Department of Health and Human Services

DEPARTMENTAL APPEALS BOARD

Civil Remedies Division

Mountain View Rehab, LLC d/b/a Avamere Rehab of Oregon City,
(CCN: 38-5125),

Petitioner,

v.

Centers for Medicare and Medicaid Services.

Docket No. C-09-285

Decision No. CR2167

Date: June 25, 2010

DECISION

I sustain the determination of the Centers for Medicare and Medicaid Services (CMS) to impose remedies against Mountain View Rehab, LLC d/b/a Avamere Rehab of Oregon City (Petitioner or facility). For the reasons that follow, I uphold the per-instance civil money penalty (CMP) of $1,500.

I. Background

Petitioner is a long-term care facility located in Oregon City, Oregon. Petitioner is authorized to participate in the federal Medicare program as a skilled nursing facility (SNF). On October 17, 2008, the Oregon Department of Human Services, Client Care Monitoring Unit (state survey agency) conducted a survey of the facility. The state survey agency determined that Petitioner was not in substantial compliance with Medicare participation requirements, specifically: 42 C.F.R. § 483.25 (Tag F309) and 42 C.F.R. § 483.25(i)(1) (Tag F325).

By letter dated October 24, 2008, the state survey agency notified Petitioner of the survey results. *See* P. Ex. 1; CMS Ex. 3. The state survey agency directed Petitioner to submit a plan of correction by November 4, 2008, and advised that it was recommending that CMS impose a CMP of $1,500 and a denial of payment for new admissions (DPNA) if Petitioner did not achieve substantial compliance by December 6, 2008. *See* P. Ex. 1;

CMS Ex. 3. The state survey agency told Petitioner that its provider agreement would be terminated on April 17, 2009, if it did not achieve substantial compliance by that date.

In a notice letter dated October 28, 2008, CMS informed Petitioner that it agreed with the state survey agency that Petitioner was out of substantial compliance with the Medicare participation requirement found at 42 C.F.R. § 483.25. CMS Ex. 2. CMS notified Petitioner that it was imposing a DPNA, effective December 6, 2008, and also stated its intention to impose a CMP in the amount of $1,500. CMS informed Petitioner that it could submit any financial information for CMS to consider in its process of making a final decision on the CMP amount. CMS Ex. 2.

Petitioner requested an Informal Dispute Resolution (IDR) hearing, and participated in an IDR hearing on December 8, 2008.

On December 18, 2008, the state survey agency revisited the facility and determined that Petitioner had returned to substantial compliance as of November 13, 2008. In a notice letter dated December 29, 2008, CMS advised Petitioner that based on the December 18, 2008 revisit, the DPNA would be discontinued, effective November 13, 2008. CMS Ex. 4. CMS notified Petitioner further that it was imposing a $1,500 per-instance CMP for incidents of noncompliance cited under 42 C.F.R. § 483.25 (Quality of Care), that had been identified during the October 17, 2008 survey. CMS Ex. 4.

On January 2, 2009, the state survey agency issued a letter to Petitioner informing it of the results of the IDR process. P. Ex. 3. The letter stated that Tag F325 would stand as written. The letter stated further that, with respect to Tag F309, the severity level had not changed, but the text for this citation had been modified. Enclosed with the letter was a revised Statement of Deficiencies (SOD) for the October 17, 2008 survey. P. Ex. 3, at 1.

In a letter dated February 12, 2009, Petitioner timely requested a hearing.

I conducted an in-person hearing in Portland, Oregon, on September 1-2, 2009. CMS offered exhibits (CMS Exs.) 1 through 12, and Petitioner offered exhibits (P. Exs.) 1 through 11. I admitted all of the exhibits into evidence. Hearing Transcript (Tr.) at 18, 19, 22, 23, and 237. CMS elicited testimony from Patricia Townsend, a state agency surveyor, and Madhuri Reddy, M.D. Petitioner elicited testimony from Demetria Haffenreffer, a consultant and Petitioner's chief quality officer at the time of the survey. Tr. at 282. At the hearing, Petitioner moved for a directed verdict at the close of CMS's case-in-chief (Tr. at 187-88), and I advised the parties that I would take the motion under advisement. Tr. at 188, 223. As I explain below, I deny Petitioner's motion for a directed verdict.

Each party submitted a post-hearing brief (CMS Brief and P. Brief, respectively) and a reply brief (CMS Reply and P. Reply, respectively). Each party received a copy of the hearing transcript.

Petitioner's motion for a directed verdict is denied.

At the close of CMS's case-in-chief, Petitioner made an oral motion for a directed verdict. Tr. at 187-88. I told the parties that I would take Petitioner's motion under advisement. Tr. at 188, 223. A motion for a directed finding or verdict is granted when all the evidence, viewed in the light most favorable to the opponent, favors the movant so that no contrary ruling could be reached by a reasonable finder of fact. In other words, in this case, a directed verdict or finding should be granted if the opponent, CMS, has not established a *prima facie* case. I deny Petitioner's oral motion for a directed verdict. CMS has clearly established a *prima facie* case, as I discuss further below.

II. Issues

The issues before me are:

(1) whether the facility was in substantial compliance with 42 C.F.R. §§ 483.25 and 483.25(i)(1) at the time of the October 17, 2008 survey; and

(2) if the facility was not in substantial compliance, whether the penalty imposed, a $1,500 per-instance CMP, was reasonable.

III. Applicable Law and Regulations

Petitioner is considered a long-term care facility under the Social Security Act (Act) and regulations promulgated by the Secretary of Health and Human Services (Secretary). The statutory 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 and other remedies against a long-term care facility for failure to comply substantially with participation requirements.

Pursuant to the Act, the Secretary has delegated to CMS the authority to impose various remedies against a long-term care facility that is not complying substantially with federal participation requirements. Facilities which participate in Medicare may be surveyed on behalf of CMS by State survey agencies in order to ascertain whether the facilities are complying with participation requirements. 42 C.F.R. §§ 488.10-488.28; 42 C.F.R. §§ 488.300-488.335. Under Part 488, CMS may impose a per instance or per day CMP against a long-term care facility when a State survey agency ascertains that the facility is not complying substantially with 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.

Pursuant to 42 C.F.R. Part 488, CMS may terminate a long-term care facility's provider agreement when a survey agency concludes that the facility is not complying substantially with federal participation requirements. CMS may also impose a number of alternative enforcement remedies in lieu of or in addition to termination. 42 C.F.R.

§§ 488.406; 488.408; 488.430. In addition to termination and the alternative remedies CMS is authorized to impose, pursuant to section 1819(h)(2)(D) of the Act and 42 C.F.R. § 488.417(b), CMS must impose the "mandatory" or "statutory" DPNA. Section 1819(h)(2)(D) requires the Secretary to deny Medicare payments for all new admissions to a SNF, beginning three months after the date on which such facility is determined not to be in substantial compliance with program participation requirements. The Secretary has codified this requirement at 42 C.F.R. § 488.417(b).

The regulations specify that a CMP imposed against a facility can be either a per day CMP for each day the facility is not in substantial compliance or a per instance CMP for each instance that a facility is not in substantial compliance. 42 C.F.R. § 488.430(a).

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 $3,050 per day to $10,000 per day, is reserved for deficiencies that constitute immediate jeopardy to a facility's residents, and in some circumstances, for repeated deficiencies. 42 C.F.R. §§ 488.438(a)(1)(i), (d)(2). The lower range of CMP, from $50 per day to $3,000 per day, is reserved for deficiencies that do not constitute immediate jeopardy, but either cause actual harm to residents, or cause no actual harm, but have the potential for causing more than minimal harm. 42 C.F.R. § 488.438(a)(1)(ii). There is only a single range of $1,000 to $10,000 for a per instance CMP, which applies whether or not immediate jeopardy is present. 42 C.F.R. §§ 488.408(d)(1)(iv); 488.438(a)(2).

The regulations define the term "substantial compliance" to mean "a level of compliance with the requirements of participation such that any identified deficiencies pose no greater risk to resident health or safety than the potential for causing minimal harm." 42 C.F.R. § 488.301. Noncompliance that is immediate jeopardy is defined as "a situation in which the provider's noncompliance with one or more requirements of participation has caused, or is likely to cause, serious injury, harm, impairment, or death to a resident." *Id.* The Act and regulations make a hearing before an administrative law judge (ALJ) available to a long-term care facility against whom 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 F.2d 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). 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 Ctr.*, DAB No. 1726, at 9, 39 (2000), *aff'd*, 363 F.3d 583 (6th

Cir. 2003). The Departmental Appeals Board (the Board or DAB) 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).

In a CMP case, CMS must make a *prima facie* case that the facility has failed to comply substantially with participation requirements. To prevail, a long-term care facility must overcome CMS's showing by a preponderance of the evidence. *Hillman Rehab. Ctr.*, DAB No. 1611 (1997), *aff'd, Hillman Rehab. Ctr. v. U. S. Dep't of Health & Human Servs.*, No. 98-3789 (GEB) (D.N.J. May 13, 1999).

IV. Findings of Fact, Conclusions of Law, and Discussion

I make three findings of fact and conclusions of law to support this decision. I set them forth below as separate headings in bold type and then discuss each in detail.

1. Petitioner failed to comply substantially with the requirement at 42 C.F.R. § 483.25 (Quality of Care, Tag F309).

The regulation at 42 C.F.R. § 483.25 requires that "[e]ach resident must receive and the facility must provide the necessary care and services to attain or maintain the highest practicable physical, mental, and psychosocial well-being, in accordance with the comprehensive assessment and plan of care."

CMS's allegations of noncompliance with 42 C.F.R. § 483.25 center on the care provided to Resident 1 (R1) after he returned to Petitioner's facility on July 3, 2008, following a stay at the hospital, where a left below-the-knee amputation was performed on him. With respect to this citation, the SOD alleges that based on observation, interview, and record review, Petitioner failed to provide the appropriate care and services, including timely assessment and monitoring, for R1, who had surgical incisions. P. Ex. 3, at 3; CMS Ex. 1, at 1. The SOD alleges that R1's incision required further surgical intervention. P. Ex. 3, at 3; CMS Ex. 1, at 1.

R1, an 86-year-old male at the time of the survey, was originally admitted to the facility on June 1, 2008, after a fall that fractured his pelvis and elbow. *See* CMS Ex. 11. R1's diagnoses included peripheral vascular disease, gangrene of his left toes, chronic atrial fibrillation, coronary artery disease, and hypothyroidism. CMS Ex. 8, at 1; *see* P. Ex. 5, at 1; P. Ex. 11, at 29. R1 was discharged to the hospital on June 25, 2008, where a left below-the-knee amputation was performed. R1 returned to Petitioner's facility around noon on July 3, 2008. CMS Ex. 8, at 3. He had a dressing and ace bandage on the left stump. *See* P. Ex. 3, at 4; CMS Ex. 1, at 2; *see* Tr. at 240-41.

The facility's interdisciplinary progress (IDP) note dated July 3, 2008, acknowledges R1's amputation, but does not describe its condition in any way. CMS Ex. 8, at 3. In an IDP note written around 1:00 p.m. the next day, July 4, 2008, a nurse states, *inter alia*, that she had requested treatment orders from R1's physician since there were no orders in the initial hospital materials, and that she "[w]ill not take off compression wrap until I receive orders." CMS Ex. 8, at 3. Another IDP note written around 9:25 p.m. that night states, "Ace drsg (L) lower stump intact & clean." CMS Ex. 8, at 3.

On July 5, 2008, an IDP note written around 3:30 p.m. states, *inter alia*, that R1's ace dressing was "intact, clean, dry." CMS Ex. 8, at 3. In an IDP note written at 9:00 p.m. that night, staff notes that R1's ace dressing was "intact & clean." CMS Ex. 8, at 3.

At 5:30 a.m. on July 6, 2008, an IDP note indicates that R1 was in pain, and the nurse put an ice bag on his stump. The nurse observed that R1's dressing had leaked, so she "redressed L left exactly as it had been in lieu of txment orders which have been requested." The nurse stated, "[n]o swelling noted, but reddness [sic] at incision site which extends out about 2 cm." P. Ex. 4, at 1; CMS Ex. 8, at 2.

At 7:00 a.m. on July 7, 2008, an IDP note states, "[c]hecked patient at 0530, dressing off all over bed – stump bleeding, appears quite infected, patient very confused, foley line clogged with blood clots, patient's bed bloody . . . [R1] very confused in pain, pulling on catheter line. Called Dr. Silver, who ordered UA [urinalysis] and will see [R1] this pm to check for infection. Some dehiscence, area within 2 cm of actual incision – reddness [sic] 6-7 cm entire area."[1] P. Ex. 4, at 1; CMS Ex. 8, at 2.

R1's physician, Dr. Silver, saw R1 on the afternoon of July 7, 2008. Dr. Silver's report of the office visit noted that R1 was seen for confusion. Dr. Silver indicated that R1 had been pulling on his catheter and taking down his stump dressing. He noted that R1 denied pain other than in his back. P. Ex. 10, at 10. The "Chief Complaint," as noted in the report, was a possible infection in R1's left leg. P. Ex. 10, at 10. Among the physical findings, Dr. Silver reported that R1's left stump incision had no erythema (redness), and there was "scant bloody drainage from lat margin." P. Ex. 10, at 11. Dr. Silver ordered a urinalysis, a urine culture, and a culture of R1's wound. P. Ex. 10, at 11; *see* P. Ex. 10, at 14-18, 20-22. The report indicates that Dr. Silver's assessment was as follows: peripheral vascular disease; urinary tract infection; and delirium of unknown (axis III) etiology. Dr. Silver prescribed a 10-day course of Cipro, and lorazepam, an anti-anxiety drug, at bedtime. P. Ex. 10, at 12. In a separate progress note dated July 7, 2008, Dr. Silver documented his examination of R1 in very brief fashion. P. Ex. 4, at 2. He wrote, *inter alia*, that R1's stump had "bloody drainage, scant lat aspect, s erythema," and noted his medication orders. P. Ex. 4, at 2.

[1] At the hearing, Surveyor Townsend explained that "dehiscence" is "an opening of the layer of the tissue." Tr. at 37.

According to an IDP note written around midnight, when R1 returned to the facility from Dr. Silver's office, his dressing was poorly wrapped, among other things, and staff re-wrapped his left leg as "best as possible" because he was uncooperative. CMS Ex. 8, at 2, 6.

The urine culture revealed that R1 had MRSA (Methicillin Resistant Staphylococcus Aureus). P. Ex. 6 (duplicate at P. Ex. 10, at 21).

An untimed morning IDP note dated July 8, 2008, states, *inter alia*, that R1 "responds to pain when drsg [changed] to LT incision; site red minimal seroussang [sic] drainage no odor; difficult to place splint posterior to LT amputee leg & is painful." P. Ex. 8, at 2; CMS Ex. 8, at 5.

The next entry pertaining to the condition of R1's wound occurs six days later, on July 14, 2008. An IDP note, timed at 4:00 p.m., states, *inter alia*, "L stump redressed as ordered. Very painful to touch." P. Ex. 8, at 4; CMS Ex. 8, at 11.

On July 15, 2008, an IDP note written around 10:52 p.m. indicates that staff faxed information on R1's condition to Dr. Silver. The note states that his wound was red, draining a small amount of blood from the left inner incision, and was tender to touch. P. Ex. 8, at 4; CMS Ex. 8, at 11. The fax communication that was sent to Dr. Silver contained the foregoing information about R1's wound, and also stated that R1 "is in severe pain when wound site is lightly touched," and he "refused to have ace bandage placed on." P. Ex. 4, at 5 (duplicate at P. Ex. 10, at 25).

An IDP note written on July 16, 2008, at 9:00 a.m., states, "[n]oted incision site of L BKA [below knee amputation] has dehisced at lateral end at first suture. Noted copious serosanguineous drainage c lots of slough." P. Ex. 8, at 4; CMS Ex. 8, at 11. Another IDP note written around 2:30 p.m. states that Dr. Silver, via phone, instructed staff to contact R1's surgeon, Dr. Budden, and "obtain his thoughts on the resident's incision." The note stated further that Dr. Silver did not want to place a PICC line until staff had spoken further with Dr. Budden. P. Ex. 4, at 6; CMS Ex. 8, at 12. The note indicated that Dr. Budden called and stated that the open area of the incision was where he had placed the drain for the incision during surgery. Dr. Budden stated that the increase in serosanguineous drainage was not surprising since R1 had been having poor food intake, which contributed to poor wound healing. He ordered that R1's dressing be changed daily and as needed, and physical therapy be continued to decrease the contracture to the stump. Dr. Budden ordered a wound culture of the incision. P. Ex. 4, at 6; CMS Ex. 8, at 12. He also instructed facility staff to contact Dr. Silver about placing the PICC line. CMS Ex. 8, at 12.

The facility's staff faxed a request to Dr. Silver that day, informing him of Dr. Budden's statements and stating that Dr. Budden would allow him to decide on placing a PICC line. Facility staff asked Dr. Silver for authorization to send R1 to the emergency room to have a PICC line placed. Dr. Silver did not authorize this, and told the staff to call him on July 18 with the status of R1's oral intake and the appearance of his stump. P. Ex. 4,

at 9 (duplicate at P. Ex. 10, at 34). The laboratory report of R1's wound culture, dated July 18, 2008, and collected at the hospital, revealed that R1 was infected with MRSA in his surgical wound. *See* CMS Ex. 1, at 2; P. Ex. 7, at 1.

Two days later, on July 18, 2008, at 11:00 a.m., an IDP note states that R1's dressing was changed, and indicates, "[s]mall amt of bleeding noted. Has open area approx. 2 cm long. Staples intact." The note also states that R1 had an appointment with the surgeon, Dr. Budden, later that day. CMS Ex. 8, at 13.

In the "history and physical" section of his report on his examination of R1 on July 18, 2008, Dr. Budden stated that he evaluated R1 and "it became evident that his left below-the-knee stump was badly infected, with purulent drainage, and he had a severe flexion contracture of the left knee, which could not be straightened." P. Ex. 9, at 10; P. Ex. 11, at 22; CMS Ex. 8, at 14-15. In a separate progress note for the July 18 visit, Dr. Budden stated that the drainage from R1's stump "is a lot worse than what was reported to me by his nurse on July 15th . . . Today the situation is completely different . . . and he has a grossly infected stump." P. Ex. 11, at 7. In the history and physical, Dr. Budden noted that the incision was barely held together with staples and that the distal part of the stump was erythematous. P. Ex. 9, at 12; P. Ex. 11, at 24; CMS Ex. 8, at 16. Dr. Budden did not believe that R1's stump "[could] be salvaged and the best course would be to go ahead with an above the knee amputation." P. Ex. 11, at 7. R1 was admitted to the hospital directly after seeing Dr. Budden for IV antibiotic therapy for the MRSA infection of his stump, and plans were made to perform a left above-the-knee amputation on July 21, 2008. P. Ex. 9, at 10-11, 13; P. Ex. 11, at 22, 25; CMS Ex. 8, at 15, 16. Petitioner asserts that the testimony and documentary evidence do not show that its staff failed to perform appropriate wound assessments. Petitioner argues that CMS has not presented any evidence to show that R1 suffered actual harm or was exposed to the risk of more than minimal harm due to its alleged deficient care. Along this line of argument, Petitioner focuses on the fact that there were two versions of the SOD, a pre-IDR version and a post-IDR version, and contends that the post-IDR version of the SOD no longer alleges that Petitioner's deficiencies caused any harm to R1.

As reviewed above, R1 suffered from multiple medical problems, including gangrene, which necessitated a below-the-knee amputation of his left leg in late June 2008. When R1 returned to Petitioner's facility on July 3, 2008 following the operation, his new surgical wound presented another layer to his already complex medical condition. Given R1's situation, it was thus incumbent upon staff to monitor and assess his wound.

The IDP note dated July 3, 2008 around noon, documented Petitioner's return to the facility and acknowledged his amputation, but, as CMS points out, did not assess it. CMS Ex. 8, at 3; CMS Brief at 13-14. Other than noting that R1 had had a left leg below-the-knee amputation due to peripheral artery disease, the IDP note does not contain any information that indicates that staff assessed R1's surgical wound on re-admission. Petitioner does not dispute CMS's claim that there was no assessment, but suggests, through the testimony of its witness, Ms. Haffenreffer, that the reason its staff did not assess R1's wound when he returned is that they did not want to take off the

compression dressing that covered the wound until they received orders from his physician. Tr. 240-41.

The record shows that no wound assessments were done on July 4 or July 5. In an IDP note dated July 4, 2008, at 1:00 p.m., a nurse stated that she would not take off R1's compression wrap until she received orders from his physician. CMS Ex. 8, at 3.[2] Another IDP note at 9:25 p.m. that night stated that R1's dressing was "intact & clean." CMS Ex. 8, at 3. The observations in the two July 5, 2008 IDP notes run in the same vein, with staff not documenting anything about the condition or appearance of R1's surgical wound and only noting that his dressing was intact, clean, and dry. *See* CMS Ex. 8, at 3.

In fact, no one on Petitioner's staff looked at R1's wound until the early morning of July 6, 2008. According to an IDP note written at 5:30 a.m., over 65 hours after R1 was readmitted to Petitioner's facility, R1 was in "10+/10 pain." P. Ex. 4, at 1; CMS Ex. 8, at 2. A nurse put an ice bag on R1's stump, which helped his pain, and because his dressing had leaked, the nurse "redressed L leg exactly as it had been in lieu of txment orders which have been requested." P. Ex. 4, at 1; CMS Ex. 8, at 2. The nurse did not see any swelling, but noted redness at the incision site that extended about 2 cm. P. Ex. 4, at 1; CMS Ex. 8, at 2.

When a nurse checked R1 at 5:30 a.m. on July 7, 2008, she found his dressing all over his bed, with his stump bleeding and appearing "quite infected." The corresponding IDP note (written at 7:00 a.m) provides some information about the wound's appearance, stating that it had "[s]ome dehiscence, area within 2 cm of actual incision – reddness [sic] 6-7 cm entire area." P. Ex. 4, at 1; CMS Ex. 8, at 2. As discussed above, R1 was seen by Dr. Silver later that day. Among his findings, Dr. Silver reported that R1's left stump incision had no erythema, and there was "scant bloody drainage from lat margin." P. Ex. 10, at 11.

The next day, July 8, 2008, according to an IDP note that was not timed, R1 experienced pain when his dressing was changed. Petitioner's staff noted that R1's wound site was red, with minimal serosanguineous drainage, and no odor was present. *See* P. Ex. 8, at 2; CMS Ex. 8, at 5.

After July 8, 2008, the record contains no further documentation of the appearance and status of R1's wound until *July 14, 2008, a gap of six days*. On July 14, 2008, at 4:00 p.m., an IDP note states, "L stump redressed as ordered. Very painful to touch." P. Ex. 8, at 4; CMS Ex. 8, at 11.

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[2] The record contains a fax communication, dated July 4, 2008, to Dr. Silver from a nurse on Petitioner's staff. The nurse informed Dr. Silver that R1 had been admitted to the facility on July 3, 2008, with a "L BKA," and they had no orders for dressing changes. She requested that Dr. Silver "outline trmt as [he] would like it done." On the same fax communication sheet, Dr. Silver, in response, instructed the staff to contact R1's surgeon, Dr. Budden. P. Ex. 10, at 45.

Given this body of evidence, there can be no serious dispute that beginning with R1's readmission to Petitioner's facility, Petitioner failed to adequately assess and document the status of R1's wound. At the hearing, Dr. Madhuri Reddy, CMS's expert witness on wound care and post-surgical wound care (Tr. at 149),[3] testified that Petitioner's IDP notes "were inadequate in their frequency as well as what they contained. Both." Tr. at 158. Dr. Reddy testified that a comprehensive wound assessment should be done "at least on admission, at least once weekly and then with any change in status such as . . . postoperatively or if the wound seems to deteriorate at all . . . ." Tr. at 152-53; *see* Tr. at 158. When asked if there were circumstances that would warrant more frequent assessments, Dr. Reddy testified: "If there are changes in the wound status . . . new or worsening infection, drainage, odor, after an operation . . . ." Tr. at 153.

Dr. Reddy noted that R1 had a "complicated medical condition" and testified that "the most important factor that warranted more frequent checking of his wound was the fact that he just came back from hospital with this post-surgical condition and, secondly, because it was noted that the wound was looking somewhat infected." Tr. at 154. Based on her review of Petitioner's IDP notes, Dr. Reddy concluded that Petitioner's staff had failed to do an admission assessment of R1's wound when he returned to Petitioner's facility and had also failed to do weekly assessments. *Id*.

With respect to what should be documented in a wound assessment, Dr. Reddy testified that the assessment should describe the "specific features of the wound": "approximations of the wound margins, any drainage, if there's evidence of infection and if there's a presence of a palpable . . . healing ridge along the incision site." Tr. at 157; *see* Tr. at 158. According to Dr. Reddy, IDP notes are subjective, while a comprehensive wound assessment addresses the aforementioned objective criteria. Dr. Reddy concluded that Petitioner's IDP notes did not constitute wound assessments. Tr. at 155-56, 161.[4]

When asked about the July 6, 2008 and July 7, 2008 IDP notes on cross-examination, Dr. Madhuri testified that both notes failed to describe R1's wound adequately. With respect to the July 6, 2008 IDP note, Dr. Reddy testified that staff "should have noted specific characteristics such as the measurement of the wound which is not included, the type of drainage. . . if there was no drainage, whether or not it looked infected." Tr. at 170. Dr. Reddy explained that although the nurse wrote that she observed no swelling and noted redness at the incision site, the nurse "should have also said the wound measured such and such, no other signs of infection, no drainage, etc." *Id.* With respect to the July 7, 2008 IDP note (7:00 a.m.), which described R1's stump as "bleeding" and appearing "quite infected," Dr. Reddy opined that it was not an adequate wound assessment. Tr. at 170-71.

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[3] Dr. Reddy is a Board-Certified internist and geriatrician with a specialty in chronic wound healing. Tr. at 147.

[4] Dr. Reddy stated that nurses can complete a separate "comprehensive wound assessment sheet," but she did not see any such forms in R1's medical record. Tr. at 158.

The most glaring evidence of Petitioner's deficient care is its failure to assess R1's wound for six days, between July 8 and July 14, 2008. On the morning of July 8, 2008, according to an untimed IDP note (CMS Ex. 8, at 5), a nurse indicated that R1's wound site was red, and there was minimal serosanguineous drainage. The nurse also noted that R1 experienced pain when his wound dressing was changed. CMS Ex. 8, at 5.

It is evident that by July 8, 2008, Petitioner's staff would have become aware that R1's wound might not be healing properly and could be infection prone. The condition of R1's wound was such that it should have alerted Petitioner's staff that vigilant monitoring and assessment were needed to prevent the wound from worsening.

Instead of documenting the status of R1's wound, however, Petitioner's staff failed to do any assessments for six days. The record shows that, after July 8, 2008, no one on Petitioner's staff evaluated or documented the condition of R1's wound again until 4:00 p.m. on July 14, 2008.

In fact, Petitioner's witness Ms. Haffenreffer did not dispute that Petitioner's IDP notes do not contain any information that shows that staff assessed R1's wound between July 8 and July 14, 2008. Ms. Haffenreffer testified that between July 7 and July 14 "the notes just talk about dressing changes. They do not describe the wound." Tr. at 294; *see* P. Ex. 4, at 7. She testified that "[t]here's no proof of documentation of a wound assessment other than those dressing changes that are documented." Tr. at 300. [5] Although Ms. Haffenreffer opined that staff would have looked at the wound each time a dressing change was done, she conceded that, in terms of documentation, a dressing change is simply not the same thing as a wound assessment. Tr. at 295, 296. On this point, Ms. Haffenreffer's testimony is consistent with that of Surveyor Townsend, who also testified that a dressing change "is an opportunity to assess the wound, but it isn't an assessment of the wound. You are only documenting changed [sic] the dressing and your initials. But it is not an assessment." Tr. at 141.

On July 14, 2008, when a nurse finally looked at R1's wound, the only information the nurse recorded in the IDP note at 4:00 p.m. is that R1's stump was "redressed as ordered" and was "[v]ery painful to touch." CMS Ex. 8, at 11. Despite the fact that six to seven days earlier the IDP notes had stated that R1's stump had shown drainage, had been bleeding, and had appeared "quite infected," there is nothing in the July 14 IDP note to suggest that a thorough wound assessment of R1's stump was performed. The IDP note fails to document whether R1's wound was examined for drainage, infection, or any other objective signs or symptoms, as discussed in Dr. Reddy's testimony.

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[5] Besides sporadically documenting dressing changes, IDP notes dated July 8, July 9, July 10, July 11, July 12, and July 13, 2008, mainly show that R1's foley catheter and IV were being monitored. *See* P. Ex. 8, at 2, 3; P. Ex. 10, at 27, 28, 39, 43; CMS Ex. 8, at 9-10.

Ms. Haffenreffer conceded that the July 14, 2008 IDP note was inadequate, stating:

> [T]he note is not as comprehensive as I would like the note to be. . . . there definitely are missing pieces to this note. It doesn't give us measurements. And it just tells us it's painful. So it doesn't really tell us if there are signs of infection or not. It could be better.

Tr. at 247. When asked what "elements" should be included in an assessment, Ms. Haffenreffer's response echoes Dr. Reddy's earlier testimony on this topic:

> The drainage, and what the drainage looks like and the amount; the measurement of the wound which is kind of difficult to do with a surgical wound because it's closed, other than that one area where the drain was. The external perimeter of the wound and how that – and whether or not that's red, if the wound is open, the wound edges and the depth of that wound, and then whether or not there's pain, symptoms of infection, and also how it is responding to treatment.

Tr. at 296-97.

Following the IDP note of July 14, 2008, Petitioner's staff documented the progress of R1's wound on July 15 and July 16, 2008. I note that, on July 15, 2008, an IDP note written at 10:52 p.m. indicates that R1's wound was red, draining a small amount of blood from the left inner incision, and was tender to touch. CMS Ex. 8, at 11. Petitioner's staff was concerned enough at this point that they faxed a note to Dr. Silver describing R1's condition and informing him that R1 "is in severe pain when wound site is lightly touched." P. Ex. 4, at 5. Dr. Silver called back, and told staff to contact Dr. Budden about R1's staples and dressing. P. Ex. 4, at 5. The IDP note written the next morning, July 16 at 9:00 a.m., indicates that R1's wound had dehisced and there was "copious serosanguineous drainage c lots of slough." CMS Ex. 8, at 11. When asked about this note, Ms. Haffenreffer did not deny that R1's wound had worsened. She testified, "it's obvious it's infected just by that note with serosanguineous drainage. That indicates that there's copious amounts of drainage which indicates infection and also slough which is necrotic tissue." Tr. at 292.

The record shows that after the July 16 IDP note, there was a 44 ½ - hour documentation gap during which Petitioner's staff failed to assess R1's wound. By the time Petitioner's staff checked R1's wound on July 18, 2008, at 11:00 a.m., R1's wound was bleeding and had an open area approximately 2 cm long. When R1 was seen by his surgeon later that day, his stump was "badly infected, with purulent drainage." CMS Ex. 8, at 14. R1 was admitted to the hospital for IV antibiotic therapy for the MRSA infection of his stump, and underwent a left above-the-knee amputation on July 21, 2008. CMS Ex. 8, at 15, 16.

As a way of rebutting CMS's arguments, Petitioner argues that nothing in the record indicates that R1 suffered actual harm or was exposed to more than minimal harm as a result of any alleged deficient care by its staff. Petitioner points to the fact that there are two versions of the SOD, a pre-IDR version and a post-IDR version, and contends that the post-IDR version of the SOD no longer alleges that Petitioner's deficiencies caused any harm to R1.

According to Petitioner, the state survey agency sent Petitioner a letter dated January 2, 2009, informing it of the results of the IDR meeting. Among other things, the state survey agency advised Petitioner that, with respect to tag F309: "[t]his citation remains and the severity level **has not** changed. The text has been modified." P. Ex. 3, at 1 (emphasis in original); CMS Ex. 2, at 1 (emphasis in original). With the letter, the state survey agency enclosed a revised SOD for the October 17, 2008 survey, and informed Petitioner that "[y]ou may replace the previous report with the revised version." P. Ex. 3, at 1; CMS Ex. 2, at 1.

CMS does not dispute that the pre-IDR SOD and the post-IDR SOD are different. CMS Reply at 3. CMS states that the difference between the two versions of the SOD concerns one sentence in one paragraph. The pre-IDR SOD states:

> Based on observation, interview and record review it was determined that the facility failed to provide the appropriate care and services including timely assessment and monitoring, for 1 of 3 sampled residents (#1) who had surgical incisions. **The incision became infected and required further surgical intervention.** Findings include . . .

CMS Ex. 1, at 1 (emphasis added).

The post-IDR SOD states:

> Based on observation, interview and record review it was determined that the facility failed to provide the appropriate care and services including timely assessment and monitoring, for 1 of 3 sampled residents (#1) who had surgical incisions. **Resident required further surgical intervention.** Findings include . . .

P. Ex. 3, at 3 (emphasis added).

Petitioner claims that this difference between the two versions "removed the central allegation of harm caused to Resident 1 by the alleged deficiencies." P. Brief at 2. CMS, however, disputes the significance, noting that the textual change did not lead to a change in CMS's citation of scope and severity. Moreover, CMS notes, although the phrase "the incision became infected" was removed, this phrase is in fact accurate because the record reflects that R1's incision *did* become infected. CMS argues further that although the phrase does not indicate who or what caused the infection, the source of the infection

is not critical to determining whether Petitioner was in non-compliance with Medicare requirements. CMS Reply at 4-5.

I agree with CMS that Petitioner attaches undue importance to the revised language of the post-IDR SOD. It is quite simply immaterial to this case that the post-IDR SOD was revised and no longer contains the phrase "the incision became infected." As CMS pointed out, the scope and severity level of Tag F309 did not change. It is not necessary for me to reach any conclusion as to whether failures by Petitioner's staff caused R1 to experience an infection in order to find that Petitioner was out of compliance with 42 C.F.R. § 483.25.

Petitioner also contends that Surveyor Townsend gave testimony that the allegations under Tag F309 concerned solely "assessment" and "monitoring," and that she denied that Petitioner caused R1 any harm or exposed him to more than minimal harm. P. Brief at 9-10. Petitioner's attempt to focus on the issue of harm is misguided. The allegations in the SOD under Tag F309 pertain to Petitioner's alleged failure to provide appropriate care and services to R1, specifically, its failure to timely assess and monitor R1's wound. Whether R1 suffered harm is not material to my analysis. Petitioner fails to realize that it is not necessary for me to find a causal connection between any harm that R1 may have suffered and the care provided by Petitioner's staff in order to find that Petitioner's care fell short of the requirements of 42 C.F.R. § 483.25.

In characterizing Surveyor Townsend's testimony in the way that it has, Petitioner chooses to ignore a central point of her testimony: that is, that the purpose of providing appropriate assessments and monitoring is so that facility staff can track a wound's progression to determine whether it is healing or deteriorating. Surveyor Townsend testified as follows:

> Due to lack of documentation and ongoing consistent assessment, looking at the last nursing documentation related to the wound, going to the hospital immediately from the surgeon's office with a highly involved inflammatory infectious wound, the lack thereof the monitoring, the continual assessment, it doesn't mean it caused the infection but why do we want to monitor, why do we want to assess? So that we maybe can reevaluate treatment or prevent further problems on down the line. It's to provide the best care and services possible to this population.

Tr. at 107. Although Petitioner claims that Surveyor Townsend "speculat[ed] on the wider public good of requiring regular wound assessment" (*See* P. Brief at 10), I find that her testimony is not based in speculation, but rather, derives from and is supported by the most basic notions of the care owed to all residents.

Petitioner also argues that CMS's witnesses offered contradictory testimony on whether wound assessments were done or not. According to Petitioner, Surveyor Townsend did not testify that no wound assessments had been done, only that "they had not been made

in a timely manner." P. Brief at 10. Petitioner claims, however, that Dr. Reddy testified that there were no wound assessments in the record at all. P. Brief at 10. Contrary to Petitioner's contention, I do not agree that any contradiction exists between the testimony of Surveyor Townsend and that of Dr. Reddy.

Dr. Reddy testified as to what objective criteria a wound assessment should address, and opined that the IDP notes were not adequate assessments because they lacked documentation of these criteria. *See* Tr. at 172. Surveyor Townsend reviewed the same IDP notes as Dr. Reddy, and also concluded that they were "incomplete," and therefore, were not adequate assessments. *See* Tr. at 34, 36, 38. In fact, Surveyor Townsend's testimony as to what should be described in a wound assessment ("What does the tissue look like surrounding that incision? Is there any erythema, is it red around the edges? . . . What is the drainage? Is there any odor?) is very similar to Dr. Reddy's testimony. Tr. at 34-35. I see no inconsistency between the testimony of Dr. Reddy and that of Surveyor Townsend. Moreover, it is clear that both Surveyor Townsend and Dr. Reddy agreed on the main point at issue: that staff did not adequately assess and document the status of R1's wound.

Finally, Petitioner claims that the record demonstrates that both R1's attending physician and his surgeon were kept informed by staff with regard to R1's wound status. *See* P. Reply at 4. As support for this claim, Petitioner relies on the testimony of its witness Ms. Haffenreffer. *See* P. Reply at 4-5. According to Ms. Haffenreffer, the record shows that R1's attending physician and his surgeon engaged in a "debate" as to whether R1 should have a PICC line inserted. Tr. at 251-52. In her opinion, their discussion indicates that they were both "adequately kept up to date as to Resident 1's wound condition." Tr. at 252.

Ms. Haffenreffer's testimony refers to an IDP note dated July 16, 2008, at 2:30 p.m., which I have previously described above. *See* Tr. at 250; *see* P. Ex. 4, at 6. Contrary to her statements, I find that it is questionable whether R1's physicians engaged in any "debate" regarding the placement of R1's PICC line. According to the IDP note, Dr. Silver did not want to place a PICC line until staff had spoken further with Dr. Budden. When Dr. Budden called the facility, among other things he ordered a dressing change to be done daily and as needed, ordered that a wound culture be done, and instructed the facility's staff to contact Dr. Silver about placing the PICC line. When Petitioner's staff faxed a request to Dr. Silver to send R1 to the ER to have the PICC line inserted, Dr. Silver did not authorize it. CMS Ex. 8, at 12; *see* P. Ex. 4, at 9. There is nothing in the IDP notes that suggests that Dr. Silver and Dr. Budden engaged in a "debate" or any discussion between themselves about either the placement of R1's PICC line or the condition of R1's wound.

Aside from Ms. Haffenreffer's unsupported assertions, Petitioner has offered no other evidence that R1's physicians were consistently kept informed about the state of R1's wound. As noted above, Dr. Silver examined R1 on July 7, and received a fax on July 15 that described the status of R1's wound. It is true that, on July 16, 2008, both Dr. Silver and Dr. Budden received communications from Petitioner's staff pertaining to R1's

wound status. But Petitioner's claim that they were "adequately kept up to date" is disingenuous. As discussed above, Petitioner's staff failed to do any assessments of R1's wound over the six-day period from July 8 to July 14, 2008. On July 14, 2008, staff noted that R1's wound was painful to touch, but failed to perform any sort of meaningful assessment. Petitioner's staff again failed to check R1's wound over a period of 44½ hours, from July 16 through July 18, 2008. Given that the facility failed to monitor R1's wound over long periods and therefore would not have been aware of its day-to-day status, I cannot find credible Petitioner's claim that its staff kept R1's physicians informed of his wound status, when they themselves clearly were not.

For a facility to provide the necessary quality of care that is required pursuant to 42 C.F.R. § 483.25, it must do more than merely provide care and services; a facility has an affirmative duty to provide the necessary quality and quantity of care and services such that each resident may achieve favorable outcomes "to the highest practicable degree." *See Windsor Health Care Ctr.*, DAB No. 1902, at 16-17 (2003); *Woodstock Care Ctr.*, DAB No. 1726, at 25-30.

In examining the concept of "highest practicable," CMS acknowledges in its posthearing brief that "this standard is not blind to the reality of a patient's condition." CMS Brief at 10. Thus, where a resident experiences a lack of improvement or suffers a decline, the question that must be asked is whether the occurrence was avoidable or unavoidable. In such a situation, a facility may put forward available clinical evidence to show that a negative resident care outcome was unavoidable. *See Clermont Nursing & Convalescent Ctr.*, DAB No. 1923, at 10 (2004). Hence, neither the concepts of "highest practicable" or "avoidable" are absolute values; they are patient-specific concepts that must be evaluated in the particular context of an individual case.

At the same time, however, CMS recognizes that whatever the individual circumstances of a given case might be, a facility's response must be commensurate with recognized professional standards that apply to that individual case. CMS Brief at 12 (citing *Morrisons Cove Home*, DAB CR1581 (2007)). In *Morrisons Cove Home*, ALJ S. T. Kessel found that in failing to document and assess the appearance of a resident's wound on a daily basis, Petitioner contravened professionally recognized standards of care and the requirements of 42 C.F.R. § 483.25. DAB CR1581.

I find instructive Dr. Reddy's testimony about the duty of care that Petitioner's staff owed to R1. Citing R1's complicated condition, particularly his post-surgical condition, and the fact that his wound looked somewhat infected, Dr. Reddy testified that R1's wound "warranted more frequent checking." Tr. at 154. Dr. Reddy is well-qualified to testify about the documentation and assessment of wound appearance, and Petitioner offered no evidence to refute Dr. Reddy's testimony as to the standard of care that was owed to R1. Thus, it is clear that Petitioner's staff owed R1 a high degree of diligence to ensure that his wound was watched carefully and assessed appropriately.

Even though R1's medical problems were complex, Petitioner offered no evidence to suggest that the worsening of R1's wound was unavoidable. I find that Petitioner's staff failed to monitor vigilantly and assess R1's wound and to document its condition, even as his wound began to show possible signs of infection. On the very few occasions when Petitioner's staff documented the appearance of R1's wound, such documentation was often incomplete and inadequate as a wound assessment. I find that Petitioner did not provide R1 the care and services he needed to attain or maintain his highest practicable physical well-being and was therefore not in substantial compliance with 42 C.F.R. § 483.25.

2. Petitioner failed to comply substantially with the requirement at 42 C.F.R. § 483.25(i)(1) (Nutrition, Tag F325).

The regulation at 42 C.F.R. § 483.25(i)(1) requires that, "[b]ased on a resident's comprehensive assessment, the facility must ensure that a resident – (1) [m]aintains acceptable parameters of nutritional status, such as body weight and protein levels, unless the resident's clinical condition demonstrates that this is not possible." 42 C.F.R. § 483.25(i)(1).

In decisions addressing this regulation, the Board has held that unplanned weight loss may raise an inference of inadequate nutrition and support a *prima facie* case of a deficiency. *The Windsor House*, DAB No. 1942 (2004); *Carehouse Convalescent Hosp.*, DAB No. 1799 (2001). If CMS makes a *prima facie* showing of noncompliance based on unplanned weight loss, the facility must prove that it provided adequate nutrition or that the weight loss was attributable to non-nutritive factors which establish that the weight loss was unavoidable. *The Windsor House*, DAB No. 1942, at 17-18; *Carehouse Convalescent Hosp.*, DAB No. 1799, at 22.

CMS's allegations of noncompliance with 42 C.F.R. § 483.25(i)(1) center again on the care provided to R1. With respect to this citation, the SOD alleges that, based on interview and record review, Petitioner failed to monitor and provide appropriate interventions for R1, who experienced weight loss. P. Ex. 3, at 7; CMS Ex. 1, at 1.

The SOD alleges that R1's Minimum Data Set dated July 13, 2008, assessed R1 at risk for dehydration and weight loss. P. Ex. 3, at 8; CMS Ex. 1, at 4; *see* CMS Ex. 8, at 21, 22. The SOD alleges that R1's care plan dated July 3, 2008, listed interventions that included placing R1 on a meal monitoring program and taking weekly weights. P. Ex. 3, at 8; CMS Ex. 1, at 4; *see* P. Ex. 8, at 7; CMS Ex. 8, at 20.

According to the SOD, when R1 was admitted to Petitioner's facility for the first time on June 1, 2008, he weighed 164 pounds. P. Ex. 3, at 8; CMS Ex. 1, at 4. On June 2, 2008, R1's weight was recorded at 157 pounds, and, on June 9, 2008, his weight was 155.2 pounds. The SOD states that no additional weights were recorded. R1 had a hospital stay from June 16, 2008 through June 19, 2008. He returned to Petitioner's facility, and from June 19, 2008 through June 24, 2008, no weights were recorded. R1 went to the

hospital on June 24, 2008 for surgery, and returned to Petitioner's facility on July 3, 2008. P. Ex. 3, at 8; CMS Ex. 1, at 4.

R1's weight upon his re-admission on July 3, 2008, was 147.8 pounds. P. Ex. 3, at 8; CMS Ex. 1, at 4; *see* CMS Ex. 8, at 23. The SOD notes that R1 had had a "left below-the-knee amputation on July 1, 2008, so a weight change would have been expected from previous admission weights." P. Ex. 3, at 8; CMS Ex. 1, at 4-5.

On July 8, 2008, R1's weight was recorded at 136.8 pounds, and on July 14, 2008, his recorded weight was 133.1 pounds. P. Ex. 3, at 8; CMS Ex. 1, at 5; *see* CMS Ex. 8, at 23. No additional weights had been recorded. R1 lost 14.7 pounds in 11 days. P. Ex. 3, at 9; CMS Ex. 1, at 5.

According to the SOD, when R1 was admitted to the hospital on July 18, 2008, the hospital records indicated that his albumin level was 2.6, which indicated nutritional compromise. P. Ex. 3, at 9; CMS Ex. 1, at 5.

The SOD states that in an interview on October 17, 2008, Petitioner's Director of Nursing Services stated that R1 should have been placed on the Nutrition at Risk Committee and should have been weighed weekly. She also stated that a Registered Dietician consultation should have been done for dietary recommendations. P. Ex. 3, at 9; CMS Ex. 1, at 5. According to the SOD, R1's meal intake had been monitored and it had been noted that he ate poorly. P. Ex. 3, at 9; CMS Ex. 1, at 5.

I find that the evidence is sufficient to establish a *prima facie* case that Petitioner failed to ensure that R1 maintained acceptable parameters of nutritional status pursuant to 42 C.F.R. § 483.25(i)(1). Petitioner failed to take all reasonable steps to ensure that R1 received nutrition adequate to his needs.

Petitioner asserts that R1's weight loss pre-dated his re-admission to the facility and was due to his clinical condition. Petitioner maintains that it monitored R1's nutrition and did all it could to prevent his weight loss. Petitioner also characterizes this deficiency as being a problem with documentation, and nothing more than "an administrative failure." P. Brief at 17.

Petitioner's arguments are unpersuasive. The record shows that R1 lost 14.7 pounds between July 3 (147.8 pounds) and July 14, 2008 (133.1 pounds), a 10% decline in body weight in 11 days. CMS Ex. 8, at 23. I find no evidence that Petitioner responded appropriately to R1's severe and abrupt weight loss.

Petitioner claims that its staff monitored R1's meal intake and offered substitutes and supplements. P. Brief at 18. Both parties introduced R1's meal monitoring sheet for July 2008, on which Petitioner recorded R1's meal intake from July 3 through July 18, 2008. P. Ex. 8, at 5; CMS Ex. 8, at 25. At the top of this document appears the following instruction: "Record amounts consumed at meals: offer replacement if intake is 50% or less." Not all of the hand-written entries are completely legible, and in reviewing them I have tried to give Petitioner the "benefit of the doubt" when the entries are not clear. But

my review of R1's meal monitoring sheet shows that R1 was offered approximately 43 meals (breakfasts, lunches, and dinners) between July 3 and July 18, 2008. Of those meals, R1 ate less than half the offered meal or refused replacement supplements *more than three-quarters of the time*. With particular reference to R1's dinner intake, the document shows that R1 refused or ate less than half his dinner *almost two-thirds of the time*. And perhaps even more significantly, Petitioner's staff recorded that replacement supplements at dinner were offered after R1's refusals on only two occasions, July 7 and July 14, and he refused these replacements as well. P. Ex. 8, at 5; CMS Ex. 8, at 25. Thus, if the document created by Petitioner's staff is correct, R1 had no lunch and no dinner at all on those two days, and may very well have had no breakfast then, as well.

Had Petitioner truly been monitoring R1's meal intake, it could not have failed to recognize that R1 was not eating enough, was thus not receiving adequate nutrition, and that interventions were needed immediately to address his rapidly falling weight. As Surveyor Townsend stated in her Declaration, "[t]he meal monitoring flow sheet should have created concern due to poor meal intake and refusal of replacement meals." CMS Ex. 10, at 4 (¶ 18).

However, despite the fact that R1's nutritional status was compromised, there was no response from Petitioner's staff. Surveyor Townsend testified that the Director of Nursing Services, Vicki Robbins, and the Administrator, Nilda Miranda, admitted in an interview that R1 should have been brought to the attention of the Nutrition at Risk Committee because of his weight loss, and staff also should have ordered a consultation by a registered dietician immediately when they knew that R1 was not receiving adequate nutrition. *See* Tr. at 116, 129, 139-40.[6] Surveyor Townsend testified further that Ms. Robbins told her that these interventions "fell through the cracks and he had neither." Tr. at 129. She found no evidence that R1 was referred to a registered dietician between July 3 and July 18, 2008.

Petitioner points out that its staff did effect interventions such as mashing R1's food, giving him pudding with higher caloric content, offering shake supplements, and prescribing Megestrol, a drug to stimulate appetite. Tr. at 112-115, 128, 178, 264-65, 280-81; *see* P. Ex. 8, at 8.[7] While Surveyor Townsend did not dispute that these were steps taken by staff to address R1's nutrition intake, it is evident that these alone were not

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[6] According to Surveyor Townsend, a Nutrition at Risk Committee is an "inter-disciplinary committee that discusses residents with nutrition at risk and what interventions should be implemented" related to that risk. Tr. at 140. Ms. Haffenreffer testified that this committee "completes an assessment of the residents' nutritional status. And gets input using the . . . Resident Assessment Protocols to determine the cause of the weight loss." Tr. at 288-89.

[7] When asked whether the IV fluids R1 received were a nutritional intervention, Surveyor Townsend explained that the IV fluids were given to address his dehydration, and did not supply any nutrients other than sugar (dextrose) and normal saline. Tr. 91-92, 119.

adequate measures. Even Petitioner's Director of Nursing Services, Ms. Robbins, and the Administrator, Ms. Miranda, recognized after-the-fact that R1's situation was serious and should have received additional scrutiny from the Nutrition at Risk Committee and a registered dietician. However, the record is clear that no action was taken at all to refer R1's situation to the committee and the dietician.[8]

As further support for its claim that its staff assessed R1, Petitioner points to R1's RAP (resident assessment protocol) module document titled "Nutritional Status," a checklist which was completed on July 17, 2008. P. Ex. 8, at 6; *see* Tr. 137. According to Ms. Haffenreffer, the fact that Petitioner's staff completed this RAP document to assess R1's nutritional status shows that they were aware that R1 had nutritional deficiencies. Tr. at 279. When questioned about this document, CMS's witness Surveyor Townsend testified that she considered it to be a nutritional assessment, but stated that the summary at the bottom contained inaccurate information. Tr. at 123. She pointed out that the document incorrectly described R1 as being independent with eating, when he required assistance with meals, and also incorrectly states that R1 had had a three-pound weight loss since his readmission, when the record shows that what he actually experienced was a significant weight loss of 14.7 pounds since his readmission. Tr. at 123. Dr. Reddy testified that this document provided only basic information about R1's nutritional status in the form of "yes or no answers" and did not go into any details "about what the issues are or why he isn't eating." Tr. at 180-81. I note that while this RAP document is an assessment, it contains inaccurate information about R1, was not completed by a registered dietician, and the "yes" or "no" answers in the checklist do not thoroughly examine why R1 was losing weight and not receiving adequate nutrition. Other than this document, Petitioner has offered no evidence that an in-depth nutritional assessment of R1 was done or that either a registered dietician or the Nutrition at Risk Committee evaluated R1's situation.

There was also testimony regarding R1's "Intake and Output Record," dated July 15, 2008. P. Ex. 8, at 1. On this document, there is a section "RD recommendations," and underneath, there appears a handwritten entry -- "Supplements." When questioned about this entry on cross-examination, Surveyor Townsend testified that there is no indication that this entry was actually made by the registered dietician since none is identified on this document, and since the handwriting on the critical section is consistent with that of the nurse who signed it. Tr. at 128.[9] Her testimony was corroborated by that of

[8] At the hearing, Petitioner's witness Ms. Haffenreffer confirmed that there were no records that indicated that R1 was seen by the Nutrition at Risk Committee in June or July 2008. Tr. at 288. Surprisingly, she testified that she did not think that R1 would have benefited from this intervention. Ms. Haffenreffer stated, "I don't think it would have made any difference. They knew what the causes were and they were doing the best they could to get the appropriate nutrition into him. So I don't believe that it would have made a difference." Tr. at 290. Among the witnesses who testified, Ms. Haffenreffer stands alone in her speculation that the Nutrition at Risk Committee would not have helped R1.

Petitioner's witness Ms. Haffenreffer, who stated that a registered nurse had completed the Intake and Output Record. Tr. at 306. Ms. Haffenreffer testified that this nurse was not the registered dietician, and confirmed that there was no evidence that the registered dietician was involved in writing the entry "Supplements." Tr. at 306. That is certainly my evaluation of the document

Further evidence that R1 was nutritionally compromised is contained in a hospital laboratory report dated July 18, 2008, which was done after R1 was admitted to the hospital. This report indicates, among other results, that R1 had an albumin level of 2.6. CMS Ex. 8, at 24. The normal reference range for albumin is 3.2 to 4.9 g/dL. CMS Ex. 8, at 24. Dr. Reddy explained that albumin is a type of protein and can be "a possible marker for malnutrition." Tr. at 162. When asked about the significance of R1's albumin level, Dr. Reddy testified that an albumin level of 2.6 g/dL "would indicate that the patient has a moderately low albumin which means that he is very likely to be malnourished." Tr. at 163.

Dr. Reddy testified that there is a relationship between a patient's level of nourishment and the ability of his or her wounds to heal. Tr. at 163. According to Dr. Reddy, there are "two main linkages between nutrition and wound healing. One is the ability to form . . . the skin that's necessary in order to heal the wound and, secondly, nutrition actually increases the risk for infection in a wound." Tr. at 164. As discussed above, R1's condition included a wound that progressively worsened over several days, and this condition coincided with the period of his severe weight loss.

Petitioner also argues that R1's weight loss pre-dated his re-admission to the facility and was caused by his severe medical condition. In support of this claim, Petitioner points to R1's weight as recorded on June 1, June 2, and June 9, 2008.[10] According to Petitioner, what this shows is that R1's weight loss was on a downward trend prior to July 2008 and was unavoidable.

As the Board has explained, the mere presence of a significant clinical condition, without additional evidence, does not prove that maintaining acceptable nutritional status is not possible. *The Windsor House*, DAB No. 1942, at 15-20 (2004). The "clinical condition exception" is narrow and applies only when a facility demonstrates that it cannot provide adequate nutrition for the resident's overall needs so that weight loss is unavoidable. *The Windsor House*, DAB No. 1942, at 15.

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[9] Dr. Reddy also testified that she did not find any evidence that R1 was seen by a registered dietician. Dr. Reddy testified that she did not know who wrote the word "supplements" and that whoever wrote it "didn't have to be a dietician." Tr. 165-66.

[10] Other than the three recorded weights listed above, Petitioner produced no other recorded weights for R1 in June. As stated above, R1 had a hospital stay from June 16 through June 19, 2008, and went to the hospital again for surgery on June 24, 2008.

Petitioner has not made that showing here. Petitioner offered no testimony or evidence that suggested that R1's various medical problems caused his weight loss or made it impossible for its staff to provide R1 with adequate nutrition.[11] In fact, Petitioner's own Director of Nursing Services, Ms. Robbins, did not even attribute R1's weight loss to his condition, but, instead, admitted to Surveyor Townsend that other interventions should have been ordered to address R1's weight loss, and that these were never implemented. The record clearly shows that Petitioner's staff failed to respond to R1's unplanned weight loss, and failed to demonstrate that his weight loss was the unavoidable result of his overall clinical condition.[12]

Finally, Petitioner's claim that its shortcomings amount to an administrative failure attributable to poor documentation is specious. R1 experienced a severe weight loss, and Petitioner's staff failed to act on it and implement other interventions. Petitioner's failure to respond appropriately to R1's weight loss has nothing to do with a failure to document. It would be far more accurate to say that the crisis in R1's weight-and-nutritional-status should have been obvious to Petitioner on the face of the documents reviewed in this decision, and the facility's failure to respond is proven by the absence of recorded responses in far too many documents for the absence to be the result of simple, or even repeated, oversights or lapses in its record-keeping.

I conclude that CMS has established a *prima facie* case that Petitioner failed to comply substantially with the requirements of 42 C.F.R. § 483.25(i)(1) with respect to R1. Petitioner has not rebutted CMS's *prima facie* showing by a preponderance of the evidence that it took all reasonable steps to ensure that R1 received adequate nutrition or that R1's weight loss was unavoidable.

3. The proposed per-instance CMP of $1,500 is reasonable.

Regulations provide that CMS may impose either a per-diem or per-instance CMP to remedy a nursing facility's deficiencies. 42 C.F.R. §§ 488.438(a)(1)-(2). CMS may impose penalties in the range of $3,050 to $10,000 per day for deficiencies constituting

[11] At the hearing, there was brief questioning with both Surveyor Townsend and Ms. Haffenreffer on the topic of how much of R1's weight loss may have been due to the amputation of his limb. Surveyor Townsend testified that "you don't know the weight of that limb so it's difficult to make a determination how much of this was the limb." Tr. at 134. Ms. Haffenreffer testified that it is "[n]ot really" possible to determine how much of a person's weight loss may be due to an amputation of a limb. Tr. at 307. In response to my questioning as to whether the record contained enough to "try to assign an amount of weight attributable to the removal of some or all of [R1's] limb," Ms. Haffenreffer confirmed that it did not. Tr. at 309-10. I note that, on the RAP Module document titled "Nutritional Status," which I discussed above, Petitioner's staff indicated that R1's weight loss was not due to his amputation. P. Ex. 8, at 6.

[12] Surveyor Townsend testified that after R1 left the hospital after his second surgery, he went to another facility. She stated that she interviewed nurses at the facility, who said that R1 "was thriving, . . . doing quite well, that he had gained weight." Tr. at 55-56.

immediate jeopardy, and $50 to $3,000 per day for non-immediate jeopardy deficiencies. 42 C.F.R. § 488.438(a)(1). A per-instance CMP may range from $1,000 to $10,000 regardless of whether or not the deficiencies constitute immediate jeopardy. 42 C.F.R. § 488.438(a)(2). In this case, CMS determined to impose a per-instance CMP in the amount of $1500.

In determining whether the amount of the CMP is reasonable, the following factors specified at 42 C.F.R. § 488.438(f) must be considered: (1) the facility's history of noncompliance, 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.

I note that with respect to facility history CMS submitted documentation, which Petitioner does not challenge, that shows that the facility has a significant history of substantial noncompliance. CMS Ex. 9. In prior survey cycles since May 2005, Petitioner has been cited six times for violating the Quality of Care requirement under Tag F309 (twice at the "G" scope and severity level), and has previously paid CMPs. Petitioner has provided no evidence to show that its financial condition precludes it from paying the proposed CMP.

The deficiencies in this case were serious. Petitioner's staff failed to adequately assess and document the status of R1's wound and also failed to ensure that R1 received nutrition adequate to his needs. I agree with CMS that Petitioner must be considered culpable.

The $1,500 per-instance CMP imposed by CMS is at the very low end of the range for per-instance CMPs. I find that the amount is fully supported by the evidence in this case. Therefore, I find that the $1,500 per-instance CMP is reasonable.

V. Conclusion

For all of the reasons discussed above, I uphold CMS's determination that the facility was not in substantial compliance with program participation requirements, specifically, 42 C.F.R. § 483.25 and 42 C.F.R. § 483.25(i)(1). I sustain as reasonable the $1,500 per-instance CMP.

/s/
Richard J. Smith
Administrative Law Judge