Department of Health and Human Services

DEPARTMENTAL APPEALS BOARD

Civil Remedies Division

In the Case of:	)	
	)	
Gooding Rehabilitation & Living Center, (CCN: 13-5083),	)	Date: August 26, 2008
	)	
Petitioner,	)	
	)	
- v. -	)	Docket No. C-07-78
	)	Decision No. CR1834
Centers for Medicare & Medicaid Services.	)	
	)	

DECISION

Petitioner, Gooding Rehabilitation & Living Center (Petitioner or Gooding), challenges a determination by the Centers for Medicare & Medicaid Services (CMS) that it was not in substantial compliance with requirements for participation in the Medicare and Medicaid programs from September 14, 2006 through November 6, 2006, and challenges the remedies imposed on it by CMS as a result: a Civil Money Penalty (CMP) totaling $164,700; a Denial of Payment for New Admissions (DPNA) from October 19, 2006 through November 6, 2006; and the suspension of Petitioner's Nurse Aide Training and Competency Evaluation Program (NATCEP) for two years, effective September 14, 2006. For the reasons set out below, I sustain CMS's determination and affirm all three remedies.

I. Procedural Background

Petitioner is a long-term care facility located in Gooding, Idaho. It participates in the Medicare and Medicaid programs. The Idaho Department of Health and Welfare (IDHW) completed a complaint investigation survey of Petitioner's facility on September 14, 2006. The survey findings were based on an incident at Petitioner's facility that began several weeks before the survey, and ended when one of the facility's residents was admitted to the local hospital through its emergency room. That survey found Petitioner not to be in substantial compliance with three of the requirements for participation in those programs, specifically, the requirements set out at 42 C.F.R. §§ 483.13(c) (Tag

F224, at a scope and severity level G[1]), 483.25(c) (Tag F314, at a scope and severity level J), and 483.25(d) (Tag F315, at a scope and severity level G).[2] CMS Ex. 1.

As a result of the survey's findings, and the findings of a revisit survey conducted by IDHW on December 14, 2006, CMS notified Petitioner that it would impose a CMP of $3050 per day, beginning September 14, 2006 and continuing through November 6, 2006, based on a period of substantial noncompliance creating a condition of immediate jeopardy at a scope and severity level of "J." CMS also imposed the additional sanctions noted, the suspension of Petitioner's NATCEP and the DPNA from October 19, 2006 through November 6, 2006. CMS notified Petitioner of its determinations on October 4, 2006 and December 28, 2006. CMS Exhibits (Exs.) 14, 17.

Petitioner perfected its appeal of CMS's actions timely, in its November 27, 2006 Request for Hearing, docketed as C-07-78, and its February 22, 2007 Request for

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[1] A "Tag" designation refers to the part of the State Operations Manual (SOM), Appendix PP, "Survey Protocol for Long-Term Care Facilities," "Guidance to Surveyors," that pertains to the specific regulatory provisions allegedly violated. The cited deficiencies are set forth in the statement of deficiencies (SOD), also called a Form 2567, prepared by surveyors, such as the SOD in this case found at CMS Ex. 1. Each deficiency includes a scope and severity level. A scope and severity level is designated by an alpha character, A through L, selected by CMS or a state agency such as IDHW, from the scope and severity matrix published in the SOM at section 7400E. A scope and severity level of A, B, or C indicates a deficiency that presents no actual harm, but has the potential for minimal harm. Facilities with deficiencies of a level no greater than C remain in substantial compliance. 42 C.F.R. § 488.301. A scope and severity level of D, E, or F indicates a deficiency that presents no actual harm, but has the potential for more than minimal harm that does not amount to immediate jeopardy. A scope and severity level of G, H, or I indicates a deficiency that involves actual harm that does not amount to immediate jeopardy. Scope and severity levels J, K, and L are deficiencies that constitute immediate jeopardy to resident health or safety. Letters A, D, G, and J indicate an isolated occurrence; letters B, E, H, and K indicate a pattern of occurrences; and letters C, F, I, and L indicate widespread occurrences. The matrix, which is based on 42 C.F.R. § 488.408, specifies which remedies are required and optional at each level based on the frequency of the deficiency. *See* SOM, section 7400E.

[2] In this decision I address only the deficiency asserted at 42 C.F.R. § 483.25(c) (Tag F314) because the remedies imposed are amply justified by the presence of this immediate jeopardy level deficiency. I have the discretion, as an exercise in judicial economy, not to address findings that are not material to the outcome of a case. Making findings concerning the two other deficiencies, which were cited at a level G and involve the same resident, are not material to the outcome of this case. *Grace Healthcare of Benton*, DAB No. 2189, at 5 (2008), citing *Western Care Management Corp. D/B/A Rehab Specialties*, DAB No. 1921, at 19 (2004).

Hearing, docketed as C-07-286. By Order of March 21, 2007, I consolidated the two cases under C-07-78 and established procedures by which the consolidated case could proceed to a hearing on the merits.

That hearing on the merits was conducted in Boise, Idaho, from January 14 through January 17, 2008. At the beginning of the hearing, CMS proffered CMS Exs. 1-31; all were admitted in the absence of objection. Similarly, Petitioner proffered Petitioner's Exhibits (P. Exs.) 1-27 at the beginning of the hearing and, in the absence of objection, all were admitted. At a later stage in the hearing, Petitioner proffered P. Exs. 28 and 29, to which CMS objected. For reasons that appear in the transcript of those proceedings, neither P. Ex. 28 nor P. Ex. 29 were admitted, but Petitioner is preserving its objection only to the exclusion of P. Ex. 28. Transcript (Tr.) at 15-16, 428, 608-10, 624, 785-87.

Following the preparation and settling of the hearing transcript, a post-hearing briefing schedule was established by Order of April 7, 2008. Both parties submitted briefs (CMS and P. Br.) and replies (CMS and P. Reply). The cycle of briefing has now closed, and this case stood submitted for decision as of June 16, 2008.

II. Issues

The issues before me in this appeal are:

1. Whether Petitioner was in substantial compliance with requirements for participation in the Medicare and Medicaid programs, in this case, the specific requirements set out at 42 C.F.R. § 483.25(c);

2. Whether CMS's determination that Petitioner's noncompliance constituted immediate jeopardy is clearly erroneous; and

3. Whether the CMP, DPNA, and suspension of NATCEP imposed on Petitioner by CMS as a result of its alleged noncompliance are reasonable.

III. Controlling Statutes and Regulations

Petitioner is a long-term care facility. Its participation in Medicare and Medicaid is governed by sections 1819 and 1919 of the Social Security Act (Act), 42 U.S.C. § 301 *et seq*., and the regulations at 42 C.F.R. Part 483. Sections 1819 and 1919 of the Act invest the Secretary with authority to impose remedies, including CMPs, DPNAs, and suspension of NATCEPs, against long-term care facilities for failure to comply substantially with participation requirements.

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.

The Secretary has delegated to CMS and the states the authority to impose remedies against long-term care facilities not complying substantially with federal participation requirements. The applicable regulations at 42 C.F.R. Part 488 provide that facilities participating in Medicare and Medicaid 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. The regulations contain special survey conditions for long-term care facilities. 42 C.F.R. §§ 488.300-488.335.

Under Part 488, a state or CMS may impose a CMP against a long-term care facility if a state survey agency ascertains that the facility is not complying substantially with participation requirements. 42 C.F.R. §§ 488.406, 488.408, and 488.430. The CMP may begin to accrue as early as the date that the facility was first substantially out of compliance, and may continue to accrue until the date the facility achieves substantial compliance, or until CMS terminates the facility's provider agreement. 42 C.F.R. § 488.440. The regulations specify that if a CMP is imposed against a facility on a per day basis, it must fall into one of two broad ranges of penalties. 42 C.F.R. §§ 488.408, 488.438. The upper range of CMP, of from $3050 per day to $10,000 per day, is reserved for deficiencies that constitute immediate jeopardy to a facility's residents, and, in some circumstances, for repeated deficiencies. 42 C.F.R. §§ 488.438(a)(1)(i), (d)(2). The lower range of CMP, from $50 per day to $3000 per day, is reserved for deficiencies that do not constitute immediate jeopardy, but either cause actual harm to residents, or cause no actual harm, but have the potential for causing more than minimal harm. 42 C.F.R. § 488.438(a)(1)(ii).

"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.

42 C.F.R. § 488.301.

CMS may also impose a DPNA for each day that a facility is not complying substantially with participation requirements. Act, § 1819(h)(2)(B)(i) and 1919(h)(2)(A)(i); 42 C.F.R. § 488.417(a). In situations where a substandard quality of care is cited, a DPNA is imposed, or where a CMP of more than $5000 is imposed, a facility's NATCEP is subject to suspension for a mandatory period of two years. Act, §§ 1819(f)(2)(B) and 1919(f)(2)(B); 42 C.F.R. §§ 483.151(b)(2)(iv), 483.151(b)(3)(ii) and (iii).

The requirement of participation directly at issue in this litigation is set out at 42 C.F.R. § 483.25(c) and is part of a broad regulatory scheme intended to assure that facilities provide, and that their residents receive, the care and services necessary to attain and maintain each resident's highest practicable level of physical, mental, and psychosocial well-being. The specific terms of the regulatory requirement are set forth below.

A facility may challenge the scope and severity of noncompliance cited by CMS only if a successful challenge would affect the range of CMP amounts imposed by CMS or would affect the facility's nurse aide training program. 42 C.F.R. §§ 498.3(b)(14) and (d)(10)(i). CMS's determination as to the scope and severity of noncompliance "must be upheld unless it is clearly erroneous." 42 C.F.R. § 498.60(c)(2). This includes CMS's finding of immediate jeopardy. *Woodstock Care Center*, DAB No. 1726, at 9 (2000), *aff'd, Woodstock Care Center v. U.S. Dept. of Health and Human Services*, 363 F.3d 583 (6th Cir. 2003). Since the scope and severity of Petitioner's alleged noncompliance with Tag F314 between September 14, 2006 and November 6, 2006 is cited and sanctioned at "J," a level of immediate jeopardy, the scope and severity of that alleged noncompliance is properly before me.

IV. Burden of Proof

Board precedent has established that a facility must prove by the preponderance of the evidence that it is in substantial compliance. *Woodland Village Nursing Center,* DAB No. 2172 (2008); *Batavia Nursing and Convalescent Center*, DAB No. 1904 (2004), *aff'd Batavia Nursing and Convalescent Ctr. v. Thompson,* 129 Fed. Appx. 181 (6th Cir. 2005); *Hillman Rehabilitation Center*, DAB No. 1611 (1997), *aff'd*, *Hillman Rehabilitation Center v. HHS*, No. 98-3789 (GEB), slip op. at 25 (D.N.J. May 13, 1999). In order to put the facility to its proof, CMS must initially present a *prima facie* case of noncompliance with Medicare participation requirements. Once CMS has presented such *prima facie* evidence as to any material disputed facts, the burden of proof shifts to a petitioner to show at the hearing that it is more likely than not that the facility was in substantial compliance. *Woodland Village Nursing Center*, DAB No. 2172, at 5. Here, the evidence is not in equipoise. Petitioner has failed to show that it is more likely than not that its facility was in substantial compliance.

V. Findings and Conclusions

I make findings of fact and conclusions of law to support my decision in this case. I set forth each finding below, in italics, as a separate heading. I discuss each finding in detail.

> *A. Petitioner was out of substantial compliance with the participation requirement at 42 C.F.R. § 483.25(c), Tag F314, and its noncompliance with the requirement constituted immediate jeopardy.*

This section of the regulations is a subsection of the quality of care regulation cited at 42 C.F.R. § 483.25, which section requires:

> Each 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.

The subsection at 42 C.F.R. § 483.25(c) requires:

> *Pressure sores.* Based on the comprehensive assessment of a resident, the facility must ensure that —
>
> (1) A resident who enters the facility without pressure sores does not develop pressure sores unless the individual's clinical condition demonstrates that they were unavoidable; and
>
> (2) A resident having pressure sores receives necessary treatment and services to promote healing, prevent infection and prevent new sores from developing.

In the recent case of *Woodland Village Nursing Center*, DAB No. 2172, an appellate panel of the Departmental Appeals Board (Board) explained:

> [A]s the ALJ recognized . . . the regulatory requirement is that each resident "must receive 'necessary treatment and services' for healing, prevention of infection, and prevention of yet more pressure sores." Clermont Nursing and Convalescent Center, DAB No. 1923, at 9 (2004) (emphasis added in DAB No. 1923). Further, the Board has explained that regulatory language on pressure sore treatment and prevention applies a particularly demanding standard, i.e., that the facility must "ensure" healing and prevention as the outcomes of that treatment and those services unless the facility can prove with clinical evidence that a negative outcome was unavoidable despite the facility having furnished all necessary care. Koester Pavilion, DAB No. 1750, at 30. Further, the Board has repeatedly held that the regulation imposes a duty on facilities to "go beyond merely what seems reasonable to, instead, always furnish what is necessary to prevent new sores, unless clinically unavoidable, and to treat existing ones as needed." Id. at 32; see also Josephine Sunset Home, DAB No. 1908, at 7 (2004); Meadow Wood Nursing

> Home, DAB No. 1841, at 21 (2002), aff'd, Meadow Wood Nursing Home v. Dep't of Health & Human Services, No. 02-4115 (6th Cir. March 2, 2004). . . . [E]vidence showing that a resident developed a pressure sore or that a resident's pre-existing pressure sore worsened or grew infected while under a facility's care is enough to show a deficiency in the absence of clinical evidence from the facility proving such negative outcomes to have been clinically unavoidable . . . In order to avoid a deficiency finding . . . the facility would have to show that the failure to achieve healing was clinically unavoidable, despite implementing measures to address the persistent sore, even if the sore had not actually grown even worse or become infected . . . [and] where the facility is proven to have been providing improper care or not providing care as ordered by the physician or planned for by the facility itself as necessary to protect against or treat pressure sores, CMS need not wait to see if an infection or aggravation of a sore ensues before citing a deficiency.

Woodland Village Nursing Center, DAB No. 2172, at 13-14.

The SOD[3] alleges that Petitioner failed to assess, develop and implement appropriate interventions in a timely manner related to pressure ulcers, which resulted in serious harm to Resident 1 (as well as placing all other residents in the facility at risk for pressure sores).[4] Specifically, it asserts the facility failed to prevent, identify, assess, and appropriately intervene to prevent further deterioration of two Stage II pressure ulcers for Resident 1, which led to his hospitalization and the surgical debridement of his Stage IV gangrenous sacral decubitus. CMS Ex. 1.

Resident 1, an 81-year-old man, was originally admitted to Petitioner's facility on October 29, 2002. His medical history included such diagnoses as coronary artery disease, organic brain syndrome with dementia, emphysema, aortic abdominal aneurysm, atrial fibrillation, benign prostatic hypertrophy, peripheral vascular disease, and peptic ulcer disease. CMS Ex. 15, at 40; CMS Ex. 29, at 4-5.

The following facts regarding this case were stipulated by the parties (CMS Exs. 30, 31; P. Br. at 25). I here set them forth *verbatim* as found in CMS Ex. 30 and adopt them without editorial alteration:

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[3] Petitioner asserts that because of deficiency findings at surveys in 2004 and 2005 it was placed on an "underperforming list," and insinuates that this somehow affected the survey results in this case by causing the surveyors to overstate results and to overlook Resident 1's severe medical condition at the time of the survey in question. *See* P. Br. 2-3. This argument is simply irrelevant to my finding that a deficiency exists in this case.

[4] In this decision I refer to the open areas of Petitioner's skin variously as "sores," "wounds," "ulcers," or "decubitus(ii)." They are so variously described in the record.

1. Gooding Rehabilitation and Living Center (Gooding Rehabilitation) is located at 1220 Montana Street in Gooding, Idaho. It is less than a tenth of a mile from Gooding County Memorial Hospital (GCMH) which is located at 1120 Montana Street.

2. Gooding Rehabilitation and GCMH are separate facilities, that are owned by separate corporations.

3. St. Lukes Magic Valley Regional Medical Center (St. Lukes) is located in Twin Falls, Id, approximately 35 miles from Gooding Rehabilitation.

4. The person identified as Resident 1 on the CMS form 2567 dated September 14, 2006, underwent an above-knee amputation to his right leg on July 29, 2007. Dr. James Retmier performed this surgery at St. Lukes. On July 29, 2007, Dr. Retmier documented Resident 1's amputation by dictating the Operative Report identified as CMS Ex. 15, pp 101-102.[5]

5. After discharge from St. Lukes on August 1, 2006, Resident 1 was readmitted to Gooding Rehabilitation. At this time, Gooding Rehabilitation staff prepared an Initial Data Collection Tool/Nursing Service concerning Resident 1. Among other things, this documentation describes Resident 1 as having a right above knee amputation, occasional incontinence (dribbles), a stage I pressure sore on the left buttocks and a pain level of 7-8 (on a 1-to-10 scale with 10 the worst pain). CMS Ex. 16, at 26-28.

6. Between August 1, 2006 and August 28, 2006 Gooding Rehabilitation documented Resident 1's skin condition on Skin Impairment forms identified as CMS Ex. 15, pp 105-115.

7. On August 14, 2006, Gooding Rehabilitation evaluated Resident 1 and completed a Minimum Data Set (MDS) Basic Tracking form CMS Ex. 15, pp 1-25.

8. Gooding Rehabilitation documentation of an Interdisciplinary Team Care Plan Meeting on August 24, 2006, describes Resident 1's amputation as "healing well . . . no s/s [signs or symptoms] of infection . . . no new acute problems . . . [but] has decline in ADL [activities of daily living] functions and mobility and continence." CMS Ex. 15, p. 178.

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[5] Although the parties have stipulated that the surgery occurred on July 29, 2007, the record reflects that the surgery occurred on July 29, 2006.

9. On August 29, 2006, Resident 1 was readmitted to St Lukes where Dr. Retmier performed a revision of the right above-knee amputation stump. CMS Ex. 15, pp 103-104. Dr. Retmier described this procedure in the Operation Report identified as CMS Ex. 15, p 103. This report describes the surgery as follows:

> He had a large central eschar, which I started out by excising, I basically did a radical debridement, created an entire new wound distally and removed all of the previous wound. He had deep wound breakdown, deep sepsis, and mulitple areas of deep necrotic tissue . . . He had another wound in his medial groin, which was very superficial, I debrided that as well. CMS Ex. 15, p 103-104.

10. Dr. Retmier dictated a discharge summary for Resident 1 on September 1, 2006, and directed that the wound care team will follow wound vac on a "q. 3 day [three times per day] basis. CMS Ex. 15, p. 46. Under the section entitled Evaluation and Treatment, the September 1, 2006, physician order also directs "wound care team and [wound] vac per protocol." *Id.* at p 89.

11. Resident 1 was readmitted to Gooding Rehabilitation at 1630 on September 1, 2006; he arrived via facility van. CMS Ex. 9, p 4. Gooding staff prepared a care plan dated September 1, 2006, which described Resident 1 as incontinent and directed that he be checked at least "q2h" [every two hours]. The Gooding Care Plan for Resident 1 is identified as CMS Ex. 15, 179-190.

12. Between September 1, 2006, and September 11, 2006, Gooding Rehabilitation nursing staff composed the nursing notes identified at CMS Ex. 15, pp 69-72.

13. On September 6, 2006, at 1515 hours (3:15 PM) Gooding Rehabilitation staff prepared a nursing note that describes Resident 1 as having an open area to coccyx which appears necrotic and is larger than prior to hospitalization. CMS Ex. 15, p 71. This note also describes Resident 1 as having a "healing, scabbed areas to (R) groin from previous procedure." CMS Ex. 15, p 71.

14. Gooding documented Resident 1's wound care on Wound Care Sheets dated September 6, 2006. CMS Ex. 15 pp, 73, 122-123.

14.[6] At 1500 hours (3:00 PM) on September 8, 2006, Gooding Rehabilitation nursing notes describe Resident 1's as "emitting yellow drainage" through his Foley Catheter. CMS Ex. 15, p. 70.

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[6] The stipulation includes two paragraphs numbered 14.

15. On September 9, 2006, at 1545 hours (3:45 PM) Gooding Rehabilitation nursing notes describe resident 1 as emitting "dk [dark] yellow drainage" through his Foley Catheter. CMS Ex. 15, p 70. Staff document that Resident 1 yells out whenever he is touched.

16. On September 10, 2006, at 0215 hours (2:15 AM) Gooding Rehabilitation nursing notes describe Resident 1 as emitting "dk [dark] yellow drainage" through his Foley Catheter. CMS Ex. 15, p 70.

17. At 0200 hours (2:00 PM) on September 11, 2006, Gooding Rehabilitation nursing notes describe Resident 1's Foley Catheter as emitting "dark amber drainage." CMS Ex. 15, p. 69; CMS Ex. 9, p 1. This same note documents that Resident 1 was quieter but continues to yell out every once in a while. *Id.*

18. At 2150 hours (9:50 pm) on September 11, 2006, Gooding documented a physician telephone order to transfer Resident 1 to the hospital. CMS Ex. 15, p 138. Resident 1 arrived in the emergency room at GCMH at 2208 hours (10:08 PM).

19. On September 14, 2006, Idaho State Surveyors visited Gooding Rehabilitation to conduct a complaint investigation on behalf of CMS.

20. On October 4, 2006, CMS notified Gooding Rehabilitation that it concurred with state survey agency findings of substandard quality of care and that it intended to impose a $3,050 per day civil monetary penalty and a denial of payment remedy. CMS Ex. 14.

CMS Ex. 30.

Upon Resident 1's return to Petitioner's facility from St. Luke's on September 1, 2006, his physician's admissions orders were for "careful skin care." CMS Ex. 15, at 136. His September 1, 2006 care plan noted that Resident 1 was at high risk for skin problems because of his activity and mobility levels, his diagnoses and health condition, and the above-knee amputation with the wound vac. Approaches to address Resident 1's skin problems included providing him with a special type of air mattress described as "air loss," turning him every two hours, providing him dietary supplements and encouraging him to eat and drink, moisturizing his skin, providing barrier ointment with his incontinent care, weekly "body audits" by a licensed nurse, a daily bath and shower, briefs to wick urine away from his skin, and requiring certified nursing assistants (CNAs) to report all skin issues to the nurses (including red skin, not resolving, excoriations, rashes, scabs and open or discolored areas, pain management, and care planning for current ulcers or skin conditions). CMS Ex. 15, at 181-82.

Specific to the issues here, on September 1, 2006, the facility care-planned for two open areas, as nurse's notes indicate that Resident 1 was admitted on that date with open areas to his coccyx and right inner thigh. CMS Ex. 10, at 3. One wound, on his coccyx, received a high risk score on an admission care plan. The facility listed as interventions for the coccyx wound a daily skin check, a two-hour turning schedule, not to position the resident on his back, the use of an "air loss mattress," and catheter care every shift and as needed.[7] CMS Ex. 15, at 183.

A September 1, 2006 facility record entitled "Skin at Risk Actual" noted the coccyx "pressure ulcer" as a Stage II, and noted as approaches to Resident 1's care that the physician gave orders for care and treatment, including to turn the Resident every two hours, to assess and treat pain prior to each treatment and every shift, to evaluate the dressing status and surrounding area daily, and to do a weekly assessment with measurements. CMS Ex. 15, at 186. There were also "Skin at Risk Actual" sheets for the surgical site. CMS Ex. 15, at 187-89.

A skin impairment sheet dated September 1, 2006, notes the coccyx wound as 5.5 by 3.5 cm., depth of .1 cm. no drainage or odor, pink in color, no tunneling, and does not describe signs or symptoms of an infection. CMS Ex. 15, at 65, 120. On September 4, a necrotic area was found measuring 4 x 2 cm. out of a 5 x 2 cm. area. CMS Ex. 15, at 120. The right inner thigh wound was indicated as 6 cm. by 3 cm., with a depth of .8 cm., bloody drainage, and pink in color. As noted in stipulation 13, a nurse's note dated September 6, 2006, states that Resident 1 had "an open area to coccyx, which appears necrotic and is larger than prior to hospitalization. Has healing scabbed area to [right] groin from previous . . . procedure. Will follow and review in one week." CMS Ex. 9, at 3. On September 10, 2006, it was measured as the same width, .15 cm. in depth, drainage was still bloody, and no improvement was noted. CMS Ex. 15, at 67.

Physician's telephone orders note that when Resident 1 returned to the facility, he had skin ulcers — one on the area of his coccyx and one on his right inner thigh. Duoderm was to be applied to coccyx and inner thigh sores every three days. CMS Ex. 15, at 139. On September 6, 2006, physician's telephone orders specify a "low air loss mattress replacement system." CMS Ex. 15, at 137. On September 6 and 7, 2006, physician's telephone orders reflect changes to vitamins and diet. CMS Ex. 15, at 137-38. On

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[7] The facility was also to measure the coccyx wound every week, but there appears to be a conflict in the treatment sheets about whether the sheets were completely or timely filled out. A treatment sheet faxed from Petitioner's nursing station on November 12, 2006, shows that the coccyx wound was measured only once, on September 1, 2006. CMS Ex. 15, at 73. Another copy of the same sheet shows the coccyx wound was measured on September 4, but that sheet must have been filled out after Resident 1's transfer. CMS Ex. 15, at 122. However, a skin impairment sheet does show measurement of the coccyx on September 4. CMS Ex. 15, at 120.

September 11, 2006, physician's telephone orders at 2150 (9:50 p.m.) reflect Resident 1's transport to Gooding County Memorial Hospital.

On September 11, 2006, at 2208 (10:08 p.m.), Resident 1 was sent to Gooding County Memorial Hospital because the nurses noted he had tachycardia and hypotension. CMS Ex. 29, at 4; CMS Ex. 15, at 97.

At Gooding County Memorial Hospital, Resident 1 was assessed by David White, PA-C. Mr. White prepared a "Stat Report" on September 12 with regard to Resident 1's skin conditions. He wrote:

> He does have a very large decubitus ulcer, and deep, on his right inner thigh, approximately 3" long, 1 ½" wide and ½" deep. He also has a second decubitus ulcer over his sacrum, very large. It appears to be necrotic. The first previously mentioned decubitus ulcer is probably a stage 2 to 3. The sacral decubitus ulcer, which is large, being somewhere around 6" in diameter, appears necrotic and is stage 3 to 4.

Mr. White prepared an addendum with regard to the ulcers, which states:

> It is important to note that his current state of two very serious decubitus ulcers appears to be due to extreme neglect and his Power of Attorney will be contacted. Today being the 11th it appears that his most recent examination was performed almost a week ago and based on weekly documentation and previous to that of three days before, in any case, the state of these wounds is very severe and appears to have been allowed to proceed with very little monitoring.

CMS Ex. 15, at 40-42; *see* CMS Ex. 15, at 38; CMS Ex. 21 (pictures taken at Gooding County Memorial Hospital of the wounds on Resident 1's thigh and coccyx); CMS Ex. 15, at 52, 90-91.

On September 12, 2006, Resident 1 was admitted to St. Luke's Magic Valley Regional Medical Center for his large infected sacral decubitus ulcer, his right thigh decubitus ulcer, and his infected non-healing right above-knee amputation. CMS Ex. 15, at 97. Stephen Schmid, M.D, Petitioner's physician at St. Luke's, noted that Resident 1's "[s]acrum shows a large, very foul smelling, obvious stage 4 sacral decubitus ulcer measuring 10 x 15 centimeters with overlying skin gangrene. I did sharply open up the dead skin and there was underlying necrotic tissue, but no purulence was drained. On his right medial thigh is a 4 x 7 centimeter deep non-healing ulcerated wound." Dr. Schmid started Resident 1 on antibiotics and stated he needed "aggressive wound debridement of his sacral and thigh decubitus ulcers." CMS Ex. 15, at 99-100. However, Resident 1 developed severe hypotension in the operating room and died on September 14, 2006. Dr. Schmid opined that the cause of death was intraoperative myocardial infarction. CMS Ex. 29, at 4-5. Resident 1's death certificate states that the cause of death was

perioperative myocardial infarction due to surgery for sacral decubitus ulcer. P. Ex. 6, at 1.

CMS argues that it has met its duty and shown a *prima facie* case that Petitioner failed to provide necessary treatment and services to promote healing, prevent infection, and prevent new pressure sores from developing and that Petitioner's failures created a situation in which the noncompliance caused serious injury, harm, impairment, or death. Thus, CMS argues that the burden shifts to Petitioner to rebut CMS's *prima facie* case and to demonstrate that it was in substantial compliance with the regulations.

Specifically, CMS asserts that between September 1 and September 11, 2006, the skin over Resident 1's coccyx deteriorated to a very large and deep wound with extensive central necrosis. Compare CMS Ex. 15, at 116, 120, with CMS Ex. 15, at 41, 98, 99; CMS Ex. 21, at 4; Tr. at 187; CMS Br. at 4-9. Petitioner knew that Resident 1's coccyx area had a significant risk of skin breakdown. But, CMS asserts, Petitioner's treatment sheets do not confirm that its staff followed the planned schedule for Resident 1's treatment, which included repositioning the resident every two hours, assessing for pain prior to each treatment, evaluating dressing changes daily, and assessing and measuring the sore weekly. CMS Br. at 4, citing CMS Ex. 15, at 136, 180, 181, 186; Tr. at 209. Specifically, CMS asserts that treatment sheets do not establish that weekly measurements of the wound were made. CMS Ex. 15, at 73. CMS also asserts that although Resident 1 was care-planned to receive a special mattress to relieve pressure on his back, Surveyor Kaiser testified that the surveyors could not verify that the mattress was provided. CMS Ex. 15, at 181; Tr. at 210-11.

CMS notes that on September 4, 2006, Petitioner's skin impairment sheets showed development of a necrotic area to Resident 1's coccyx. CMS Ex. 15, at 120. Surveyor Kaiser testified that she saw this note and became concerned that the "necrotic area tells me that the wound's deteriorated, but I don't see that that really jelled with anybody else . . . I don't see any other documentation about what else occurred after that." Tr. at 187; *see* Tr. at 189-90. CMS also refers to the nurse's note of September 6, 2006, regarding the development of necrosis in the wound. CMS Ex. 9, at 3.

CMS asserts that Petitioner should have notified Resident 1's physician on September 4, 2006, when the necrotic tissue appeared in the wound. CMS states that Petitioner's expert witness, Florian John Gies, IV, M.D., in response to a question as to what nurses should do to take necrosis of a coccyx wound seriously, testified that on September 4, 2006, Petitioner's staff should have:

> alert[ed] the appropriate people, ma[d]e sure the regular wound checks are accomplished and that whatever orders they receive for dressings, et cetera, are accomplished . . .

Tr. at 640. Dr. Gies qualified his statement to say that there is a "matter of magnitude" regarding the size of the necrosis in terms of how many people should be alerted and what needed to be done, but agreed that "in general, necrosis is always an important thing to watch." Tr. at 641. CMS asserts however, that on September 4, 2006, Petitioner did not alert the appropriate people or get orders for dressings.

CMS also asserts that after September 9, 2006, Petitioner's documentation of the coccyx wound is even more sparse, and refers to nurse's notes at CMS Ex. 15, at 69-71. Specifically, it asserts the only relevant nurse's note on September 10, 2006, was written at 1340 (1:40) p.m., and states only "[dressing] intact to coccyx." The note does not describe the wound. And, CMS asserts that September 9, 2006, was the last time Petitioner's DON saw the wound. CMS Ex. 6, at 4; CMS Ex. 7, at 1. Surveyor Kaiser testified that the facility did not provide documentation of the DON's assessment of the wound on September 9, 2006. Tr. at 214. CMS asserts Petitioner has not offered any evidence of staff who saw the wound between September 9 and 11, 2006.[8]

CMS argues that it is irrelevant here whether Petitioner provided care according to its policy and care plan. Surveyor Bouse testified that she was told by the facility's DON that it was not Petitioner's policy to assess the wound every day. Tr. at 50; CMS Ex. 6, at 4; CMS Ex. 7. LPN Joyce Heath testified that it was Petitioner's policy to document by exception, a protocol whereby a nurse makes notes in a resident's chart only if something changes or appears different. Tr. at 661. CMS asserts that meeting its own care plan and policies does not establish Petitioner's compliance, as Petitioner's obligation to provide necessary care is not — and cannot be — circumscribed or limited by the plan of care if it is inadequate. *See Western Care Management Corp*, DAB No. 1921, at 57 (2004). Surveyor Bouse testified that:

> I found that we couldn't determine that [the facility did everything it could to prevent deterioration in the wound], based on documentation and interviews. We felt that they had not because monitoring was not present in the form of documentation or if there was an indication that the resident had gotten worse that a physician had been called to change the treatment. There wasn't a care plan that

[8] CMS notes Petitioner's argument that IDHW surveyors were remiss for not talking to nurses at Petitioner's facility who cared for Resident 1 in an effort to discover, outside the documentation, what care Petitioner was actually providing between September 9 and 11. CMS Br. at 6; *see* P. Br. at 21. I agree with CMS that it is Petitioner who has the burden to demonstrate the condition of Resident 1's wound and its treatment at the relevant times. The failure to document care raises at least an inference that the undocumented care was not provided, and it is Petitioner's burden to show that it was provided.

> addressed everything . . . for instance . . . indicating that he would flip over on his back keeping him from relieving pressure off that area.

Tr. at 104-05.

CMS points out that nurse's notes during the time period September 1 through 11, 2006, repeat the phrase "dressing intact to coccyx" at least four times, but do not include qualitative descriptions of the wound's condition. CMS also asserts that it was not until Mr. White, the physician assistant at Gooding County Memorial Hospital, assessed the condition of the coccyx that Resident 1's wound was thoroughly and accurately documented. CMS Br. at 7. Significantly, medical records at Gooding County Memorial Hospital corroborate the photographs taken of the wound and highlight the severity of Resident 1's condition. CMS Ex. 15, at 38-41.[9]

CMS also asserts that Petitioner's staff knew of the odor in the wound as early as 8:30 p.m. on September 11, 2006, but did not report that important information to Gooding County Memorial Hospital upon Resident 1's transfer, reporting only that Resident 1 was hypotensive and tachycardic. Tr. at 138. Moreover, CMS argues that the 18-hour gap in nurse's notes on September 11, 2006 (from 2:00 a.m. through 10:30 p.m.) demonstrates neglect during a critical time in Resident 1's care. CMS. Br. at 9. Specifically, the final facility nursing note before Resident 1's transfer was written at 2:00 a.m. on the morning of September 11. CMS Ex. 9, at 1. It notes that Resident 1 would "not stay positioned off (his) back," but does not mention the condition of the skin over his coccyx or the smell of the wound. CMS Ex. 9, at 1. Petitioner updated its nurse's notes at 2250 (10:50 p.m.) on September 11, 2006, after Resident 1's transfer to Gooding County Memorial Hospital. It observes that at 2030 (8:30 p.m.) the coccyx wound is described as "very foul smelling." CMS Ex. 9, at 1. Surveyor Kaiser's surveyor notes document an interview with a CNA who confirmed the pronounced odor: the surveyor quoted the CNA as insisting that a window be opened "because it was making me sick." CMS Ex. 6, at 9. And, when Resident 1 arrived at Gooding County Memorial Hospital, Mr. White testified that it was the coccyx wound's smell that caught the emergency room staff's attention in a dramatic fashion. Tr. at 118. Within minutes of Resident 1's arrival at Gooding County Memorial Hospital, Mr. White was called to take a look at the wound, and, during the hearing, he described the wound as "purulent," "rotting," and "very foul." Tr. at 118, 121.

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[9] CMS points out that the photograph of the coccyx wound and the three photographs of the thigh wound taken in the Gooding County Memorial Hospital emergency room were taken between 10:00 p.m. on September 11, 2006 and 1:00 a.m. on September 12, 2006. P. Br. at 8, citing CMS Ex. 21; Tr. at 128; CMS Ex. 15, at 38, 43.

CMS also asserts that Petitioner failed to use a coordinated approach to track the progression of the wound on Resident 1's right thigh. On September 1, 2006, the wound was described as 6 cm. by 3 cm., bloody, with no signs or symptoms of infection. CMS Ex. 15, at 119. On September 11, 2006, the size of the wound had not changed, but emergency room staff noted the presence of "mild exudate" and a "strong sweet odor." CMS Ex. 15, at 39. Pictures of the wound show two darkened areas which indicate possible development of necrosis. CMS Ex. 21, at 1, 2; Tr. at 228. Staff initials on treatment sheets confirm only that Petitioner applied duoderm to the thigh wound every three to five days and measured it weekly. CMS Ex. 15, at 122. No evidence of daily checks have been found in nurse's notes. CMS Ex. 9. Nurse's notes document only one dressing change, on September 1. CMS Ex. 9, at 4.

In its reply, CMS presses the following specific lapses as evidence that Petitioner's wounds were avoidable: Petitioner did not notify Resident 1's physician on September 4, 2006, when necrotic tissue developed on the coccyx wound; Petitioner did not report the development of necrotic tissue on Resident 1's thigh; and, Petitioner did not alert the emergency room about Resident 1's coccyx wound during the transfer. CMS Reply at 2-3. CMS refers to the testimony of its expert witness, Dan Robert Berlowitz, M.D., that if Petitioner had been checking Resident 1 every day for signs and symptoms of infection he would have "expected you would have seen it earlier than 11:00 at night." Tr. at 335. CMS asserts that instead of having current knowledge of Resident 1's condition on September 11, 2006, many staff were surprised by its condition (Tr. at 468, 594-95) and the DON had not even seen the wound since September 9.

In its brief and reply, Petitioner asserts that Resident 1 had severe vascular problems, and that each time he went to the hospital, he returned to Petitioner's care facility with worsening wound symptoms. Petitioner asserts Resident 1 did not have any wounds or dead tissue prior to the amputation of his right leg. Resident 1 came back to Petitioner's facility after the August amputation surgery with some type of ulcer in the region of his buttocks. Petitioner argues that all sores on Resident 1 at the time of the survey were stasis ulcers and unavoidable and occurred as a result of Resident 1's diagnosed peripheral vascular disease and the "melt down" that Resident 1 was experiencing during the first two weeks in September 2006. And, although there was a decubitus ulcer on Resident 1's sacrum or coccyx area (a weight-bearing area of Resident 1's body, since he was bed-ridden), Resident 1 also had ulcers that were not over weight-bearing body areas.[10]

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[10] At hearing, Petitioner offered a theory to explain Resident 1's coccyx wound. It asserted that it was a theoretical phenomenon known as a "Kennedy Terminal Ulcer" or "death wound." Tr. at 315-18. The theoretical phenomenon is named for its early proponent, K. L. Kennedy-Evans, R.N., C.S., F.N.P., and posits that as a chronically-ill terminal patient approaches the point of death, many long-compromised body-systems and organs — including the skin — simply shut down and the patient's recuperative

(continued...)

Petitioner asserts that it recognizes that in this case the question is not really whether Resident 1's wounds were avoidable (although asserting they were unavoidable due to his poor circulation as a result of peripheral vascular disease) but whether or not the facility did what it could to heal and reduce the spread or size of the ulcers. Petitioner believes it did everything in its power to help and care for Resident 1 during his stay at Petitioner's facility. P. Br. 20.

As evidence of its compliance, Petitioner argues that its nurses knew the difference between a stasis ulcer and a pressure ulcer and that its DON saw the ulcer on Resident 1's back "two or three days prior to his admission to the Gooding Hospital . . . but was not concerned about it as its condition had not changed from his admission date on September 1, 2006." P. Br. at 20, citing Tr. at 66. Petitioner asserts that its nurses were reporting what they saw on Resident 1 in facility records, changing Resident 1's dressing every three to five days, checking for signs and symptoms of infection, noted necrotic skin problems as early as September 4, 2006, and were treating Resident 1's wounds by applying Duoderm. P. Br. at 31; P. Reply at 24. Petitioner asserts it used a coordinated approach to deal with Resident 1's wounds, but it does not specify exactly what that approach was. P. Reply at 33-34.

Petitioner also asserts that Resident 1's wounds were so severe they most likely caused a septic infection of the blood from the coccyx wound (or one of the other wounds) and that, as a result, Resident became tachycardic, hypotensive, and febrile. P. Br. at 32, citing Tr. at 294, 312, 344-45. Petitioner cites Dr. Berlowitz's testimony that "if the deep tissue insult occurred in the hospital, it may not appear until later on when the person was in the nursing home. So, it would have been unavoidable for the nursing home." Tr. at 348. And, Petitioner states that in the case of peripheral vascular disease, when a

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[10](...continued)
powers diminish to the point of vanishing, thus making the patient's development of ulcerating lesions virtually inevitable. This theory was adopted by the facility after the death of Resident 1. Tr. at 515-17. Dr. Gies also did not formulate his opinion that the coccyx wound was a "Kennedy Terminal Ulcer" until after Resident 1 died. Tr. at 591, 615. Dr. Berlowitz, CMS's expert witness, testified with regard to whether the theoretical "Kennedy Terminal Ulcer" exists in reality, that he did not believe that there was "anything special about the terminal stages independent of other factors such as low blood pressure and things like that or patients not being turned. So I don't think that the fact that you're necessarily at end stages from cancer means that you develop a pressure ulcer." Tr. at 316. Dr. Berlowitz preferred using the terms "avoidable" and "unavoidable." Tr. at 316-17. In this case it is irrelevant what the cause of the ulcers were as it is the *facility's response to the ulcers* that is in question. I decide neither the validity of the "Kennedy Terminal Ulcer" concept in general, nor its presence in this case in particular. However, below, I note that the preponderance of the evidence is that the coccyx wound was in fact a pressure sore, in that pressure more likely than not played a role in its development.

procedure is done there is always the possibility of a poor outcome. P. Br. at 32. Petitioner refers to the opinion of Dr. Gies that:

> This patient did, obviously, have decubitus ulcers . . . how [did] his ulcers [go] from 5 or 6 cm of ertythema with 2 cm of central necrosis to 15 or 20 cm full thickness within just one or two days. The answer is that this wound did not develop in just one or two days. In point of fact this patient likely experienced deep hematogenous spread of infection from his gangrenous stump weeks earlier. His sacral decubitus ulcer simply provided an exit wound for this extensive area of gangrenous and devitalized tissue (i.e. skin infections that "work from the inside-out.") Thus, the "exploded appearance" of the patients buttocks and sacrum as well as the copious foul smelling discharge.

P. Ex. 5, at 3. Petitioner notes that "wounds can develop and deep wounds in the case of Resident 1 . . . within 24-48 hours. Any pressure ulcer in the right circumstances can be healed. In the case of a terminal patient, the underlying factors need to be corrected that are making the person terminal for the wound to heal." Tr. at 335-36; P. Reply at 24.

Although hotly contested by the parties, for purposes of my decision it is irrelevant whether the wounds in question are termed pressure sores or some other type of ulcer or wound, because the preponderance of the evidence would indicate that the coccyx wound at least was a pressure sore. Contemporaneous facility records refer to the coccyx wound as a pressure ulcer. CMS Ex. 15, at 186, *see* 120. Mr. White, who actually saw the coccyx wound, describes the wound as a pressure sore, and notes that it is common for pressure ulcers to develop over the sacrum. Tr. at 135. Mr. White, who testified that he has seen pressure sores through the emergency room, described Resident 1's coccyx wound as the "worst I've ever seen . . . I've never seen a pressure sore that had necrosis before. I mean blackened, dead tissue . . . I could see his sacrum as well . . . you could see the bone." Tr. at 123. He also described the coccyx wound as the "worst pressure ulcer he had ever seen." Tr. at 123. Facility records indicate that they had trouble keeping Resident 1 off his back, and Resident 1 had been assessed as at moderate or high risk for friction and shear. CMS Ex. 15, at 36-37. Thus, the sore may have been caused by a combination of Resident 1's disease process and his multiple diagnosed conditions as well as pressure on his back.

The evidence in this case shows that Resident 1's wounds grew worse while at Petitioner's facility, culminating in his hospitalization and the final surgery to debride the wounds. The first question I must address and resolve is: while Resident 1 was at the facility between September 1 and 11, 2006, did Petitioner implement measures to address Resident 1's wounds and, given that the condition of the wounds worsened, was that wound-deterioration clinically unavoidable? And, I must address and resolve this second question: in implementing measures to address Resident 1's wounds, did Petitioner "go beyond merely what seems reasonable to, instead, always furnish what is necessary to prevent new sores . . . and to treat existing ones as needed." *Woodland Village Nursing*

Center, DAB No. 2172, at 13-14, citing *Meadow Wood Nursing Home*, DAB No. 1841, at 21 (2002), *aff'd, Meadow Wood Nursing Home v. Dep't of Health & Human Services*, No. 02-4115 (6th Cir. March 2, 2004). I find Petitioner did not.

As noted by CMS during the period September 1 through 11, 2006, Resident 1's coccyx skin deteriorated into a very large and deep wound with extensive central necrosis. As early as September 4, 2006, it was apparent that necrotic tissue was developing on the coccyx wound. On September 6, 2006, staff noted the open necrotic area to the coccyx. According to Surveyor Kaiser, the identification of necrotic tissue warranted a phone call to Resident 1's physician for further instructions and, perhaps, a change in Resident 1's plan of care. Tr. at 211-12. Even Dr. Gies agreed that such necrosis was important to watch. Tr. at 640-41. Equally as important, there is little documentation after September 9, 2006, with regard to the coccyx wound, despite the development of necrosis noted in the wound on September 4 and 6, and the only relevant nurse's note being that the dressing was intact to the coccyx, this despite the fact that Resident 1 had an order for "careful skin care." The DON checked the wound on September 9, 2006, but there is no documentation of the DON's assessment of that wound. Tr. at 214. And, there is no evidence that other staff actually saw the wound between September 9 and 11, 2006 (and notations that Resident 1's dressing was intact to coccyx do not describe the wound's condition in any meaningful way). There was also a very noticeable, noisome odor from the wound as early as 8:30 p.m. on September 11, 2006, but Petitioner's staff did not investigate it nor did they tell the emergency room about the smell or the sores — instead, they transferred Resident 1 for other *stated* reasons. Petitioner's failure to more carefully assess the development of the wound and contact Resident 1's physician when necrotic tissue developed, or to give an accurate assessment of Resident 1's condition to the emergency room given the state of Resident 1's skin issues, persuades me that Petitioner failed to furnish what was necessary to treat Resident 1's existing sores. Petitioner certainly did not go beyond what "seems reasonable" in this case, and utterly failed "always to furnish what was necessary" to treat Resident 1's wounds, and is thus deficient under this regulatory requirement.

I find also that Petitioner's noncompliance constituted immediate jeopardy. Immediate jeopardy is defined under the regulations as a situation where a provider's noncompliance with a participation requirement has caused, or is likely to cause, serious injury, harm, impairment, or death to a resident. 42 C.F.R. § 488.301. CMS's determination regarding the level of noncompliance must be upheld unless it is clearly erroneous. 42 C.F.R. § 498.60(c)(2). There is no requirement that there need be more than one resident involved in a deficiency citation in order for CMS to cite immediate jeopardy. In fact, only a single resident need be involved. *Windsor House*, DAB No. 1942, at 63 (2004); *Alden-Poplar Rehabilitation Creek and Health Care Center,* DAB No. 1873, at 1 (2003). CMS's finding of immediate jeopardy here is not clearly erroneous. I have found Petitioner noncompliant in its care of Resident 1, the resident's wounds became worse under Petitioner's care, becoming necrotic and necessitating transfer to a hospital and then to another hospital where he died during an operation to debride the wounds. I agree

with CMS (CMS Reply at 5) that Petitioner's staff failed to monitor Resident 1 adequately by documenting his care and reporting changes in his wounds to his physician. I also agree that, although there were no other residents in the facility whose wounds were as severe as Resident 1's (and I note Petitioner's argument that there were no other residents with problem ulcers at the facility (P. Br. at 25, 37)), the potential existed for neglect of those other residents until Petitioner demonstrated substantial compliance.

B. The remedies imposed are reasonable.

CMS has imposed a per day CMP of $3050. The amount of the CMP is at the lowest amount possible for deficiencies that constitute immediate jeopardy and is thus inherently reasonable as a matter of law. 42 C.F.R. § 488.438(a)(1)(i). CMS also found that Petitioner was out of substantial compliance from September 14, 2006 through November 6, 2006. Petitioner has the burden to prove the date it returned to substantial compliance. *Lake City Extended Care Center*, DAB No. 1658, at 12-13 (1998). Petitioner has not proved that it returned to substantial compliance at an earlier date.

Specifically, IDHW conducted an onsite revisit to the facility on December 14, 2006, and determined that Petitioner came into compliance as of November 7, 2006, the date Petitioner annotated "11/7/06" in the completion date column of the SOD as the date it would return to substantial compliance. CMS Ex. 1, at 1, 7; CMS Ex. 17. Although Petitioner signed the plan of correction on October 12, 2006, and Petitioner estimated at hearing that it returned to compliance on October 12, 2006 (Tr. at 567), I accept the evidence set forth in the completion date column that Petitioner did not, in fact, intend to come back into substantial compliance until November 7, 2006. Based on the noncompliance found, I also uphold the DPNA, and the suspension of Petitioner's NATCEP for two years (as CMS cited substandard quality of care (CMS Ex. 14, at 2), the CMP is greater than $5000, and a DPNA has been imposed).

VI. Conclusion

Petitioner was out of substantial compliance with the participation requirement at 42 C.F.R. § 483.25(c), at a level of immediate jeopardy, from September 14, 2006 through November 6, 2006. The remedies imposed based on that noncompliance, a CMP totaling $164,700, a DPNA from October 19, 2006 through November 6, 2006, and the loss of NATCEP for two years, effective September 14, 2006, are reasonable.

/s/
Richard J. Smith
Administrative Law Judge