Department of Health and Human Services

DEPARTMENTAL APPEALS BOARD

Civil Remedies Division

Fort Madison Health Center,
(CCN: 16-5227),

Petitioner

v.

Centers for Medicare & Medicaid Services.

Docket No. C-10-783

Decision No. CR2331

Date: March 3, 2011

DECISION

Petitioner, Fort Madison Health Center challenges the determination of the Centers for Medicare & Medicaid Services (CMS) that it was not in substantial compliance with program participation requirements. Petitioner also challenges CMS's imposition of a per instance civil money penalty (PICMP) of $5,000. For the reasons discussed below, I sustain CMS's imposition of the $5,000 PICMP. I sustain also a two-year prohibition on Petitioner's ability to offer a nurse aide training and competency evaluation program (NATCEP) and competency evaluation program (CEP).

I. Background

Petitioner is a long-term care facility located in Fort Madison, Iowa. Petitioner participates in the Medicare and Medicaid programs. The Iowa Department of Inspections and Appeals (state agency) completed a complaint investigation survey of Petitioner's facility on April 2, 2010. The survey cited a deficiency under 42 C.F.R. § 483.25(h) (Tag F323, scope and severity level J).[1] By letter dated April 19, 2010, CMS notified Petitioner that it was imposing the $5,000 PICMP and that federal law prohibited

[1] A scope and severity level of J denotes an isolated deficiency that constitutes immediate jeopardy to resident health and safety. State Operations Manual (SOM), section 7400E; 42 C.F.R. §§ 488.301, 488.408.

the approval of a NATCEP or CEP where a facility has been assessed a CMP of not less than $5,000. Petitioner requested a hearing by letter dated June 18, 2010.

CMS filed a motion for summary disposition (CMS Br.) on July 21, 2010, accompanied by CMS Exhibits (CMS Exs.) 1 and 2.[2] Petitioner filed an answer (P. Br.) on August 18, 2010, accompanied by Petitioner's Exhibits (P. Exs.) 1-3. In the absence of objection, I admit CMS Exs. 1 and 2 and P. Exs. 1-3.

II. Issues

The issues before me are:

1. Whether Petitioner was in substantial compliance with participation requirements in the Medicare and Medicaid programs; and

2. Whether the remedies imposed are reasonable.

III. Controlling Law

Sections 1819 and 1919 of the Social Security Act (Act) and the regulations at 42 C.F.R. Part 483 govern Petitioner's participation in Medicare and Medicaid. Sections 1819 and 1919 of the Act provide the Secretary of Health and Human Services (Secretary) with authority to impose remedies, including CMPs, against long-term care facilities for failure to comply with participation requirements.

Regulations define the term "substantial compliance" to mean"

> [A] level of compliance with the requirements of participation 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.

The Secretary has delegated to CMS and the states the authority to impose remedies against long-term care facilities not complying substantially with federal participation requirements. The applicable regulations at 42 C.F.R. Part 488 provide that state survey agencies, on behalf of CMS, may survey facilities participating in Medicare and Medicaid to ascertain whether the facilities are complying with participation requirements. 42 C.F.R. §§ 488.10-488.28. The regulations contain special survey conditions for long-term care facilities. 42 C.F.R. §§ 488.300-488.335. Under Part 488, a state or CMS may impose a CMP against a long-term care facility if a state survey agency ascertains that the facility is not complying substantially with participation

[2] CMS filed a motion to dismiss on July 6, 2010. Petitioner responded to the motion on July 19, 2010. I do not address that motion here.

requirements. 42 C.F.R. §§ 488.406, 488.408, and 488.430. The CMP may begin to accrue as early as the date that the facility was first substantially out of compliance or may continue to accrue until the date the facility achieves substantial compliance, or until CMS terminates the facility's provider agreement. 42 C.F.R. § 488.440.

The regulations specify that if a CMP is imposed against a facility based on an instance of non-compliance, the CMP will be in the range of $1,000 to $10,000 per instance. 42 C.F.R. § 488.438(a)(2). When a CMP is imposed against a facility on a per-day basis, it must fall into one of two broad ranges of penalties. 42 C.F.R. §§ 488.408, 488.438. The upper range of CMP, from $3,050 per day to $10,000 per day, is reserved for deficiencies that constitute immediate jeopardy to a facility's residents and, in some circumstances, for repeated deficiencies. 42 C.F.R. § 488.438(a)(1)(i), (d)(2). The lower range of CMP, from $50 per day to $3,000 per day, is reserved for deficiencies that do not constitute immediate jeopardy, but either cause actual harm to residents or cause no actual harm, but have the potential for causing more than minimal harm. 42 C.F.R. § 488.438(a)(1)(ii). "Immediate jeopardy" is defined as:

> [A] situation in which the provider's noncompliance with one or more requirements of participation has caused, or is likely to cause, serious injury, harm, impairment, or death to a resident.

42 C.F.R. § 488.301.

Sections 1819(f)(2)(B) and 1919(f)(2)(B) of the Act prohibit approval of a NATCEP/CEP if within the last two years the facility has been subject to, among other things, an extended or partial extended survey; imposition of a CMP of not less than $5,000; or imposition of a denial of payment for new admissions.

A facility may challenge the scope and severity that CMS cites only if a successful challenge would affect the range of CMP amounts that CMS imposed or would affect the facility's NATCEP. 42 C.F.R. § 498.3(b)(14), (d)(10)(i). CMS's determination as to the scope and severity of non-compliance "must be upheld unless it is clearly erroneous." 42 C.F.R. § 498.60(c)(2). This includes CMS's finding of immediate jeopardy. *Woodstock Care Center*, DAB No. 1726, at 9 (2000), *aff'd, Woodstock Care Center v. U.S. Department of Health and Human Services*, 363 F.3d 583 (6th Cir. 2003).

The Departmental Appeals Board (Board) has long held that the net effect of these regulations is that a provider has no right to challenge the scope and severity assigned to a non-compliance finding except in the situation where that finding is the basis for an immediate jeopardy determination. *See, e.g., Ridge Terrace*, DAB No. 1834 (2002);

Koester Pavilion, DAB No. 1750 (2000).[3]

CMS has moved for summary disposition. An appellate panel of the Board recited the standard for summary disposition or judgment in the case of *Senior Rehabilitation and Skilled Nursing Center,* DAB No. 2300, at 3 (2010), *aff'd, Senior Rehabilitation and Skilled Nursing Center v. Health & Human Services,* No. 10-60241 (5th Cir. Dec. 20, 2010). It stated that summary judgment is appropriate where 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. The party moving for summary judgment bears the initial burden of showing that there are no issues of material fact for trial and that it is entitled to judgment as a matter of law. To defeat an adequately supported motion, the non-moving party may not rely on the denials in its pleadings or briefs, but must furnish evidence of a dispute concerning a material fact – a fact that, if proven, would affect the outcome of the case under governing law. In determining whether there are genuine issues of material fact, the reviewer must view the evidence in the light most favorable to the non-moving party, drawing all reasonable inferences in that party's favor. In *Holy Cross Village at Notre Dame, Inc.*, DAB No. 2291, at 5 (2009), the Board stated that the role of an Administrative Law Judge (ALJ) in deciding a summary judgment motion differs from the ALJ's role in resolving a case after hearing, and that in the context of a motion for summary judgment, an ALJ should not assess credibility or evaluate the weight of conflicting evidence. Below, I find there are no material facts in dispute precluding summary disposition.

IV. Discussion

I make numbered findings of fact and conclusions of law (Findings) to support my decision. I set them forth below as separate headings, in bold and italic type, and discuss each in detail.

1. Petitioner failed to comply substantially with the participation requirement at 42 C.F.R. § 483.25(h).

42 C.F.R. § 483.25 requires that:

> Each resident must receive and the facility must provide the necessary care and services to attain or maintain the highest practicable physical, mental, and psychosocial well-being, in accordance with the comprehensive assessment and plan of care.

[3] Petitioner argues that CMS's finding of immediate jeopardy is clearly erroneous. I do not have the authority to consider the scope and severity of the deficiency in this case, as CMS imposed only a PICMP and the range of CMP will not be affected. Although CMS also prohibited Petitioner from offering a NATCEP, the NATCEP is based on imposition of the PICMP.

The subsection at 42 C.F.R. § 483.25(h) references accidents[4] and requires that:

> (h) *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 the case of *Meridian Nursing Center*, DAB No. 2265, at 3 (2009), the Board described the requirements of this subsection, stating:

> Section 483.25(h)(1) requires that a facility address foreseeable risks of harm from accidents "by identifying and removing hazards, where possible, or where the hazard is unavoidable because of other resident needs, managing the hazard by reducing the risk of accident to the extent possible." *Maine Veterans' Home – Scarborough*, DAB No. 1975, at 10 (2005). Section 483.25(h)(2) requires that a facility take "all reasonable steps to ensure that a resident receives supervision and assistance devices that meet his or her assessed needs and mitigate foreseeable risks of harm from accidents." *Briarwood Nursing Center*, DAB No. 2115, at 11 (2007), citing *Woodstock Care Ctr. v. Thompson*, DAB No. 1726 (2000) (facility must take "all reasonable precautions against residents' accidents"), *aff'd*, *Woodstock Care Ctr. v. Thompson*, 363 F.3d 583 (6th Cir. 2003).

A resident's "environment" is to be broadly construed and encompasses the situation in which a facility transports a resident under its care in a van. The van is then the resident's "environment" and the regulation at 42 C.F.R. § 483.25(h) applies. *SunBridge Care and Rehabilitation for Pembroke*, DAB No. 2170 (2008); *Liberty Nursing and Rehabilitation Center – Mecklenberg County*, DAB No. 2095 (2007).

The violations of 42 C.F.R. § 483.25(h) that CMS asserts in this case involve Petitioner's failure to provide adequate supervision to Resident 1, who, following a medical appointment on March 23, 2010, was left unattended in a transport van for approximately two hours. CMS then cites an incident related to Residents 2 and 3, where it asserts that Petitioner failed to properly implement a system that was designed to prevent a repeat of the incident with Resident 1 (a sign-out board to document when residents left and then

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[4] The Board references the SOM in defining an accident as:

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

Woodstock Care Center, DAB No. 1726, at 4 (2000).

returned to facility premises). State agency surveyors found that Residents 2 and 3 were out of the facility for medical appointments on March 31, 2010, but their names were not on the sign-out board so as to indicate that they had left the facility. CMS argues that this failure to document that Residents 2 and 3 were out of the facility supports its determination that the deficiency assessed was system-wide. Petitioner argues in response that any acts or omissions by the van driver who left Resident 1 in the van were not foreseeable. Further, if any risk was identified, Petitioner asserts that it implemented measures to mitigate that risk.

The following material facts, both those which are genuinely undisputed and those additional facts that Petitioner asserts and I accept as true, support a finding that Petitioner was out of compliance with 42 C.F.R. § 483.25(h).

Resident 1: Resident 1 was admitted to the facility on February 18, 2005. Resident 1 had a diagnosis of pernicious anemia for which her physician prescribed periodic blood transfusions. CMS Ex. 2, at 5, 6. Resident 1 was also diabetic and had orders for Metformin ER (extended release), a medication used to control blood sugars, which she received once a day at 5:00 p.m. before her evening meal. CMS Ex. 2, at 7, 8. CMS notes that Metformin should be taken at the same time every day to maintain an even level of the medication in the blood. CMS Br. at 3. Petitioner notes, and I accept, that its protocol allows for Metformin to be administered up to an hour before or after the designated time it is to be administered. P. Br. at 4.

Petitioner arranges transportation services for residents needing medical tests or services at off-premises locations. The annex section of Fort Madison Community Hospital provides blood transfusion services for residents of Petitioner's facility, including Resident 1. The hospital is less than one mile from Petitioner's facility. CMS Ex. 2, at 2; P. Br. at 3; CMS Br. at 2. Petitioner uses the services of a company named Inpropco to transport its residents to the hospital for medical tests or services. Inpropco employs van drivers to transport these residents. Inpropco is under common ownership with the company that owns and operates Petitioner's facility. P. Br. at 3; CMS Br. at 2.

Resident 1's care plan for pernicious anemia, dated March 15, 2010, states that Petitioner was to:

> 5. Arrange for transportation to [and] from FMCH [Fort Madison Community Hospital] Annex for Blood Transfusion as needed.
> 6. Monitor [and] report signs of reaction to transfusion i.e. elevated temp/decreased BP/chills/pain/hematuria/dyspnea/chest pain/Lung congestion/Frothy Sputum/ rash.

CMS Ex. 2, at 9.

On the morning of March 23, 2010, Resident 1 was transported to the hospital for a blood transfusion. P. Br. at 3; CMS Br. at 3. The Inpropco van driver picked the Resident up at

the hospital presumably for the purpose of transporting her safely back to the facility, and returned to Petitioner's facility at about 4:30 p.m. Upon arriving at Petitioner's facility the van driver became distracted or forgetful, parked the van, locked it, and left for home, leaving Resident 1 sitting in the van unattended. Paperwork related to Resident 1's treatment was in the van driver's pocket, where the driver had placed it before abandoning Resident 1 and the van. P. Br. at 5; CMS Br. at 4; CMS Ex. 2, at 6, 15, 20, 21; P. Ex. 2, at 3-6. The exact location where the van was parked is described in at least two accounts as the "back area" or "back lot," and is thus presumably not near the facility's front entrance. P. Ex. 2, at 3, 6. At 6:30 p.m., a nurse at Petitioner's facility called the hospital to inquire about Resident 1 and her whereabouts. The hospital informed the nurse that Resident 1 had been picked up. The nurse called the Inpropco van coordinator/supervisor who contacted the van driver. At 6:45 p.m., the coordinator/supervisor and the van driver went to the facility, found Resident 1 still sitting in the van, and escorted her back into the facility. P. Br. at 4; CMS Br. at 4; P. Ex. 2, at 6; CMS Ex. 2, at 22, 23. Resident 1 was assessed, and her vital signs were taken and found to be within normal limits. Resident 1 did not complain of pain or severe discomfort. P. Br. at 4; CMS Ex. 2, at 23. She did, however, suffer an unaccustomed episode of urinary incontinence during the two hours she was locked in the van. P. Ex. 2, at 6; CMS Ex. 1, at 7-8. Metformin was administered and dinner served to Resident 1 at approximately 7:00 p.m. P. Br. at 4; P. Ex. 1, at 2. The van driver was terminated from her employment with Inpropco. P. Br. at 5; P. Ex. 2, at 2.

Following the incident, and effective March 23, 2010, Petitioner adopted a new transport sign-out policy requiring that:

> All van drivers or employees transporting residents will sign the resident out on the marker board in the nurse's station before leaving the building. When returning with the resident you will take the resident's name off the board. Nurses will check the board at the beginning of your shift. If the resident has not returned to the building by 5 PM you will call the van driver or employee to verify the status of the resident.

CMS Ex. 2, at 28, 29, 30.

Petitioner and CMS differ about the protocol that existed between the hospital, Inpropco, and the facility on March 23, 2010, regarding notification of when a resident is to be returned to the facility. For purposes of summary disposition, I accept Petitioner's assertion that pursuant to the protocol between the facility and Inpropco, for non-routine medical visits,[5] the hospital normally would contact the facility when a resident was

[5] I accept Petitioner's categorization of Resident 1's blood transfusion as a non-routine medical appointment. However, if Petitioner's protocols for routine and non-routine transport are different, that might have led to the confusion attendant to Resident 1's return to the facility.

ready to be returned to the facility, in order to arrange transportation and to provide updates or new orders relating to treatment. I accept Petitioner's assertion that the facility's charge nurse became aware that Resident 1 had not yet returned to the facility as dinner was winding down at approximately 5:45 p.m., because at that time the nurse realized that Resident 1 was not present for the routine administration of her Metformin; that the nurse waited about a half hour to contact the hospital; that Petitioner was not provided with a concrete timeline as to how long the Resident would be out of the facility, other than that it would be "all day;" that the estimates of Resident 1's return time changed from 3:00 to 3:30 to 4:15 p.m.; that it was not unusual for Resident 1 to be at the hospital for observation for a lengthy period; and that facility staff were aware that Resident 1 was under supervision by licensed staff at the hospital. I accept that Resident 1 was uninjured as a result of her two-hour period of abandonment and immobility in the locked van. I accept that the van driver, who had been employed by Inpropco since 2006, did not report to anyone at the facility about the Resident's expected return time nor did the van driver notify the facility from the van that the Resident was in the process of being returned to the facility. I accept that the van driver had earlier directed the hospital to call her instead of the facility, which precluded the facility from receiving notice from the hospital as to when Resident 1 would return. I accept that Inpropco routinely transports between four and five residents per day, five days a week, to medical appointments averaging 40 to 50 one-way transports per week, and that over the past several years Inpropco has transported in excess of 1,000 resident round-trips per year, without a resident being left unattended in a transport van. P. Br. at 3, 5, 6, 11; P. Ex. 1, at 1, 2; P. Ex. 2, at 3-4.[6]

Resident 2: Petitioner does not dispute that Resident 2 was admitted to the facility on January 17, 2008, with a diagnosis of chronic renal failure for which renal dialysis was ordered. She had a history of chronic pain/degenerative joint disease, for which she was prescribed topical Lidocaine as needed and a Fentanyl patch every 72 hours. Her care plan indicated she was at risk for dehydration. On March 31, 2010, Resident 2 left the facility for a dialysis appointment at 6:45 a.m. The surveyor observed that at 7:30 a.m. and 9:40 a.m. the facility sign-out board by the nurses' station did not list any resident, including Resident 2, as out of the building. Resident 2's records contained no

[6] I do not accept Petitioner's assertion that Resident 1 did not have a significant health condition requiring treatment or medications that would be exacerbated if there was a delay in her return to the facility. Petitioner does not dispute that Resident 1 is a diabetic who did not timely receive a scheduled medication for controlling blood sugars. Further, I do not accept Petitioner's assertion that there were no environmental hazards posed by Resident 1's sojourn in the van simply because she was properly secured and not at risk for falls. P. Br. at 5, 11. While the temperature was not "unseasonable" (ranging from 64 to 68 degrees, P. Ex. 2, at 7; CMS Ex. 1, at 8), that does not mean the inside of the van was a comfortable temperature, that the Resident might not have tried to get up from her restraints and harmed herself, or that someone else could have attempted to get into the van while it sat abandoned in the "back lot." Resident 1 did tell her rescuers that she had suffered an incident of incontinence, telling them "I think I'm wet." P. Ex. 2, at 6.

documentation of her leaving the facility, how she left, or when she was expected to return. P. Br. at 15; CMS Br. at 4-5; CMS Exs. 31-35.

Resident 3: Petitioner does not dispute that Resident 3 was admitted to the facility on September 14, 2006, with diagnoses of, among other things, kidney disease, renal failure, and cerebral vascular accident. On March 31, 2010, Resident 3 left the facility for a dialysis appointment at 6:45 a.m. The surveyor observed at 7:30 a.m. and 9:40 a.m. that the facility sign-out board by the nurses' station did not list any resident, including Resident 3, as out of the building. Resident 3's records contained no documentation of his leaving the facility, when he left, or how he was expected to return. P. Br. at 15; CMS Br. at 5; CMS Exs. 36, 37.

CMS argues that Petitioner is responsible for ensuring adequate supervision of its residents outside the facility's premises and simply failed to do so. With regard to Resident 1, CMS asserts that a van is the resident's "environment" when a resident is in a van and the regulations apply, including the requirement for ensuring adequate supervision. *Sunbridge Care and Rehabilitation for Pembroke*, DAB No. 2170; *Liberty Nursing and Rehabilitation Center – Mecklenberg County*, DAB No. 2095; *St. Michael's Nursing Center*, DAB CR2038 (2009). That the van driver was not an employee or under Petitioner's control does not discharge the facility from its responsibility to supervise Resident 1. Facilities may very well "contract out" services such as resident transportation, and may very well do so frequently. If that "contracting out" is hoped or intended to insulate the contracting facility from some measure of responsibility for the activities of a hypothetically "independent" contractor, then such a hope or intention is misplaced: the fact that services are contracted out does not relieve a facility of its responsibility to make sure that the services provided meet professional standards of quality. *St. Michael's Nursing Center*, DAB CR2038.

CMS argues also that Petitioner must be alert to the expected return time for a resident who is outside the facility, and that it must take steps to locate a resident who fails to return at the expected time. *Eastwood Convalescent Center*, DAB No. 2088 (2007). CMS notes that the van driver picked Resident 1 up from the hospital at 4:15 p.m. The drive from the hospital to the facility is less than one mile. However, Petitioner did not contact the hospital for more than two hours.

Petitioner disputes CMS's assertion that it must ensure that the contracted transportation services meet professional standards of quality, and points out — correctly — that the facility was not cited for a violation of 42 C.F.R. § 483.20(k), the regulation requiring that the services a facility arranges must meet professional standards of quality. Petitioner asserts that the services and standards described in that regulation are clinical services and standards of clinical practice, not transportation services. And Petitioner asserts that its past practices and protocols show that it met reasonable standards of quality, in that there have been thousands of resident-transports over the last several years, including many by the van driver in question, without a single incident of a resident left unattended. Thus, Petitioner says that it could not have anticipated that this

van driver would leave a resident unattended without notifying anyone that she had returned the van to the facility, left Resident 1 restrained and locked in the van, and then had simply gone home.

Petitioner argues that CMS's comparison of Resident 1 to the resident described in *St. Michaels Nursing Center*, DAB CR2038, is not applicable, as that resident had a history of falls and was sent to the hospital in a van without the facility's verifying the driver's training or competence to provide the resident the level of supervision he required. Here, argues Petitioner, there is no evidence that the van driver was not competent and there is no evidence to establish that Petitioner should have questioned the driver's competence or anticipated that she would leave Resident 1 unattended in the van. And there was nothing in Resident 1's history to indicate that there was any problem in allowing the driver to accompany Resident 1 back to the facility alone.[7]

Petitioner argues that CMS's reliance on the Board's decision in *Eastwood Convalescent Center*, DAB No. 2088, is misplaced because the factual situations are different. Petitioner asserts that in *Eastwood* a resident with highly compromised health, a need for multiple medications, and who was totally dependent on staff for care, did not make a return trip to the facility in the facility van following dialysis but instead accompanied her spouse on an errand. The facility administrator was told that they would return in about an hour and a half. However, facility staff was not informed of this and made no attempt to locate the resident. Five hours later the facility received a call from a hospital indicting that the resident had been admitted following a fall. Petitioner asserts that the Board's concern was with the facility's failure to mitigate the foreseeable risk of the resident having an accident after leaving with her husband in light of her compromised health, her need for multiple medications, and her total dependence for care. In contrast, in this case, Petitioner argues that the facility charge nurse became aware Resident 1 had not returned, Petitioner did not know when Resident 1 was supposed to return to the facility, Resident 1 did not have any health problems requiring medical treatment or medications that would be exacerbated if there was a delay in her return to the facility, facility staff knew she was under the supervision of licensed personnel at the hospital, she was uninjured, and there were no environmental hazards in the van posing a risk of harm to her.

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[7] Petitioner analogizes that under CMS's theory an injury to a resident being transported by ambulance, where the driver is negligently involved in a traffic accident, would impose "regulatory liability." Assuming that Petitioner had arranged such a hypothetical transport it very well might be exposed to some liability. However, the quantum of proof necessary to establishing liability based on a hypothetical situation involving a negligently-caused traffic accident is hardly comparable to the proof here showing the actual abandonment of a resident in a van parked on a remote corner of facility premises for over two hours.

Here the system Petitioner had in place on March 23, 2010 to transport its residents to non-routine or non-regular hospital visits failed utterly, and that utter failure produced real, concrete, disturbing consequences. Petitioner was and is responsible for residents' care while they are being transported in an Inpropco van because that van was and is part of its residents' environment. It was and is Petitioner's responsibility to ensure that the Inpropco drivers transporting its residents understand its practices and protocols, including those for communicating among other Inpropco drivers, the facility, and the hospital with regard to a resident's return. The van driver in this case, despite having transported Petitioner's residents for several years, apparently did not understand Petitioner's practices and protocols for these non-routine or non-regular hospital trips. That there were no previous problems at the facility is not evidence of Petitioner's compliance with the regulations. It is simply luck, and luck is a notoriously-unreliable charm against mishap. It is no defense to a citation for non-compliance with a regulation intended to protect the vulnerable from mishap or worse.

Petitioner notes, with regard to Residents 2 and 3, that although the two Residents were not listed on the sign-out board on the morning of March 31, 2010, the surveyor observed both Residents in the building following their incident-free return from routine dialysis treatment. P. Br. at 15; P. Ex. 3, at 2, 4. Petitioner asserts that because the new transport sign-out policy was in the process of being implemented, there was some "expected confusion" regarding whether the policy applied to residents with regularly scheduled as opposed to non-regularly scheduled appointments. P. Br. at 15. Now, it may be an obvious point, and discussing it further may belabor that obvious point, but it seems inarguable that the very reason for the existence of any policy is to avoid confusion on matters within its purview by providing explicit and practical guidance, and by establishing clear and readily-followed procedures, for situations governed by the policy. Thus, to suggest as Petitioner does that some "expected confusion" existed concerning the new policy is virtually to admit that the policy was inadequate. Petitioner's admission — and it is precisely that, an admission — is hardly evidence of compliance with the regulations. When a facility attempts to address a risk of harm to its residents it should "expect" not confusion, but immediate and substantial compliance. Petitioner's failure with regard to implementation of the sign-out board, exemplified by Residents 2 and 3 not having been signed out on March 31, 2010, shows that Petitioner's problems supervising its residents were system-wide and not yet corrected.

2. The $5,000 PICMP imposed is reasonable, and so the two-year prohibition against Petitioner conducting a NATCEP/CEP is required by law.

Petitioner argues that issues of material fact exist regarding whether the immediate jeopardy finding is clearly erroneous. Petitioner is mistaken in this argument. As I have written previously, Petitioner does not have the right to challenge the scope and severity of a deficiency citation except when such a finding would affect the range of the CMP imposed. As CMS imposed a PICMP in this case, whether I find immediate jeopardy or not cannot affect the range of CMP. And although imposition of a NATCEP is also a

basis for challenging the scope and severity of a citation, since the NATCEP here is based on imposition of the PICMP, I do not consider the scope and severity of this one.

Petitioner's arguments regarding immediate jeopardy, however, also relate to whether the remedies imposed are reasonable. Petitioner asserts that Resident 1 did not sustain any injury, harm, or impairment in the two hours she was in the van unattended. She denied sustaining physical injury. A nursing assessment noted no injury or change in condition and her vital signs were normal. Resident 1 was appropriately strapped in her wheelchair, which was strapped into the van. The temperature was clement and she was not exposed to outside environmental factors, was not at risk for falls or coming into contact with traffic, water hazards, or other physical hazards. There is no evidence that Petitioner's failure to monitor her for two hours after her blood transfusion was likely to, or reasonably could be expected to, result in serious injury, harm, impairment or death. According to Petitioner, any theoretical risk of serious harm to Resident 1 is irrelevant in light of the fact that the Resident exhibited no negative reactions or symptoms as a result of the transfusion or her abandonment in Petitioner's parking lot.

In determining whether the PICMP imposed is reasonable, I apply the factors listed in 42 C.F.R. § 488.438(f): 1) the facility's history of non-compliance; 2) the facility's financial condition; 3) factors specified in 42 C.F.R. § 488.404; and 4) the facility's degree of culpability, which includes neglect, indifference, or disregard for resident care, comfort or safety. The absence of culpability is not a mitigating factor. The factors at 42 C.F.R. § 488.404 include: 1) the scope and severity of the deficiency; 2) the relationship of the deficiency to other deficiencies resulting in non-compliance; and 3) the facility's prior history of non-compliance in general and specifically with reference to the cited deficiencies.

Petitioner does not dispute that its care plan regarding Resident 1's anemia required it to monitor and report for signs of reaction to the transfusion. Had it not been important for Petitioner to do so, and could the failure to do so not potentially harm Resident 1, checking for and reporting signs of reaction to the transfusion would not have been included in Resident 1's care plan in the first place. Clearly Petitioner could not monitor Resident 1 for reactions to the transfusion while she was sitting unsupervised in the van. And even if I accept that Resident 1's Metformin could be administered an hour late without adverse consequences to Resident 1, the medication was in this instance administered two hours late. Moreover, although Petitioner downplays the risk to Resident 1 sitting unsupervised in the van, there is no way now to know whether the actual temperature in the van was subjectively comfortable to the person who was made without explanation or reassurance to endure it in silence and solitude for two hours. The Resident could in desperation or confusion have attempted to get up from her restraints and harmed herself. Someone could have attempted, for a variety of motives, to get into the van. The Resident could have suffered emotional or psychological harm from not knowing when — or whether — she would be rescued. She did endure an episode of urinary incontinence as a result of her confinement in the van. The somber fact is that, unsupervised and alone in the locked van for two hours, anything could have happened to

Resident 1. The fact that she may not have sustained actual physical harm is sheer luck, not the happy result of appropriate or adequately-supervised care. Moreover, the fact that Petitioner did not comply with its own protocol or procedure for signing residents out of the facility, as exemplified by its failures with Residents 2 and 3, shows that Petitioner was not in compliance with the regulations a week later.

A $5,000 PICMP is in the middle range of PICMP that CMS may impose for an instance of non-compliance. Given Petitioner's failure to supervise Resident 1, and its continuing failure to supervise Residents 2 and 3, the amount of PICMP imposed is reasonable. The prohibition on Petitioner's offering a NATCE/CEP is reasonable as a matter of law.

V. Conclusion

For the reasons set forth above, CMS's motion for summary disposition must be, and it is, GRANTED. CMS is authorized to impose a $5,000 PICMP, and thus must prohibit Petitioner from offering a NATCEP/CEP for two years.

/s/
Richard J. Smith
Administrative Law Judge