Department of Health and Human Services

DEPARTMENTAL APPEALS BOARD

Civil Remedies Division

In the Case of:	)	
	)	
Heartland of Madeira (CCN: 36-5186),	)	Date: November 21, 2008
	)	
Petitioner,	)	
	)	
- v. -	)	Docket No. C-07-761
	)	Decision No. CR1867
Centers for Medicare & Medicaid Services.	)	
	)	

DECISION

Petitioner, Heartland of Madeira (Petitioner or facility), is a long term care facility located in Madeira, Ohio, that is certified to participate in the Medicare program as a provider of services. The parties have agreed that, from July 19 through August 26, 2007, the facility was not in substantial compliance with most of the Medicare requirements cited following a July 19, 2007 facility survey. However, Petitioner continues to challenge the Centers for Medicare & Medicaid Services' (CMS's) determination that it was not then in substantial compliance with the quality-of-care regulation, 42 C.F.R. § 483.25.

I conclude that the facility was not in substantial compliance with 42 C.F.R. § 483.25, along with the nine uncontested requirements. I affirm the civil money penalty (CMP) imposed, $950 per day for 39 days ($37,050 total).

I. Background

The Social Security Act (Act) sets forth requirements for nursing facility participation in the Medicare program, and authorizes the Secretary of Health and Human Services to promulgate regulations implementing those statutory provisions. Act, section 1819. The Secretary's regulations are found at 42 C.F.R. Part 483. To participate in the Medicare program, a nursing facility must maintain substantial compliance with program requirements. To be in substantial compliance, a facility's deficiencies may pose no

greater risk to resident health and safety than "the potential for causing minimal harm." 42 C.F.R. § 488.301.

The Secretary contracts with state survey agencies to conduct periodic surveys to determine whether skilled nursing facilities are in substantial compliance with program participation requirements. Act, section 1864(a); 42 C.F.R. § 488.20. The regulations require that each facility be surveyed once every twelve months, and more often, if necessary, to ensure that identified deficiencies are corrected. Act, section 1819(g)(2)(A); 42 C.F.R. §§ 488.20(a); 488.308.

Here, following an annual survey, completed July 19, 2007, CMS determined that the facility was not in substantial compliance with the following Medicare participation requirements:

- 42 C.F.R. § 483.10(c)(2)-(5) (Tag F159 – protection of resident funds) at a D level of scope and severity (isolated instance of noncompliance that causes no actual harm with the potential for more than minimal harm);

- 42 C.F.R. § 483.13(a) (Tag F221 – physical restraints) at a D level of scope and severity;

- 42 C.F.R. § 483.15(e)(1) (Tag F246 – accommodation of needs) at a D level of scope and severity;

- 42 C.F.R. § 483.15(h)(2) (Tag F253 – housekeeping/maintenance) at an E level of scope and severity (pattern of noncompliance that causes no actual harm with the potential for more than minimal harm);

- 42 C.F.R. §§ 483.20, 483.20(b) (Tag F272 – comprehensive assessments) at a D level of scope and severity;

- 42 C.F.R. §§ 483.20(d), 483.20(k)(1) (Tag F279 – comprehensive care plans) at a D level of scope and severity;

- 42 C.F.R. § 483.25 (Tag F309 – quality of care) at a G level of scope and severity (isolated instance of noncompliance that causes actual harm that is not immediate jeopardy).

- 42 C.F.R. § 483.25(h)(2) (Tag 324 – accidents) at a D level of scope and severity;

- 42 C.F.R. § 483.25(m)(1) (Tag F332 – medication errors) at a D level of scope and severity;

and

- 42 C.F.R. § 483.25(m)(2) (Tag F333 – medication errors) at a D level of scope and severity.

CMS subsequently found the facility in substantial compliance with certification requirements as of August 27, 2007. CMS has imposed against the facility a CMP of $950 per day for 39 days of substantial noncompliance ($37,050 total). CMS Ex. 1.

In its hearing request, Petitioner initially challenged all ten deficiency findings. The parties subsequently resolved their disputes with respect to all of the deficiencies cited except one, 42 C.F.R.§ 483.25 (quality of care). Order (July 22, 2008). To resolve this remaining issue, I held a hearing by telephone on July 29, 2008. Thomas W. Hess appeared on behalf of Petitioner, and Juanita S. Temple appeared on behalf of CMS. I have admitted into evidence CMS Exhibits (Exs.) 1-38, including CMS Exhibits 3A, 35A, and 36A[1], and P. Exs. 1-3. Tr. 2-3.

The parties have also filed opening briefs (Br.), closing briefs (Cl. Br.) and reply briefs (Reply).

II. Issues

By conceding its noncompliance with nine of the ten Medicare requirements cited, Petitioner admits that it was not in substantial compliance, and CMS is therefore authorized to impose a remedy. Act, section 1819(h); 42 C.F.R. §§ 488.400, 488.402, 488.406. I have no authority to review CMS's determination to impose a remedy nor its selection of remedies – in this case a per day CMP. 42 C.F.R. §§ 488.408(g)(2), 488.438(e). The per day penalty must be at least $50 per day. 42 C.F.R. § 488.438.

[1] CMS initially submitted unsigned witness declarations: CMS Exhibits 34 (Louderback Decl.), 35 (Gilmore Decl.), and 36 (Smith Decl.). It subsequently submitted signed versions of those documents, marked CMS Ex. 35A (Gilmore Decl.), CMS Ex. 36A, at 1-4 (Louderback Decl.), and CMS Ex. 38 (Smith Decl.).

The following issues remain:

- whether, from July 19 through August 26, 2007, the facility was in substantial compliance with 42 C.F.R. § 483.25 (quality of care);

and

- whether the $950 per day CMP is reasonable.

III. Discussion

A. The facility was not in substantial compliance with 42 C.F.R. § 483.25.[2]

Under the statute and the "quality-of-care" regulation, each resident must receive, and the facility must provide, the necessary care and services to allow a resident to attain or maintain the highest practicable physical, mental, and psychosocial well-being, in accordance with the resident's comprehensive assessment and plan of care. Act, section 1819(b); 42 C.F.R. § 483.25. The regulation also requires that the facility "take reasonable steps to ensure that a resident receives supervision and assistance devices designed to meet his assessed needs and to mitigate foreseeable risks of harm from accidents." *Guardian Health Care Center*, DAB No. 1943, at 18 (2004) (citing 42 C.F.R. § 483.25(h)(2)). The facility must anticipate what accidents might befall a resident and take steps to prevent them.

> A facility is permitted the flexibility to choose the methods it uses to prevent accidents, but the chosen methods must constitute an "adequate" level of supervision under all the circumstances.

Windsor Health Care Center, DAB No. 1902, at 5 (2003).

1. Facility staff did not provide Resident 56 with a two-person assist as her assessments required.

Resident 56 (R56) was a 68-year-old woman with a below the knee amputation of her right leg, severely impaired vision, and incontinence of bowl and bladder. Her diagnoses

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[2] My findings of fact and conclusions of law are set forth, in italics and bold, in the discussion captions.

included Parkinson's Disease, contractures of the hands, diabetes, cardiomyopathy, coronary artery disease, congestive heart failure, hypertension, intractable back pain causing general weakness, end-stage renal disease, and depression. She took several medications, was on dialysis, had an in-dwelling catheter, and had frequent nausea. CMS Ex. 12, at 1, 14, 18, 51, 59, 60, 61, 68, 74; Tr. 50.

From as early as November 2006, R56's assessments have consistently called for two-person assists with "bed mobility," which is defined as "[h]ow resident moves to and from lying position, turns side to side, and positions body while in bed." CMS Ex. 12, at 67; *see* CMS Ex. 12, at 60 (February 2007 assessment also calls for a two-person assist with bed mobility). Yet, on March 6, 2007, a lone certified nurse assistant (CNA) "rolled [the] patient over on her left side to clean her bottom[.]" CMS Ex. 12, at 20. According to the CNA, R56 then "proceeded to slide off side of bed. I could not stop her . . . ." Both side rails were up, but they did not prevent the fall. CMS Ex. 12, at 20.

R56 sustained a subacute left hip fracture, which required open reduction/internal fixation surgery. CMS Ex. 12, at 36, 45.

In her statement, the CNA acknowledged that R56 needed assistance from two people when being changed. CMS Ex. 12, at 20. The facility's subsequent incident report, dated March 7, 2007, reiterates that R56 required a two-person assist with bed mobility. CMS Ex. 12, at 30; *see also* CMS Ex. 12, at 88 (March 7, 2007 care plan requiring two-person assist with bed mobility).

Thus, the facility appropriately anticipated that an accident might befall the resident, and took steps to prevent it by requiring a two-person assist when turning or otherwise repositioning R56 in her bed. Unfortunately, staff failed to follow the unambiguous instruction and an accident resulted – an error that plainly constitutes a deficiency under 42 C.F.R. §§ 483.25 and 483.25(h)(2).

Petitioner, however, claims no violation. While not disputing that the CNA turned R56 without assistance, Petitioner notes that the repositioning was incidental to providing "personal care," and R56's care plan required only a one-person assist for providing "personal hygiene." CMS Ex. 12, at 60, 67. In Petitioner's view, the CNA was not obligated to follow the "bed mobility" instructions in R56's care plan, but could instead follow the "personal hygiene" instructions. I disagree.

I recognize that personal care, even perineum care, may not always require a two-person assist. So long as the resident could be cared for without changing her position in bed, one staff member might safely have performed the function. But the critical factor here is resident safety. For its argument to prevail, Petitioner would have to show that the

underlying reason for changing R56's position somehow alters the level of risk posed by not providing her the requisite two-person assist. Petitioner has made no such showing.

I am not persuaded that R56's purported ability to assist her care-giver by holding on to the side rails changed the level of risk. *See* Tr. 50. Certainly, at the time of R56's fall, nothing in her care plan even suggested that her ability to grasp the side rail would alleviate the need for an additional person to reposition her in bed. Moreover, some months later, a rehabilitation assessment dated August 10, 2007, reiterated that R56 required two staff members to move her from a supine to side lying position. She was then able to maintain her side-lying position so long as her left hand was free so that she could grab the bed rail, which meant that one person could safely care for her so long as she was already in position and holding the side rail. However, she was unable to use her right hand to hold the bed rail, so if her left hand was encumbered, she still required a two-person assist for back and perineum care. CMS Ex. 12, at 11. In any event, the assessment found that she *always* required a two-person assist when her position was being changed; only *after* the position change, when she was safely on her side with her left hand securely grasping the side rail, could the facility reduce the assist to one staff member. Thus, the August 13, 2007 amendment to R56's care plan still required "2 staff assist for bed mobility," although it added "may use one staff member if patient able to *maintain* side lying position for back and peri care." CMS Ex. 12, at 82.

The facility understood that safely changing R56's position in bed required a two-staff assist, and it care planned accordingly. Staff unfortunately did not follow the care plan's instructions, and a plainly foreseeable accident resulted. The facility was therefore not in substantial compliance with 42 C.F.R. §§ 483.25 and 483.25(h)(2).

2. Facility staff did not provide Resident 95 with the appropriate number of Heparin flushes.

Resident 95 (R95) had diagnoses of lung cancer, renal failure, congestive heart failure, hypertension, deep vein thrombosis, and anemia. She had two portacaths in place.[3] CMS Ex. 7, at 17; CMS Ex. 17, at 1, 14. Her physician ordered that the portacaths be flushed every 12 hours with 5 cubic centimeters (ccs) of normal saline, and 3 ccs of the blood-thinning medication, Heparin. CMS Ex. 7, at 17; CMS Ex. 17, at 13.

[3] A portacath is a small medical appliance that is installed beneath the skin and connected to a vein, providing easier access to the vein for administering medications or drawing blood.

According to a July 2007 Medication Administration Record (MAR), staff administered the ordered flushes at 10:00 a.m. on July 1. From July 2 through July 9, and on July 11, they administered the flushes twice daily, as ordered, at 10:00 a.m. and at 10:00 p.m. On July 10, at 10:00 a.m., the MAR indicates that staff administered one of the two ordered flushes. From July 12 through 13, the MAR indicates once daily flushes, each at 10:00 p.m. The document records no additional flushes for the month. CMS Ex. 17, at 13 (First MAR); *see* CMS Ex. 7, at 17.

However, a second MAR shows an undated order for flushing twice daily with 10 ccs of normal saline and 5 ccs of Heparin.[4] According to this document, flushes were administered at 6:00 p.m. on July 9; at 6:00 p.m. on July 11, 12, and 13; at 6:00 a.m. on July 14; and at 6:00 a.m. and 6:00 p.m. on July 15. CMS Ex. 17, at 5. Surveyors observed staff administering 10 ccs of normal saline and 5 ccs of Heparin. CMS Ex. 35A, at 4 (Gilmore Decl. ¶ 9).

It appears that staff were inconsistently following inconsistent orders. CMS suggests that the First MAR was, in fact, the valid order, and Petitioner has not suggested otherwise. So staff should have been administering 3 ccs of Heparin twice per day (total 6 ccs per day). But, as the two documents establish, for at least half the time from July 1 through July 15, 2007, staff were not following the valid physician order. On July 1 and July 10, 2007, they administered only one flush (3 ccs). Probably even more troubling, on July 9 and 11, they administered three flushes – totaling 11 ccs. For two days (July 12-13), they administered 3 ccs of Heparin at 10:00 p.m., and 5 ccs of Heparin at 6:00 p.m. (total 8 ccs per day). On July 14, they administered only one flush, at 6:00 a.m., containing 5 ccs of Heparin. Finally, on July 15, they administered two flushes, each containing 5 ccs of Heparin, at 6:00 a.m. and 6:00 p.m. (total 10 ccs).

Petitioner has neither denied CMS's allegations, nor explained how or why this erratic and potentially dangerous situation arose. Instead, pointing to testimony from Surveyor Sharon Smith, Petitioner asserts that no harm befell R95 as a result of the medication errors, and argues that, in the absence of actual harm, no penalty should be imposed. P. Reply at 3-4 (citing Tr. 29).

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[4] Although the document is dated July 5, 2005, its individual orders are dated July 2007, so the 2005 date appears to be in error. The alternative explanation is even more problematic for the facility: its staff were occasionally referring to and following an out-of-date order.

For its part, CMS contends that Surveyor Smith did not observe R95 nor assess this deficiency, so her opinion is not dispositive. *See* Tr. at 30-32. CMS also offers some evidence of actual harm, pointing out that R95 experienced itching and burning, which are side effects of Heparin. CMS Ex. 37, at 4; CMS Ex. 17, at 4, 10. Surveyors also found that R95 had also fallen recently and had "bleeding by the cath site," possibly related to excessive blood thinners, although the facility did not adequately assess the situation. CMS Ex. 27, at 40.

I need not find actual harm in order to sustain the finding of substantial noncompliance. Whenever a deficiency poses the potential for more than minimal harm, the facility is not in substantial compliance, and CMS has the authority to impose a remedy. Act, section 1819(h); 42 C.F.R. §§ 488.301, 488.402, 488.406. Failure to follow a valid physician's order almost inevitably presents the potential for more than minimal harm. *See, e.g., Premier Living and Rehab Center*, DAB No. 2146 (2008); *Barn Hill Care Center*, DAB No. 1848 (2002). Failure to clarify vague or conflicting physician orders almost inevitably presents the potential for more than minimal harm. *See, e.g., Hawthorne Inn of Danville*, DAB CR1801 (2008); *Rosewood Care Center of Peoria*, DAB No. 1912 (2004). Moreover, here, R95 was also taking the blood thinner, Coumadin. Exceeding the physician's order for an additional blood thinner (Heparin) placed R95 at increased risk for bleeding complications. *See, e.g., Rosewood Care Center of Peoria*, DAB No. 1912.

Because facility staff did not clarify inconsistent physician orders, and likely administered excessive Heparin doses, it failed to provide the care necessary for R95 to attain or maintain her highest practicable physical well-being and was not in substantial compliance with 42 C.F.R. § 483.25.

B. The amount of the CMP – $950 per day for 39 days – is reasonable.

I next consider whether the CMP was reasonable by applying the factors listed in 42 C.F.R. § 488.438(f): 1) the facility's history of noncompliance; 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 in 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 noncompliance; and 3) the facility's prior history of noncompliance in general and specifically with reference to the cited deficiencies.

CMS has imposed a penalty of $950 per day, which falls within the lower to mid-range for non-immediate jeopardy situations ($0 – $3000). 42 C.F.R. § 488.438(a)(1).

With respect to facility history, CMS points to multiple deficiencies cited during the facility's June 2006 survey, some of which were repeated at the time of the July 2007 survey. Notably, in June 2006, the facility was also not in substantial compliance with the quality-of-care regulation, 42 C.F.R. §§ 483.25 (Tag F309) and 483.25(h)(2) (Tag F324). Its violation of section 483.25(h)(2) was at a G level of scope and severity (isolated instance of noncompliance that causes actual harm that is not immediate jeopardy). CMS Ex. 26, at 1. During both surveys, deficiencies were cited under 42 C.F.R. §§ 483.20(d) and 483.20 (k)(1) (Tag F279 – comprehensive care plans). The June 2006 survey included multiple additional deficiencies at scope and severity levels D and E and one deficiency at a level H (pattern of noncompliance that causes actual harm but is not immediate jeopardy). *Id*.[5] CMS has thus established a significant history of noncompliance.

Petitioner has not argued that its financial condition affects its ability to pay the penalty.

With respect to the remaining factors, I note that the sheer number of deficiencies cited in July 2007, each of which poses the potential for more than minimal harm, justifies an increase in the penalty. In addition to the quality-of-care problems:

- facility management of patient funds was inadequate, violating 42 C.F.R. § 483.10(c)(2)-(5) (CMS Ex. 7, at 2-3);

- two residents were inappropriately restrained, violating 42 C.F.R. § 483.13(a) (CMS Ex. 7, at 3-5);

- staff did not ensure that one resident's call light would be within her reach, which is required by 42 C.F.R. § 483.15(e)(1) (CMS Ex. 7, at 5-7);

- surveyors cited a lengthy list of housekeeping and maintenance problems, 42 C.F.R. § 483.15(h)(2) (CMS Ex. 7, at 7-9);

- for two residents, the comprehensive assessments, required by 42 C.F.R. §§ 483.20 and 483.20(b), were inadequate (CMS Ex. 7, at 10-11);

[5] CMS's OSCAR (On-line Survey, Certification and Reporting System) Report does not include citations to regulations, but only to the tag numbers. Those cited in June 2006 were F164, F248, F274, F278, F279, F281, F309, F314, F324, F371, F431, and F469. CMS Ex. 26, at 1.

- two of the sampled residents had inadequate care plans, violating 42 C.F.R. §§ 483.20 and 483.20(k)(1) (CMS Ex. 7, at 12-14);

and

- medication errors were observed and documented, putting the facility out of compliance with 42 C.F.R. §§ 483.25(m)(1) and 483.25(m)(2).

Moreover, the facility's quality-of-care deficiencies caused R56 serious harm, and put R95 at significant risk. Staff's actions threatened resident comfort, health and safety, for which the facility is culpable. This, along with facility's significant substandard history, justifies the CMP imposed.

IV. Conclusion

For all of the reasons discussed above, I uphold CMS's determination that Petitioner was not in substantial compliance with program participation requirements and I find that the CMP imposed was reasonable.

/s/
Carolyn Cozad Hughes
Administrative Law Judge