Department of Health and Human Services

DEPARTMENTAL APPEALS BOARD

Appellate Division

In the Case of: Alden Town Manor Rehabilitation & HCC, Petitioner, - v. - Centers for Medicare & Medicaid Services.	DATE: November 2, 2006 Civil Remedies CR1398 App. Div. Docket No. A-06-59 Decision No. 2054

FINAL DECISION ON REVIEW OF
ADMINISTRATIVE LAW JUDGE DECISION

The Centers for Medicare & Medicaid Services (CMS) appealed the January 24, 2006 decision of Administrative Law Judge (ALJ) Keith W. Sickendick which held that CMS failed to establish a prima facie case that Alden Town Manor Rehabilitation & HCC (Alden) was not in substantial compliance with Medicare participation requirements. Alden Town Manor Rehabilitation & HCC, DAB CR1398 (2006) (ALJ Decision). CMS had imposed a civil money penalty (CMP) of $200 per day from February 14, 2003 through March 30, 2003 after a complaint survey found that the facility was not in substantial compliance with a quality of care provision requiring each facility to ensure adequate supervision and assistance devices to prevent accidents. See 42 C.F.R. § 483.25(h)(2) (also referred to as tag F324). CMS also alleged before the ALJ that the same evidence demonstrated noncompliance with another provision requiring a facility to maintain an environment as free of accident hazards as possible. See 42 C.F.R. § 483.25(h)(1)(also referred to as Tag F323). CMS argued that it had presented evidence sufficient to establish a prima facie case under either tag F324 or tag F323 or both. It is undisputed that

the incident at issue for both tags involved Resident 1, who found an unattended bottle of disinfectant and sprayed it at his face with his mouth open and required treatment at an emergency room.

We conclude that the ALJ's conclusion that CMS failed to establish a prima facie case was erroneous. He based that conclusion largely on his findings that CMS did not offer proof of the concentration of disinfectant in the bottle and that the concentration was essential to determining whether the spray presented any risk to the resident. We conclude that CMS presented sufficient evidence on both tags to meet the initial burden of a prima facie showing and therefore to require Alden to show by the preponderance of the evidence on the whole record that it was in substantial compliance in order to prevail. For the reasons more fully explained below, therefore, we reverse the ALJ Decision and vacate certain Findings of Fact and Conclusions of Law (FFCLs) in it. We make substitute FFCLs reflecting our analysis of the record using the correct standards.

Because the parties agreed to a hearing on the written record, no in-person testimony was received. For that reason, we determined that it would be more efficient for us to review the record to determine whether Alden carried its burden of proof than to remand to the ALJ for further review. After a complete review, we conclude that Alden failed to prove by the preponderance of the evidence that it was in substantial compliance. For reasons which are also more fully explained below, therefore, we uphold CMS's imposition of the original CMP, totaling $9,000, as a reasonable amount based on the relevant factors.

Factual and procedural background

We provide here a summary of the undisputed facts set out in the ALJ Decision; most of them are drawn from the parties' joint stipulation of facts (Jt. Stip.). See ALJ Decision at 2-3, 7-9. We leave for our analysis below the discussion of those factual issues that are still in dispute on appeal. We also briefly describe the proceedings to date.

Alden is a long-term care facility in Illinois at which Resident 1 was housed from December 18, 2002 until December 23, 2002. Resident 1 suffered from multiple disorders on admission, including Alzheimer's dementia and coronary artery disease, congestive heart failure, and cerebral vascular accident. He was assessed by Alden as being high risk for aspiration and as requiring supervision. Alden planned to provide the latter by

keeping him in common areas where staff could supervise him and by diverting him from wandering behavior.

On the morning of December 23, 2002, Resident 1 was found by a nurse in the dining room where he was spraying UNO Disinfectant-Cleaner-Sanitizer (UNO) in and around his mouth. His mouth was wide open and the solution was dripping down his chin. The staff took the bottle from Resident 1 and followed the label directions to give milk. Resident 1 had normal vital signs immediately afterward. Nevertheless, the treating physician, Dr. Fahmy, ordered Resident 1 taken to the hospital emergency room. At the hospital an hour or so later, he was gagging and spitting out thick mucous secretions and required suctioning twice. A chest x-ray the same day showed possible pneumonia. He remained in the hospital until he died on December 30, 2002. The official cause of death was cardiopulmonary arrest due to aspiration pneumonia which was due to his multiple conditions of dementia, congestive heart failure, cerebral vascular accident, and coronary artery disease.

State surveyor Kelly P. Way conducted a complaint survey at Alden on February 14, 2003 in the wake of this episode. Based on her record review and interviews with staff, the state survey agency recommended and CMS agreed to cite Alden under tag F324 and impose the CMP described above.

Alden requested a hearing on June 24, 2003. ALJ Decision at 2. Alden later waived its right to an oral hearing. Id. The matter proceeded to decision on the written record after both parties submitted briefing and exhibits, all of which the ALJ admitted without objection. Id. and record citations therein. In its briefs before the ALJ, CMS asserted that its factual showing was sufficient to constitute a prima facie case that Alden violated both tag F324 and tag F323, even though the surveyor originally cited only the former. Id. at 8, and record citations therein. Alden objected on due process grounds to any consideration of tag F323. Id.

The ALJ concluded that CMS had not made out a prima facie case under either tag F324 or tag F323. ALJ Decision at 12-13. He stated that, given his disposition of the case, he did not need to resolve Alden's due process issue regarding tag F323. Id. at 8. This appeal followed.

Applicable legal authority

The federal statute and regulations provide for surveys to evaluate the compliance of skilled nursing facilities with the

requirements for participation in the Medicare and Medicaid programs and to impose remedies when a facility is found not to comply substantially. Sections 1819 and 1919 of the Social Security Act; 42 C.F.R. Parts 483, 488, and 498.[1] "Substantial compliance" is defined as "a level of compliance with the requirements of participation such that any identified deficiencies pose no greater risk to resident health and safety than the potential for causing minimal harm." 42 C.F.R. § 488.301. "Noncompliance" means "any deficiency that causes a facility to not be in substantial compliance." Id.

"Quality of care" requirements reflect the overarching regulatory objective that "[e]ach resident must receive and the facility must provide the necessary care and services to attain or maintain the highest practicable physical, mental, and psychosocial well-being, in accordance with the comprehensive assessment and plan of care." 42 C.F.R. § 483.25. Among the required measures to that end, a facility must ensure that "[e]ach resident receives adequate supervision and assistance devices to prevent accidents." 42 C.F.R. § 483.25(h)(2)(tag F324). A facility must also ensure that the "resident environment remains as free of accident hazards as is possible[.]" 42 C.F.R. § 483.25(h)(1)(tag F323).

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

Board precedent has established that a facility must prove by the preponderance of the evidence that it is in substantial compliance. Batavia Nursing and Convalescent Center, DAB No. 1904 (2004), aff'd Batavia Nursing & Convalescent Center v. Thompson, No. 04-3325, 129 Fed. App. 181, 2005 WL 873514 (6th Cir. April 15, 2005). In order to put the facility to its proof, CMS must initially present a prima facie case of noncompliance with Medicare participation requirements, providing evidence on any factual issue that the facility disputes that is "[s]ufficient to establish a fact or raise a presumption unless disproved or rebutted." ALJ Decision at 6, quoting Black's Law

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

Dictionary 1228 (8th ed. 2004). Once CMS has made such a showing as to any disputed facts, the burden of proof shifts to the facility to show at the hearing that it is more likely than not that the facility was in substantial compliance.

Standard of review

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

Substantial evidence is "more than a mere scintilla. It means such relevant evidence as a reasonable mind might accept as adequate to support a conclusion." Richardson v. Perales, 402 U.S. 389, 401 (1971), quoting Consolidated Edison Co. v. NLRB, 305 U.S. 197, 229 (1938). Under the substantial evidence standard, the reviewer must examine the record as a whole and take into account whatever in the record fairly detracts from the weight of the decision below. Universal Camera Corp. v. NLRB, 340 U.S. 474, 488 (1951).

Analysis

1. CMS established a prima facie case.

The ALJ began his analysis by considering what elements were required for CMS to establish a prima facie showing under tag F324. ALJ Decision at 7. He stated that the evidence must show that either "an accident occurred, with or without harm to a resident" or "the facility failed to do what it could to supervise residents or provide assistance devices to minimize risks that could lead to accidents." Id. The ALJ noted that "accident" is defined in CMS's State Operations Manual (SOM) as "an unexpected, unintended event that can cause a resident bodily injury," other than "adverse outcomes" directly resulting from treatment or care. Id., quoting then-applicable SOM, App. P, at PP-105 (Rev. 274, June 1995).

The ALJ's formulation mistakenly elevates the occurrence of an accident to the status of an independent basis for a deficiency finding under tag F324. The circumstances surrounding an accident may provide evidence of the inadequacy of the supervision or devices used by the facility to protect a resident, or it may not. On the other hand, an event or

condition that is not an "accident" may nevertheless provide such evidence. Woodstock Care Center, DAB No. 1726 (2000), aff'd, Woodstock Care Ctr. v. Thompson, 363 F.3d 583 (6th Cir. 2003). The salient point is not whether the evidence is derived from an accident or not, but whether the evidence demonstrates that the facility has failed to provide adequate supervision and assistance devices to prevent accidents, given what was reasonably foreseeable.

The ALJ's conclusion that CMS had not made an adequate prima facie showing centered on his finding that the "problem for CMS is that there is no evidence of the actual contents of the spray bottle," because the parties did not agree as to the concentration of the UNO disinfectant.[2] ALJ Decision at 9. The ALJ found that when UNO is diluted to a solution normal for cleaning use it does "not present a hazard of acute or chronic health effects in exposed persons." ALJ Decision at 3 (FFCL No. 8). Further, the ALJ declined to accept CMS's proposed inference that the solution was concentrated based on the resident's suctioning and chest x-ray. ALJ Decision at 11. The ALJ reasoned that concentrated UNO would have caused burning or irritation of the resident's mouth, nose or throat, but he found no evidence of these symptoms. Id.

The ALJ also stated that "no credible evidence" indicated that the manifestations of aspiration pneumonia would occur "in such a brief period" as four hours after the exposure. Id.[3] He rejected the declaration of CMS's medical expert, Dr. Gaines, to that effect as not "particularly weighty given the dearth of evidence upon which he formed his opinions." Id.

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[2] The parties stipulated that the bottle contained UNO but Alden argued that UNO may be used in various concentrations for disinfecting and cleaning (called use dilutions).

[3] At some points, the ALJ's analysis veers from evaluating the existence of a prima facie case in the first instance, to assessing the weight to be given to conflicting evidence in the record. The latter process is a component of assessing whether a preponderance of the evidence supports a facility's claims of substantial compliance. Evidence adduced at hearing (by either side) may perfect a prima facie case that would have been found incomplete if challenged prior to the hearing. Testimony or exhibits conflicting with the evidence setting out the prima facie case may rebut it or may serve to undercut its credibility or may otherwise demonstrate compliance, but not justify a determination that a prima facie case never existed.

The ALJ further concluded that the resident's pneumonia and ultimate death were the result of underlying disease processes present prior to the incident and were not caused by the UNO exposure. Id. at 11-12. The nurse who observed the resident spraying his face noted that she did not see him swallow the substance or see any coughing, choking or vomiting and reported that she took the bottle away from him within seconds. Id. at 12. Finally, the ALJ concluded that Resident 1 was under appropriate supervision in the common areas with two nurses who were able to observe him as he moved in and out of the dining room. Id. at 12-13. Since the record did not show prior episodes of this kind involving this resident, according to the ALJ, Alden had "no reason to know that closer supervision and/or physical restraint by staff would be necessary." Id. at 13.

We find, as a matter of law, that CMS presented sufficient evidence to shift the burden to Alden to show substantial compliance with both the tags involved. The primary error which appears to have misled the ALJ is his assumption that CMS must prove the actual contents of the bottle in order to establish that Alden failed to take appropriate steps either to supervise the resident to prevent an accident or to make the environment safe from accident hazards. On the contrary, it sufficed for CMS to show that a product which potentially was and was believed to be hazardous was left unattended within reach of extremely vulnerable residents.

To understand why, we must revisit the analytical standards under the regulations, as articulated in prior Board decisions, in order to determine what CMS needed to set out under each of the tags involved to make out a prima facie case of noncompliance. As to tag F323, the Board has explained the responsibility imposed on a facility as follows:

> A facility must determine whether any condition exists in the environment that could endanger a resident's safety. If so, the facility must remove that condition if possible, and, when not possible, it must take action to protect residents from the danger posed by that condition. If a facility has identified and planned for a hazard and then failed to follow its own plan, that may be sufficient to show a lack of compliance with the regulatory requirement. In other cases, an ALJ may need to consider the actions the facility took to identify, remove, or protect residents from the hazard. Where a facility alleges (or shows) that it did not know that a hazard existed, the facility cannot prevail if it could have reasonably foreseen that an endangering condition

> existed either generally or for a particular resident or residents.

Maine Veterans' Home - Scarborough, DAB No. 1975 (2005) (footnote omitted). A prima facie case of noncompliance with this requirement would correspondingly be made out if CMS presented evidence to show that a potentially dangerous condition existed in the facility which was identified or foreseeable but was not removed and that the facility did not take appropriate steps to protect residents from that danger. If CMS set out such evidence, the burden shifts to the facility to rebut the evidence or present other evidence showing substantial compliance.

As part of its prima facie case, CMS presented evidence that a spray bottle that was left by housekeeping staff where it was accessible to residents contained UNO and that UNO was capable of causing harm. It was undisputed that UNO is hazardous in at least some, if not all, concentration levels. The facility stipulated that the bottle contained UNO, but did not stipulate regarding the actual concentration of the solution. The evidence on the latter point which CMS offered included the actual label from the spray bottle. CMS Ex. 43. The label warns of "DANGER," lists the active ingredients (various forms of ammonium chloride) and included the following instructions in case of exposure:

> Statement of Practical Treatment
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> In case of contact immediately flush eyes or skin with plenty of water for at least 15 minutes. For eyes, call a physician. Remove and wash contaminated clothing before reuse. If swallowed, drink promptly a large quantity of milk, egg whites, gelatin solution; or if these are not available, drink large quantities of water. Avoid alcohol. Call a physician immediately. NOTE TO PHYSICIAN: Probable mucosal damage may contraindicate the use of gastric lavage. Measures against circulatory shock, respiratory depression, and convulsion may be added.

Id.

Alden did not dispute the facts asserted by CMS about the labeling on the bottle, but asserted in response that the contents were actually diluted for use and were not hazardous in that form. This assertion, if supported by evidence, might tend to rebut CMS's prima facie case but would not serve to establish that CMS had not presented a prima facie case as to the danger presented by the access to the bottle by vulnerable residents.

In fact, nothing on the label indicated that the contents were other than as set out or had been further diluted. Nor did Alden offer any direct evidence to show that any staff member diluted the solution nor that the bottle was marked in any way on which other staff could rely in handling the bottle as demonstrating the dilution of the contents.

CMS also presented evidence about the facility staff's actions. It was not disputed that the bottle was not observed or removed by any of the staff members supervising residents in the vicinity before Resident 1 was seen with it already spraying himself. In responding to his exposure, the staff acted in accord with the label directions (by forcing milk and calling a physician immediately). On their face, the staff's responses to the resident's exposure implied a belief on their part that the label was accurate and the contents were dangerous. It was also undisputed that the housekeeper who left the bottle unattended had worked at Alden for less than 30 days and was fired immediately after the incident. Her firing implies that her action was viewed as a serious breach of facility policies and practices. It was also undisputed that Resident 1 had been assessed as having poor safety awareness and suffering from dementia. It was undisputed that he had a history of ailments, suggesting high risk for aspiration pneumonia and congestive heart failure.

The inferences which could reasonably be drawn from the evidence presented by CMS formed part of its prima facie case, along with the undisputed facts and the evidence put forward on disputed facts. CMS's case collectively was sufficient to establish a presumption that a hazardous product was left unattended within reach of a vulnerable resident, unless Alden could disprove or otherwise rebut that case.

The evaluation of the existence of a prima facie case does not prejudge whether the opposing party may rebut or disprove CMS's case effectively. The burden simply shifted to Alden, and the record had then to be considered in terms of where the preponderance of the evidence lay as to tag F323.[4] CMS thus

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[4] In that light, the absence of evidence as to the possible dilution of the disinfectant in the bottle must be construed against Alden, rather than against CMS. Even assuming that UNO in fully diluted form presented no more than a minimal risk of harm (a view taken by the ALJ which we discuss below), Alden offered no evidence showing that the UNO in the bottle was so

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presented a prima facie case that Alden was not in compliance with tag F323.

As to tag F324, the Board has explained the responsibility of the facility to comply with this requirement as follows:

> The Board has held that section 483.25(h)(2) cannot properly be read to impose strict liability on facilities for accidents that occur. Instead, the Board has found that the regulatory requirement of "adequate supervision and assistance devices to prevent accidents" obligates the facility to provide supervision and assistance devices designed to meet the resident's assessed needs and to mitigate foreseeable risks of harm from accidents. Id. [Northeastern Ohio Alzheimer's Research Center, DAB No. 1935 (2004)]; see also Tri-County Extended Care Center, DAB No. 1936 (2004); Odd Fellow and Rebekah Health Care Facility, DAB No. 1839 (2002). In addition, the Board has indicated that a facility must provide supervision and assistance devices that reduce known or foreseeable accident risks to the highest practicable degree, consistent with accepted standards of nursing practice. Woodstock Care Center, DAB No. 1726, at 21, 25, 40 (2000), aff'd, Woodstock Care Ctr. v. Thompson, 363 F.3d 583 (6th Cir. 2003); Florence Park Care Center, DAB No. 1931 (2004).

Residence at Kensington Place, DAB No. 1963, at 9 (2005); see also Estes Nursing Facility Civic Center, DAB No. 2000 (2005); Northeastern Ohio Alzheimer's Research Center, DAB No. 1935 (2004). Facilities have the "flexibility to choose the methods of supervision" to prevent accidents so long as the methods chosen are adequate in light of the resident's needs and ability to protect himself or herself from a risk. Golden Age Skilled Nursing & Rehabilitation Center, DAB No. 2026, at 11 (2006), citing Woodstock.

A prima facie case of noncompliance with this requirement would correspondingly be made if CMS presented evidence to show that a facility failed to provide adequate supervision and/or assistance devices to reduce the foreseeable risk of an accident to the highest practicable degree. If CMS set out such evidence, the

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diluted or that its staff had any way to know whether the dilution was sufficient to render it harmless to residents. Cf. ALJ Decision at 11.

burden shifts to the facility to rebut the evidence or present other evidence showing substantial compliance.

The ALJ concluded that CMS failed to make out a prima facie case under this tag because it did not show there was "an 'accident' or risk of accident." ALJ Decision at 12. Again, this conclusion was founded on the premise that CMS was obliged to show in its prima facie case that the concentration of UNO was sufficient to create a risk of bodily injury, and that CMS failed to do so. Id. The ALJ thus concluded that CMS failed to show that the UNO in the spray bottle "had any potential for causing the resident 'bodily injury'," and that, hence, the resident's access to the bottle could not be considered an accident. Id. at 4, 9. We have already addressed why CMS presented sufficient evidence to raise a presumption that the spray bottle of UNO was potentially dangerous to residents and thus set out a prima facie case sufficient, if it were not effectively rebutted by Alden, to make out noncompliance. The burden thus shifted to Alden to prove by the preponderance of the evidence that it was in compliance with the relevant tags.

The ALJ's focus on whether the actual bottle presented a risk of bodily injury was, furthermore, misplaced in determining whether a prima facie case of noncompliance had been made out. The error was partly derivative of the misstatement of the elements of CMS's case, which we have already discussed, in treating occurrence of an accident as an independent basis for finding noncompliance. As the Board held in Woodstock, an accident is neither a necessary nor a sufficient condition to determine whether tag F324 is properly cited, given that -

> [o]ccurrences that do not themselves constitute accidents may well be evidence that the supervision provided was not adequate to prevent accidents.
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> 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.

Woodstock at 35. Even had the bottle turned out to be mislabeled and to contain an entirely harmless substance, evidence that the staff had not acted to remove a bottle with a label warning of potential ill effects from residents' reach until after a resident had picked it up and sprayed it into his open mouth would call into question whether the supervision of those residents (or of control of the cleaning materials) was adequate.

We note that, in the circumstances presented here, the question of compliance with the two tags at issue is inextricably intertwined. If the facility had trained the housekeeping staff adequately to maintain control of potentially hazardous supplies, a vulnerable resident might not require as much supervision as was needed when such supplies might be left unattended and accessible. By the same token, if vulnerable residents were supervised more closely during cleaning periods, the housekeeping staff's inattention to guarding cleaning supplies might be less dangerous since the residents would not be able to access the supplies unobserved and unchecked by staff. We therefore consider whether either the supervision was adequate to prevent accidents in light of the access to cleaning supplies and/or the training and practices of the housekeeping staff permitted an accident hazard to exist.

We look next at the level and kind of supervision provided to this resident to prevent such untoward events. The ALJ found that there was "really no question that Resident 1 required supervision." Id. Indeed, the facility assessment cited by the ALJ noted the resident's poor safety judgment and need for redirection and respite from constant wandering. CMS Ex. 19. The care plan included keeping the resident in common areas to provide for staff supervision. ALJ Decision at 12; CMS Ex. 19. The ALJ found, and CMS did not dispute, that after breakfast, Resident 1 was going back and forth between the dining room and a common area, and that at least one nurse could see him in each room. ALJ Decision at 13.[5] This led the ALJ to conclude that

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[5] The ALJ actually went further to state that it was undisputed that Nurse Cordero "actually observed Resident 1 spray himself," but was "apparently too far away from the resident to prevent him from picking up the bottle and spraying himself." ALJ Decision at 13. The ALJ concluded that the resident "was under direct observation and supervision, really one-on-one supervision at the time of the incident." Id. Clearly, steering the resident to common rooms in which staff is present performing other duties and watching other residents does not equate to one-on-one supervision. On the contrary, the denomination of the areas as common space implied the potential presence of multiple residents at any give time. Nor is it apparent that any staff member was specifically assigned to watch the residents in each room or to observe any particular resident continuously. No witness reported seeing Resident 1 pick up the bottle or begin spraying. Nurse Cordero was placed by facility witnesses outside the dining room with her medication cart, but in a position to see into the

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Alden was providing the level of supervision for which it planned. Id. He further concluded that this intervention was reasonable and that no prior behavior of this resident provided notice that "closer supervision and/or physical restraint by staff would be necessary." Id. Consequently, he concluded that the facility should not have been cited under tag F324.

CMS established that a relatively new member of Alden's housekeeping staff (later fired for it) placed a spray bottle of potentially hazardous disinfectant in an area where there were residents who were known to be susceptible to aspiration pneumonia, who had multiple serious health problems, and who were mentally incapable of protecting themselves or observing safety precautions. CMS did not allege that Alden was obliged to have those residents under constant one-on-one supervision or under restraints. The facility could have responded in alternative ways to assure that the supervision needs of Resident 1, and others, were adequately met. For example, the facility could have ensured that no substances were accessible to such residents in the common areas where such residents were encouraged to stay that could present a risk of bodily injury to them in the time in which a resident might be exposed without being immediately noticed. CMS did not allege that Alden failed to carry out its plan of keeping Resident 1 in the common areas. CMS's allegations focused, rather, on evidence that the plan was not adequate absent effective precautions to keep dangerous substances out of reach of residents in the common areas. CMS presented evidence that housekeepers were expected to be trained on a checklist of tasks before working independently, but that no task list signed by the fired housekeeper was produced on the

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dining room. Petitioner's [P.] Ex. 3, at 1; P. Ex. 4, at 1. The nursing records, filled in by Director of Nursing Cascolan based on Nurse Cordero's report to her of the events, describe the resident having been "found sitting in the Dining Room spraying disinfectant in and around his face, [with] his mouth wide open & disinfectant solution dripping down his chin." CMS Ex. 20, at 3; see also ALJ Decision at 2 (resident "found" by Nurse Cordero spraying disinfectant in and around his mouth). No one has suggested that the nurses failed to respond promptly when they spotted the resident in the process of spraying himself, as Nurse Cordero stated in her statement. P. Ex. 3, at 1-2. Neither the description in the nursing notes nor Nurse Cordero's statement, however, suggests that Nurse Cordero was specifically watching the resident or observed him pick up the bottle. CMS Ex. 20; P. Ex. 3, at 1-2.

surveyor's request, nor was the housekeeping supervisor able to provide information as to when or whether the housekeeper involved had been trained on the safety precautions for handling disinfectants around residents. CMS Ex. 1, at 3. CMS's evidence thus tended to show that Alden failed to provide supervision adequate to protect residents, with the conditions which Resident 1 was assessed as having, from the risk of access to potentially hazardous materials caused by Alden's own failure to train its housekeeping staff to prevent such materials from being left unattended within the residents' reach.

Alden suggests that the incident was unforeseeable to the facility because the same incident had not happened before so as to make Alden aware that this resident would react in this way to an unattended spray bottle. A resident is not required to undergo the same hazard more than once in order to establish foreseeability. Alden foresaw that the resident lacked safety awareness and therefore might act in ways which endangered him absent staff supervision, if the opportunity presented. Furthermore, access to a potentially hazardous product without adequate supervision to prevent exposure presented a danger to any resident who might handle it unsafely, not only to Resident 1. Alden clearly foresaw the risk from such cleaning materials since it had developed training and material to ensure that housekeepers were aware of safety precautions for disinfectant.

Furthermore, the facility is composed of and responsible for its staff and should have foreseen that allowing an untrained housekeeper to work with potentially hazardous materials in areas to which vulnerable residents had access might result in a resident obtaining access to those materials. Alden never claimed that the spray bottle was left by a visitor or appeared in any other unforeseeable manner. It was indisputably left there by facility staff in the course of their duties. The facility cannot deny awareness of the potential for danger in actions taken by its own staff failing to comply with facility policy due to inadequate training. CMS thus presented a prima facie case that Alden was not in compliance with tag F323.[6]

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[6] Alden also refers vaguely to a question of whether "possible consumption of a disinfectant" can actually constitute an "accident" under the regulation in the same way that a fall may be considered an accident with the potential for bodily injury even if the resident is not actually injured. Alden Br. at 9. Alden has shown no reason to distinguish a risk of accidental

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Alden further argues that CMS did not prove that the resident suffered bodily harm. Alden Br. at 11. Alden argues that the resident was not actually seen to ingest the disinfectant he sprayed at his face and mouth. Further, the death certificate does not mention ingestion of disinfectant but rather cites aspiration pneumonia and congestive heart failure leading to cardiopulmonary arrest. P. Ex. 1. Alden argues that the "only reasonable conclusion" is that "IF R1 developed aspiration pneumonia and CHF on December 23, when he was hospitalized after spraying Uno in and around his mouth, it was not because R1 swallowed the Uno, and not because the Uno caused these conditions." Alden Br. at 11-12 (capitals in original). We disagree that the only reasonable conclusion is that the exposure to UNO was unrelated to the need for repeated suctioning and development of aspiration pneumonia hours later, for reasons we discuss later in this decision. Nevertheless, it is not essential to disentangle the relationships of the exposure and the resident's serious underlying conditions to his fatal illness, for the same reason we need not trace the line of causation to his death in order to determine that CMS made a prima facie showing.

CMS cited the deficiency at scope and severity level "G," meaning that the incident was isolated and involved actual harm that is not immediate jeopardy. Facilities have a right to a hearing as to deficiency findings that lead to the imposition of remedies, but may challenge the scope and severity level of the findings only if the outcome could affect the applicable range of CMP amounts that CMS could impose or the loss of approval of a nurse aide training program. 42 C.F.R. §§ 498.3(b)(13) and (14). A facility is not permitted to appeal CMS's choice of which remedy to impose. 42 C.F.R. § 488.408(g)(2). Since CMS did not assert that the situation presented immediate jeopardy to the resident, the range of CMP amounts applicable to this deficiency finding, if found to constitute noncompliance, is not subject to change as a result of any challenge to the scope and severity level assigned. The regulations thus require the ALJ and the Board, if

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poisoning or other harm from exposure to a disinfectant from a risk of injury from falling, whether or not the potential harm materializes. In each case, even if a particular resident is fortuitously spared the worst possible consequences of an accidental occurrence, the regulation asks whether the event exposes a failure to provide adequate supervision and assistance devices to prevent such accidents from occurring which might in the future result in worse outcomes.

the facts as found support CMS's allegations of the basis for its CMP, to defer to CMS's evaluation of the appropriate severity level.

In any case, the CMP actually imposed here was $200 per day, at the low end of this applicable range for noncompliance at any level below immediate jeopardy, which was from $50 to $3,000 per day. This amount was low enough to be reasonable even had CMS not determined that actual harm occurred.

Before continuing in the next section to resolve Alden's due process objections to CMS's reliance on tag F323 and then to apply the preponderance of the evidence standard ourselves, we first note that this case illustrates why it is particularly appropriate for the facility to have the burden of disproving evidence, which on its face, establishes a prima facie case of noncompliance. The facility staff was immediately aware of the incident. Thus, the facility had the opportunity to preserve the contents of the bottle for later examination. Indeed, Alden should have had every motivation to conduct a thorough examination of the contents in order to provide the best information to the physician and hospital in attempting to treat him after the exposure. When the surveyor arrived in response to a complaint, she was given an empty bottle. Thus, the facility, not CMS, had control of the physical evidence which might have demonstrated that the solution was so diluted as to be harmless. In addition, Alden had the opportunity to interview the housekeeper before terminating her and could have recorded information from her about precisely what the bottle contained. If she actually diluted the solution, Alden could have obtained and offered her statement to that effect. By the time the surveyor arrived, the housekeeper was no longer employed so the surveyor had no opportunity to determine her version of the events. In sum, it is thus reasonable to expect that Alden would come forward with evidence which it had the opportunity and motivation to preserve and present if it were exculpatory, and unreasonable to expect CMS to prove the dilution level of the contents of a bottle already emptied by the facility before the complaint survey. Furthermore, to reverse the responsibility for coming forward with evidence under the exclusive control of the facility would risk creating an incentive to fail to collect or even to destroy evidence which might be inculpating. Such a perverse incentive would tend to undermine the primary purpose of the program participation requirements to protect residents and ensure quality care.

2. Alden had sufficient notice of the allegations under tag 323.

It is not entirely clear whether Alden continues to press on appeal its complaint that tag F323 was not properly before the ALJ. Alden simply "requests the Board to note for the record that the Statement of Deficiencies [SOD or 2567] issued in this case cited only tag F324, not F323." Alden Br. at 2, n.1., citing CMS Ex. 1, at 1-3. Since Alden prevailed below, Alden had no reason to appeal the ALJ's treatment of tag F323. Given that we reverse that conclusion and reach the merits of the dispute, we address the question of whether CMS properly raised allegations of noncompliance with tag F323.

There is no question that the surveyors did not cite tag F323 in the SOD. CMS Ex. 1. There is also no dispute that the factual allegations on which CMS made its case under tag F323 were identical to those set out in the SOD in relation to tag F324. CMS made plain in pre-hearing briefing before the ALJ its contention that the facts demonstrated noncompliance with both tags. See, e.g., CMS Prehearing Br. at 10, n.3.

Alden pointed to no authority for its evident view that CMS is strictly constrained by the allegations in the SOD. Board decisions hold to the contrary. For example, the Board found prejudicial error where -

> [t]he ALJ appeared to treat the statement of deficiencies as rigidly framing the scope of evidence to be admitted concerning any allegation relating to a cited deficiency, and requiring formal amendment of the 2567 to allow any additional supporting evidence. We find this treatment of the 2567 erroneous. The 2567 is a notice document, and is not designed to lay out every single detail in support of a finding that a violation has been committed. If the opposite were the case, there would not be much of a need for an exchange of documents or, for that matter, a hearing. This approach is consistent with the intention of the regulations governing surveys as embodied in this exchange from the preamble to the regulations -
>
>> Some commenters further suggested that the facility should be provided with full information that supports each citation and the survey agency's decisions including the underlying reason, basis or rationale for the findings of noncompliance with a regulatory requirement.

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

> 59 Fed. Reg. 56,116, at 56,155 [November 10, 2004]. This is not to say that an ALJ may not require adequate notice before the hearing of testimony and evidence to be presented, but rather to say that such disclosure is a matter of pre-hearing development of the record and clarification of the issues rather than a matter of amending the 2567.

Pacific Regency Arvin, DAB No. 1823, at 9-10 (2002). The purpose of the SOD, thus, in the context of these appeals, is to give notice of the bases for imposition of remedies. Fairness requires that facilities know, going into a hearing, what they are required to answer to. The SOD is not, however, the sole possible source of notice. Pre-hearing record development may also provide a fair context to provide such notice, as we find it did here.

Alden objected to the ALJ permitting CMS to raise issues about the additional tag after the issuance of the SOD. Alden Hearing Br. at 2-4. The ALJ declined to resolve the objection, considering it unnecessary in light of how he disposed of the case.[7] ALJ Decision at 8-9.

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[7] The ALJ did not specify what about how he disposed of the case persuaded him that it was unnecessary to determine if CMS properly raised an issue about noncompliance under tag F323. Since the ALJ went on to find no prima facie case under tag F324, the question of whether the noncompliance under tag F323 was properly raised and whether CMS presented a prima facie case on that issue would appear to be material to the outcome. Possibly, the ALJ meant that his factual conclusions on CMS's failure of proof of the concentration of UNO in the bottle would also preclude a prima facie case under tag F323, so that he did not need to decide whether that issue was properly before him when it was already clear how he would resolve it if it were. See also ALJ Decision at 12 ("Not only has CMS not shown that there was an

(continued...)

We conclude that the issue was properly placed before the ALJ and that no prejudice occurs to Alden by our resolving it now. Alden had ample notice and opportunity to respond to the alleged noncompliance under tag F323. The facts were the same as those alleged under relation to tag 324, so it is hard to see how Alden could have been prejudiced even if the allegation were not made prior to the hearing. In this case, Alden was informed of CMS's position well before the hearing and thus might be expected to have adduced any additional evidence needed to address tag F323.

3. Alden failed to prove substantial compliance with either tag by the preponderance of the evidence.

The next question is whether Alden presented evidence sufficient to show by the preponderance of the evidence that it was in compliance with the requirements cited under tags F323 and 324 so as to rebut the prima facie case against it. Since the ALJ erroneously concluded that CMS failed to make out a prima facie case, he did not conduct a full review of the record to determine where the preponderance of the evidence lay.[8] In order to expedite the resolution of this case, we are, as noted above, resolving the matter ourselves rather than remanding the case to the ALJ. The Board has the option under section 498.88(a) of issuing a decision or remanding a case to the ALJ. Neither party suggested that the Board should remand the case to the ALJ. While a remand would be appropriate if in-person assessment of the credibility of witnesses were at issue, it is not always necessary where, as here, the credibility is not central and, in fact, the matter went to hearing on the written record alone. See generally Lake City Extended Care Center, DAB No. 1658, at 17, n.20 (1998).

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[7](...continued)
'accident' or risk of an accident, but CMS has not shown that the UNO sprayed was the 'accident hazard' necessary to support a finding of a violation of 42 C.F.R. § 483.25(h)(1)."),

[8] While at times the ALJ referred to evidence going to whether Alden demonstrated it was in substantial compliance, ultimately the ALJ resolved the case based only on CMS's failure to present a prima facie case. See, e.g., ALJ Decision at 9 ("I consider first whether CMS has made a prima facie case showing . . . I also consider whether Petitioner's supervision of Resident 1 was adequate."); id. at 4, 8, 12-13. Having rejected the ALJ's conclusion as to CMS's prima facie case, we review afresh whether Alden proved substantial compliance.

Alden presented evidence generally attempting to establish that the bottle contained diluted UNO, that the diluted solution was not hazardous to the residents, and that the staff was providing adequate supervision because they took the bottle away from the resident within seconds and cared for him properly thereafter.

Alden argues that the container was undisputedly a spray bottle "as opposed to the one-gallon container of Uno concentrate," by way of proving that the contents must have been diluted. Alden Br. at 4. Yet, Alden offered no evidence of the size of the spray bottle nor any explanation why the label (which it did not dispute was from the spray bottle) states that the net contents were one gallon.

Alden bases the argument that diluted UNO was not a threat to the residents on its reading of the "material safety data sheet" (MSDS) for UNO and of regulations on chemical hazards in the workplace issued by the Occupational Safety and Health Administration (OSHA), and the ALJ adopted Alden's reasoning. ALJ Decision at 9; CMS Ex. 13, at 3; 29 C.F.R. § 1910.1200. The MSDS is provided under OSHA requirements to companies purchasing the product "for the purpose of providing current health and safety information to your management and for your employees who work with this material." CMS Ex. 13, at 1. The ALJ quoted from the manufacturer's MSDS the following excerpt from the section on health hazards, protective measures and first aid:

> Protection for use solutions: The use dilution solutions of disinfectant prepared according to the current label instructions are not considered hazardous according to criteria of 29 C.F.R. § 1910.1200. However safety protection is recommended for eyes and skin when handling product concentrates.

ALJ Decision at 9, quoting CMS Ex. 13, at 3 (emphasis in original).[9] The quoted part follows a section on inhalation, skin and eye exposure risks and the recommended protective gear for workers to avoid the hazards, including splash proof goggles, protective gloves, and respirators. In that context, the section on protection for use solutions may be read as indicating only that the gear required to handle concentrated UNO is not necessary for handling diluted solutions.

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[9] The MSDS provides directions for two dilutions, one for disinfecting (1:64) and one for sanitizing (1:256). CMS Ex. 13, at 1. Presumably, these are the referenced "use solutions."

The ALJ omits, furthermore, the following excerpt which comes after the use solution protection quote:

> Ingestion: Can cause mouth, throat (mucosal) and abdomen damage, with possible severe swelling of the larynx; skeletal muscle paralysis affecting the ability to breathe; circulatory shock, respiratory depression and/or convulsions. Avoid swallowing. Rinse mouth. Drink large amounts of milk, or, if this is not available lots of water. Get medical attention.

CMS Ex. 13, at 3 (emphasis in original). The ALJ evidently read the statement that use dilutions are not considered hazardous as being more general than simply a statement about whether protective measures were required for handling diluted UNO. There is no other indication in the MSDS that ingestion risks are not present with internal exposure to UNO diluted for use.

In determining how to interpret the MSDS, the ALJ considered two sources: (1) the definition of "health hazard" from OSHA regulations and (2) the declaration of CMS expert witness Dr. Sam Gaines. Under OSHA regulations, "hazardous chemical" means one which is a physical or health hazard, with the former referring to combustibility and the latter defined as follows:

> *Health hazard* means a chemical for which there is statistically significant evidence based on at least one study conducted in accordance with established scientific principles that acute or chronic health effects may occur in exposed employees. The term "health hazard" includes chemicals which are carcinogens, toxic or highly toxic agents, reproductive toxins, irritants, corrosives, sensitizers, hepatotoxins, nephrotoxins, neurotoxins, agents which act on the hematopoietic system, and agents which damage the lungs, skin, eyes, or mucous membranes. Appendix A provides further definitions and explanations of the scope of health hazards covered by this section, and Appendix B describes the criteria to be used to determine whether or not a chemical is to be considered hazardous for purposes of this standard.

29 C.F.R. § 1910.1200(c)(italics in original).[10]

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[10] The referenced Appendix A sets out some of the difficulties and ambiguities involved in determining chronic and acute health

(continued...)

The ALJ concluded that the use dilution protection statement in the MSDS, in light of the regulatory definitions, meant that "exposure to use dilution solutions of UNO present no statistically significant incidence of acute or chronic health effects." ALJ Decision at 10.

Dr. Gaines offered an expert opinion on the meaning of the MSDS statement. Alden stated that it does not challenge "CMS's characterization of Dr. Gaines as an expert on interpreting

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[10](...continued)
risks from chemical exposure, including the following statements:

> Although safety hazards related to the physical characteristics of a chemical can be objectively defined in terms of testing requirements (e.g. flammability), health hazard definitions are less precise and more subjective. Health hazards may cause measurable changes in the body -- such as decreased pulmonary function. These changes are generally indicated by the occurrence of signs and symptoms in the exposed employees -- such as shortness of breath, a non-measurable, subjective feeling. Employees exposed to such hazards must be apprised of both the change in body function and the signs and symptoms that may occur to signal that change.
>
> The determination of occupational health hazards is complicated by the fact that many of the effects or signs and symptoms occur commonly in non-occupationally exposed populations, so that effects of exposure are difficult to separate from normally occurring illnesses. . . . The situation is further complicated by the fact that most chemicals have not been adequately tested to determine their health hazard potential, and data do not exist to substantiate these effects.

42 C.F.R. § 1910.1200, App. A. Appendix A also defines levels of toxicity. Appendix B provides guidance for manufacturers in evaluating study data to determine what hazards must be disclosed. "Standard," as used in these regulations is defined as a "standard which requires conditions, or the adoption or use of one or more practices, means, methods, operations, or processes, reasonably necessary or appropriate to provide safe or healthful employment and places of employment." 29 C.F.R. § 1910.2(f). This definition again makes explicit that the evaluation of a health hazard is done within the context of providing safe conditions for employees.

information from the [MSDS] for Uno, as well as from the Micromedex Health Series Poisindex Management database [Poisindex] for the ammonia compounds in Uno disinfectant" nor that the doctor is "an emergency room physician who has extensive experience dealing with patients who have been exposed to various cleaning products, poisons and/or other toxic substances." Alden Br. at 8. Dr. Gaines stated that the MSDS and the Poisindex are regularly consulted by doctors treating chemically-exposed patients. CMS Ex. 45, at 3-4. He explained that the statement quoted by the ALJ from the MSDS "refers to the fact that safety protection, such as safety glasses and gloves, is not required when handling the diluted solution. It does not mean that exposure to the diluted solution could not result in potentially serious health consequences." Id. at 4. Alden offered no expert testimony on the health risks of UNO exposure.

The ALJ stated that he accepted Dr. Gaines' statement "as correct, however it is incomplete," but then goes on to say that Dr. Gaines' opinion about the potential health effects of even diluted UNO, "is contrary to the representation" in the MSDS. ALJ Decision at 10. The ALJ substituted his reading for that of the only expert to testify on the point. While the MSDS statement read in a vacuum might be amenable to the interpretation suggested by the ALJ, it is far from the only reasonable interpretation, and becomes less supportable when read in context. The placement of the statement in the MSDS and its reference not to the general safety of use dilutions but to the "protections" for use dilutions, as well as the reference to materials being considered hazardous for the purpose of specific OSHA criteria, better support Dr. Gaines' reading. The question then is whether the absence of "statistically significant" results for a health hazard in the context of the MSDS statement means that no such results exist that require employee use of protections or that use dilutions present no health risks to anyone. The former is much more probable since the MSDS is specifically designed to assess risks in the normal employment context. To read it as an assurance that a seriously compromised nursing home resident could run no risk of ill health effects by spraying UNO in use dilution into his face and mouth or by ingesting it is implausible. Furthermore, Dr. Gaines was undisputedly an expert in interpreting MSDS material in the context of patient care. His uncontradicted declaration about the hazards of diluted UNO based on this MSDS could not properly be dismissed as contrary to the MSDS on its face, since the MSDS language could plainly be read as the doctor read it. Furthermore, the ALJ failed to explain why an "accident hazard" cannot be presented to residents in a nursing home by materials

or conditions that might well not be "hazardous" under the OSHA regulations.

Dr. Gaines also noted, based on the Poisindex entries, that the ammonia chloride ingredients in UNO "can cause significant problems with gastrointestinal burns in the appropriate concentration" and that other potential side effects of exposure to such solutions "whether in a diluted or concentrated form, include respiratory muscle paralysis, pulmonary edema (fluid in the lungs), occupational asthma, and hypoxemia (low oxygen level)." CMS Ex. 45, at 5; see also CMS Ex. 42, at 1-2. The ALJ discounted this part of Dr. Gaines' opinion as "at odds" with the Poisindex because that document notes "health effects for concentrations above a certain level." ALJ Decision at 11.

The Poisindex entry does not support the ALJ's conclusion. Various parts of the discussion of cationic detergents (the category into which UNO falls) do discuss specific concentration levels and the differing degrees of various harms to be anticipated at different levels of exposure. The respiratory effects, however, are not represented as tied to any specific concentration level. CMS Ex. 42, at 1-2. Moreover, in the overview of clinical effects of exposure, the following statements appear:

> There are insufficient data to determine a "non-toxic" amount following ingestion of non-corrosive concentrations (probably less than 7.5 percent). . . . If ingested, concentrated solutions (greater than 7.5 percent) . . . may result in corrosive burns of the mouth, pharynx, and esophagus. Medical evaluation is generally justified except in patients who have ingested an unintentional "taste" of a dilute (less than 1 percent) cationic detergent solution.

Id. at 1.

Since the dilution to be used for disinfecting is 1:64, even this normal use dilution would fall in the range requiring medical evaluation even for a "taste." Alden presented no evidence of the dilution practices in the facility nor evidence that the housekeeper involved was meticulous in diluting products despite evidently being careless about handling them. While greater dilutions are possible for other uses, therefore, it is unreasonable to presume, in the absence of any proof offered by Alden, that the solution was so dilute as to present the potential for no more than minimal harm when sprayed at the open

mouth of a resident with these special vulnerabilities, in an amount sufficient to cause the solution to drip down his chin.

The ALJ's general skepticism of Dr. Gaines' opinion, despite his acknowledgment of Dr. Gaines' relevant expertise, expressly arose from the fact that Dr. Gaines had no information about concentration or duration of exposure. See ALJ Decision at 11. The ALJ noted that Dr. Gaines said that "[a]lmost any substance, even those considered relatively safe, such as mouthwash or Tylenol, can have potentially serious health consequences depending on the nature, quantity, and duration of the exposure." Id. Yet, according to the ALJ, Dr. Gaines went forward to offer an opinion of the hazard presented to Resident 1 "without the very information he recognizes is important." Id. This criticism is apparently connected with the ALJ's erroneous position that CMS was responsible for proving the concentration of UNO in a bottle which had been emptied by the time of the survey, a position which we rejected above. By that reasoning, no expert could give an opinion on the potential effects of concentrated and diluted solutions without also knowing the specific dilution involved in the incident. Dr. Gaines made clear that respiratory and other effects can result from exposure to UNO diluted for use. He did not have to know whether or to what degree the housekeeper at Alden actually diluted the solution in that spray bottle to be able to testify about the general hazards of use dilutions of UNO. If any evidence suggested the solution was so dilute as to be essentially harmless, Alden had both the opportunity and incentive to bring forward that evidence, and did not do so.

The ALJ also faults Dr. Gaines for relying on "a note in an incident report that indicates Resident 1 had a 'cough from irritant' (CMS Ex. 45 at 5-6; CMS Ex. 3), which I conclude was in error as Nurse Cordero, who observed Resident 1 spray the UNO and responded, noted no cough. P. Ex. 3 at 1-2." ALJ Decision at 11. The ALJ does not explain why Nurse Cordero, having discovered the resident spraying himself and having intervened, was the only person who could plausibly have reported that the resident had a cough.[11] In fact, the incident report was

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[11] The ALJ went so far as to say that "Nurse Cordero was the only nurse to witness the incident." ALJ Decision at 12. This statement is accurate only if the ALJ defined "the incident" as beginning and ending with her discovery of the resident spraying himself. It is undisputed, however, that no staff person observed the resident find the unattended bottle and start to

(continued...)

completed by another nurse, Veronica Jones. CMS Ex. 23. Nurse Jones was in the common area when the incident occurred but did not see the resident while he was in the dining room. P. Ex. 4, at 1. She participated in assessing and treating the resident immediately after his exposure was discovered. Id. at 2. Alden presented written direct testimony from Nurse Jones. She disputed a report by the surveyor in the SOD that Nurse Jones had said in an interview that she did not know how or when the resident obtained the spray bottle, but that she knew "he ingested some of it." CMS Ex. 1. Nowhere does Nurse Jones dispute her signed statement on the incident report written within 40 minutes of the 10:05 AM exposure that the resident had a "cough from irritant." Further, the report of coughing is consistent with the resident's undisputed condition on arrival at the hospital where he was gagging and spitting out thick mucous requiring suctioning by 11:30 AM. CMS Ex. 29, at 4. It was not appropriate for the ALJ to simply dismiss as "erroneous" evidence that was both uncontested and corroborated by the course of events afterward. Furthermore, even were Alden's nurse somehow mistaken in recording a cough, Dr. Gaines made clear that he relied on many factors, not just the cough, in concluding that Resident 1 suffered actual harm, in particular the findings made at the hospital and his relatively stable condition prior to this event. CMS Ex. 45, at 5-7.

The evidence relating to Resident 1's condition after the incident favors the conclusion that the exposure had untoward effects on the resident, if not directly causing his abrupt decline and death, contrary to the ALJ's discussion of the events. The ALJ emphasized the absence of skin or eye irritation as evidence that the resident must not have been exposed to a potentially hazardous concentration of UNO. ALJ Decision at 11. This inference is not supported by the evidence cited. While a sufficient concentration of UNO may indeed cause skin and eye irritation, according to the MSDS cited by the ALJ, nothing in the MSDS suggests that the product is harmful ONLY when the concentration is sufficient to cause corrosive skin and eye damage. On the contrary, the MSDS, as quoted above, specifically warns about "throat (mucosal)" damage, as well as effects on breathing and circulation. CMS Ex. 13, at 3. It was therefore

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[11](...continued)
spray himself, which might be a reasonable point to consider the incident as beginning. It is not contested either that other nurses assisted in taking vital signs and providing emergency treatment, so others had an opportunity to observe the aftereffects of the exposure.

unreasonable for the ALJ to discount as irrelevant the resident's need for repeated suctioning of thick mucous from his mouth and throat on arrival from the hospital. Cf. ALJ Decision at 11.

The ALJ acknowledges that, "less than four hours" after exposure,[12] the resident's hospital x-ray showed evidence of pneumonia. Id.; see also CMS Ex. 31, at 2. Nevertheless, he did not find it probable that the resident's exposure to UNO was related to his aspiration pneumonia because, according to the ALJ, he had "no credible evidence which indicates that such objective manifestations can or would occur in such a brief period." ALJ Decision at 11. It is not clear why the ALJ believed that skin and eye irritation must be obvious immediately

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[12] Alden raises an issue about the CMS's use of the broader term "exposure" when the SOD referred to the resident's "ingestion" of the disinfectant. See CMS Ex. 1. Alden argued that CMS failed to prove that the product was actually ingested. Alden Br. at 7, n.3. Only one staff member reported seeing Resident 1 swallow, and that nurse disputed the surveyor's report of her statement and denied seeing the resident ingest the product. P. Ex. 4, at 4. Nurse Cordero asserted that she "felt it was only a matter of seconds" before she took the bottle away from Resident 1, and that "no swallowing was observed." CMS Ex. 25. While she may well have acted promptly to remove the bottle once she saw the resident spraying its contents into his open mouth, she nowhere explains how she would know how long before her observation the resident began spraying. The ambulance dispatch record reports that Alden called about a patient "who ingested cleaner per staff," and gave the diagnosis as "ingested cleaner." CMS Ex. 24. This record does not show who at Alden communicated this information but certainly suggests that facility staff believed that the resident had indeed ingested the product. The record shows that the staff gave the resident milk to flush down the UNO, the treatment for ingestion per the label, but does not explain how this was done in a manner that would avoid ingestion of any of the substance he sprayed into his open mouth if he had somehow not ingested any before then. In any case, the question of whether the resident's aspiration pneumonia was triggered by the UNO spray really rests on the UNO entering his lungs rather his stomach. Even if the word "ingestion" may have been too narrow to cover all the possible routes of exposure, it accurately reported the diagnosis at the point that the resident was received in the emergency room. In any case, Alden had ample notice that CMS's allegations were broader than whether the resident swallowed the UNO and encompassed the risks of inhalation and skin exposure.

to demonstrate that the exposure had any effect on the resident but that mucosal and respiratory symptoms should take more than four hours to occur in order to be connected.

The only testimonial evidence in the record on the timing to be expected for symptom development came from CMS's expert, Dr. Gaines. He stated as follows:

> The side effects of exposure to these compounds are not always immediately apparent. Side effects may not become apparent for several hours after exposure depending on the length of time, manner, and quantity of the product to which the person was exposed.

CMS Ex. 45, at 5.

His statement was corroborated by an article from an e-medicine website on aspiration pneumonia authored by two internal medicine physicians. The article states that chemical pneumonia (CP), unlike bacterial aspiration pneumonia, is characterized by "[a]cute onset" with the "[d]evelopment of symptoms within a few minutes to 2 hours." CMS Ex. 39, at 3. This is consistent with Dr. Gaines' observation that it "is clear that within two hours of being exposed to the disinfectant spray, Resident # 1 began to show symptoms of exposure to the disinfectant, including pulmonary vascular congestion, low oxygen saturation level, rhonchi, and an infiltrate in his lungs," all prior to the onset of aspiration pneumonia. CMS Ex. 45, at 6. The article also reports that lab work "demonstrates acute hypoxemia in patients with CP," (id. at 6) which is consistent with the low oxygen levels pointed out by Dr. Gaines in his review of the hospital records. CMS Ex. 45, at 6; CMS Ex. 29. The article further states that "chest radiograph findings in patients with CP are characterized by the presence of infiltrates . . . in one or both lower lobes or diffuse simulation of pulmonary edema," which is consistent with the resident chest x-ray showing lower lobe infiltrate. CMS Ex. 22, at 6; CMS Ex. 45, at 6. Finally, the article reports a mortality rate for CP of 30-62%. CMS Ex. 39, at 3.

The ALJ's conclusion that Resident 1 suffered no harm was based on his finding that the resident developed "heart failure and pneumonia before he ever sprayed the UNO." ALJ Decision at 12. He read the source relied on by CMS to corroborate Dr. Gaines as instead consistent with his own conclusion because the article agreed that "there are many possible causes for aspiration pneumonia for someone in a compromised state such as Resident 1." Id. It does not follow from the facts that the Resident 1 was

indeed compromised and that many things can cause aspiration pneumonia in such a resident, that spraying himself in the face with a chemical disinfectant did not trigger this episode of aspiration pneumonia.[13]

Certainly, the fact that the resident underwent what may have been his first (and ultimately fatal) episode of aspiration pneumonia within a few hours of his exposure makes it difficult to conclude that the timing was mere coincidence with a flare-up of his preexisting diagnoses of congestive heart failure and coronary artery disease. The ALJ did not address the similarities mentioned above between the medical records of the resident's symptoms and the anticipated course of aspiration pneumonia due to aspiring a foreign substance (also referred to as chemical, as opposed to microbial, pneumonia). While it is clearly true that the facility was aware that the resident was at high risk of aspiration due to his other illnesses and his general compromised status (and therefore should have been especially conscious of not leaving cleaning materials within his reach), there is no basis to dismiss the likelihood that the timing of this attack was related to the exposure.

We conclude that Alden failed to prove by the preponderance of the evidence that it was in substantial compliance with either of the cited tags. Alden permitted a chemical product potentially harmful to its impaired residents to be left unattended within their reach. Alden's supervision of Resident 1 was inadequate for conditions where such a product was accessible to him. As a result, Resident 1 suffered actual harm, at the very least in the form of coughing, gagging, and requiring suctioning and, more likely, in the form of aspiration pneumonia.

4. The CMP amount is reasonable.

CMS imposed a CMP of $200 per day from February 14, 2003 through March 30, 2003 for a total of $9,000. Alden argued that, even if the Board reversed the ALJ's finding of substantial compliance,

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[13] The ALJ also asserts that Resident 1 had a "history" of aspiration. ALJ Decision at 3. The cited exhibits nowhere provide support for this finding. CMS Exs. 14, 16, 17, 19, and 22. To the contrary, the lists of present and past medical conditions do not show any prior history of aspiration pneumonia. See CMS Exs. 14, at 2; 17; and 22, at 3. The physician's orders specify "aspiration precautions" as of December 18, 2002, but do not identify any history of aspiration having actually occurred prior to the episode at issue. CMS Ex. 22, at 4.

as we have done, CMS failed to justify the amount under the factors set forth in 42 C.F.R. § 488.438(f). Alden Br. at 15. The cited regulation provides factors for CMS to take into account in determining the amount of CMP to impose. Those factors are:

> (1) The facility's history of noncompliance, including repeated deficiencies.
>
> (2) The facility's financial condition.
>
> (3) The factors specified in § 488.404.
>
> (4) The facility's degree of culpability. Culpability for purposes of this paragraph includes, but is not limited to, neglect, indifference, or disregard for resident care, comfort or safety. The absence of culpability is not a mitigating circumstance in reducing the amount of the penalty.

42 C.F.R. § 488.438(f). The provision incorporated by reference sets out general factors to be considered in selecting a remedy. 42 C.F.R. § 488.404. That regulation explains that the initial question in selecting any remedy is the seriousness of the deficiencies, as determined by at least considering how severe the harm involved and how widespread each deficiency was. 42 C.F.R. § 488.404(a) and (b). CMS may then consider other factors in setting the specific remedy, which –

> may include but are not limited to the following:
>
> > (1) The relationship of one deficiency to other deficiencies resulting in noncompliance.
> >
> > (2) The facility's prior history of noncompliance in general and specifically with reference to the cited deficiencies.

42 C.F.R. § 488.404(c).

In light of CMS's determination that the deficiency here did not rise to the level of immediate jeopardy, and CMS's unreviewable choice to impose a per-day CMP, the choice of amount was limited by the regulations to the range of $50 to $3,000 per day set in $50 increments. 42 C.F.R. § 488.438(a); see also 42 C.F.R. § 488.438(e)(2). Also, the ALJ (and here the Board) is prohibited from setting or reducing a CMP amount to zero, which effectively means that the minimal CMP amount permissible where,

as here, a basis has been found for imposing a remedy and CMS has selected a CMP, is $50 per day. 42 C.F.R. § 488.438(e)(1). We are therefore asked to determine in that context whether a CMP of $200 per day is unreasonable and, if so, what amount between $50 and $150 per day is reasonable.

CMS is not required to present evidence on any or all of these factors or to explain its reasoning process in determining the amount to impose as part of its case in chief. Clermont Nursing & Convalescent Ctr., DAB No. 1923 (2004), aff'd sub nom. Clermont Nursing & Convalescent Ctr. v. Leavitt, 142 Fed. App. 900 (6th Cir. 2005). If the facility offers evidence on any of the factors to suggest that the amount is unreasonable, the ALJ (and, in this case, the Board) weighs that evidence along with any other evidence present in the record relevant to those factors in determining whether the CMP is reasonable. Emerald Oaks, DAB No. 1800 (2001).

Alden argued before us that "CMS has identified no deficiencies in the previous four years for F324, which was the only tag cited in the [SOD] as the basis for the imposition of the CMP." Alden Br. at 15. This carefully-worded assertion fails to acknowledge that the regulations encompass any prior history of noncompliance, which includes but is expressly not limited to repeated deficiencies in general and prior instances of specific cited deficiencies. 42 C.F.R. § 488.438(1) and 488.404(c)(2). It avoids the fact that Alden had previously been found noncompliant with tag F323 and had been found out of compliance with other provisions during six surveys between February 25, 1999, and November 7, 2001. CMS Ex. 5, at 5.

Alden also questions the seriousness of the deficiency on the basis that it claimed to have "more than established that CMS has not proven actual harm to R1." Alden Br. at 16. As discussed above, the record contains clear evidence that actual harm did occur, at a minimum because of the gagging and suctioning of mucous occurring in a short time after the resident's exposure to UNO. We also consider it more likely than not that the development of aspiration pneumonia was related to the aftereffects of the exposure on top of the pre-existing conditions that the resident had, which Alden was well aware made such exposure especially dangerous for him. In any case, since we find that the facts are consistent with CMS's alleged basis for finding noncompliance, we are not authorized to reevaluate the scope and severity which CMS assigned to the deficiency finding.

Furthermore, the potential for harm as a result of the exposure to the unattended bottle was quite serious, including risks that were not documented as occurring to Resident 1, such as severe skin, eye and throat burns, respiratory paralysis, vomiting and central nervous system depression. CMS Ex. 42, at 1. We would have found $200 per day to be a reasonable amount for this level of potential harm as well. Alden suggests that these potential outcomes are not relevant because the staff took the bottle away immediately and administered milk and because no prior history was shown of Resident 1 doing this before nor of Alden staff previously leaving cleaning products within reach of dementia patients. Alden Br. at 16. Alden was not cited for failing to take appropriate action after the resident was discovered spraying the UNO, but that does not detract from the seriousness of having allowed him access to a hazardous product without supervision adequate to prevent him from exposing himself to potential danger from the product. It does not matter either that the record did not show that this resident had previously displayed this specific behavior or that no prior inappropriate access to cleaning products at the facility was documented.

The assessment of the resident's lack of safety awareness and need for supervision to control wandering, together with the failure to train the housekeeping staff, made it foreseeable that, if not adequately supervised, the resident might engage in any number of dangerous behaviors. Although Alden repeatedly disclaims responsibility for the neglect by one of its cleaning staff to follow the policy for handling cleaning products, it is well-established that a facility acts through its staff and is responsible for those actions, particularl6 where, as here, the facility did not take steps it had identified as needed to make housekeeping staff aware of safety issues. This reasoning also applies to Alden's argument that it was not culpable because the resident's "access to the bottle of disinfectant was not expected." Alden Br. at 17. The facility should certainly have expected that if its staff left a bottle of cleaning product where dementia patients had access to it, one of them might use it unsafely.

We conclude that the CMP amount imposed by CMS is amply supported on this record.

Conclusion

For the reasons set out above, we reverse the ALJ Decision. CMS challenged the ALJ's Findings of Fact 8, 9, 11, and 13, as well as Conclusions of Law 4-8. We vacate the challenged FFCLs in accordance with our analysis above. We also vacate Conclusion of

Law 3 which misstated the prima facie showing required under tag 324. We affirm and adopt the remaining FFCLs from the ALJ Decision. We make the following additional FFCLs based on our analysis and review of the record evidence above:

> Appellate FFCL 1: A spray bottle of potentially hazardous cleaning product (UNO) was left unattended in the dining room into which Resident 1 was freely wandering.
>
> Appellate FFCL 2: Alden failed to prove that the spray bottle contained a solution of UNO so dilute as not to present more than a potential for minimal harm. CMS Exs. 39, 45.
>
> Appellate FFCL 3: Resident 1 was an 83-year-old man with a prior history of dementia, congestive heart failure and swallowing difficulties who was assessed as needing precautions to prevent aspiration pneumonia. CMS Exs. 14, 16, 17, 19, and 22.
>
> Appellate FFCL 4: On December 23, 2002, after breakfast, Resident 1 was placed in the common area near the nurses' station but permitted to wander in and out of the dining room. CMS Ex. 1, at 2-3. One nurse was standing with a medication cart in a location where she had a view into the dining room. P. Exs. 3, at 1-2, and 4, at 1.
>
> Appellate FFCL 5: Resident 1 suffered actual harm as a result of his exposure to the solution, in the form of, at a minimum, gagging and requiring suctioning, and most likely also in the form of aspiration pneumonia. CMS Exs. 1, at 2, 13, 29, at 4, 39, and 45.
>
> Appellate FFCL 6: In order for CMS to make a prima facie showing of noncompliance with 42 C.F.R. § 483.25(h)(1), CMS must offer, as to any fact disputed by the facility, evidence sufficient to show, if unrebutted by the facility, that a potentially dangerous condition existed in the facility which was identified or foreseeable but was not removed, and that the facility did not take appropriate steps to protect residents from that hazard.
>
> Appellate FFCL 7: In order for CMS to make a prima facie showing of noncompliance with 42 C.F.R. § 483.25(h)(2), CMS must offer, as to any fact disputed by

the facility, evidence sufficient to show, if unrebutted by the facility, that the facility failed to provide adequate supervision and/or assistance devices to reduce the foreseeable risk of an accident to the highest practicable degree.

Appellate FFCL 8: CMS presented evidence sufficient to establish a prima facie showing that Alden was not in substantial compliance with both 42 C.F.R. §§ 483.25(h)(1) and 483.25(h)(2).

Appellate FFCL 9: Alden had adequate notice that it had to respond to allegations that the incident involving Resident 1 constituted noncompliance under both regulatory provisions.

Appellate FFCL 10: Resident 1 was able to enter the dining room, find an unattended bottle of a potentially hazardous chemical and begin spraying his face unobserved, despite his acknowledged need for supervision, his lack of safety awareness and his high risk for aspiration.

Appellate FFCL 11: Alden failed to show by a preponderance of the evidence that it was in substantial compliance with 42 C.F.R. § 483.25(h)(1) and (2) despite the record evidence that Resident 1 was not adequately supervised for the circumstance where a hazardous cleaning product was left unattended and was not protected from the evident hazard presented by such products, despite the fact that Alden’s failure to take steps to make housekeeping staff aware of safety precautions made it foreseeable that such products might be left where residents could access them.

Appellate FFCL 12: There is a basis for the imposition of an enforcement remedy.

Appellate FFCL 13: The amount of the CMP imposed here, $200 per day for 45 days, is reasonable.

Judith A. Ballard

Donald F. Garrett

Leslie A. Sussan
Presiding Board Member