the staffing level was not itself found to present an immediate jeopardy). However, the noncompliant staffing levels contributed to the severity of the danger

---

[19] In this regard, HCFA's guidance on determining immediate jeopardy specifically describes the relevance of training limitations:

> The absence of adequate staff training does not, in and of itself, pose the threat. However, if the staff lacks the skill or knowledge necessary to properly care for the patients, this may present the same serious problems as when there are insufficient numbers of staff and will make it more difficult for the provider to correct or eliminate the problems.

SOM, Appendix Q, at Q-2.

[20] The ALJ questioned whether these measures were sufficient to reduce the danger below the level of immediate jeopardy but made no finding to that effect since HCFA made no allegation that immediate jeopardy persisted after March 14th. ALJ Decision at 12.

presented by inadequate supervisory measures to prevent accidents. Once arrangements were made by other means to reduce the urgency of the situation, HCFA could reasonably conclude that the existing number of staff were more likely to be capable of adequately and safely supervising the remaining residents.[21]

D. Woodstock, not the State or Federal government, ultimately bears responsibility for providing quality care to residents.

Woodstock argued strongly that the Federal government was responsible for the predicament in which Woodstock found itself because the most disruptive patients had been transferred under contract from VA hospitals. According to Woodstock, the VA facilities had over-medicated the residents, resulting in the need to reduce psychotropic drugs and to risk instability in trying to find the lowest possible doses as required by regulation. See, e.g., Woodstock Br. at 22-23, 28-30; Woodstock Reply Br. at 15, 18. Woodstock described the "government" as "perpetrating a fraud in the placement of the assaultive residents" only to now blame Woodstock for the consequences. Woodstock Reply Br. at 6. Thus, Woodstock asserted that the "irony is that the same government which destroyed the quality of life for R. 11 and R. 17 now seeks to impose a fine upon Woodstock for ultimately admitting that it could not undo what the government created and then lied about." Woodstock Reply Br. at 12.

Woodstock's argument that the VA and/or the State agency affirmatively misled Woodstock about these residents so that Woodstock did not get sufficient notice of their problems is entirely without support in the record. Cf. Woodstock Reply Br. at 6. Woodstock's own records, as discussed above, reflected awareness of the relevant history of the residents involved here at the time of admission and their serious potential for mental and behavioral problems. See, e.g., Woodstock Ex. 7, at 23. Yet, as noted above, Woodstock failed to take appropriate escalating measures to address the hazardous behaviors even after they did materialize. As the ALJ noted, Woodstock's position might have been different if it had reacted promptly and

---

[21] For similar reasons, we find no inconsistency in HCFA's conclusion that the risk of accidents was great enough to warrant immediate jeopardy but that the numerical staffing deficiencies in themselves presented a lower level of harm, since other measures could be instituted to address the danger of further accidents instead of or in addition to improving the staffing deficiencies.

effectively to the problems when they materialized at its facility. ALJ Decision at 15.

Woodstock's basis for attributing blame to the State agency arose from the State's role in determining whether the residents' needs required and were appropriate for long-term care facility care.[22] Woodstock implied that the PASARR screen somehow forced or misled Woodstock into admitting these residents unaware of their severe problems. Woodstock Br. at 15; Woodstock Reply Br. at 6. Applicable regulations prohibit facilities from admitting any new resident with mental illness without a determination by the state mental health authority as to whether the individual requires the level of services provided by a long-term care facility and, if so, whether the individual also requires specialized services. 42 C.F.R. § 483.20 (m)(1)(i); see 42 C.F.R. Part 483, Subpart C. Woodstock pointed to no statute or regulation requiring Woodstock to accept potential new admissions based on their PASARR screens even when Woodstock lacked the capacity to provide the appropriate levels of supervision and treatment for their diagnosed illnesses and assessed needs.

We cannot judge in retrospect and in a vacuum the quality of care provided at the VA facilities or whether the treatment of some of these residents there exacerbated rather than improved their conditions. Even were Woodstock correct in its assertions that the residents were over-medicated at the VA facilities and that Woodstock properly sought to have them "wake up" in order to improve their quality of life, Woodstock would remain responsible for protecting the residents from increased risks to themselves and other residents associated with these changes. Given the uncontrolled and destructive manifestations that took place during Woodstock's care of these residents, it is not immediately obvious that the medication levels provided to them at the VA facility were excessive for their conditions. Even were the VA's care inappropriate, Woodstock showed no basis to treat the "government" as a monolithic entity in some sense which would cause HCFA to be barred from enforcing program requirements on long-term care facilities that accept Federal funds to care for residents simply because another Federal agency earlier provided inadequate treatment of the same residents.

---

[22] This required preadmission screening and annual resident review (PASARR) implements section 1919(e)(7) of the Act.

E. The amount of the CMP was reasonable.

Woodstock also challenged the amount of the CMP set at $3,050 per day as unwarranted based on its arguments as to the lack of evidentiary and legal support for the ALJ's other disputed findings. Woodstock Br. at 32. We summarily reject this contention. We have already addressed and rejected Woodstock's legal and factual disputes with the ALJ's findings of noncompliance under the cited tag and of immediate jeopardy during the cited period. Given those conclusions, we must conclude that the amount was reasonable because HCFA imposed the lowest daily CMP amount possible in an immediate jeopardy situation. In our view, the record as a whole would support a substantially greater sanction than that sought here by HCFA.

CONCLUSION

For the reasons set out above, we conclude that the ALJ Decision was based on substantial evidence in the record as a whole and on a correct legal interpretation of the relevant provisions in the regulations. Therefore, we sustain the ALJ Decision in its entirety and affirm and adopt each of the FFCLs.

_____/s/_____
Donald F. Garrett

_____/s/_____
Marc R. Hillson

_____/s/_____
Judith A. Ballard
Presiding Board Member