Department of Health and Human Services

DEPARTMENTAL APPEALS BOARD

Civil Remedies Division

In the Case of:	)	
Desert Lane Care Center, (CCN: 29-5017)	)	Date: March 9, 2009
Petitioner,	)	
	)	Docket No. C-07-630
v.	)	Decision No. CR1914
Centers for Medicare & Medicaid Services.	)	

DECISION

Desert Lane Care Center, (Petitioner or facility) was not in substantial compliance with Medicare participation requirements as alleged by the Centers for Medicare & Medicaid Services (CMS) based on a survey of Petitioner's facility on January 12, 2007, and I find that the per instance civil money penalty (CMP) of $10,000 that CMS determined to impose is reasonable. I further find that Petitioner manifested at least one deficiency during the April 20 and June 6, 2007 revisit surveys, and therefore CMS was authorized to impose a mandatory denial of payment for new admissions (DPNA) effective April 20, 2007 through June 15, 2007.

I. Background

Petitioner, located in Las Vegas, Nevada, is authorized to participate in Medicare as a skilled nursing facility (SNF) and in the Medicaid program as a nursing facility (NF). Petitioner was subject to surveys by the Nevada Department of Health and Human Services (state agency). The state agency completed an initial re-certification survey on January 12, 2007, and conducted revisit surveys on April 20, 2007, and June 6, 2007. The survey findings for the re-certification survey on January 12, 2007 identified 13 deficiencies under the following regulations: 42 C.F.R. § 483.15(h)(1), 42 C.F.R. § 483.20, 42 C.F.R. § 483.20(b), 42 C.F.R. § 483.20(d), 42 C.F.R. § 483.20 (k)(1), 42 C.F.R. § 483.25(c), 42 C.F.R. § 483.25(d), 42 C.F.R. § 483.25(e)(2), 42 C.F.R. § 483.25(i)(1), 42 C.F.R. § 483.25(l), 42 C.F.R. § 483.35(i)(2), 42 C.F.R. § 483.70(b), 42 C.F.R. § 483.70(c)(2), 42 C.F.R. § 483.70(f), 42 C.F.R. § 483.75(h).

CMS notified Petitioner that it was imposing remedies of a per instance CMP of $10,000, termination of the provider agreement if Petitioner did not return to substantial compliance by July 12, 2007, and a DPNA[1] effective April 20, 2007.

The per instance CMP was based on a deficiency under Tag F-325 (42 C.F.R. § 483.25(i)(1). Although other deficiencies were noted regarding the January 12, 2007 survey, no remedies were attached to those deficiencies. As a consequence, Petitioner now only contests F-Tag 325, and none of the remaining 12 deficiencies.

A revisit survey was conducted on April 20, 2007, and the surveyors found that two deficiencies (Tags F-328 and F-442) still remained and that the DPNA would remain in effect.

Another revisit survey was conducted on June 6, 2007. The surveyor concluded that the deficiencies identified during the April 20, 2007 survey had not been corrected.

On June 15, 2007, the surveyors found that Petitioner had returned to substantial compliance, and the termination of Petitioner's provider agreement was rescinded.

Thus, Petitioner has appealed CMS deficiency determinations F-325, F-328, F-442, and CMS's determination to impose a per instance CMP of $10,000, and the basis for CMS's decision to continue the DPNA from April 20 through June 15, 2007.

The case was assigned to me for hearing and decision and I scheduled this case for hearing on July 22-25, 2008 in Las Vegas, Nevada. Shortly thereafter, the parties advised that they wished to waive the in-person hearing and have the case decided based on written submissions. I granted the parties' request, and set a briefing schedule. CMS and Petitioner[2] each filed an initial brief (CMS Br. and P. Br.) along with proposed exhibits, and CMS filed a reply brief (CMS Reply Br.). No objection has been made to the admissibility of any of the proposed exhibits, and therefore, CMS Exhibits (CMS Exs.) 1 through 41, and Petitioner's Exhibits (P. Exs.) 1 through 105, are admitted.

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[1] A statutory or mandatory DPNA is triggered whenever a long-term care facility does not return to substantial compliance within three months of the date of the end of the survey by which it is first found not to be in substantial compliance. 42 C.F.R. § 488.417(b).

[2] Petitioner filed briefs dated December 21, 2007, and August 26, 2008 both of which are entitled, "Petitioner's Reply Memoranda." Virtually all of Petitioner's arguments from its December 21, 2007 brief are incorporated into its August 26, 2008 brief. Therefore, in order to simplify matters I refer to Petitioner's August 26, 2008 brief as "Petitioner's Brief" (P. Br.), and cite it when referencing Petitioner's arguments.

II. Discussion

A. Issues

The issues in this case are:

> Whether there is a basis for the imposition of enforcement remedies; and,
>
> Whether the remedies imposed are reasonable.

B. 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 state 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 a "mandatory" or "statutory" DPNA, pursuant to section 1819(h)(2)(D) of the Act and 42 C.F.R. § 488.417(b). 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 the 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, § 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 F2d. 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) and (d)(10)(I). 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 Center*, DAB No. 1726, at 9, 38 (2000), *aff'd, Woodstock Care Center v. U.S. Dept. of Health and Human Services*, 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 Rehabilitation Center*, DAB No. 1611 (1997); *aff'd*, *Hillman Rehabilitation Center v. United States Department of Health & Human Services*, No. 98-3789 (GEB) (D.N.J. May 13, 1999).

C. Findings of Fact, Conclusions of Law, and Analysis

I make findings of fact and conclusions of law (Findings) to support this decision. I set forth each Finding below as a separate heading and discuss each in detail.

January 12, 2007 Survey - Tag F 325

1. Petitioner failed to comply substantially with the requirements of 42 C.F.R. § 483.25(i)(1) (Tag 325).

The regulation at 42 C.F.R. § 483.25(i)(1) requires that a facility ensure that a resident maintains acceptable parameters of nutritional status, such as body weight and protein levels, unless the resident's clinical condition demonstrates that this is not possible.

The State Operations Manual (SOM)[3] instructs surveyors that the ideal body weight for the institutionalized elderly have not yet been validated and any analysis of weight loss or gain should be examined in light of the resident's usual weight through adult life, the care plan for weight management, as well as the current diagnosis. The SOM suggests parameters for evaluating the significance of unplanned and undesired weight loss:

Interval	Significant Loss	Severe Loss
1 month	5%	Greater than 5%
3 months	7.5%	Greater than 7.5%
6 months	10%	Greater than 10%

SOM, Appendix PP - Guidance to Surveyors for Long Term Care Facilities.

[3] While the Secretary of Health and Human Services (Secretary) may not seek to enforce the provisions of the SOM, he may seek to enforce the provisions of the Act or regulations as interpreted by the SOM. State of Indiana by the Indiana Department of Public Welfare v. Sullivan, 934 F. 2d 853 (7th Cir. 1991); Northwest Tissue Center v. Shalala, 1 F. 3d 522 (7th Cir. 1993).

The January 12, 2007 Statement of Deficiencies (SOD) alleges that Petitioner failed to identify and address weight loss for Resident 23, Resident 3, and Resident 9.[4] A significant number of residents at Petitioner's facility, including Residents 23 and 3, received all of their nutrition through gastrostomy feeding tubes. CMS Ex. 36, at 3-4.

Resident 23

Resident 23 was a 24 year-old male admitted initially on August 27, 2002, and re-admitted on June 16, 2006, with diagnoses including, persistent vegetative state, pseudomonas pneumonia, hypertension, retention of urine, and anoxic brain damage. CMS Ex. 10, at 18-20.

CMS alleges that Resident 23 experienced unplanned severe weight loss over a period of approximately seven months. CMS points to Resident 23's clinical records, which for the most part, indicate a steady weight loss from his June 16, 2006 facility admission weight of 143.2 pounds:

Weigh Date	**Pounds (lbs.)**
June 17, 2006	143.2
July 6, 2006	133.4
July 13, 2006	131.7
July 20, 2006	133.3
August 4, 2006	131.5
August 19, 2006	129.2
August 26, 2006	129
September 3, 2006	129
September 10, 2006	130
September 15, 2006	130.2
September 22, 2006	127.7
October 6, 2006	126.9
October 21, 2006	123.9
October 27, 2006	121.9
November 4, 2006	122.4
December 3, 2006	123.7
January 8, 2007	122

CMS Ex. 10, at 5.

[4] As CMS's allegations of noncompliance under this regulation focus on Resident's 23 and 3, I limit my findings to these Residents. I make no findings with respect to Resident 9.

CMS maintains that Petitioner failed to take reasonable steps to ensure that Resident 23 received adequate nutrition, failed to notify Resident 23's physician of the significant weight loss, and has not demonstrated that Resident 23's weight loss was caused by an unavoidable illness or condition. CMS Br. 9-13.

I find that CMS has made a *prima facie* case that Petitioner failed to ensure that Resident 23 maintained acceptable parameters of nutritional status pursuant to 42 C.F.R. § 483.25(i)(1). CMS has introduced sufficient documentary evidence of Resident 23's weight loss, which Petitioner does not dispute, to raise an inference of inadequate nutrition sufficient to make out a *prima facie* showing of a deficiency. *See*, *Carehouse Convalescent Hospital*, DAB No. 1799 (2001).

Petitioner argues that its staff identified and addressed Resident 23's weight loss issues and contends that the medical records demonstrate that the facility was in compliance with applicable regulations. P. Br. 8-11. Petitioner points out that it provided Resident 23 with adequate nutrition, administering Isosource 1.5 cal @ 80 ml/hr for 16 hours per day, providing 1920 calories and 87 grams of protein, and that he maintained a normal body mass index, adequate serum albumins, and iron stores. CMS Ex. 10, at 11; P. Ex. 16, at 1; P. Ex. 17, at 2. Petitioner maintains that these facts demonstrate that it provided adequate nutrition to Resident 23, and argues that if a facility can demonstrate that it provided adequate nutrition such that a resident's weight loss is not a parameter of nutrition, then it has demonstrated substantial compliance with the regulation and is not required to show that the "clinical condition" exception applies. P. Br. 9.

Additionally, Petitioner contends that Resident 23's weight loss was unavoidable, and was brought about by a result of non-nutritive factors such as multiple serious infections evidenced by nine courses of antibiotics, a possible reduction in retained urine, and other clinical conditions. P. Br. 11-13; P. Ex. 1, at 3-5.

Petitioner's arguments are unpersuasive. The record reflects that Resident 23 experienced unplanned weight loss of almost 15% of his total body weight from the time he was admitted in June 2006 until January 2007. This amount of weight loss would be classified as "severe" under the SOM guide for evaluating the significance of unplanned weight loss. More significantly, Petitioner's response to Resident 23's severe weight loss was tardy and insufficient.

The appropriate standard of care based on the facility's own policies and procedures, indicate that the following should have been done, at a minimum, once the facility became aware of Resident 23's weight loss: (1) monthly dietary reevaluations of Resident 23's nutritional status, particularly because he received all of his nutrition through a feeding tube, and because he lost a significant amount of weight in the first 3 months of admission; (2) timely interventions and recommendations by the registered dietician or dietary technician in response to Resident 23's unplanned weight loss; (3) monthly documentation

in Resident 23's plan of care demonstrating that his unplanned weight loss was addressed by the registered dietician or dietary technician; and (4) notification of Resident 23's physician when his weight declined , particularly when he showed a total weight loss of 7.6% about 1 month from the time he was readmitted. CMS Ex. 1, at 52-54; CMS Ex. 25, at 10-13; CMS Ex. 27, at 11-12.

Moreover, the evidence shows based on record and document review, and the observations and interviews of the surveyors that Petitioner failed to timely intervene and respond appropriately under the regulations. For example, between June 16 and July 13, 2006, Resident 23 showed a weight decline of 7.6%, yet the registered dietician made no changes in Resident 23's feeding plan, and in fact, indicated that the current plan would continue to be followed unless further weight loss was noted, despite the fact that a 7.6% weight decline is classified as "severe" under SOM guidelines. CMS Ex. 10, at 6. Indeed, there is no evidence in the care plan that Resident 23's weight loss was addressed until October 17, 2006, some four months after Resident 23's re-admission to the facility, and three months after he began to experience significant weight loss. P. Ex. 11, at 2.

In addition, there is no evidence that Petitioner responded to Resident 23's weight loss by modifying his feeding tube formula between June 16, 2006 and October 6, 2006. On October 6, 2006, the registered dietician finally recommended an increase to Resident 23's nutrition formula. CMS Ex. 10, at 6. Because Resident 23 was completely dependent on the facility for all his nutritional needs and because modifying Resident 23's formula would have been the most effective and expedient way of responding to his weight loss, clearly this intervention should have been attempted much sooner. I find that Resident 23 suffered actual harm as a result of Petitioner's failure to respond to his nutritional needs in a timely fashion.

Moreover, there is no evidence in the record that Resident 23's physician was notified of his weight loss between June 16 and January 10, 2007, a clear violation of the facilities own policy and the standard of care. CMS Ex. 27, at 11. In addition, there are no further dietary progress notes between July 13, 2006 and October 6, 2006. CMS Ex. 10, at 6.

Finally, Petitioner simply has not demonstrated that Resident 23's unplanned weight loss was due to infections, fever, antibiotics treatment, or his overall clinical condition, as Petitioner urges. P. Br. 11-15.

The Departmental Appeals Board's (Board) interpretation of the regulation is that a facility is not strictly liable for a resident's weight loss but a "facility is responsible for taking all reasonable steps to ensure that the resident receives nutrition adequate to his or her needs." *Windsor House*, DAB No. 1942, at 15 (2004); s*ee also*, *Carehouse,* at 21.

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. *Windsor*, at 15. The presence of a significant clinical condition alone does not prove that maintaining acceptable nutrition is unavoidable. *Id*. at 17. In *Windsor*, the Board found that evidence that the facility was slow to react to a resident's weight loss was sufficient evidence that the facility failed to provide the resident with adequate nutrition. *Windsor House*, DAB No. 1942 (2004). Such is the case here where Petitioner was very slow in responding to Resident 23's unplanned weight loss. Thus, I find Petitioner failed to comply substantially with the requirements of 42 C.F.R. § 483.25(i)(1) (Tag 325) with respect to Resident 23.

Resident 3

The manner in which Petitioner cared for and assessed Resident 3 was strikingly similar to Resident 23.

Resident 3 was a 74 year-old male admitted on August 19, 2005, and readmitted on May 19, 2006 with diagnosis of Alzheimer's disease, Dementia with Behavioral Disturbance, Hypertension, Renal/urethral Disorder, Dysphagia due to Cerebrovascular Accident, Esophageal reflux, Urinary Tract Infection, and Attention to Gastrostomy. Resident 3 received all of his nutrition through a gastrostomy feeding tube; was noted for having at least two pressure wounds; and was to be monitored for skin breakdown. CMS Ex. 8, at 7-14; CMS Ex. 1, at 64.

CMS alleges that Petitioner violated 42 C.F.R. § 483.25(i)(1) by failing to take all reasonable steps to ensure Resident 3 was maintaining acceptable parameters of nutritional status, in that Petitioner failed to develop interventions to promote and implement weight maintenance.

The record shows that Resident 3 lost 32.1 pounds from May 19, 2006 (195.4 pounds) until August 15, 2006 (163.3 pounds), an almost 20% decrease. CMS Ex. 8, at 42. However, on November 7, 2006 Resident 3 weighed 161.6 pounds, and then on December 2, 2006, his weight was recorded as 190.6 pounds, an increase of 29 pounds in less than a month. *Id*.

The evidence is sufficient to establish a *prima facie* case that Petitioner failed to ensure that Resident 3 maintained acceptable parameters of nutritional status pursuant to 42 C.F.R. § 483.25(i)(1).

Petitioner argues that it provided adequate nutrition for Resident 3 to maintain acceptable parameters of nutritional status given his clinical condition, and that any weight loss was unavoidable. Petitioner points out that Resident 3 received 2736 calories and more than 114 grams of protein from a tube feeding formula of up to 95ml/hr of Fibersource HN for

24 hours per day, and that CMS does not dispute that this is a reasonable amount for a person of Resident 3's size, height, age, gender, condition, and activity level. P. Br. 17-19.

Petitioner maintains that Resident 3's severe health problems caused his weight loss which was unavoidable. P. Br. 19-25. The health issues include a urinary tract infection, diarrhea, swallowing problems, chewing problems, renal failure, missing teeth, and other problems, all of which placed Resident 3 at risk for malnutrition according to Petitioner. P. Ex. 27; P. Ex. 30. Petitioner asserts that it responded to these medical issues and maintains that Resident 3's medical record contains consistent documentation of monthly nutritional assessments and/or nutritional changes from May 19, 2006, through December 2006.

I find that Petitioner failed to take all reasonable steps to ensure that Resident 3 received nutrition adequate to his needs.

Petitioner did note Resident 3's weight loss in the dietary progress notes for June 2006, however, no modification was made to his tube feeding plan until July 24, 2006, one month later. CMS Ex. 8, at 49-52. Even with the 5 ml/hr Fibersource HN nutritional increase, Resident 3 continued to lose weight. Despite this, there were no further nutritional changes suggested, and no evidence that the dietary technician or registered dietician monitored Resident 3's weight loss until September 11, 2006. CMS Ex. 8, at 46.

Inexplicably, for the months of October and November 2006, there is no evidence of any nutritional status review notes or dietary progress notes for Resident 3 from the dietary technician or registered dietician. CMS Ex. 46. More troubling, was the facility's lack of response to Resident 3's recorded 29 pound weight gain between November 7, and December 2, 2006. The issue here is not so much whether Resident 3, did in fact gain 29 pounds or whether or not an error was made in recording his weight. The problem is that not only was there no response by the facility, but apparently the dietician technician was completely unaware of the recorded change in weight, and did not have this weight change information when she conducted her nutritional status review of Resident 3 for the month of December 2006. CMS Ex. 8, at 4. The fact that facility staff was unaware of Resident 3's weight fluctuations suggest that Petitioner did not properly monitor his nutritional status. The dietary technician's inaccurate review of Resident 3's nutritional status and failure to identify his weight gain in the December 7, 2006 dietary progress notes is evidence of the facility's failure to ensure that Resident 3 maintained acceptable parameters of nutrition. At the very least, facility staff should have notified Resident 3's physician of his severe weight fluctuations, but they did not.

Petitioner contends that the Braden Scale assessment it conducted on October 31, 2006, and the speech therapy evaluation order of November 20, 2006, shows that Petitioner conducted the necessary nutritional assessments required under the regulations. P. Br. 21-25. However, as CMS points out, the Braden Scale which assesses the risk of developing pressure ulcers, and the order for a speech therapy evaluation are not evidence of the

monthly nutritional assessments that should have been performed by the dietary technician or registered dietician in accordance with the regulatory requirements, facility policies, or the acceptable standard of care in the nursing home industry.

Finally, Petitioner has not shown that Resident 3's unplanned weight loss was due to his poor overall clinical condition as Petitioner maintains. P. Br. 21-25. As outlined above, the facility has not demonstrated that it took all reasonable steps to ensure that Resident 3 received nutrition adequate to his needs. *Windsor House*, DAB No. 1942, at 15 (2004). I find Petitioner failed to comply substantially with the requirements of 42 C.F.R. § 483.25(i)(1) (Tag 325) with respect to Resident 3.

April 20, 2007 Survey - Tag F 328, Tag F 442

2. Petitioner failed to comply substantially with the requirements of 42 C.F.R. § 483.25(k) (Tag 328).

The regulation at 42 C.F.R. § 483.25(k) requires that the facility must ensure that residents receive treatment and care for certain special services. In this case the special services are enteral feedings.

The SOD from the April 2007 survey alleges that the Petitioner failed to ensure that Residents 5, 11, and 14 received their enteral feedings as ordered.[5] CMS Ex. 2, at 1-2. The evidence is sufficient for CMS to establish a *prima facie* case of a violation of this regulation.

On April 17, 2007, Resident 11's feeding order was changed for him to receive enteral feedings of Renal Novasource at 50 ml/hr x 24. CMS Ex. 12, at 6. However, facility staff misread the medication record and misinterpreted the "@" symbol for the number six. CMS Ex. 2, at 7. Facility staff read the medication record as "650" and this was further misinterpreted as 65 ml x 24. *Id*; CMS Ex. 12, at 19. As a result, Resident 11 received 65 ml, instead of 50 ml, and as a consequence received an additional 15 ml per hour of his enteral feeding in error, for eight consecutive shifts. CMS Ex. 2, at 7.

Resident 14 had diagnoses including renal failure, and diabetes, and was required to receive dialysis treatment three times per week. CMS Ex. 13, at 36, 54. Physician's orders indicated that Resident 14 was to receive tube feeding of Novasource Renal @ 50 ml/hr x 24 hours, and 850 cc of free water and water flushes of 250 cc each shift for a total of 1600 cc of fluid daily. CMS Ex. 13, at 46.

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[5] As CMS's allegations of non-compliance under this regulation focus on Residents 11 and 14, I limit my findings to these two Residents. I make no findings with respect to Resident 5.

However, Resident 14's comprehensive intake-output record indicates that a number of tube feedings and water flushes were missed on shifts from April 11, 2007 through April 20, 2007.[6] P. Ex. 66; CMS Ex. 13, at 73-75.

Petitioner makes similar arguments regarding both residents; that is that any deviations in the prescribed care were minor and that any errors that did occur were insignificant and caused no harm or did not have the potential for harm. P. Br. 34-41.

I disagree with Petitioner, and I find that Petitioner failed to comply with applicable regulations at 42 C.F.R. § 483.25(k).

Petitioner's failure to administer residents' enteral feedings as ordered, indicates that the facility was unable to deliver treatment and care for special services as required by the regulations.

CMS says that, in fact, Resident 11 received more than double (1,920) the calories prescribed by his physician. CMS Br. 37-39. Petitioner disputes that claim. Nevertheless, Petitioner does not deny that it's staff gave Resident 11 through his feeding tube at least 960 calories more than was ordered by the physician. P. Br. 34-36.

Surveyor Geary opined that she believed that Petitioner's feeding tube errors were not minor, but were significant, and that Resident 11's blood sugar and fluid levels could be adversely affected as a result of receiving excess calories above his identified needs, and that the facility's error had the potential for more than minimum harm. CMS Ex. 36, at 16.

In the case of Resident 14, the record shows that the facility failed to provide water flushes and tube feedings as ordered for at least four shifts out of 28. P. Ex. 66; CMS Ex. 13, 73-75. Both Surveyor's Geary and Betcher believed that Resident 14's renal failure and other conditions could have been adversely affected by Petitioner's failure to provide nutrition and water as prescribed, and that the facility's error had the potential for more than minimum harm. CMS Ex. 36, at 6, 15; CMS Ex. 38, at 4-5. Petitioner argues that several of the missed tube feedings and water flushes that Resident 14 missed were caused by the fact that she had to leave the facility three times per week to receive dialysis treatment, and that the overall effect of the missed feedings was minimal. P. Br. 36-41. I reject Petitioner's arguments. Resident 14's renal failure and overall poor health made her particularly susceptible to dehydration, therefore several missed water flushes and tube

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[6] There is a discrepancy in the comprehensive intake-output record of Resident 14, as set forth in P. Ex. 66 and CMS Ex. 13, at 73-75, which purport to be identical documents. P. Ex. 66 contains several more entries than CMS Ex. 13, at 73-75. I will not speculate as to why this difference exist, however, I will note that Petitioner does not dispute that several tube feedings and water flushes were missed during this period. *See* P. Br. 36-41.

feedings over a relatively short period of time could be particularly harmful. The facility was obligated to meet Resident 14's needs and to find alternatives to meet her needs, even though she had to leave the facility three times per week to receive dialysis treatment. The regulations require a facility to provide for a resident's special needs, such as enteral feedings, and these must be administered in accordance with physician's orders.

Therefore, I conclude that Petitioner failed to comply substantially with 42 C.F.R. § 483.25(k).

3. Petitioner failed to comply substantially with the requirements of 42 C.F.R. § 483.65(b) (Tag 442).

The regulation requires a facility to isolate a resident when the infection control program determines that a resident needs isolation to prevent the spread of infection. 42 C.F.R. § 483.65(b).

The SOD alleges that Petitioner failed to assess Resident 10,[7] who tested positive for MRSA,[8] to determine if contact isolation was needed to prevent the spread of infection. CMS Ex. 2, 7-12.

Specifically, CMS alleges that Petitioner did not meet the regulatory requirements in that the facility failed to: 1) assesses Resident 10's cough to determine if contact/isolation procedures were necessary under their policies and procedures; 2) make facility staff aware that Resident 10 tested positive for MSRA; and 3) ensure that facility staff was using precautions such as goggles and masks, to prevent the spread of MRSA as required by facility policy and procedure. CMS Ex. 2, at 7-12; CMS Br. 29-47. The evidence is sufficient for CMS to establish a *prima facie* case of a violation of this regulation.

Petitioner maintains that it assessed Resident 10 and determined that standard universal precautions[9] were the appropriate means of infection control given his persistent vegetative

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[7] This is the same resident referred to as Resident 23 from the January 2007 survey.

[8] MRSA (Methicillin Resistant Staphylococcus Aureus,) is a bacteria infection which is highly virulent and contagious, and often resistant to antibiotics. CMS Ex. 14, at 70.

[9] One approach to infection control is to treat all human blood and certain human body fluids as if known to be infectious, for viruses and other blood borne pathogens. SOM, Appendix PP - Guidance to Surveyors for Long Term Care Facilities.

state, and that the facility properly communicated his infection status to its staff in order to prevent spread of infection. P. Br. 42-44.

The crux of CMS's complaint is that given the highly contagious nature of MRSA, Petitioner's staff should have assessed Resident 10 to determine if contact isolation was needed to prevent the spread of infection, and that its staff caring for Resident 10 was informed of his infection. According to Surveyor Caudal, when Resident 10 tested positive for MRSA on March 31, 2007, Petitioner should have assessed him to determine if an "active cough" was present. CMS Ex. 25, at 1. An "active cough" is a cough that dislodges or brings up secretions from the respiratory system; this secretion can often contain the MRSA bacteria. CMS Ex. 25, at 1. Facility records do not indicate that Petitioner 10 was assessed to determine if he had an "active or spontaneous productive cough." Petitioner maintains that Resident 10 could not have had an "active or spontaneous productive cough," because he was in a persistent vegetative state. P. Br. 42-44. However, Surveyor Caudal indicates that the fact that suctioning of Resident 10's passage way was occurring, suggests that there was some level of spontaneous body functioning occurring, and therefore, an assessment of his "active cough" was still warranted. CMS Ex. 36; CMS Ex. 39, at 6. This is important because as Surveyor Caudal points out, a cough or secretion containing the MRSA bacteria could be expelled by Resident 10, which could have come in contact with facility staff, and unwittingly spread the MRSA bacteria to other residents and staff. CMS Ex. 39, at 6.

Finally, CMS argues that Petitioner: (1) failed to indicate in Resident 10's comprehensive care plan that he tested positive for MRSA; (2) failed to identify whether contact precautions were needed; (3) failed to note whether a mask and goggles should be used when facility staff provided care for Resident 10; and (4) failed to note signs on Resident 10's room door indicating that gowns, goggles, and masks might be needed due to the existence of an active infection. CMS Ex. 39, at 10.

Surveyor Caudal's opinion is persuasive in light of his education, background, and experience, and the fact that the medical records support his conclusions. CMS Exs. 29; 39. Petitioner has not offered any evidence that refutes Surveyor Caudal's opinion. Therefore, I find that Petitioner failed to comply substantially with the applicable regulations at 42 C.F.R. § 483.65(b).

June 6, 2007 Survey - Tag F 328

4. Petitioner failed to comply substantially with the requirements of 42 C.F.R. § 483.25(k) (Tag-328).

The regulation at 42 C.F.R. § 483.25(k) requires that the facility must ensure that residents receive treatment and care for certain special services. In this case, the special services are respiratory care.

The SOD from the June 2007 survey alleges that Petitioner failed to ensure respiratory assessments were completed on residents requiring ventilator support and respiratory treatments as ordered for 9 of 18 residents sampled — Residents 7, 9, 10, 11, 12, 13, 16, 17, and 18. The SOD and the record as a whole provide sufficient evidence to establish the violation of 42 C.F.R. § 483.25(k) for Residents 17 and 7.[10]

Resident 17

Resident 17 was an 85-year old female who was admitted on July 28, 2004 and re-admitted on November 14, 2005, with diagnoses of peripheral vascular disease, dysphagia, convulsions, and esophageal reflux.

CMS alleges that Petitioner was in violation with applicable regulations because the facility failed to conduct a complete follow up assessment of Resident 17 after noticing signs of respiratory distress on May 17, 2007, which resulted in Resident 17 eventually being sent to the hospital on May 19, 2007 for assessment and treatment, where she was ultimately identified as suffering from hyponatremia.[11]

Petitioner argues that it did conduct all necessary assessments of Resident 17, that CMS's allegation that Resident 17's medical record did not contain notes dated May 18, 2007 is incorrect, and that the nurse practitioner did actively assess and intervene in the care of this Resident prior to May 19, 2007. P. Br. 44-47, 51-52.

I disagree with Petitioner, and I find that it failed to comply substantially with applicable regulations at 42 C.F.R. § 483.25(k).

Nurses notes from May 17, 2007 indicate that Resident 17 was having difficulty breathing, that her oxygen saturation rate was in the middle of the acceptable range, and that her abdomen was distended. CMS Ex. 23, at 79. Surveyor Sims indicated that she believed that these sudden changes in Resident 17's condition should have signaled to facility staff that Resident 17's condition was in need of further assessment to determine if changes to her medical treatment or medications were needed. CMS Ex. 41, at 15. Indeed, on May 17, 2007 at 9:45 a.m. a facility nurse practitioner noted Resident 17's change in condition and indicated that she should be monitored. CMS Ex. 23, at 79. However, there was nothing in the record to indicate that anyone followed up with Resident 17 until May 19,

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[10] As CMS's allegations of noncompliance under this regulation are better supported for Residents 17, and 7, I limit my findings to these Residents. I make no findings with respect to Residents, 9, 10, 11, 12, 13, 16, and 18.

[11] A condition characterized by an abnormally low concentration of sodium in the blood which occurs when sodium in the blood is diluted by excess water. *Webster's New World Medical Dictionary* 3rd Edition (May 2008).

2007, some five shifts after her initial problems were noticed. *Id.* Despite Petitioner's claims, the nurses notes do not indicate that facility staff intervened in the care of Resident 17 prior to May 19, 2007, or that the nurse practitioner actively assessed and intervened in the care of this Resident prior to May 19, 2007. *Id.*

Moreover, physician's orders required facility staff to listen to Resident 17's breathing sounds each shift regardless of whether any other symptoms of respiratory distress were present. CMS Ex. 23, at 29. Surveyor Sims stated that in her opinion, there is reason to doubt that this "auscultation" or "listening to lung sounds" occurred because there would have been notations in the nurses notes after May 17, 2007 indicating that Resident 17 was having difficulties, and that some follow up measures were in order. CMS Ex. 41, at 16.

Finally, on May 19, 2007, Petitioner did respond with new orders for supplemental oxygen and treatments for Resident 17. CMS Ex. 23, at 80. However, despite this, her respiratory status continued to decline. *Id.* On May 19, 2007, Resident 17 was taken to the hospital emergency room for evaluation and treatment. Surveyor Sims concluded that:

> Because of this failure to conduct respiratory assessments, [Petitioner] failed to identify Resident 17's need for additional respiratory treatment and services. As a result, her condition appears to have worsened and she was admitted to the hospital. In my professional opinion, had the facility been assessing the resident each shift and more often if necessary, they may have been able to identify the respiratory difficulties and distress and intervene appropriately.

CMS Ex. 41, at 20-21.

I find Surveyor Sims' opinion persuasive in view of her education, background, and experience, and the fact that the weight of the evidence supports her conclusions. CMS Exs. 29, 41. Therefore, I find that Petitioner failed to comply substantially with the applicable regulations at 42 C.F.R. § 483.25(k).

Resident 7

Resident 7 was a 84-year old female who was admitted on February 2, 2007, with various ailments, including atrial fibrillation, decubitus ulcer, and hypertension. CMS Ex. 16, at 1.

CMS alleges that Petitioner failed to administer respiratory care treatments (small volume nebulizer (SVN) of Xopenex 0.63%) every four hours as ordered by Resident 7's physician on March 23, 2007. CMS Ex. 16, at 24; CMS Ex. 3, at 12.

Petitioner argues that facility staff did administer SVN treatments as ordered by the physician, and that Resident 7's medical record shows that facility staff administered SVN treatments on March 25, 2007, March 26, 2007, and March 31, 2007. P. Br. 53; P. Ex. 86, at 6-9.

Resident 7's May 2007 Medication Administration Record (MAR) indicates that the respiratory therapist would provide treatments. CMS Ex. 16, at 13. But there was no documented evidence in the MAR or in the respiratory therapist notes that indicate the SVN was administered as ordered by Resident 7's physician. P. Ex. 87, at 2. Petitioner is correct that Resident 7's medical records indicate that facility staff administered SVN treatments on March 25, 2007, March 26, 2007 and March 31, 2007. However, there are only three instances of SVN treatments in the record and no evidence of administration every four hours as ordered by Resident 7's physician. CMS Ex. 3, at 12; CMS Ex. 16. Thus, I conclude that Petitioner failed to substantially comply with 42 C.F.R. 483.25(k) because it did not demonstrate that it administered SVN treatments according to physician's orders.

CMS has established Petitioner's noncompliance with at least one regulation from the January 12, 2007, April 20, 2007, and June 6, 2007 surveys. A single deficiency is sufficient for CMS to impose a remedy of DPNA. The DPNA was triggered by the deficiencies from the January survey. Petitioner had to return to substantial compliance within three months of the last day of the survey or a statutory DPNA would be triggered effective April 20, 2007, and until Petitioner returned to substantial compliance on June 15, 2007 as determined by CMS and the state agency. 42 C.F.R. § 488.417(b).

5. CMS's imposition of the DPNA is reasonable as a matter of law.

Petitioner was not in substantial compliance with applicable regulations on January 12, 2007, April 20, 2007, and June 6, 2007, and did not come back into substantial compliance at any time during the ensuing three-month certification cycle prior to June 15, 2007. Neither the Secretary, CMS, or the state have discretion with respect to the imposition of the mandatory DPNA. Therefore, the Act requires CMS to impose the mandatory DPNA effective April 20 through June 15, 2007. Act, § 1819(h)(2)(D) ; 42 C.F.R. § 488.417(b).

6. I find reasonable the $10,000 per instance CMP.

Having found a basis for imposing a CMP, I now consider whether the amount imposed is reasonable, applying the factors listed in 42 C.F.R. § 488.438(f): (1) the facility's history of noncompliance; (2) the facility's financial condition; (3) factors specified in 42 C.F.R. § 488.404; and (4) the facility's degree of culpability, which includes neglect, indifference, or disregard for resident care, comfort or safety. The absence of culpability is not a

mitigating factor. 42 C.F.R. § 488.438(f). The factors in 42 C.F.R. § 488.404 include: (1) the scope and severity of the deficiency; (2) the relationship of the deficiency to other deficiencies resulting in noncompliance; and 3) the facility's prior history of noncompliance in general and specifically with reference to the cited deficiencies.

It is well-settled that, in reaching a decision on the reasonableness of the CMP, I may not look into CMS's internal decision-making processes. Instead, I consider whether the evidence presented on the record concerning the relevant regulatory factors supports a finding that the amount of the CMP is at a level reasonably related to an effort to produce corrective action by a provider with the kind of deficiencies found and in light of the other factors involved (financial condition, facility history, culpability). I am neither bound to defer to CMS's factual assertions, nor free to make a wholly-independent choice of remedies without regard for CMS's discretion. *Barn Hill Care Center*, DAB No. 1848, at 21 (2002); Community Nursing Home, DAB No. 1807, at 22 et seq. (2002); Emerald Oaks, DAB No. 1800, at 9 (2001); *CarePlex of Silver Spring*, DAB No. 1683, at 8 (1999). CMS has imposed a penalty of $10,000, which is the maximum per instance penalty ($1,000 - $10,000). 42 C.F.R.§ 488.438(a)(2).

Petitioner has not claimed that its financial condition affects its ability to pay the penalty. However, it does argue that based on a "per instance CMP grid" created by CMS, and based on a scope and severity level of "G" such as in this case, the recommended CMP should be $1,500. Further, Petitioner argues that the citations it received in the recent past (2005-2006) were low level deficiencies and does not justify an increase from the recommended $1,500 per instance CMP to the $10,000 CMP imposed in this case. P. Br. 5-7.

Indeed, CMS has called attention to Petitioner's prior history of non-compliance. CMS points out that Petitioner had been previously cited for deficiencies during annual surveys completed on February 7, 2006, and February 2, 2005. These deficiencies generally included citations for pressure sores, inadequate nursing staff, and failure to provide necessary care and services to residents. CMS Ex. 5.

The scope of the deficiency was widespread and the potential for more than minimum harm was evident. These factors are sufficient to support my finding that the $10,000 per instance CMP is reasonable. Moreover, I place no weight on a "per instance CMP grid" recommendation as Petitioner urges. The regulations give an ALJ the authority to make independent decisions as to what penalty amounts are reasonable based on the criteria set forth at 42. C.F.R. § 488.438(f). I am not bound by suggested CMP amounts from a party.

Thus, while I recognize that the imposition of the maximum per instance penalty should generally be reserved for particularly egregious situations, after carefully reviewing the circumstances of this case, in light of the section 488.438 factors, I am not able to find $10,000 an unreasonable amount.

III. Conclusion

Petitioner was not in substantial compliance with Medicare participation requirements as alleged by CMS based on surveys of Petitioner's facility on January 12, 2007, and subsequent revisit surveys on April 20, and June 6, 2007. I find that the per instance CMP's of $10,000 that CMS determined to impose is reasonable. I further find that CMS was authorized to impose a mandatory DPNA effective April 20 through June 15, 2007.

/s/
José A. Anglada
Administrative Law Judge