Department of Health and Human Services

DEPARTMENTAL APPEALS BOARD

Civil Remedies Division

Altercare of Mentor,
(CCN: 36-6011),

Petitioner,

v.

Centers for Medicare & Medicaid Services.

Docket No. C-12-1165

Decision No. CR2870

Date: July 25, 2013

DECISION

In this case, I again consider a long-term care facility's obligation to prevent pressure sores. Specifically, must facility staff ensure that the elastic on a resident's underwear is not so tight that it puts the resident at risk?

Petitioner, Altercare of Mentor (Petitioner or facility), is a long-term care facility, located in Mentor, Ohio, that participates in the Medicare program. Based on a survey completed March 7, 2012, the Centers for Medicare & Medicaid Services (CMS) determined that the facility was not in substantial compliance with Medicare program requirements. CMS imposed a $3,200 per instance civil money penalty (CMP) for one of the cited deficiencies: 42 C.F.R. § 483.25(c) (quality of care: prevention and treatment of pressure sores). Petitioner appealed.

For the reasons set forth below, I find that the facility was not in substantial compliance with the quality of care requirements for the prevention and treatment of pressure sores and that the modest penalty imposed is reasonable.

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 § 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. Act § 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 § 1819(g)(2)(A); 42 C.F.R. §§ 488.20(a); 488.308.

Here, following a recertification survey completed March 7, 2012, CMS determined that the facility was not in substantial compliance with four Medicare participation requirements, specifically:

- 42 C.F.R. § 483.25(a)(2) (Tag F311 – quality of care: activities of daily living);
- 42 C.F.R. § 483.25(c) (Tag F314 – prevention/treatment of pressure sores);
- 42 C.F.R. § 483.25(h)(2) (Tag F323 – accident prevention); and
- 42 C.F.R. § 483.65 (Tag F441 – infection control).

CMS Ex. 13. CMS subsequently determined that the facility returned to substantial compliance on March 30, 2012, and imposed against the facility a $3,200 per instance CMP, based solely on the deficiencies cited under 42 C.F.R. § 483.25(c). CMS Ex. 1.

Petitioner timely requested a hearing.

On March 20, 2013, I held a hearing, via video teleconference, from the offices of the Departmental Appeals Board in Washington, D.C. Counsel and witnesses convened in Beechwood, Ohio. Transcript (Tr.) 4. Ms. Joan M. Zanzola appeared on behalf of CMS, and Mr. Christopher Tost appeared on behalf of the Petitioner.

I have admitted into evidence CMS Exhibits (CMS Exs.) 1-22 and Petitioner's Exhibits (P. Exs.) 1-4 and P. Ex. 6. Tr. 5-6; Summary of Prehearing Conference and Order at 2 (February 8, 2013). The parties have filed pre-hearing briefs (CMS Pre-hrg. Br.; P. Pre-

hrg. Br.), post-hearing briefs (CMS Post-hrg. Br.; P. Post-hrg. Br.) and CMS filed a reply brief (CMS Reply).

II. Issues

The issues before me are:

1. Was the facility in substantial compliance with 42 C.F.R. § 483.25(c) (Tag F314 – prevention/treatment of pressure sores); and

2. If the facility was not in substantial compliance with 42 C.F.R. § 483.25(c), is the penalty imposed -- $3,200 per instance -- reasonable?

III. Discussion

A. The facility was not in substantial compliance with 42 C.F.R. § 483.25(c) because it failed to take all necessary precautions to prevent pressure sores from developing.[1]

Program requirements. 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 § 1819(b); 42 C.F.R. § 483.25. To this end, the facility must (among other requirements) ensure that a resident who enters the facility without pressure sores does not develop them, unless his/her clinical condition shows that they were unavoidable, based on the resident's comprehensive assessment. 42 C.F.R. § 483.25(c)(1). If the resident has pressure sores, the facility must ensure that he/she receives the treatment and services necessary to promote healing, prevent infection, and prevent new sores from developing. 42 C.F.R. § 483.25(c)(2). In assessing the facility's compliance with this requirement, the relevant question is: did the facility "take all necessary precautions" to prevent new sores from developing. If they did so, and the resident develops sores anyway, I could find no deficiency. But if the evidence establishes that the facility fell short of taking all necessary precautions, then the regulation is violated. *Senior Rehab. and Skilled Nursing Ctr.*, DAB No. 2300 at 13-14 (2010), *aff'd , Senior Rehab. and Skilled Nursing Ctr.* v. HHS, No. 10-60241 (December 20, 2010); *Koester Pavilion*, DAB 1750, at 32 (2000).

[1] My findings of fact and conclusions of law are set forth, in bold and italics, as captions in the discussion section of this decision.

Resident 198 (R198). R198 was a 93-year-old woman, admitted to the facility on October 19, 2011, following surgical repair of a fractured hip. Her diagnoses included neuropathy, confusion, and muscular atrophy. Tr. 12-13; CMS Ex. 6 at 9. Among other problems, her mobility was impaired and she was incontinent of bowel and bladder. CMS Ex. 12 at 10; P. Ex. 1 at 1. She was dependent on staff to dress her, and at least two persons were required to complete that task. CMS Ex. 6 at 9; CMS Ex. 22 at 3 (Gilligan Decl. ¶ 8). At the time of her admission, she suffered from unhealed pressure sores on her right heel and left buttock. CMS Ex. 12 at 8. Facility staff recognized that she was at risk for further skin breakdown and, in a care plan dated October 28, 2011, listed some interventions (*e.g.*, dietary consultation; encouraging her not to "slide/scoot" when in bed or up in a chair; float heels in bed, etc.) geared toward preventing that. CMS Ex. 12 at 10; CMS Ex. 15 at 8-9.

In a nurse's note, dated November 20, 2011 at 4:28 p.m., Licensed Practical Nurse (LPN) David Moore documented a bruise on the resident's right inner thigh "consistent with brief positioning." The resident denied pain, but said "It's obviously from my underwear, but it wasn't hurting at all." CMS Ex. 12 at 1. According to the note, LPN Moore "educated" staff about the proper size of briefs and ensuring that briefs fit properly before placing the resident in her wheel chair. LPN Moore testified that he observed the area and determined that "the bruise was consistent with and likely caused by the elastic band from the resident's undergarment briefs." CMS Ex. 6 at 9; CMS Ex. 12 at 1; P. Ex. 4 at 2 (Moore Decl. ¶¶ 7, 8); *see* Tr. 45-46. Both parties attribute the bruise to the resident's ill-fitting underwear. P. Br. at 2.

According to nurses' notes, on November 23, 2011, the bruise was an open blister. CMS Ex. 6 at 9; CMS Ex. 12 at 4. On that day, staff began tracking the wound. Staff described it as "a Stage II pressure wound (partial thickness skin loss involving epidermis, dermis, or both) on her right inner thigh measuring 7.0 centimeters (cm) long by 0.5 cm wide by less than 0.1 cm deep." CMS Ex. 6 at 9-10.[2] According to the report,

[2] Pressure sores (also referred to as pressure ulcers or decubitus ulcers) are classified into stages, based on the extent of the damage to skin and underlying tissues. At stage I, the skin may appear reddened, *like a bruise*. Although the integrity of the skin remains intact, the area is at high risk of further breakdown, so it is crucial that the area be identified promptly and treated properly. At stage II, the skin breaks open, wears away, and forms an ulcer. At stage III, the sore worsens and extends beneath the skin surface, forming a small crater, presenting a high risk of tissue death and infection. By stage IV, deeper tissues (muscles, tendons, bones) suffer extensive damage, which can cause serious complications, such as osteomyelitis (infection of the bone) or sepsis (infection carried through the blood). *Journal of the American Medical Association*, Vol. 296, No. 8, at 1020 (available at www.jama.com).

the resident complained of pain at the wound site, at level 3 on a scale of 1 to 10. CMS Ex. 6 at 10; CMS Ex. 12 at 6.

On November 29, a registered nurse described "an elongated linear pressure, like a line that split open, area from elastic underwear sliding and pinching skin on thigh." The area was 14 cm X 0.3 cm X 0.1 cm and the most medial 6 cm had yellow slough; the remaining 8 cm was "beefy red granulation." No odor, no drainage, and the resident denied pain. CMS Ex. 12 at 2, 7.

Thereafter, R198 no longer wore the ill-fitting briefs. CMS Ex. 13 at 8. The facility promised that other residents wearing incontinence briefs would be fitted by a licensed nurse, using the Attends sizing guide, and the size would be included in the resident's care plan. CMS Ex. 13 at 8.

No one disputes that R198 was especially vulnerable to skin breakdown and the development of pressure sores. To prevent them, staff needed to be especially vigilant. Everyone agrees that wearing tight-fitting clothes increases the individual's risk for developing pressure ulcers. CMS Ex. 21 at 2. At a minimum, staff should have insured that her clothing fit properly and did not put her at risk. Tr. 38. At least two staff members dressed her every day, and numerous others changed her due to her incontinence. I find it inconceivable that staff would not have noticed that the elastic on her underwear was too tight, if they knew to check and if they knew how to check. Indeed, when LPN Moore checked the bruise on her inner thigh, he immediately identified the problem.

Petitioner now argues that, until the bruises appeared, facility staff were not obligated to identify ill-fitting underwear as a risk. P. Post-hrg. Br. at 2-3. I find no support for this position. That tight-fitting clothes increase the risk of pressure sores is well known. CMS Ex. 21 at 2. Surveyor Melissa Gilligan, who is a registered nurse, testified that staff should have ensured that R198's undergarments were not too tight. CMS Ex. 22 at 3 (Gilligan Decl. ¶ 8). She characterized as "routine" staff's checking the fit of undergarments when dressing a resident. Tr. 38. Petitioner's own witness agreed. In his testimony, LPN Moore conceded that staff were responsible for checking the fit of the resident's undergarments, but he claimed that they did so: "[E]very time she [was] dressed by anyone in the facility that's something that is checked for." Tr. 44. I did not find this claim credible. I see no other support for it in the record. R198's care plan did not instruct staff to check the fit of her underwear, and no records document that any one did so. The facility produced no in-service training records to show that it trained staff to check clothing for proper fit.

Moreover, LPN Moore made this claim for the first time under cross-examination. In his written direct testimony, he said that he observed the bruises on November 20, replaced the underwear with a larger size, discussed the issue with staff, and educated them

regarding the use of proper-sized briefs. He also said that, in the days following, he "personally monitored" the fit of R198's undergarments and he "routinely reminded facility staff regarding the need for proper fitting briefs." P. Ex. 4 at 2 (Moore Decl. ¶¶ 11, 12, 14). He never suggested that staff had been checking the fit all along.

Further, the evidence establishes that R198's hip was swollen following surgery. Tr. 48, 54. That alone should have triggered a reassessment as to the fit of her underwear. Underwear that may once have fit perfectly well would be too small if her hip and leg were swollen.

I am not persuaded that the facility avoids its responsibilities in this regard because the resident's son provided the underwear. He was not in a position to assess whether it fit properly; not only is he not a health care professional, charged with knowing the risks posed by tight elastic, he was not even in a position to know whether the underwear fit properly, since he did not dress or change his mother. As the Board determined in a similar context involving ill-fitting shoes provided by a resident's family:

> While it is understandable that a facility would wish to accommodate the preferences of a resident or his/her family members, the facility has an obligation under the regulations to take any necessary precautions to prevent pressure sores. Certainly, the facility cannot shift the blame for its inaction to the [family for] not providing different shoes at their request. The facility should accommodate the family's preferences as much as possible, but must still take necessary measures to prevent the predictable consequences of pressure sores.

Koester Pavilion, DAB No. 1750 at 15. Unlike the family in *Koester*, who very much insisted that she wear the shoes they provided, no evidence suggests that R198 or her family had any objections to changing the size of her undergarments.

Nor am I persuaded that the facility could not have been expected to act earlier because R198 did not complain about her underwear and, until November 20, she displayed no visible markings. As CMS points out, R198 suffered from neuropathy, which, as the facility well knew, can cause numbness. CMS Ex. 22 at 3 (Gilligan Decl. ¶ 6). She was unable to tell when she was urinating (Tr. 49); when the bruise appeared, she denied pain (CMS Ex. 12 at 1); even when she had an open split along her thigh, she apparently experienced no pain. CMS Ex. 12 at 2, 7. Nor could she even be expected to recognize that the elastic around her thighs was too tight; many people regularly wear tight clothing without recognizing that it does not fit properly.

Petitioner also points out that R198's care plan included interventions aimed at preventing pressure sores. No one has suggested that these were not appropriate.

However, by themselves, they were not adequate to prevent pressure sores from developing. *See Bradford County Manor*, DAB No. 2181 at 20 (2008).

I agree that, at a minimum, staff should have ensured that R198's undergarments fit properly. Failing to do that meant that they were not "taking all necessary precautions" to prevent new sores from developing. The facility was therefore not in substantial compliance with 42 C.F.R. § 483.25(c).

B. The penalty imposed -- $ 3,200 per instance -- is reasonable.

To determine whether a CMP is reasonable, I apply 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.

I consider whether the evidence supports a finding that the amount of the CMP is at a level reasonably related to an effort to produce corrective action by a provider with the kind of deficiencies found, and in light of the section 488.438(f) factors. I am neither bound to defer to CMS's factual assertions, nor free to make a wholly independent choice of remedies without regard for CMS's discretion. *Barn Hill Care Ctr.*, DAB No. 1848 at 21 (2002); *Cmty. Nursing Home*, DAB No. 1807 at 22 *et seq*. (2002); *Emerald Oaks*, DAB No. 1800 at 9 (2001); *CarePlex of Silver Spring*, DAB No. 1638 at 8 (1999).

Here, the penalty imposed -- $ 3,200 per instance -- is at the low end of the penalty range for per-instance CMPs ($1,000-$10,000). 42 C.F.R. §§ 488.408(d), 488.438(a)(2).

The facility has a less-than-stellar history, and this was a repeat deficiency. In November 2009, it was not in substantial compliance with the same regulation, 42 C.F.R. § 483.25(c) (Tag F314). Nor was it then substantially compliant with 42 C.F.R. § 483.25(h) (Tag F323 – accident prevention). In January 2011, it was not in substantial compliance with two regulations: 42 C.F.R. § 483.15(a) (Tag F241—dignity and respect) and 42 C.F.R. § 483.65 (Tag F441 – infection control). CMS Ex. 17. The facility's history alone is sufficient to justify this modest CMP.

Petitioner does not claim that its financial condition affects its ability to pay this small CMP.

With respect to the remaining factors, I find it more likely that facility staff acted (or failed to act) out of ignorance rather than malice or indifference. I see no evidence that, prior to November 20, anyone told staff how important it is that the residents' clothes fit properly. Staff were simply not aware of the potential damage that tight elastic can cause. For not properly training its staff, the facility is culpable.

For these reasons, I find the penalties imposed reasonable.

IV. Conclusion

CMS properly determined that the facility was not in substantial compliance with 42 C.F.R. § 483.25(c) and I affirm, as reasonable, the penalty imposed.

/s/
Carolyn Cozad Hughes
Administrative Law Judge