Department of Health and Human Services
DEPARTMENTAL APPEALS BOARD
Appellate Division

Fort Madison Health Center
Docket No. A-11-72
Decision No. 2403
August 5, 2011

FINAL DECISION ON REVIEW OF ADMINISTRATIVE LAW JUDGE DECISION

Fort Madison Health Center (Fort Madison) appealed the March 3, 2011 decision of Administrative Law Judge (ALJ) Richard J. Smith sustaining the Centers for Medicare & Medicaid Services (CMS) imposition of a per-instance civil money penalty (CMP) of $5,000 and a two-year bar on Fort Madison operating a nurse aide training and competency evaluation program and competency evaluation (NATCEP) program required because of the CMP amount. *Fort Madison Health Center*, DAB CR2331 (2011) (ALJ Decision). The deficiency findings involved residents for whom the facility arranged transportation for appointments at other medical institutions (for transfusions and dialysis). The ALJ found that the undisputed evidence established that the van driver abandoned one resident alone in a parked van behind the facility. He also found that a sign-out board tracking resident departures and returns, established to correct the problems that resulted in the first incident, was not being used correctly as to two other residents.

For reasons explained below, we affirm the ALJ Decision.

Case background[1]

Fort Madison is an Iowa long-term care facility participating in Medicare and Medicaid. The survey findings involved three residents at the facility. Resident 1 suffered from pernicious anemia which required Fort Madison to arrange for her periodic transportation to a nearby hospital to receive blood transfusions. ALJ Decision at 1, 6. Transportation for Fort Madison's residents was provided by van drivers employed by Inpropco, a company under common ownership with Fort Madison. *Id.* at 6.

[1] This discussion is presented for the convenience of the reader and draws on the facts that the ALJ found to be "genuinely undisputed" as well as those facts asserted by Fort Madison that he accepted as true for purposes of summary judgment. Nothing in the background section is intended to revise or replace any of the ALJ's factual findings.

On March 23, 2010, Resident 1 was transported to the hospital in the morning. The time at which she would be ready for pickup after a transfusion varied. The ALJ accepted Fort Madison's assertions that a protocol was in place for the hospital to contact the facility when the resident should be picked up but that the van driver told the hospital to call her cell phone instead.[2] ALJ Decision at 7-8. The hospital did call the driver who picked up the resident and returned to the facility at about 4:30 PM. The driver "became distracted or forgetful, parked the van, and locked it, leaving Resident 1 sitting in the van unattended" in a parking area behind the facility. *Id.* at 7. The driver then went home, carrying off in her pocket the after-care paperwork for the resident. *Id.* At 6:30 PM, a Fort Madison nurse called the hospital and learned that Resident 1 had been picked up earlier. The Inpropco supervisor was contacted and arrived at the facility with the van driver and found the resident in the van at 6:45 PM.

Resident 1 was also diabetic and was due to receive medication (Metformin) at 5 PM. The ALJ accepted Fort Madison's assertion that its medication protocol allowed the drug to be administered "up to an hour before or after the designated time." *Id.* at 6. It is undisputed, however, that Resident 1 did not receive her medication until 7 PM, or two hours after the designated time. *Id.* at 7, 8 n.6. The resident experienced an "unaccustomed episode of urinary incontinence" while locked in the van but her vital signs were found to be within normal limits when she was assessed on return to the facility. *Id.* at 7.

After that incident, Fort Madison adopted a new policy requiring that all "van drivers or employees transporting residents will sign the resident out on the marker board in the nurse's station" and will remove the name on return. *Id.* at 7, citing CMS Ex. 2, at 28-30. Nurses were to check the board at the beginning of each shift and to call to verify the status of any resident who did not return by 5 PM. *Id.* During the survey on March 31, 2010, two residents (Resident 2 and Resident 3) left for dialysis appointments in the morning but the board did not list any resident as out of the building that day even when the surveyor checked the board nearly three hours after the residents' departure. *Id.* at 8-9.

The ALJ rejected Fort Madison's argument that it was not responsible for ensuring adequate supervision of its residents while they are transported outside the facility. *Id.* at 9. The ALJ held that Fort Madison remains responsible for residents' care while receiving services arranged for by the facility whether through its own staff or under contract. *Id.* The ALJ also rejected Fort Madison's argument that it could not foresee

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[2] CMS disputed these assertions and proffered evidence that the hospital had always called the van driver when nursing home residents were ready to be transported after a transfusion. CMS Ex. 2, at 16. In deciding on CMS's summary judgment motion, however, the ALJ correctly resolved all disputes of fact in favor of the facility.

that a previously reliable driver would fail to follow its protocol on notifying the facility when a resident was to be picked up for return to the facility or would leave a resident. *Id.* at 11. The ALJ concluded that Fort Madison was responsible for ensuring that its system for safely transporting residents to such appointments was known to and followed by the drivers and that the system "failed utterly" in the present case. *Id.*

The ALJ also rejected Fort Madison's arguments that the failure to note the absence of the two residents on the sign-out board was harmless because they did return without incident and merely resulted from "expected confusion" from a novel system. *Id.* The ALJ concluded that failure to implement effectively the corrective measure demonstrated that Fort Madison's deficiencies in supervising its residents "were system-wide and not corrected." *Id.*

Applicable legal authority

Long-term care facilities participating in the Medicare and Medicaid programs are subject to the survey and enforcement procedures set out in 42 C.F.R. Part 488, subpart E, to determine if they are in substantial compliance with applicable program requirements which appear at 42 C.F.R. Part 483, subpart B. "Substantial compliance" means a level of compliance such that "any identified deficiencies pose no greater risk to resident health or safety than the potential for causing minimal harm." 42 C.F.R. § 488.301. "Noncompliance," in turn, is defined as "any deficiency that causes a facility to not be in substantial compliance." *Id.*

Survey findings are reported in a Statement of Deficiencies (SOD) which identifies each "deficiency" under its regulatory requirement. The regulatory requirement at issue here is at 42 C.F.R. § 483.25(h) which provides as follows:

> *Accidents*. The facility must ensure that –
>
> (1) The resident environment remains as free of accident hazards as is possible; and
>
> (2) Each resident receives adequate supervision and assistance devices to prevent accidents.

In choosing an appropriate remedy for a SNF's noncompliance, CMS considers the "seriousness" of the deficiencies and may consider other factors, including the SNF's history of noncompliance. 42 C.F.R. § 488.404(a), (c). The seriousness of a SNF's noncompliance is a function of its "severity" (whether the noncompliance has created a "potential" for "more than minimal" harm, resulted in "actual harm," or placed residents in "immediate jeopardy") and "scope" (whether the noncompliance is "isolated," constitutes a "pattern," or is "widespread"). 42 C.F.R. § 488.404(b); State Operations

Manual (SOM), CMS Pub. 100-07, Appendix P — *Survey Protocol for Long-Term Care Facilities*, sec. IV.

The most severe noncompliance is that which puts one or more residents in "immediate jeopardy." *See* 42 C.F.R. §§ 488.404 (setting out the levels of severity and scope that CMS considers when selecting remedies); SOM § 7400.5.1. Immediate jeopardy is defined as a situation in which the noncompliance "has caused, or is likely to cause, serious injury, harm, impairment, or death to a resident." 42 C.F.R. § 488.301.

A long-term care facility found not to be in substantial compliance is subject to various enforcement remedies, including CMPs. 42 C.F.R. §§ 488.402(b),(c), 488.406. CMS has the option to impose one or more of the remedies in section 488.406 whenever a facility is not in substantial compliance. *Id.* CMS may impose a per-day CMP for the number of days a facility is not in substantial compliance with one or more requirements or a per-instance CMP for each instance of noncompliance. 42 C.F.R. § 488.430(a).

Standard of review

Whether summary judgment is appropriate is a legal issue that the Board addresses de novo. *1866ICPayday.com, L.L.C.*, DAB No. 2289, at 2 (2009), citing *Lebanon Nursing and Rehabilitation Center*, DAB No. 1918 (2004). Summary judgment is appropriate when the record shows that there is no genuine issue as to any material fact, and the moving party is entitled to judgment as a matter of law. *See 1866ICPayday.com* at 2, citing *Celotex Corp. v. Catrett*, 477 U.S. 317, 322-25 (1986).

Analysis

1. Fort Madison's arguments relating to Resident 1 lack merit.

On appeal, Fort Madison disputes what it characterizes as two findings of fact (FF) and two conclusions of law (CL) relating to the incident with Resident 1. Request for Review (RR) at 5, 7-9. (Actually, only one of the conclusions challenged by Fort Madison was a numbered FFCL; the other statements were comments in the ALJ's supporting discussions.) We discuss first the factual and then the legal disputes.

(a) We find no requirement to show a prior staff failure or absence of staff training in order to determine that a resident was not provided with adequate supervision to prevent accidents.

Fort Madison challenges the ALJ's statement that its system "to transport its residents to non-routine or non-regular hospital visits failed utterly" on March 23, 2010. RR at 5. Fort Madison argues that the ALJ failed to take into account that the system worked in numerous other cases, a point which the ALJ expressly accepted for purposes of summary judgment. *Compare* RR at 5 *with* ALJ Decision at 8. Fort Madison argues further that this event merely involved one individual (i.e., the van driver) "who failed to comply with facility protocols" rather than a "system failure" because the evidence did not show inadequate training or inadequate response by the nurse once Resident 1's non-return was noticed. RR at 6.

We observe that the ALJ's statement simply reports that the system broke down on a particular date, and does not necessarily distinguish whether the breakdown resulted from weaknesses in the protocol or training or from the actions of one individual in failure to follow the protocol. Fort Madison suggests that this distinction is essential based on an ALJ decision to which it cites that held that a facility could not be "liable" for failure to provide adequate supervision during a transfer "if the evidence only establishes an isolated error by a member of [the facility's] staff which occurred despite – and not because of – the way that [the facility] instructed and supervised its staff." RR at 6, quoting *JFK Hartwick at Edison Estates*, DAB CR840, at 5 (2001).

The Board has explicitly rejected the reasoning of the ALJ in the *Hartwick* case:

> The ALJ did not find persuasive here the decision of another ALJ who declined to hold a different facility responsible for an isolated staff error in using a lift to transfer a resident. ALJ Decision at 29, discussing *JFK Hartwick at Edison Estates*, DAB CR840 (2001). NHC relies on *Hartwick* again on appeal, but we too do not find persuasive NHC's suggestion that CMS must show inadequate training or supervision of a staff person before CMS may cite a failure to provide a resident with care in accordance with its care plan. The regulation at issue does not speak to staff training or supervision; indeed, it does not specify how the facility may elect to carry out the care responsibilities which it undertakes toward its residents. Having undertaken to provide care of the nature and quality required by the regulation by using a CNA, the facility does not shed its regulatory responsibility to "ensure" that each resident "receives" the requisite level of supervision and assistance devices needed "to prevent accidents." 42 C.F.R. § 483.25(h)(2). We agree with the ALJ that NHC's "lack of

> knowledge as to whether the facility knew that its staff was not complying with its policies does not shield it from responsibility." ALJ Decision at 30, citing *Beverly Health Care Lumberton*, DAB No. 2156 (2008), *pet. to reopen denied*, Ruling No. 2008-5, at 6-7 (facility cannot "disown the acts and omissions of its own staff ... [having] elected to rely on them to carry out its commitments").

NHC Healthcare Athens, DAB No. 2258, at 14 (2009) (addressing section 483.25(h), the same regulation at issue before us now).

Fort Madison also challenges the ALJ's statement that the van driver "apparently did not understand" the facility's policy for handling such transportation to non-routine hospital visits, despite "having transported [Fort Madison's] residents for several years." RR at 7, quoting ALJ Decision at 11. Fort Madison argues that this statement is speculative since no evidence directly shows such lack of understanding and the absence of prior "identified concerns" with this driver over many trips supports "knowledge of the well-established transport practices." RR at 7. We see no need to resolve the precise state of mind of the driver. The point of the ALJ's observation was that the driver did not follow what the facility described as its protocol of having the hospital call the facility rather than call the driver directly when the resident was ready for pickup. Whether this was because the van driver was not clear on this practice or was clear but nevertheless deviated makes no difference to the outcome.[3]

We adopt here the same reasoning stated by the Board in *NHC Healthcare Athens*. We agree with the ALJ that, even accepting as true for purposes of summary judgment the facility's claims that its protocol was for the hospital to call the facility for pickup and that the van driver previously complied but deviated from the protocol in this single instance, the facility remained responsible to ensure that the resident received adequate supervision to protect her from foreseeable hazards. Leaving her alone in a van for two hours exposed her to significant foreseeable hazards, especially when the time for her medication had already passed. We do not find any basis to require a showing that the facility failed to train the driver or was aware of prior noncompliance by the driver.

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[3] Of course, the other possibility, for which CMS argued and offered some evidence, is that the practice was not as Fort Madison now claims but rather had been for the hospital to call the drivers directly. We accept, however, as did the ALJ, Fort Madison's factual allegations on this point as true, for purposes of summary judgment.

Fort Madison further suggests that any confusion on the part of the driver about the protocol was not the "proximate cause" of the "incident" because the resident was in fact picked up from the hospital "in a timely manner." RR at 7. Instead, the "sole proximate cause" was the driver's becoming distracted and leaving the resident in the parked van. *Id.* Proximate cause is a concept from tort law that has no relevance to the question of whether the facility was in substantial compliance with its regulatory obligations.

In any case, Fort Madison's premise that the only error here was committed by the driver is not supported by the undisputed facts. As we discuss later, facility staff had ample reason to inquire about the resident's whereabouts much sooner than they did given their awareness of when the driver expected to pick her up and when she required her medication.

> (b) The facility remains responsible for the care provided to a resident during the provision of services for which the facility arranged, as with the transportation here, even where the facility chooses to use contractors rather than facility employees.

Fort Madison contends that the ALJ erred in holding the facility responsible for the resident's safety and supervision while she was transported when the van driver was "not an employee of Fort Madison or under its control." RR at 8, quoting ALJ Decision at 9.[4] The Board has long held that a facility's duty to ensure that "the resident environment remains as free of accident hazards as is possible" under section 483.25(h) extends to ensuring residents' safety while being transported in a van off the facility's premises. *Liberty Nursing and Rehabilitation Center – Mecklenberg County*, DAB No. 2095 (2007), *aff'd sub nom. Liberty Nursing and Rehabilitation Center – Mecklenberg County v. Leavitt*, No. 07-1667 (4th Cir. 2008); *SunBridge Care & Rehab. for Pembroke*, DAB No. 2170, at 28-29 (2008). Fort Madison argues that the ALJ should have rejected CMS's reliance on these prior Board cases as inapposite where the facility did not own the van or employ the driver. RR at 8.

In *Liberty*, the facility transported residents in wheelchairs in vans without consistently using appropriate safety devices to restrain the wheelchairs. DAB No. 2095, at 5-7. The Board concluded that the residents' "environment" was not limited to the facility's premises but included the vehicle in which the facility transported them. *Id.* at 8. The Board explained that --

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[4] We note that the SOD cited the deficiency here under both prongs of section 483.25(h), implying that the surveyors found that the abandonment of the resident in the parked van demonstrated both a failure to ensure an environment free of accident hazards and a failure to provide adequate supervision. CMS Ex. 1, at 1. Neither the ALJ nor the parties distinguished clearly between the two aspects of the deficiency findings. Our discussion of why Fort Madison's legal arguments are not persuasive is applicable to both.

> "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 . . . designed to achieve those outcomes to the highest practicable degree." *Estes Nursing Facility Civic Center*, DAB No. 2000, at 6, *citing Woodstock Care Center v. CMS*, DAB No. 1726, at 25, *aff'd, Woodstock Care Ctr. v. Thompson*, 363 F.3d 583 (6th Cir. 2003). The Sixth Circuit described the federal standard as "a higher standard than the common law," 363 F.3d at 590, and as requiring the facility to take "all reasonable precautions against residents' accidents," 363 F.3d at 589 (emphasis in original). Finding that residents travel at their own risk when a facility that has undertaken their care and treatment transports them to treatment or services rendered off-site (such as the dialysis treatments to which Liberty's vans transported its residents) would not be consistent with this high standard of care.

Id. at 8. In affirming the Board, the Fourth Circuit expressly interpreted section 483.25(h)(1) to include in the resident's environment "all locations under the facility's control," including vehicles in which the facility transports them off-site. *Liberty Nursing and Rehabilitation Center – Mecklenberg County v. Leavitt*, No. 07-1667, at 3 n2. *SunBridge* also involved failure to properly secure wheelchair-bound residents while carrying them in a facility van to off-site appointments. DAB No. 2170, at 4. The Board reiterated that the vans constituted an extension of the residents' environment for purposes of section 483.25(h). *Id.* at 28-29.

In these two cases, the facilities arranged their residents' transportation using vans that they owned or leased and drivers who were employed by the facilities. Fort Madison suggests its use of a separate company to provide the vans and drivers insulates it from responsibility for "any misfortune that may result to a resident" absent proof the facility "knew or should have known that a contracted service was deficient in some manner." RR at 9. We disagree. Whether the driver and van belonged to the facility directly or were hired contractually in order to provide transportation services makes no legal difference to the facility's responsibility to "ensure" the safety of the resident's environment and adequacy of the resident's supervision while receiving services arranged for by the facility as part of the resident's care.

Resident 1's care plan explicitly provided that the facility would "[a]rrange for transportation to & from [hospital] for blood transfusion as needed" and would "monitor & report signs of reaction to transfusion i.e. elevated temp/decreased BP [blood pressure]/chills/pain/hematuria/dypnea/chest pain/lung congestion/frothy sputum/rash." CMS Ex. 2, at 9. It was the facility's decision to arrange for the transportation through Inpropco and to rely on Inpropco's driver to supervise and monitor Resident 1 while

carrying her to and from the hospital. Whether a facility employs its own staff and equipment or contracts for services and equipment to provide care and services, the regulatory obligation to ensure safety remains with the facility. [5]

We also note that, although the ALJ did not rely on these points, the undisputed facts on the record demonstrate that neither the transport company that owned the vans nor the driver who transported Resident 1 were entirely independent of Fort Madison. Fort Madison acknowledged that Inpropco was owned by the same parent company that owns Fort Madison. RR at 3. It is also undisputed that, on the day that Resident 1 was taken for her transfusion, the van driver worked at the facility assisting with other residents while awaiting word to return to pick up Resident 1. CMS Ex. 2, at 11 (driver's time sheet).

CMS regulations elsewhere expressly require that the "services provided or arranged by the facility must-- (i) Meet professional standards of quality; and
(ii) Be provided by qualified persons in accordance with each resident's written plan of care." 42 C.F.R. § 483.20(k)(3). The ALJ acknowledged that Fort Madison was not cited for violating that regulation. ALJ Decision at 9. Nevertheless, section 483.20(k)(3) makes clear that CMS has not distinguished between services which a facility provides directly and those for which it arranges in order to carry out the resident's plan of care. We find no merit to Fort Madison's unsupported assertion that section 483.20(k)(3) applies only to "clinical nursing standards" and "is not broad enough to encompass contracted transportation services." RR at 9. The transportation services for which Fort Madison arranged here were required by the resident's written plan of care. We thus conclude that the responsibility for ensuring that the environment in which those services were provided was free of accident hazards and that supervision was adequate to prevent accidents in the course of those services remained with Fort Madison.

Finally, Fort Madison argues that the incident that occurred was unforeseeable because the driver had no prior mishaps and that, under Board precedent, a facility should not be held strictly liable under section 483.25(h). RR at 9-10. We do not agree that the ALJ improperly imposed strict liability in finding that Fort Madison failed to ensure the resident's safety. The actions of the individual driver here in becoming distracted and parking the van without bringing the resident into the facility may well have been unforeseeable. But a facility need not have notice in advance of precisely how an accident might take place in order to put in place reasonable measures to forestall or mitigate the risks of accidents. *Josephine Sunset Home*, DAB No. 1908 (2004);

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[5] The facility here undertook to make these arrangements, distinguishing the analysis from the situation where a resident departs from the facility on pass or against medical orders. *See, e.g. Van Duyn Home & Hosp.*, DAB No. 2368 (2011).

Woodstock Care Center, DAB No. 1726, at 27-28 (2000), *aff'd, Woodstock Care Ctr. v. Thompson*, No. 01-3889 (6th Cir. 2003). What was foreseeable here was that a resident being transported to or from medical care might be delayed or have the trip interrupted for any number of reasons. Indeed, the facility's own alleged protocol to have the hospital call the facility directly when a resident is leaving to return to the facility implies an awareness of these risks.

In general, the failure to use this protocol might mean that Fort Madison would not be immediately alerted to the time that a resident was to be picked up. Accordingly, facility staff, not expecting the resident's imminent arrival, would not immediately be concerned if the resident did not arrive at the facility within a reasonable period of time thereafter. In the present case, however, our decision does not depend on the failure to follow the protocol because the facility obtained actual notice of the likely time of Resident 1's return in other ways. Fort Madison acknowledges that the van driver told nursing staff at 4 PM that the resident would be picked up "soon." Fort Madison Reply Br. at 3, quoting CMS Ex. 2, at 18. Furthermore, since the driver was working in the facility with residents until she left to pick up Resident 1, facility staff should have been aware of when the driver had left the facility for the pick up. It is undisputed that the hospital was less than one mile from the facility. It is also undisputed that the facility staff knew that the resident was scheduled to receive medication at 5 PM that could not be delayed by more than hour. Yet the facility nurse did not notice the resident's absence and call the hospital or van driver to try to locate the resident until 6:30PM. CMS Ex. 2 (statement of nurse). The facility's notice that the driver had gone to retrieve the resident and that her medication was due should have given rise to staff concern about the resident's absence well before that.

We find no error in the ALJ's conclusion that undisputed evidence established that Fort Madison was not in substantial compliance with section 483.25(h) in its care of Resident 1.

2. Fort Madison's arguments relating to Residents 2 and 3 lack merit.

It is undisputed that both residents left the facility by van to receive dialysis at the hospital at 6:45 AM on March 31, 2010. RR at 12. It is also undisputed that the residents' names at no time appeared on the sign-out marker board for that date. *Id.* The ALJ found that the residents' records did not document their departures or expected or actual return times. ALJ Decision at 8-9. On appeal, Fort Madison makes several arguments, all unavailing.

First, Fort Madison disagrees with CMS and the ALJ that the nursing notes for the individual residents failed to reflect their departure and return times. *Compare* RR at 12

and Fort Madison Reply Br. at 4 *with* CMS Br. at 10. Fort Madison identifies, and we find, no nursing notes or clinical records for either resident for the date at issue. The only documents cited by Fort Madison are not nursing notes, but rather surveyor's notes of her observation of the two residents in the afternoon after their return. RR at 12 and Fort Madison Reply Br. at 4, both citing Pet. Ex. 3, at 2, 4. We therefore conclude that Fort Madison has not identified a genuine dispute of material fact about whether the residents' records documented their absence from the facility.

Second, Fort Madison argues that its failure to abide by "an internal policy does not necessarily constitute a violation of a regulatory requirement." RR at 12. We disagree. Fort Madison adopted the policy involved here to correct a breakdown that had created a situation of immediate jeopardy for residents. The intent of the policy was to make sure that its staff was aware of the whereabouts of residents being transported to external appointments. Having chosen this method to correct its failure to meet regulatory requirements, Fort Madison was responsible for ensuring that its method was effectively implemented to achieve compliance. *See Claiborne-Hughes Health Center*, DAB No. 2223, at 17(2008)("A facility may choose different methods for assuring that it is providing sufficient fluid intake, but, having chosen a method, it cannot complain that CMS is relying on the facility's failure to implement its chosen method in determining whether the facility actually provided adequate hydration."). Before the ALJ, Fort Madison attributed the failure to sign out Resident 2 and 3 to "expected confusion" about the new sign-out policy. ALJ Decision at 11. We agree, however, with the ALJ that such confusion is "hardly evidence of compliance" when a facility "attempts to address a risk of harm to its residents." *Id.*

Third, Fort Madison asserts that the supervision of Residents 2 and 3 was not shown to be inadequate given that they went for their routine dialysis treatments and returned unharmed. RR at 13. Fort Madison states that there was no evidence that either resident experienced "any accidents, fall or any outcomes," was "left unattended in the van," or "missed medications or meals." *Id.* The absence of delay or harm is irrelevant. The point is that these residents were allowed to go out of the facility for treatment without being tracked only a week after a resident was indeed left unattended in a van to miss her medication and meals. Thus, the facility did not follow the policy it adopted precisely to prevent such events from recurring despite such a vivid and recent warning of the potential consequences of losing track of a resident's whereabouts. The Board has repeatedly explained that no accident need actually occur for a facility to be held responsible for failing to put in place supervision adequate to prevent the foreseeable risk of accidents. *Woodstock Care Center*, DAB No. 1726; *Alden Town Manor Rehabilitation & HCC*, DAB No. 2054 (2006). It is therefore irrelevant that Residents 2 and 3 did not encounter any mishaps or suffer any harm as a result of the facility's failure to implement its policy.

We agree with the ALJ that the undisputed evidence establishes noncompliance with section 483.25(h)(2) with regard to Residents 2 and 3.

3. The ALJ did not err in upholding the reasonableness of the amount of the per-instance CMP on summary judgment.

Fort Madison argued to the ALJ that a genuine dispute of material fact existed about whether CMS's determination of immediate jeopardy was clearly erroneous. ALJ Decision at 11. The ALJ concluded that Fort Madison had no right under the regulations to challenge the immediate jeopardy determination in this case but considered evidence cited by Fort Madison on the issue to the extent it was relevant to the reasonableness of the amount of the CMP. *Id.* at 12. He concluded that the $5,000 per-instance CMP was reasonable under the circumstances presented. *Id.*

On appeal, Fort Madison recognizes that the regulations require CMS's finding as to the scope and severity of noncompliance, including immediate jeopardy, to be "upheld unless it is clearly erroneous." RR at 13, quoting 42 C.F.R. § 498.60(c)(2). Fort Madison then incorrectly asserts that the Board has "long held that the net effect of these regulations is that a provider may challenge the scope and severity assigned to a noncompliance finding where that finding was the basis for an immediate jeopardy determination." RR at 13.

Fort Madison entirely overlooks regulations providing that a facility may appeal the level of noncompliance "only if a successful challenge on this issue would affect – (i) The range of [CMP] amounts that CMS could collect . . . ; or (ii) A finding of substandard quality of care that results in the loss of approval" for the facility's NATCEP program. 42 C.F.R. § 498.3(b)(14); *see also* 42 C.F.R. § 498.3(d)(immediate jeopardy determination or determination of level of noncompliance is not an appealable action except as provided in (b)(13)). What the Board held in the cases cited by Fort Madison is that the net effect of all of these regulations is that challenges to scope and severity are limited to *only* situations where the determination of immediate jeopardy results in a higher range of CMP or the loss of approval of a NATCEP program. *Ridge Terrace*, DAB No. 1834 (2002); *Koester Pavilion*, DAB No. 1750 (2000).

Fort Madison identifies, and we find, no error in the ALJ's conclusion that neither of the prerequisites for review of an immediate jeopardy determination is present in this case. ALJ Decision at 11-12. The amounts of per-day CMPs which CMS may impose are divided into two ranges; an upper range from $3,050 to $10,000 per day for deficiencies that constitute immediate jeopardy and a lower range from $50 to $3,000 per day for deficiencies at lower levels of scope and severity. 42 C.F.R. § 488.438(a). By contrast, only a single range of $1,000 to $10,000 applies to per-instance CMPs, whether or not immediate jeopardy is present. 42 C.F.R. § 488.438(a)(2). Consequently, where, as here,

the only CMP imposed is a per-instance CMP, a successful challenge to the immediate jeopardy determination would not affect the range of CMP amounts that CMS could collect. Furthermore, the loss of approval for a NATCEP program would not be affected by a successful challenge to the level of noncompliance because, by operation of law, the imposition of a CMP of $5,000 or more results in NATCEP loss whether or not immediate jeopardy is present. Act § 1819(f)(2)(B)(iii)(I). We therefore do not discuss further Fort Madison's contentions about whether the situation involving Resident 1 demonstrated noncompliance that met the definition of immediate jeopardy, but we do review the ALJ's conclusion that the amount of the CMP was reasonable.

The ALJ considered the factors listed at 42 C.F.R. § 488.438(f) to evaluate the reasonableness of the CMP amount as he is directed to do by 42 C.F.R. § 488.438(e)(3). ALJ Decision at 12. Neither party offered any argument relating to the facility's history of noncompliance or its financial condition. 42 C.F.R. § 488.438(f)(1) and (2). The remaining factors were the scope and severity of the deficiency and the facility's degree of culpability, which includes "neglect, indifference, or disregard for resident care, comfort or safety." 42 C.F.R. § 488.438(f)(4).[6]

The ALJ observed that a $5,000 CMP is in the middle of the range of per-instance CMPs available to CMS. ALJ Decision at 13. He emphasized that Resident 1's care plan made clear the serious possible reactions to the transfusion for which the resident was supposed to be monitored during the time she was left unattended in the van. *Id.* at 12. He further considered that Resident 1 received her diabetes medication two hours late (more than an hour past even the leeway of one hour which Fort Madison claimed). *Id.* He noted that she did endure unaccustomed urinary incontinence while confined in the van. *Id.* He also recognized the "somber fact" that the resident was exposed to the potential for harm from many directions as she sat "unsupervised and alone in the locked van for two hours." *Id.* Finally, he concluded that the facility's failure to comply with its own policy change to alleviate the dangerous condition exposed by the March 23 incident with Resident 1 demonstrated that the facility failed to correct its noncompliance over at least a week. *Id.* at 13.

Fort Madison reiterates on appeal that Resident 1 suffered no actual harm in that her assessment when she was brought into the facility did not identify reactions to her blood transfusion or injury from her time in the van. RR at 14-15. Fort Madison views the "theoretical possibility of harm" to the resident as irrelevant and considers as merely

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[6] Section 488.438(f)(3) incorporates the factors specified in section 488.404 which include the scope and severity of the deficiency. The other factors listed in section 488.404 are not relevant here because only one deficiency was cited and CMS did not rely on any history of noncompliance generally or as to the cited deficiency. We also note that absence of culpability is not a mitigating circumstance. 42 C.F.R. § 488.438(f)(4).

"hypothetical" the potential dangers to the resident from ambient temperature, from any attempt she might have made to escape, from the emotional or psychological effects of her entrapment in the van, or from any break-in to the van. *Id.* We disagree. As the ALJ pointed out, "sheer luck" alone protected the resident from suffering, unattended by those responsible for her care, any of the reactions for which she should have been monitored, including spikes in temperature, drops in blood pressure, chills, pain, or lung and breathing problems. CMS Ex. 2, at 9. The degree of seriousness and the significance of the facility's neglect of the resident's needs are reasonably assessed in light of the dangers which the facility allowed her to face alone rather than only by reference to the harm that actually materialized. Furthermore, Fort Madison does not respond to the ALJ's point that its failure to implement the policy intended to prevent further incidents of this type demonstrate continuing noncompliance and justified a higher CMP.

We conclude that the ALJ did not err in finding reasonable the amount of the CMP imposed by CMS.

Conclusion

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

/s/
Sheila Ann Hegy

/s/
Constance B. Tobias

/s/
Leslie A. Sussan
Presiding Board Member