Department of Health and Human Services

DEPARTMENTAL APPEALS BOARD

Civil Remedies Division

In the Case of:	
	Date: March 13, 2007
Odebolt Nursing & Rehabilitation Center,	
Petitioner,	Docket No. C-04-262
	Decision No. CR1574
v.	
Centers for Medicare & Medicaid Services.	

DECISION

Petitioner, Odebolt Nursing & Rehabilitation Center, violated 42 C.F.R. § 483.25(h)(2) on November 11, 2003. A per instance civil money penalty (PICMP) of $2000.00 is reasonable.

I. Background

Petitioner, is a long-term care facility located in Odebolt, Iowa that participates in the Medicare and Medicaid programs. The Iowa Department of Inspection & Appeals (the state agency) conducted a complaint survey and an abbreviated extended survey of Petitioner's facility from January 6 through 12, 2004. The state agency found that Petitioner was not in substantial compliance with Medicare and Medicaid participation requirements during the period November 11 through 25, 2003, and cited Petitioner for violation of 42 C.F.R. § 483.25(h)(2) (Tag F 324)[1] and alleged that the deficiency presented immediate jeopardy for Petitioner's residents. The Centers for Medicare & Medicaid Services (CMS) notified Petitioner by letter dated January 30, 2004, that it was imposing a $2000 per-instance civil money penalty (PICMP) as recommended by the state agency. This case was initiated by Petitioner's request for a hearing dated March 26, 2004.

[1] All references are to the version of the Code of Federal Regulations (C.F.R.) in effect at the time of the survey, unless otherwise indicated.

The case was assigned to me for hearing and decision on April 13, 2004. I convened a one-day hearing in this case on February 2, 2006, in Des Moines, Iowa. A 197-page transcript (Tr.) of the proceedings was prepared. CMS offered and I admitted CMS exhibits (CMS Exs.) 1 through 10. Tr. 16. Petitioner offered and I admitted Petitioner Exhibits (P. Exs.) 1 through 8. Tr. 29, 155. CMS offered the testimony of the state agency surveyor, Sharon Benson. Petitioner called one witness, John Schuttinga, Petitioner's Administrator. Petitioner filed a post-hearing brief (P. Brief) and a reply brief (P. Reply). CMS filed a post-hearing brief (CMS Br.) and reply (CMS Reply).

II. Discussion

A. Findings of Fact

The following findings of fact are based upon the parties joint stipulation (Jt. Stip.), the testimony at hearing, and the exhibits admitted at hearing. Citations to exhibit numbers related to each finding of fact may be found in the analysis section of this decision if not indicated here.[2]

1. Petitioner is a long-term care facility located in Odebolt, Iowa. Jt. Stip.

2. The state agency conducted a complaint survey and an abbreviated extended survey of Petitioner's facility on January 6 through 12, 2004. Jt. Stip.

3. The state agency issued a Statement of Deficiencies (SOD) dated January 12, 2004, that alleges that Petitioner was not in substantial compliance with federal requirements for nursing homes participating in the Medicare and Medicaid programs based upon an alleged violation of 42 C.F.R. §483.25(h)(2) (Tag F324), cited at a scope/severity level of "J" indicating "immediate jeopardy." Jt. Stip.; CMS Exs. 1, 10.

4. CMS notified Petitioner by letter dated January 30, 2004, that it was imposing a per instance civil money penalty in the amount of $2000.00 as an enforcement remedy. Jt. Stip.; CMS Ex. 10.

5. Petitioner requested a hearing by an administrative law judge (ALJ) by letter dated March 26, 2004.

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[2] The parties proposed findings of fact submitted post hearing reflect that there is little dispute about the facts in this case.

6. The alleged violation of 42 C.F.R. § 483.25(h)(2) involved a single resident referred to as Resident 8. Jt. Stip.; CMS Ex. 1.

7. Resident 8 was admitted to Petitioner's facility in August 2000. Tr. 46.

8. Resident 8 made 22 attempts to leave the facility following his admission – 5 attempts in 2000, 12 in 2001, 3 attempts in 2002, and 1 attempt during the first 10 months of 2003. Tr. 46, 51, 77-78, 149-50; P. Brief at 4.

9. Based on the resident's behavior, the facility assessed the resident at risk for elopement and implemented several interventions in his care plan, including observation for anxiety and agitation, diversion activities, reality orientation, and use of a WanderGuard® . Tr. 75-76; P. Ex. 1, at p. 7; CMS Ex. 7, at 43-45.

10. Petitioner also assessed Resident 8 as being at risk for falls and had a care plan for falls with interventions that included accompanying him outdoors when he wished to go out, keeping the WanderGuard® on at all times, and encouraging him to wear shoes. CMS Ex. 7, at 45.

11. Petitioner had alarms on each of its doors, except a kitchen service door that was not accessible to residents, and alarms were triggered by opening a door, except for the front door which was outfitted with the WanderGuard® alarm that was triggered whenever a resident wearing a device approached the door too closely. Tr. 144-45.

12. The door alarms were controlled by a panel of switches that did not have a cover, located at the nurses' station and each door had a corresponding switch and button that allowed each door alarm to be turned on, off, and to be reset. Tr. 63, 145, 153-57; P. Ex. 6.

13. The door alarms were checked on a daily basis during the morning as part of the facility's quality assurance program as well as weekly by the maintenance department. Tr. 146-49; P. Ex. 2.

14. The door alarm check protocol was followed on November 11, 2003, and the alarms were functioning that morning. Tr. 147; P. Ex. 2, at 4-5.

15. On November 11, 2003 at approximately 8:10 pm, staff assisted Resident 8 to bed; he was observed by staff to be asleep in bed at approximately 8:30 pm; and staff observed that the resident's door was closed at 9 pm. Tr. 160.

16. On November 11, 2003 at approximately 9:25 to 9:30 pm, staff observed that Resident 8's room door was open and the resident was absent. Tr. 161; CMS Ex. 9, at 47-48.

17. After Resident 8 was discovered missing from his room, staff observed that the stop sign attached to the frame of the emergency exit door near Resident 8's room was pulled down, the door was ajar, and staff noted a trail of fecal matter to the door. Tr. 162-63; CMS Ex. 9, at 47-48.

18. Staff immediately searched the area outside the door and found the resident, naked from the waist down, with shoes, but no socks, laying in the grass approximately 150 feet from the door. Tr. 164-67; CMS Ex. 1, at 3-5; CMS Ex. 7, at 12, 20-21; CMS Ex. 9, at 47-48.

19. Nursing assessments revealed that the resident had normal vital signs and sustained minor abrasions to his elbows and knees, but was not hospitalized nor seen by his treating physician who was notified of the event. Tr. 1168-69; CMS Ex. 7, at 12.

20. Resident exited through the emergency exit near his room but the alarm on that exit did not sound.

21. Petitioner failed to ensure that the alarm on the emergency door through which Resident 8 exited the facility was operating at the time Resident 8 exited on November 11, 2003.

22. Petitioner investigated the circumstances of the elopement through its quality assurance program and concluded that the switch for the alarm on the emergency exit door, which was not at the time protected by a cover, was most likely inadvertently bumped into the off position by staff. Tr. 157.

23. After Resident 8's elopement and fall, Petitioner took corrective action including implementing a personal alarm on the resident, attaching a personal alarm to the emergency door, reapplying the WanderGuard® device to the resident, and in-service training was given to all staff by November 25, 2003. Tr. 170-72.

24. Petitioner corrected the deficiency before the survey and Petitioner was in compliance with 42 C.F.R. § 483.25(h)(2) at the time of the survey. Tr. 98.

B. Conclusions of Law

1. Petitioner's request for hearing was timely and I have jurisdiction.

2. Petitioner violated 42 C.F.R. § 483.25(h)(2).

3. A facility may appeal a certification of noncompliance that results in imposition of an enforcement remedy, but the facility may not challenge the choice of remedy or the factors CMS or the state considered when selecting the remedy. 42 C.F.R. § 488.408(g).

4. Once an ALJ finds that there is a basis for imposing a civil money penalty (CMP), the ALJ may not reduce the penalty amount to zero; review the exercise of discretion by CMS to impose a CMP; or review factors other than those specified by the regulation. 42 C.F.R. § 488.438(e).

5. A PICMP of $2000 is reasonable in this case.

C. Issues

The general issues are:

> 1. Whether there is a basis for the imposition of an enforcement remedy; and,
>
> 2. Whether the remedy imposed is reasonable.

D. Applicable Law

Petitioner is a long-term care facility participating in the federal Medicare program as a skilled nursing facility (SNF) and in the state Medicaid program as a nursing facility (NF). The statutory and regulatory requirements for participation by a long-term care facility are found at sections 1819 and 1919 of the Act and at 42 C.F.R. Part 483. Sections 1819 and 1919 of the Act vest the Secretary with authority to impose CMPs against a long-term care facility for failure to comply substantially with federal participation requirements.

Facilities that participate in Medicare may be surveyed on behalf of CMS by state survey agencies in order to determine whether the facilities are complying with federal participation requirements. 42 C.F.R. §§ 488.10-488.28, 488.300-488.335. Pursuant to 42 C.F.R. Part 488, CMS may impose a per instance or per day CMP against a long-term

care facility when a state survey agency concludes that the facility is not complying substantially with federal participation requirements. 42 C.F.R. §§ 488.406; 488.408; 488.430. The regulations in 42 C.F.R. Part 488 also give CMS a number of other remedies that can be imposed if a facility is not in compliance with Medicare requirements. *Id.*

The regulations specify that a CMP that is imposed against a facility on a per day basis will fall into one of two broad ranges of penalties. 42 C.F.R. §§ 488.408, 488.438. The upper range of CMP, of from $3050 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 $3000 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). There is only a single range of $1000 to $10,000 for a PICMP that applies whether or not immediate jeopardy is present. 42 C.F.R. §§ 488.408(d)(1)(iv); 488.438(a)(2).

The Act and regulations make a hearing before an ALJ available to a long-term care facility against which CMS has determined to impose a CMP. Act, section 1128A(c)(2); 42 C.F.R. §§ 488.408(g); 498.3(b)(13). The hearing before an ALJ is a de novo proceeding. *Anesthesiologists Affiliated, et al*, DAB CR65 (1990), *aff'd*, 941 F2d. 678 (8th Cir. 1991). A facility has a right to appeal a "certification of noncompliance leading to an enforcement remedy." 42 C.F.R. § 488.408(g)(1); *see also* 42 C.F.R. §§ 488.330(e) and 498.3. However, the choice of remedies by CMS or the factors CMS considered when choosing remedies are not subject to review. 42 C.F.R. § 488.408(g)(2). A facility may only challenge the scope and severity level of noncompliance found by CMS if a successful challenge would affect the amount of the CMP that could be collected by CMS or impact upon the facility's nurse aide training program. 42 C.F.R. §§ 498.3(b)(14) and (d)(10)(i). CMS's determination as to the level of noncompliance "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, 38 (2000), *aff'd, Woodstock Care Center v. U.S. Dept. of Health and Human Services*, 363 F.3d 583 (6th Cir.2003). The Departmental Appeals Board (the Board) has long held that the net effect of the regulations is that a provider has no right to challenge the scope and severity level assigned to a noncompliance finding, except in the situation where that finding was the basis for an immediate jeopardy determination. *See, e.g.*, *Ridge Terrace*, DAB No. 1834 (2002); *Koester Pavilion*, DAB No. 1750 (2000). Review of a CMP by an ALJ is governed by 42 C.F.R. § 488.438(e).

E. Analysis

1. Petitioner violated 42 C.F.R. § 483.25(h)(2) (Tag F 324) and there is a basis for imposing a CMP.

A facility must ensure that "[e]ach resident receives adequate supervision and assistance devices to prevent accidents." 42 C.F.R. § 483.25(h)(2). The Board has explained the requirements of 42 C.F.R. § 483.25(h)(2) in numerous decisions. *Golden Age Skilled Nursing & Rehabilitation Center*, DAB No. 2026 (2006); *Estes Nursing Facility Civic Center*, DAB No. 2000 (2005); *Northeastern Ohio Alzheimer's Research Center*, DAB No. 1935 (2004); *Woodstock Care Center*, DAB No. 1726, at 28 (2000), *aff'd*, *Woodstock Care Center v. Thompson*, 363 F.3d 583 (6th Cir. 2003). Section 483.25(h)(2) does not make a facility strictly liable for accidents that occur, but it does require the facility to 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. *Woodstock Care Center v. Thompson*, 363 F.3d at 590 (a SNF must take "all reasonable precautions against residents' accidents"). A facility is permitted the flexibility to choose the methods of supervision it uses to prevent accidents, but the chosen methods must be adequate under the circumstances. *Id.* Whether supervision is "adequate" depends, of course, on the resident's ability to protect himself or herself from harm. *Id.* Thus, the issue is whether the quality of the supervision or the use, or lack thereof, of assistive devices at the long-term care facility was such that residents with known or foreseeable risks were subject to the risk of injury from accidental causes in their daily activities. Based on the regulation and the cases in this area, CMS meets its burden to show a *prima facie* case if the evidence demonstrates that the facility failed to provide adequate supervision and assistance devices to prevent accidents, given what was reasonably foreseeable. *Alden Town Manor Rehabilitation & HCC*, DAB No. 2054 (2006), at 5-6, 7-12. An "accident" is "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, App. P, page PP-105, Guidance to Surveyors for Long Term Care Facilities, Part 2, F324, Quality of Care (Rev. 274, June 1995), *Woodstock Care Center*, DAB No. 1726, at 4 (2000).

The pertinent facts here are not disputed. Resident 8 was identified as an elopement risk (P. Reply at 2) and as a fall risk (CMS Ex. 7, at 45). Between 9:30 pm and 10:00 pm on November 11, 2003, Resident 8 was found outside the facility, unsupervised, partially clothed, incontinent of bowel, sitting on the ground after apparently falling. Finding of Fact 18. I have no difficulty concluding there is a *prima facie* showing of a violation of 42 C.F.R. § 483.25(h)(2), *i.e.*, CMS produced sufficient evidence that, absent conflicting evidence, shows a violation occurred. *Meadow Wood Nursing Home*, DAB No. 1841, at 7 (2002); *Emerald Oaks*, DAB No. 1800, at 16 (2001).

Petitioner argues that it identified Resident 8 as an elopement risk, that its interventions were adequate, and that it was not foreseeable that the alarm on the emergency door would be turned off permitting Resident 8 to elope. P. Brief at 9-13; P. Reply at 2-4. I am not persuaded.

Resident 8's care plan and other medical records shows that Petitioner knew that Resident 8 was an elopement risk, and should not be outside the facility unsupervised. Among other things, the care plan dated September 25, 2003, and in place at the time of the incident on November 11, 2003, stated, "Alteration in behavior. Has left facility unsupervised, at times angers and does not always accept RO [reality orientation] related to Dementia and inability to realize limits . . . . Potential for injury related to history of falls, unsteady gait with attempts to leave facility related to poor cognitive status." CMS Ex. 7, at 43, 45. The care plan directed staff to "provide accompaniment if he wishes to go outside of facility." CMS Ex. 7, at 45. His plan of care also required that the staff monitor that the WanderGuard® is on the resident and functioning correctly. CMS Ex. 7, at 43, 45. The Nurse's notes indicate that on October 2, 2003, Resident 8 was found to have taken off the WanderGuard® and any attempt at placing a new one on his wrist resulted in extreme anger and refusal by the resident. CMS Ex. 7, at 15. Several other attempts were made in the beginning of October 2003 to get a WanderGuard® on Resident 8, but to no avail. CMS Ex. 7, at 15. On October 4, 2003, notes indicate that Resident 8 said that he was not in prison and that he did not like women chasing him when he went out the door. CMS Ex. 7, at 15. The Nurse's notes indicated on his first refusal that, since he was not wearing a WanderGuard®, he should be monitored closely. CMS Ex. 7, at 15. However, the care plan itself does not appear to be modified; it still requires that the WanderGuard® be on and monitored for functioning. There is no suggestion in the care plan that this intervention was removed or modified prior to the date of the incident on November 11, 2003, nor does the care plan indicate that any new interventions were put in place in early October 2003 to address Resident 8's refusal to wear the WanderGuard® and to protect the resident from elopement. CMS Ex. 7 at 43.

Nurse's notes show that on November 5, 2003, Resident 8 was transferred to the hospital by his daughter, with chills and pain associated with a urinary catheter. He was returned to Petitioner's facility on November 10, 2003, with a prescription for Cipro, an antibiotic. CMS Ex. 7, at 14. A note from November 10, 2003 at 4:25 pm, reflects that he was found lying on the floor beside his bed, shoes off, pants half-down, and unable to explain what had happened. A note on November 11, 2003 at 1:00 pm, shows that he was up in the hall without assistance, that he was encouraged to request assistance, that he was assisted to breakfast and lunch in a wheelchair by two staff, and that he seemed confused and

lethargic throughout the day. CMS Ex. 7, at 13. A note from 9:00 pm on November 11, 2003, indicates that he was again up in the hallway without assistance, that he was assisted to supper and back, that he continued to be lethargic, and ate only bites of his meal. CMS Ex. 7, at 12

The evidence shows that Resident 8 resisted wearing the WanderGuard® and even verbalized that he did not want staff following him out the door. He was sick, possibly with a urinary tract infection given the presence of the catheter on November 5 and the prescription for antibiotic on his return from the hospital on November 10. On November 10, he was found on the floor by his bed without explanation. On November 11, he was attempting to move around in the hallways without assistance. He was also noted to be confused and lethargic on November 11, 2003. All these facts were sufficient to cause Petitioner to know that Resident 8, with his history of prior exit seeking behavior, required some increased supervision. Despite the fact that Resident 8's care plan called for him to wear a WanderGuard® bracelet at all times, he was not wearing that bracelet at the time that he was found outside and he had refused to wear it for several days prior to that. Petitioner's argument that the absence of the WanderGuard® bracelet is irrelevant because Resident 8 left the facility through a door not protected by the WanderGuard® system misses the point. Resident 8 refused to wear the bracelet and he verbalized the intent not to have staff follow him out the door. Nevertheless, Petitioner failed to implement another intervention to give warning in the event Resident 8 left his room without assistance or attempted to leave the building unobserved.

Petitioner chose to use an alarm system on emergency exits, including the door through which Resident 8 eloped. The emergency exit alarms were controlled by switches just above the work surface at the nurses' station. P. Ex. 6. But as Petitioner demonstrated by its own photographs (P. Ex. 6), Petitioner did not protect against those simple toggle switches from being accidentally turned-off by a notebook or chart. Although Petitioner did daily and weekly checks to ensure the alarms on emergency exit doors worked, Petitioner has provided no evidence that it had any protocol to ensure the switches were not accidentally flipped to the off position or to ensure that the alarms were functional throughout the day. Because Petitioner chose to protect against elopement by putting such an alarm system in place, Petitioner had the duty to know whether or not the emergency exit door alarm was on and operational at all times, *i.e.*, Petitioner was obliged to know whether this intervention was effective. It was only fortuitous that Resident 8, who was known to be an elopement risk and at risk for falls, did not suffer significant harm given his apparent fall, the weather, his state of dress, and other risks related to his condition as reflected in his clinical records, and the fact that he was unsupervised.

I conclude that Petitioner has not shown it did all it reasonably could to protect the resident from foreseeable risks of harm associated with elopement and falls. Accordingly, Petitioner violated 42 C.F.R. § 483.25(h)(2) and there is a basis for imposing a CMP.

Petitioner argues in the alternative that as a matter of its own policy CMS should not impose a CMP based upon the deficiency. P. Brief at 13-20; P. Reply at 4-5. Petitioner cites the State Operations Manual, paragraph 7510A (Rev. 13, December 1999) (P. Ex. 8, at 2). The provision indicates that CMS or the state should consider imposing a CMP for serious noncompliance that has been corrected at the time of the survey. However, the provision also provides that if the facility was out of compliance between two surveys that found it in compliance and the noncompliance was corrected through the facility's quality assurance program, then the past noncompliance should not be cited by the surveyors, except where the past noncompliance was egregious, such as in the case of a death.

CMS responds that the deficiency was cited at the level of "immediate jeopardy," defined under the regulation as "a situation in which the provider's noncompliance with one or more requirements of participation caused, or *is likely to cause*, serious injury, harm, impairment, or death to a resident" and that is tantamount to egregious. CMS Reply at 1-2, *citing* 42 C.F.R. § 488.301 (emphasis added).

Section 7510 of the SOM gives guidance to CMS and the states regarding imposition of a CMP. The regulations are clear that I have no authority to review the exercise of discretion by CMS to impose a CMP, if there is a basis for imposing an enforcement remedy. 42 C.F.R. § 488.438(e). The regulations are also clear that Petitioner may not challenge the choice of remedies by CMS. 42 C.F.R. § 488.408(g). Furthermore, CMS' construction of its policies and how they are to be applied, is a matter within its discretion. My review is limited to determining whether there is a basis for the imposition of a remedy and whether the remedy is reasonable.

2. A per instance CMP of $2000.00 is reasonable on the facts of this case.

If a facility is not in substantial compliance with program requirements, CMS has the authority to impose one or more of the enforcement remedies listed in 42 C.F.R. § 488.406, including a CMP. CMS may impose a CMP for the number of days that the facility is not in compliance or for each instance that a facility is not in substantial compliance. 42 C.F.R. § 488.430(a). The minimum amount for a PICMP is $1000 and the maximum is $10,000. CMS imposed a per instance penalty here of $2000 – the low end of the range. I must consider whether the proposed PICMP is reasonable.

In determining whether the amount of the per instance CMP is reasonable, the following factors specified at 42 C.F.R. § 488.438(f) must be considered: (1) the facility's history of non-compliance, including repeated deficiencies; (2) the facility's financial condition; (3) the seriousness of the deficiencies as set forth at 42 C.F.R. § 488.404; and (4) the facility's degree of culpability.

Petitioner has not argued that the proposed PICMP is unreasonable but focused upon whether or not there is a basis for imposing such a remedy. The PICMP amount is at the low-end of the range. Petitioner has not argued or submitted any evidence that it is unable to pay the PICMP. CMS has offered no evidence of past noncompliance for me to consider. The deficiency is serious and supports the PICMP proposed. It was merely fortuitous that the resident was not more seriously injured when he eloped unnoticed from the facility. Petitioner was culpable as it did not respond to indications that the Resident required additional interventions and the obvious risk that its alarm system could be easily compromised. I note however that Petitioner did act quickly through its quality assurance process to correct the deficiency and its causes. Therefore, I conclude that given all the factors, a per instance CMP of $2000 is reasonable.

III. Conclusion

For the foregoing reasons, I conclude that Petitioner violated 42 C.F.R. § 483.25(h)(2) and that a per instance CMP of $2000.00 is reasonable.

/s/

Keith W. Sickendick
Administrative Law Judge