

Department of Health and Human Services

DEPARTMENTAL APPEALS BOARD

Civil Remedies Division

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In the Case of:)	
)	
Senior Rehabilitation & Skilled)	Date: May 18, 2009
Nursing Center (CCN: 67-5541),)	
)	
Petitioner,)	
)	
- v. -)	Docket No. C-08-755
)	Decision No. CR1953
Centers for Medicare & Medicaid)	
Services.)	
_____)	

DECISION

Petitioner, Senior Rehabilitation & Skilled Nursing Center (Petitioner or facility), is a nursing facility located in Port Arthur, Texas, that participates in the Medicare program. Based on a complaint investigation/survey completed June 12, 2008, by the Texas Department of Aging and Disability Services (State Agency), the Centers for Medicare & Medicaid Services (CMS) determined that, from June 2 through July 15, 2008, the facility was not in substantial compliance with program participation requirements, and imposed a civil money penalty (CMP) of \$800 per day for each day of substantial noncompliance (total CMP \$35,200). Petitioner appeals, and CMS now moves for summary judgment.

For the reasons discussed below, I find that summary judgment is appropriate. Based on undisputed facts, I conclude that the facility was not in substantial compliance with Medicare requirements governing notification of changes, 42 C.F.R. § 483.10(b)(11), and prevention of pressure sores, 42 C.F.R. § 483.25(c). I affirm as reasonable the penalties imposed.

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 complaint investigation/survey completed June 12, 2008, CMS determined that the facility was not in substantial compliance with Medicare participation requirements, specifically:

- 42 C.F.R. § 483.10(b)(11) (Tag F157 – resident rights: notification of changes);
- 42 C.F.R. § 483.25(c) (Tag F314 – quality of care: pressure sores); and
- 42 C.F.R. § 483.25(a)(3) (Tag F312 – quality of care: activities of daily living).

CMS subsequently determined that the facility returned to substantial compliance on July 16, 2008. CMS Exs. 1, 3; P. Exs. 1, 2, 5.

CMS has imposed against the facility a CMP of \$800 per day for the period of substantial noncompliance (44 days x \$800 = \$35,200).

Petitioner timely requested a hearing. CMS has moved for summary judgment, which Petitioner opposes. With its motion and brief, CMS has submitted 14 exhibits (CMS Exs. 1-14). With its response, Petitioner has submitted 29 Exhibits (P. Exs. 1-29).

II. Issues

I consider first whether summary judgment is appropriate.

On the merits, the issues before me are: 1) whether, from June 2 through July 15, 2008, the facility was in substantial compliance with 42 C.F.R. §§ 483.10(b)(11); 483.25(c); and 483.25(a)(3); and 2) if the facility was not in substantial compliance, was the penalty imposed, \$800 per day, reasonable?

III. Discussion

A. Because the undisputed facts establish that facility staff did not immediately consult an attending physician when Resident 26 experienced rapid weight loss nor when the facility’s dietary consultant recommended a change in treatment, the facility was not in substantial compliance with 42 C.F.R. § 483.10(b)(11), and CMS is entitled to summary judgment on that issue.

Summary judgment is appropriate if a case presents no genuine issue of material fact and one party is entitled to judgment as a matter of law. The moving party may show the absence of a genuine factual dispute by presenting evidence so one-sided that it must prevail as a matter of law, or by showing that the non-moving party has presented no evidence “sufficient to establish the existence of an element essential to [that party’s] case, and on which [that party] will bear the burden of proof at trial.” *Livingston Care Center v. U.S. Dep’t. of Health & Human Services*, 388 F.3d 168, 173 (6th Cir. 2004) (quoting *Celotex Corp. v. Catrett*, 477 U.S. 317, 322 (1986)). To avoid summary judgment, the non-moving party must then act affirmatively by tendering evidence of specific facts showing that a dispute exists. *Matsushita Elec. Indus. Co. v. Zenith Radio Corp.*, 475 U.S. 574, 586, n.11 (1986); *see also Vandalia Park*, DAB No. 1939 (2004); *Lebanon Nursing and Rehabilitation Center*, DAB No. 1918 (2004). In examining the evidence for the purposes of determining the appropriateness of summary judgment, I must draw all reasonable inferences in the light most favorable to the non-moving party. *Livingston Care Center*, 388 F.3d at 172; *Guardian Health Care Center*, DAB No. 1943, at 8 (2004). However, drawing inferences in the light most favorable to the non-moving party does not require that I accept the non-moving party’s legal conclusions. *Cf. Guardian Health Care Center*, DAB No. 1943, at 11 (“A dispute over the conclusions to be drawn from applying relevant legal criteria to undisputed facts does not preclude summary judgment if the record is sufficiently developed and there is only one reasonable conclusion that can be drawn from those facts.”).

In this case, CMS alleges as undisputed fact – and presents evidence to establish – that the facility impermissibly delayed consulting a treating physician whose extremely vulnerable patient lost almost 10% of her body weight in a month. CMS also alleges as undisputed fact – and presents evidence to establish – that the facility failed to consult the treating physician about its consulting dietician’s recommendations for treatment changes. In CMS’s view, the facility’s inaction violated the regulation governing notification of changes, which mandates that the facility *immediately* consult a resident’s physician whenever there is a significant change in the resident’s physical, mental, or psychosocial status (i.e., a deterioration in health, mental, or psychosocial status in either life-threatening conditions or clinical complications); or a need to alter treatment significantly (i.e., a need to discontinue an existing form of treatment due to adverse consequences or to commence a new form of treatment). 42 C.F.R. § 483.10(b)(11).

Specifically, CMS alleges the following facts:

Resident 26 (R26) was a 72-year-old woman suffering from organic brain syndrome, dysphagia, hypertension, and convulsions. She had a history of stroke. She had a gastric feeding tube (g-tube) in place, through which she received all of her nutrition, hydration, and medications. CMS Ex. 6, at 6, 10, 17. She was at high risk for pressure sores, and, in April 2008, had a stage IV pressure sore on her coccyx, and another pressure sore on her right lower back, which was apparently unstageable because it was obscured by eschar.¹ CMS Ex. 6, at 6, 11, 21, 39, 40; P. Ex. 12.

Facility staff weighed R26 monthly. Her weight dropped from 93.6 pounds in March 2008, to 84.6 pounds in April 2008. CMS Ex. 6, at 9.² Staff notified the facility's consulting dietician of the weight loss. In a dietary progress note dated April 17, 2008, the dietician noted R26's significant weight loss, and her pressure sores, and recommended the following treatment change: increase her nutritional intake and hydration from "Jevity 1.5 @ 60 ml x 18 [hours]" to "Jevity 1.5 @ 62 ml x 18 [hours]."³ The consulting dietician reminded staff to turn on the resident's feeding tube "in a timely manner," and recommended that she be weighed weekly, rather than monthly. CMS Ex. 6, at 6-7.

¹ 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). John L. Zeller, MD, PhD, *Pressure Ulcers*, 296 J. AM. MED. ASS'N 1020 (2006), available at www.jama.com (follow link to Past Issues); CMS Ex. 9, at 4. Eschar is a slough, or piece of dead tissue, like a scab.

² R26's quarterly assessment, signed April 23, 2008, correctly reports R26's weight at 85 pounds, but incorrectly and inexplicably denies weight loss of 5% or more in the preceding 30 days, and denies weight loss of 10% or more in the preceding 180 days. Compare CMS Ex. 6, at 17, with CMS Ex. 6, at 9. The regulations require that assessments be accurate. 42 C.F.R. § 483.20. CMS has not cited a deficiency under section 483.20.

³ Jevity is a fiber-fortified, calorically dense, tube-feeding formula. For 18 hours each day, R26 was supposed to receive 60 milliliters of the formula per hour. The dietician recommended that the hourly amount be increased to 62 milliliters.

No one told R26's attending physician about her weight loss or the dietician's recommendations until almost three weeks later, on May 7, 2008. CMS Ex. 6, at 8. In the meantime the dietician's recommendations were ignored. R26's care plan was not amended to address the weight loss problem until May 6, and the new care plan was obviously developed without regard to the dietician's recommendations and without attending physician input (since the physician had not yet been notified of the problem). CMS Ex. 6, at 36.

Petitioner tenders no evidence showing that a factual dispute exists with respect to its fulfilling its obligation to consult R26's attending physician about her weight loss and the dietician's recommendations. In fact, Petitioner's evidence confirms CMS's factual assertions. Petitioner submits an affidavit from Dr. William George, R26's attending physician, who confirms that *on May 7, 2008*, the facility "apprised" him of R26's weight loss and of the dietician's April 17 report and recommendation. P. Ex. 28 (George Decl.).

Dr. George opines, and Petitioner argues, that the facility "appropriately communicated" and "reasonably and timely informed" him about R26's care needs and changes in condition. P. Brief (Br.) at 7; P. Ex. 28 (George Decl.).⁴ These are conclusions that I need not accept for purposes of summary judgment. *See Guardian Health Care Center*, DAB No. 1943, at 11. And, to the contrary, the only reasonable conclusion to be drawn from the undisputed fact that facility staff delayed three weeks in notifying Dr. George is that the facility did not meet the regulatory requirement. A three-week delay is simply unacceptable, particularly when the resident involved is as compromised as R26. "Immediately" means "as soon as the change . . . is detected, without any intervening interval of time." *Magnolia Estates Skilled Care*, DAB No. 2228, at 8 (2009); *The Laurels at Forest Glenn*, DAB No. 2182, at 13 (2008).

Further, Petitioner does not allege that it did anything other than "communicate" or "inform" Dr. George. Simply communicating the information does not satisfy the regulatory requirement to "consult" the treating physician. As the Departmental Appeals Board ruled in *Magnolia Estates*, consultation requires more than just informing or notifying the physician.

Consultation . . . requires a dialogue with and a responsive directive from the resident's physician as to what actions are needed; it is not enough to merely notify the physician of the resident's change in condition. Nor is it enough to leave just a message for the physician.

DAB No. 2228, at 9.

⁴ Petitioner does not argue that the changes in R26's condition were not "significant," as indeed they were. *See The Laurels at Forest Glenn*, DAB No. 2182, at 11-12.

The undisputed facts establish that the facility amended R26's care plan to address the weight loss without physician consultation and without regard to the dietician's recommendations, which may explain why the revised plan does not seem to address the needs of a resident who receives nutrition through a g-tube.⁵ Some of its instructions are general: "supervise and maintain residents [sic] safety and well being"; "notify family and encourage family to participate in plan of care"; "notify family and physician of abnormalities or difficulties observed and follow physicians [sic] orders." Other instructions – "monitor meal consumption" and "offer supplemental nutrition if resident consumes less than 50% of meal" – plainly apply to an individual who is able to eat her meals, not to R26, who received all of her nutrition through a g-tube and had no control over her meal consumption. Ironically, the most relevant provisions of the plan (besides notifying the physician of abnormalities) were "obtain dietary consult if needed" and "assess for need to change dietary consistency." CMS Ex. 6, at 36.

Petitioner does not explain who decided or how that person or persons decided to reject the treatment changes recommended by the health care professional with special expertise in nutrition, but justifies its disregard of the dietician's recommendations by arguing that R26 "was already receiving more than adequate nutrition to meet her daily needs without the recommended increase of 2 ml of feeding per hour." P. Br. at 8; P. Ex. 29, at 2 (Banks Decl. ¶ 5).⁶ I accept these assertions as true for purposes of summary judgment, but I do not find them material. R26's physician (along with the interdisciplinary team charged with planning her care) might well have had sound reasons for rejecting the dietician's recommendations. However, failing to consult R26's attending physician about her dramatic weight loss risked her health and safety and presented the potential for more than minimal harm. Further, while fortuitous that Dr. George ultimately concurred (at least temporarily)⁷ with the actions (or inaction) taken by

⁵ The facility must develop for each resident an individualized comprehensive care plan describing services that are to be furnished to attain or maintain the resident's highest practicable physical, mental, and psychosocial well-being. The plan must be prepared by an interdisciplinary team *that includes the attending physician*, a registered nurse, and other appropriate staff (which could include a dietician). 42 C.F.R. § 483.20(k). CMS has not cited a deficiency under the care planning regulation. *But see* CMS Ex. 12, at 6 (McElroy Decl. ¶ 6) (in which CMS nurse consultant Daniel McElroy, R.N., points to need for "consultation with her physician for more nutrition and revision of her nutrition care").

⁶ *But see* CMS Ex. 6, at 47, 49 (Even before her dramatic weight loss, R26's care plan directs staff to "improve nutrition," an instruction that was ignored, and, based on Petitioner's assertions here, erroneous.).

⁷ A physician's order dated June 2, 2008, increases feeding to "62 cc/hr per dietary recommendation." CMS Ex. 6, at 62.

facility staff without his knowledge or approval, staff plays a dangerous game when it rejects an expert's recommendation without input from the attending physician. I find that such action poses a risk to resident health and safety and presents the potential for more than minimal harm.

The undisputed facts thus establish that the facility did not immediately consult the resident's attending physician following a significant change in her condition, and the facility was therefore not in substantial noncompliance with 42 C.F.R. § 483.10(b)(11). CMS is entitled to summary judgment on that issue.

B. The uncontroverted evidence establishes that staff did not consistently follow care plan instructions and that staff allowed a vulnerable resident to lie for up to two hours on a urine and feces contaminated incontinent pad. The facility was therefore not taking all necessary precautions to promote healing, prevent infection, and prevent new pressure sores from developing, as required by 42 C.F.R. § 483.25(c), and CMS is entitled to summary judgment on that issue.

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. The regulation further requires that the facility ensure, based on the resident's comprehensive assessment, that a resident who enters the facility without pressure sores does not develop them unless his/her clinical condition shows that they were unavoidable. 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. *Koester Pavilion*, DAB 1750, at 32 (2000).

The prevention or healing of pressure ulcers requires scrupulous and continuous attention to minimizing compression and shearing pressures, avoiding maceration from continuous moisture and contact with the skin-erosive contents of urine, feces and bacteria while maximizing blood flow, hydration and nutrition.

CMS Ex. 12, at 4 (McElroy Decl. ¶ 6).

CMS's allegations of noncompliance with section 483.25(c) center around the care provided to R26 and two other residents, R100 and R92. Because the deficiencies in the care provided to R26, by themselves, justify the penalties imposed, I do not address the citations relating to the other two residents. *See Batavia Nursing and Convalescent Center*, DAB No. 1904, at 23 (2004); *Beechwood Sanitarium*, DAB No. 1824, at 19 (2002) (within the ALJ's discretion to limit his decision to findings necessary to support the remedies imposed).⁸

As discussed above, R26 was assessed at high risk for pressure sores. CMS Ex. 6, at 21, 31; P. Ex. 12. When re-admitted to the facility in January 2008, she had pressure sores on her coccyx and left inner knee. Among other approaches, her care plan, which was originally dated January 24, 2008, with the date changed monthly thereafter, called for an indwelling catheter "to promote wound healing [due to] unstageable decub[itus] to coccyx." CMS Ex. 6, at 31, 32; P. Ex. 13, at 3.

The ulcer on R26's coccyx did not heal, and, over time, she developed additional sores. By April, she had developed a "nonstageable" (defined as "full thickness tissue loss in which the base of the ulcer is covered by slough . . . and/or eschar . . . in the wound bed") pressure sore on her right lower back. CMS Ex. 6, at 48, 49, 52. That wound did not heal either. At the time of the June survey, R26 also had stage II pressure sores on her left and right hips (CMS Ex. 6, at 43, 58; CMS Ex. 13, at 2), a stage II pressure sore on her left elbow (CMS Ex. 6, at 44; CMS Ex. 13, at 2), and a stage I pressure sore on her left lateral foot (CMS Ex. 6, at 45).

In his declaration, Dr. George opines that "the development of [R26's] skin wounds located on her feet, left elbow, hips and coccyx were medically unavoidable due to her compromised circulation and other underlying diseases." P. Ex. 28 (George Decl.).⁹ For purposes of summary judgment, I accept that R26's pressure sores were clinically unavoidable. However, this fact does not relieve the facility of its obligation, under the regulation, to provide care and services necessary to promote healing, prevent infection, and prevent other pressure sores from forming.

Citing testimony from Lisa Jackson, R.N., the facility's quality assurance nurse, Petitioner also asserts that staff conducted risk assessments, completed care plans which set forth goals and interventions, and then monitored the wounds to determine the plans' effectiveness. P. Br. at 10, 11; P. Ex. 27, at 3 (Jackson Decl. ¶ 7). CMS does not dispute the existence of some assessments and care plans, and I accept that the facility developed

⁸ For the same reason, I decline to address the deficiencies cited under 42 C.F.R. § 483.25(a)(3).

⁹ Dr. George does not include in this list the pressure sore on R26's right lower back. I assume the omission was simply an oversight.

multiple care plans to address R26's susceptibility to pressure sores. CMS criticizes the quality of the assessments and plans. As the discussion below establishes, facility assessments and care plans were often incomplete, and occasionally inconsistent, but, for purposes of summary judgment, I accept that they were adequate. *But see* CMS Ex. 12, at 4 (McElroy Decl. ¶ 6) (minimum assessment includes staging, measurement of size, exudate, wound bed characteristics, pain, surrounding skin and tunnel/sinus tract formation). Nevertheless, undisputed evidence establishes that the facility was not in substantial compliance because its staff did not consistently follow the instructions in those plans.

January 2008 assessments and plans. In addition to calling for an indwelling catheter, R26's January 24, 2008 plan directs staff to: provide incontinent care every two hours *and as needed*; insure that the resident is turned and repositioned every two hours and as needed; reinforce proper positioning with pillows if necessary; conduct ongoing assessment of skin for signs and symptoms of redness or breakdown; and notify the attending physician as necessary. The plan sets as a goal that the "res[ident] will not have skin breakdown x 90 days." CMS Ex. 6, at 31.

Specifically addressing her then-existing ulcers, the plan also sets as a goal that R26's "ulcer will be free of drainage and show signs of healing x 90 days" (i.e., by late April 2008). Approaches listed are: administer treatment as ordered by the attending physician; maintain good infection control when dealing with ulcers; monitor for drainage, odor; encourage good dietary intake to promote wound healing;¹⁰ monitor labs as ordered; resident to be out of bed daily as tolerated; turn and reposition resident every two hours and as needed; and notify the attending physician as indicated. CMS Ex. 6, at 32.

Finally, the care plan notes that R26 is incontinent of bowel, and does not voice the urge to have a bowel movement because she no longer talks. It sets as a goal that she "will remain clean and odor free for the next 90 days." Approaches listed are: closely supervise to maintain resident safety and well being; encourage family to participate in plan of care; answer resident's summons to room promptly; *check resident frequently for incontinence and provide incontinent care as needed; frequently assess skin* for signs and symptoms of breakdown or injury and treat according to physician orders; maintain resident's dignity and explain what you are going to do; and provide incontinent care every two hours *and as needed*. CMS Ex. 6, at 35.

April 2008 assessments and plans. The January care plans did not achieve their stated goals – no skin breakdown; drainage-free with signs of healing – because, by April 2008, R26's coccyx ulcer had deteriorated, and she had developed a new pressure ulcer on her

¹⁰ Again, since R26 was wholly dependent on a g-tube for her nutrition, the instruction that staff "encourage good dietary intake" does not seem relevant to her.

lower right back. A care plan, dated April 4, 2008, identifies as a problem “pressure ulcer(s) right lower back.” The goals set are: that the pressure ulcer show signs of healing and that pressure ulcer risk will be minimized, with a target date of July 4, 2008. The approaches are listed as reposition every two hours, treat with Accuzyme, *assess wound daily*, and notify MD/RP of any change in status. CMS Ex. 6, at 40.

With respect to the ulcer on R26’s coccyx, the record contains no corresponding assessment, but a care plan, dated April 11, 2008, sets as goals, that the pressure ulcer show signs of healing and that pressure ulcer risk will be minimized, with a target date of July 11, 2008. The approaches listed are: reposition (although the space for indicating frequency for repositioning is left blank); treat with Sorbsan; “*assess wound daily*”; and “notify MD/RP of any change in status.” CMS Ex. 6, at 39 (emphasis added).

Both wounds were re-assessed on April 17, 2008. An April 17 assessment worksheet describes the wound on R26’s right lower back as yellow, brown and black, and “not stageable.” It measures 1.9 cm long, 2.0 cm wide. It has eschar/slough and scant serous drainage. CMS Ex. 6, at 48. The assessment characterizes the wound as “acute non-surgical (duration less than 6 wks).” Treatment goals are underlined on the form: pressure redistribution, control bioburden, improve nutrition,¹¹ promote circulation, and promote granulation/contraction/re-epithelialization. CMS Ex. 6, at 49.

An April 17 wound assessment describes the coccyx wound as a red/pink stage III wound, 9 cm long, 8.5 cm wide, and 0.4 cm deep, with moderate serosang (blood and serum) drainage, without odor, eschar, undermining or tunneling. CMS Ex. 6, at 46. According to the assessment, the wound is “chronic” but “improving.” The treatment goals underlined are the same treatment goals as for the right lower back wound. CMS Ex. 6, at 47.

Additional assessments are dated April 25. The right lower back wound is larger than before, 5.6 cm long by 2.5 cm wide, and the treatment goals are the same with the addition of “decrease or remove necrotic tissue.” CMS Ex. 6, at 52-53. The coccyx wound assessment describes that wound as a red and pink stage III pressure sore, measuring 7.5 cm long, 7.5 cm wide and 0.4 cm deep with moderate serosang drainage. CMS Ex. 6, at 50. The earlier treatment goals are repeated, with the addition of “decrease or remove necrotic tissue.” CMS Ex. 6, at 51.

May 2008 assessments and plans. A May 2 assessment measures the right lower back wound at 5.2 cm long, 3.0 cm wide, and describes it as yellow and black. CMS Ex. 6, at 54. The treatment goals remain the same except that the goal to “decrease or remove

¹¹ Thus, according to the care plan, R26’s nutrition needed improvement, a fact that is at odds with Petitioner’s articulated position, discussed above, that no changes in nutrition were necessary.

necrotic tissue” has not been underlined. CMS Ex. 6, at 55; *see* CMS Ex. 11, at 3. A document dated May 2, labeled “weekly skin report,” which lists pressure ulcers, records the size of the coccyx wound as 6.0 x 7.8 x 0.4. CMS Ex. 11, at 3.

Petitioner submits a virtually unreadable copy of a May 5 assessment of R26’s lower back wound. P. Ex. 15, at 1. A second May 5 assessment describes the coccyx wound as at stage III, with moderate serosang drainage. The wound depth is 0.3 cm deep, but the length and width are not decipherable on the copy submitted. P. Ex. 15, at 5. A final May 5 assessment describes a right hip wound as red and pink, measuring 2.9 x 3.4, without drainage. The assessment does not stage the wound. P. Ex. 15, at 9.

The May 16 weekly skin report says the pressure ulcer on R26’s right lower back is 3.5 x 5.3 x 0, and the coccyx ulcer is 6.2 x 8.5 x 0.3. CMS Ex. 11, at 9. It does not mention a hip wound.

An assessment dated May 16 of R26’s lower back wound is also difficult to read, but seems to indicate that the wound is unstageable and has scant serous drainage. Its measurements are not decipherable. P. Ex. 15, at 2. The coccyx wound assessment, dated May 16, puts the wound at stage IV, measuring 6.5 x (an unreadable width) x 0.3. P. Ex. 15, at 6.

The May 23 skin report lists the dimensions for the lower back ulcer as 3.5 x 5.3 x 0, and describes the coccyx ulcer at 5.4 x 8.5 x 0.3. CMS Ex. 11, at 12.

Petitioner submits additional assessments, apparently dated May 22 and May 29, although the dates are difficult to read. P. Ex. 9. On May 22, the coccyx wound was assessed at stage IV and measured 5.4 x 8.5. It was red, with a small amount of serosang drainage. P. Ex. 9, at 1; P. Ex. 15, at 7. The lower back wound was not stageable. It measured at 5.4 x 2.9 and was red and yellow with a small amount of serosang drainage. P. Ex. 9, at 3. For May 29, the coccyx wound assessment does not indicate a stage, but says that the wound measures 5.7 x 7.7 with moderate serosang drainage. P. Ex. 9, at 2; P. Ex. 15, at 8. The lower back wound is assessed as unstageable and measures 5.0 x 3.4 with a small amount of serosang drainage. P. Ex. 9, at 4; P. Ex. 15, at 4. Petitioner also submits a May 29 assessment of the wound on R26’s right hip, which describes the wound as pink, measuring 3.1 x 4.0, with scant serosang drainage. No staging information is provided. P. Ex. 9, at 5; P. Ex. 15, at 10.

June 2008 assessments and plans. According to CMS, R26 had additional wounds that were neither identified nor properly assessed until pointed out by one of the surveyors. In her written declaration, Surveyor Deena Gill, R.N., asserts that on June 2, she found R26 with unreported pressure sores on her feet, her left elbow, and both hips. CMS Ex. 13, at 2 (Gill Decl.). Petitioner does not exactly deny the assertion, but offers Nurse Jackson’s declaration that “there would have not been weekly skin assessments for the areas on the elbow, the left hip and the feet since these areas were new.” P. Ex. 27, at 2 (Jackson

Decl. ¶ 4). R26's care plan is ambiguous about how frequently staff were supposed to perform skin checks, calling for "ongoing assessment of skin," and instructing staff to "frequently assess skin." CMS Ex. 6, at 31, 35. Drawing every inference in the light most favorable to the non-moving party, I allow that a weekly skin assessment could be consistent with R26's care plan for skin assessments, and I accept as true the prospect that not one of the four additional wounds listed by Nurse Jackson was detectable on or before May 23, the date of the last weekly skin assessment prior to the surveyor observations on June 2.

But Nurse Jackson does not mention the right hip wound, which was first described in an assessment dated May 5. P. Ex. 15, at 9. That wound was apparently not assessed weekly, since it is not mentioned again until the May 29 assessment. P. Ex. 9, at 5; P. Ex. 15, at 10. Further, a weekly skin report, dated June 6, 2008, lists a "right hip abrasion" measuring 3.1 x 4.0 x 0.1, along with sores on her coccyx and right back, and says that the hip sore was found on *April 28*. CMS Ex. 11, at 14. Nevertheless, the hip sore was not mentioned in the earlier weekly reports of May 2, May 9, May 16, and May 23, which suggests that staff were not adequately conducting weekly skin assessments in accordance with R16's care plan. CMS Ex. 11, at 3, 6, 9, 12.

More significant, however, R26's care plan also required that staff assess *daily* the pressure sores on her lower back and coccyx. CMS Ex. 6, at 39, 40. Petitioner presents no evidence – indeed does not claim – that staff followed the care plans in this regard. *See* P. Br. at 9; P. Ex. 29, at 3-4 (Banks Decl. ¶ 7) ("weekly skin assessments were conducted and acted upon."). The undisputed evidence establishes that the facility was not taking all necessary precautions to prevent pressure sores because staff plainly did not follow R26's care plan instructions to assess those wounds daily.

With respect to the dangers posed by R26's incontinence, her care plans call for an indwelling catheter and instructs staff to provide incontinent care every two hours *and as needed*. CMS Ex. 6, at 31, 35. Staff are also instructed to "check resident *frequently* for incontinence and provide incontinent [sic] care *as needed*" and to "*maintain good infection control* when dealing with ulcers." CMS Ex. 6, at 32, 35 (emphasis added).

Surveyor Gill testified that on June 2 she observed R26 lying on a wet incontinent pad with drying feces on her buttocks. CMS Ex. 13, at 3 (Gill Decl.); *accord* CMS Ex. 3, at 12 (R26 observed on wet incontinent pad with drying brown edges); CMS Ex. 4, at 1 ("smells like urine"; "cold wet BM on buttocks"). Petitioner does not dispute the surveyor observation, but argues that, so long as staff provided incontinent care every two hours, it complied with facility protocols and sound nursing practice. According to Director of Nursing, Dana Banks, R.N.:

The surveyors state Resident 26 was laying [sic] on an incontinent pad that had a drying brown ring and foul urine odor, and Resident 131 had a wet

incontinent pad with drying feces. These circumstances do not necessarily indicate the facility failed to provide incontinent care within a two hour period. The words “drying” and “wet” used to describe the urine, feces and brown ring indicates [sic] the bowel movements or urine could have just as easily been a recent occurrence (i.e. less than two hours old).

P. Ex. 29, at 3 (Banks Decl. ¶ 6); *see* P. Br. at 8.

Thus, in Petitioner’s view, the facility may allow a resident, even someone as compromised as R26, to lie in urine and feces for up to two hours at a time without running afoul of the requirement that it take all necessary precautions to promote healing, prevent infection, and prevent new sores from developing. I disagree.

Petitioner has not explained how R26 ended up on a wet incontinent pad in the first place. An indwelling catheter was in place to prevent that from happening. CMS Ex. 6, at 16 (indwelling catheter in place “that does not leak urine”). R26’s care planners recognized that such a catheter put her at significant risk of infection, but determined that the dangers posed by exposing her skin to urine outweighed the considerable danger of a urinary tract infection (UTI). CMS Ex. 6, at 31; *see* CMS Ex. 6, at 32, 38 (“decline since hospital stay with UTI”). Facility policy required that staff “[m]ake sure that there is no disconnection or leaking of urine from the [catheter] system (except into the drainage bag).” CMS Ex. 9, at 7 (emphasis added). But staff obviously did not do so. As a result, R26 suffered the significant risk of a UTI, without deriving the anticipated benefit of clean, dry skin.

Moreover, R26 could not safely be exposed to urine and/or feces for any significant period of time, and neither facility policy nor her care plan allowed for such ongoing exposure. Facility policy instructed staff to “[c]lean skin as soon as soiled.” CMS Ex. 9, at 2. Although both the facility’s written policy and R26’s care plans instructed staff to check the incontinent resident at least once every two hours, they also consistently said that she should be checked “frequently,” provided care “as needed,” and that staff should maintain “good infection control when dealing with ulcers.” CMS Ex. 6, at 31, 32, 35; CMS Ex. 9, at 8.

Pressure ulcers are made worse by moisture, and by irritating substances, such as feces and urine, on the resident’s skin. CMS Ex. 9, at 1. Stage III and stage IV pressure ulcers are further damaged by contact with acidic urine and the enzymes in feces. Bacteria from feces can readily infect the wounds. CMS Ex. 12, at 4 (McElroy Decl. ¶ 6). R26 had a pressure sore on her coccyx the size of a soft ball, and that sore was “tunneling.” CMS Ex. 3, at 12; CMS Ex. 6, at 56.¹² She was at high risk for infection. Far from “providing

¹² Staff did not notify Dr. George of the tunnels – the crater beneath the skin surface, which creates a high risk of tissue death and infection – until June 2, the first day of the survey. CMS Ex. 6, at 12.

treatment and services necessary to promote healing, prevent infection, and prevent new sores from developing,” the facility’s allowing R26 to lie in urine and feces for up to two hours at a time significantly increased her risk of infection and developing new sores. The facility was therefore not in substantial compliance with 42 C.F.R. § 483.25(c).

C. The penalties imposed are reasonable.

I next consider whether the CMP is 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.

In reaching a decision on the reasonableness of the CMP, 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 above 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 Center*, DAB No. 1848, at 21 (2002); *Community Nursing Home*, DAB No. 1807, at 22 *et seq.* (2002); *Emerald Oaks*, DAB No. 1800, at 9-10 (2001); *CarePlex of Silver Spring*, DAB No. 1683, at 8 (1999).

CMS has imposed a penalty of \$800 per day for the period of substantial noncompliance, which is at the low end of the penalty range (\$50-\$3000). 42 C.F.R. § 488.438(a)(1).

With respect to the facility history, CMS Nurse Consultant, Captain (Ret.) Daniel J. McElroy R.N. characterizes this as the facility’s “sixth noncompliance cycle,” and the first enforcement action since April 2005. He points out that, during an April 30, 2008 survey, surveyors also found a pattern of noncompliance with 42 C.F.R. § 483.10(b)(11) that caused no actual harm, but with the potential for more than minimal harm. CMS Ex. 12, at 7 (McElroy Decl. ¶ 7); CMS Ex. 1. Petitioner does not challenge his assertion.

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

With respect to the remaining factors, R26 was an extremely vulnerable resident at high risk for pressure sores. But facility staff did not keep her clean and dry; they did not insure that her catheter was free of leaks; and they allowed her to lie on a wet and soiled incontinent pad for up to two hours at a time. They did not assess daily her significant and deteriorating pressure sores as called for in her care plan. Notwithstanding the

importance of nutrition and hydration in preventing and treating pressure sores, staff waited three weeks before they even advised her attending physician of a dramatic and problematic weight loss. And, without consulting that physician, they completely disregarded the dietician's recommendations for changes in her treatment. Staff thus showed disregard for her care, comfort, and safety, for which they are culpable. Facility culpability, together with its less than stellar history, justifies the penalties imposed.¹³

IV. Conclusion

For the reasons discussed above, I find that, from June 2 through July 15, 2008, the facility was not in substantial compliance with Medicare requirements governing notification of changes (42 C.F.R. § 483.10(b)(11)) and quality of care – prevention of pressure sores (42 C.F.R. § 483.25(c)). I affirm as reasonable the \$800 per day CMP (total \$35,200).

/s/

Carolyn Cozad Hughes
Administrative Law Judge

¹³ Petitioner also challenges CMS's determination that its deficiencies constituted substandard quality of care, 42 C.F.R. § 488.301. I decline to review that issue since my finding would not affect the facility's loss of nurse aide training. 42 C.F.R. § 498.3(b)(16) (substandard quality of care finding reviewable only if it leads to facility's loss of approval of its nurse aide training program). Since the penalty imposed is greater than \$5000, the Act precludes approval of the facility's nurse aide training program without regard to the finding of substandard quality of care. Act § 1819(f)(2)(B).