Department of Health and Human Services

DEPARTMENTAL APPEALS BOARD

Civil Remedies Division

In the Case of:))
) Date: October 20, 2007
Bradford County Manor,)
(CCN: 39-5586),) .
Petitioner,) Docket No. C-06-619
) Decision No.CR1674
v.)
)
Centers for Medicare & Medicaid Services.)
)

DECISION

Petitioner, Bradford County Manor, violated 42 C.F.R. § 483.25(j)(Tag F327) in the case of one resident as determined by a survey completed on April 28, 2006. The proposed per instance civil money penalty (PICMP) of \$7500 is not reasonable. A PICMP of \$1250 is reasonable. Petitioner's authority to conduct a nurse aide training and competency evaluation program (NATCEP) may not be withdrawn based on this decision.

I. Background

Petitioner is a long-term care facility located in Troy, Pennsylvania. Petitioner is authorized to participate in Medicare as a skilled nursing facility (SNF) and the Pennsylvania Medicaid program as a nursing facility (NF). Petitioner was subject to an annual recertification survey by the Pennsylvania Department of Health (the state agency) that ended April 28, 2006, the results of which were reported in a Statement of Deficiencies (SOD or CMS 2567) with that date. Centers for Medicare & Medicaid Services (CMS) Exhibit (CMS Ex.) 2. CMS notified Petitioner by letter dated June 20, 2006, that it was imposing a PICMP of \$2500 for each of three violations found by the state agency during the survey ended April 28, 2006, for a total of \$7500.\(^1\) The state

¹ Counsel stipulated at hearing that the remedies of termination and denial of payment for new admissions (DPNA) were not effectuated. Tr. 39.

agency notified Petitioner by letter dated June 22, 2006, that it was required to withdraw its approval of Petitioner to conduct a NACTEP because CMS had decided to impose PICMPs against Petitioner totaling \$7500.

Petitioner requested a hearing by letter dated August 15, 2006. The case was assigned to me for hearing and decision on August 21, 2006, and a Notice of Case Assignment and Prehearing Case Development Order was issued at my direction on that date. On September 5, 2006, CMS filed an unopposed motion for a 30-day extension of the prehearing schedule and that motion was granted by order dated September 7, 2006. On December 6, 2006, I issued a Notice of Hearing setting this case for trial at Williamsport, Pennsylvania, from April 17 through 20, 2007. On December 19, 2006, Petitioner filed a motion for an expedited hearing, which was opposed by CMS, and I denied the motion by Order dated January 4, 2007.

On April 17, 18, and 19, 2007, a hearing was held at Williamsport, Pennsylvania.² CMS offered, and I admitted, CMS Exs. 1 through 19 and 21.³ Tr. 22, 317. CMS Exhibit 20 was withdrawn. Tr. 22. Petitioner offered and I admitted Petitioner's Exhibits (P. Ex.) 1

² A transcript of the oral hearing was prepared and certified. By letter dated May 7, 2007, counsel were advised that the record copy of the transcript had been received in my office and they were advised of the briefing schedule in this case. Counsel were also instructed to review the transcript and to submit a list of errata as an attachment to either their post-hearing brief or post-hearing reply brief. Counsel were advised that if they found a substantial prejudicial error or omission they were to advise me immediately so that the transcript could be corrected. Counsel did not advise me of any substantially prejudicial errors or omissions. However, on May 9, 2007, I was advised by the courtreporter that counsel had complained about errors and omissions in the transcript. The court-reporter undertook revision of the original transcript without my direction or control. An audited transcript was produced and provided to the parties. Counsel have advised me of no substantially prejudicial errors or omissions from either the original transcript or the audited transcript. I have compared the two versions of the transcript and find no prejudicial errors or omissions. Counsel are admonished that in future cases they are to comply with my instruction and advise me of perceived errors or omissions so that I may direct any required corrective action, in order to avoid post-hearing delay and to ensure that there is no confusion regarding the integrity of the official or record transcript of the proceedings. In this case both the original and audited transcripts will be preserved as part of the record of decision in this case. References in this decision are to the audited transcript (Tr.).

³ CMS Exhibits 20 and 21, as originally marked at the exchange, were withdrawn. The curriculum vitae of Barbara J. Connors, D.O., M.P.H., was marked and admitted as CMS Ex. 21 at hearing. Tr. 414-15.

through 29, 31 through 55, and 57. Tr. 30, 47, 915. CMS elicited testimony from Surveyor Rebecca Lewis, R.N.; Surveyor Denise Phoenix, R.N.; Barbara Connors, D.O., M.P.H.; Shirley Sword, Registered Dietician; and Traci Duncan (a state agency supervisor for the survey in issue). Petitioner elicited testimony from Tammy Donovan, R.N., Petitioner's current Director of Nursing (DON). The parties submitted post-hearing briefs (CMS Brief and P. Brief, respectively). CMS filed a reply brief (CMS Reply). Petitioner waived filing a reply brief.

II. Discussion

A. Findings of Fact

The following findings of fact are based upon the exhibits admitted and the joint stipulation of the parties dated November 30, 2006. Citations to exhibit numbers related to each finding of fact may be found in the analysis section of this decision if not indicated here.

- 1. Petitioner, Bedford County Manor, is a SNF located in Troy, Pennsylvania. Joint Stipulation 1.
- 2. On April 28, 2006, surveyors from the state agency conducted a standard survey at Petitioners facility to ascertain whether Petitioner was in compliance with federal participation requirements for the Medicare program. Joint Stipulation 2.
- 3. The surveyors determined that there were deficiencies which represented actual harm that was not immediate jeopardy (level G deficiencies) at 42 C.F.R. §§ 483.25(c) (Pressure Sores, Tag F314); 483.25(i)(1) (Nutrition, Tag F325); and 483.25(j) (Hydration, Tag F327). Joint Stipulation 3.
- 4. By letter dated May 5, 2006, the state agency notified Petitioner that it was recommending a PICMP of \$2500 for each of the three deficiencies noted above, a total PICMP of \$7500. Joint Stipulation 4.

⁴ CMS moved to strike Petitioner's post-hearing brief on grounds that it exceeds 30 pages, the page-limit I imposed. The CMS motion is denied. The signature page for Petitioner's brief is incorrectly numbered 39. Petitioner's brief is only 29 pages and, thus, within the page-limit I imposed.

- 5. By letter dated May 19, 2006, the state agency notified Petitioner that the three deficiencies cited were unchanged following informal dispute resolution. Joint Stipulation 5.
- 6. By correspondence dated June 20, 2006, CMS notified Petitioner that it was imposing the three \$2500 PICMPs. Joint Stipulation 6.
- 7. On August 15, 2006, Petitioner filed a hearing request.
- 8. Facts related to 42 C.F.R. § 483.25(c) (Tag F314) regarding Resident 143.
 - a. Resident 143 was readmitted to Petitioner's facility after being hospitalized for a hip fracture. P. Ex. 5.
 - b. Resident 143 was readmitted to Petitioner's facility with a pressure sore on his right heel. P. Ex. 3, at 5; P. Ex. 4, at 8; P. Ex. 5, at 9; P. Ex. 16, at 70.
 - c. Petitioner care planned appropriate interventions for the pressure sore on March 2, 2006. CMS Ex. 9, at 27.
 - d. Resident 143's pressure sore did not worsen at Petitioner's facility.
- 9. Facts related to 42 C.F.R. § 483.25(i)(1) (Tag F325) regarding Resident 9.
 - a. Resident 9 experienced unplanned weight loss at Petitioner's facility. CMS Ex. 6, at 14-20.
 - b. Petitioner took steps to address Resident 9's weight loss, including soliciting her food preferences to tailor her diet, monitoring her weight to assess the need for supplements, providing supplements, arranging for an oral surgery consult, hand-feeding the resident, and changing the consistency of her foods. CMS Ex. 6, at 5, 6, 8, 9, 10, 11, 12, 13; Tr. 843-47.
 - c. Petitioner appropriately assessed, care planned, developed and implemented interventions, assessed the effectiveness of interventions, and modified interventions as necessary, and took all reasonable measures necessary to assure the resident's nutrition.

- 10. Facts related to 42 C.F.R. § 483.25(i)(1) (Tag F325) regarding Resident 60.
 - a. Resident 60 experienced unplanned weight loss at Petitioner's facility. CMS Ex. 8, at 29-38.
 - b. Petitioner's staff and physician were aware of Resident 60's weight fluctuations, and Resident 60 was assessed, monitored and interventions were taken to address the weight fluctuations, including providing nutritional supplements and encouraging her to consume her meals. CMS Ex. 8, at 5, 9, 11, 12, 14-19, 21-23; see Tr. 609-10.
 - c. Resident 60 could not be tube fed, as only comfort measures were ordered. CMS Ex. 8, at 14, 17, 19.
 - d. Petitioner appropriately assessed, care planned, developed and implemented interventions, assessed the effectiveness of interventions, and modified interventions as necessary, and took all reasonable measures necessary to assure the resident's nutrition.
- 11. Facts related to 42 C.F.R. § 483.25(j) (Tag F327) regarding Resident CR3.
 - a. Resident CR3 was fed by a feeding tube and took no food or fluid by mouth. CMS Ex. 10, at 8, 12.
 - b. Resident CR3 was dehydrated upon admission to the emergency room at Troy Community Hospital, the emergency room physician noting clinical findings of dry oral mucosa and poor skin turgor, as well as an elevated blood urea nitrogen (BUN); and, Resident CR3 received intravenous fluids. CMS Ex. 10, at 19-20.
- 12. Facts related to 42 C.F.R. § 483.25(j) (Tag F327) regarding Resident 17.
 - a. Resident 17 was sent to the emergency room at Troy Community Hospital after a fall. CMS Ex. 7, at 15.
 - b. The emergency room physician found Resident 17's hydration status to be "good" and his tongue to be "pink and moist." CMS Ex. 7, at 15-16.

B. Conclusions of Law

1. Petitioner's request for hearing was timely and I have jurisdiction.

Tag F314

- 2. The regulation at 42 C.F.R. § 483.25(c) requires that a facility must ensure that a resident who enters the facility without a pressure sore does not develop one unless the resident's clinical condition demonstrates that the development of a pressure sore was unavoidable. The regulation also requires that for a resident with a pressure sore on admission, the facility must deliver treatment and services necessary to promote healing, prevent infection, and prevent development of new sores.
- 3. CMS did not make a *prima facie* case of a deficiency; Resident 143 entered the facility with a pressure sore and there is no evidence that Petitioner failed to deliver necessary care and services to promote healing, prevent infection, and prevent the development of new sores.

Tag F325

- 4. The regulation at 42 C.F.R. § 483.25(i)(1) requires that a facility ensure that a resident maintain acceptable parameters of nutritional status, such as body weight and protein levels, unless the resident's clinical condition demonstrates that this is not possible.
- 5. CMS made a *prima facie* case that Residents 9 and 60 experience unplanned weight loss.
- 6. Petitioner rebutted CMS's *prima facie* showing with respect to Residents 9 and 60.

Tag F327

- 7. The regulation at 42 C.F.R. § 483.25(j) requires that a facility provide each resident with sufficient fluid intake to maintain proper hydration and health.
- 8. CMS made a *prima facie* case that Petitioner violated 42 C.F.R. § 483.25(j) with respect to Resident CR3.

- 9. Petitioner failed to rebut CMS's *prima facie* showing that Petitioner violated 42 C.F.R. § 483.25(j) with respect to Resident CR3.
- 10. CMS did not make a *prima facie* case of a violation of 42 C.F.R. § 483.25(j) with respect to Resident 17.

Remedies

- 11. A PICMP of \$7500 is not reasonable.
- 12. A PICMP of \$1250 is reasonable.
- 13. The state is not required to withdraw Petitioner's approval to conduct a NATCEP, because the PICMP imposed by this decision is less than \$5000.

C. Issues

The issues in this case are:

Whether there is a basis for the imposition of an enforcement remedy; and,

Whether the remedy imposed is reasonable.

D. Applicable Law

Petitioner is a long-term care facility participating in the federal Medicare program as a SNF and in the state Medicaid program as a NF. The statutory and regulatory requirements for participation by a long-term care facility are found at sections 1819 and 1919 of the Social Security Act (Act) and at 42 C.F.R. Part 483. Sections 1819 and 1919 of the Act vest the Secretary of Health and Human Services (the Secretary) with authority to impose civil money penalties against a long-term care facility for failure to comply substantially with federal participation requirements.

Facilities that participate in Medicare may be surveyed on behalf of CMS by state survey agencies in order to determine whether the facilities are complying with federal participation requirements. 42 C.F.R. §§ 488.10-488.28, 488.300-488.335. Pursuant to 42 C.F.R. Part 488, CMS may impose a per instance or per day CMP against a long-term care facility when a state survey agency concludes that the facility is not complying

substantially with federal 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.

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, 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). There is only a single range of \$1000 to \$10,000 for a PICMP that applies whether or not immediate jeopardy is present. 42 C.F.R. §§ 488.408(d)(1)(iv); 488.438(a)(2).

In this case, the state agency withdrew Petitioner's approval to conduct a NATCEP. Pursuant to sections 1819(b)(5) and 1919(b)(5) of the Act, SNFs and NFs may only use nurse aides who have taken a training and competency evaluation program. Sections 1819(e) and 1919(e) of the Act impose upon the states the requirement to specify what NATCEPs they will approve that meet the requirements established by the Secretary and a process for reviewing and reapproving those programs using criteria set by the Secretary. Pursuant to sections 1819(f)(2) and 1919(f)(2) the Secretary was tasked to develop requirements for approval of NATCEPs and the process for review of those programs. The Secretary promulgated regulations at 42 C.F.R. Part 483, subpart D. Pursuant to 42 C.F.R. § 483.151(b)(2) and (e)(1) a state may not approve and must withdraw any prior approval of a NATCEP offered by a skilled nursing or nursing facility that: (1) has been subject to an extended or partial extended survey under sections 1819(g)(2)(B)(i) or 1919(g)(2)(B)(i) of the Act; (2) has been assessed a CMP of not less than \$5000; or (3) that has been subject to termination of its participation agreement, a DPNA, or the appointment of temporary management. Extended and partial extended surveys are triggered by a finding of "substandard quality of care" during a standard or abbreviated standard survey and involve evaluating additional participation requirements. "Substandard quality of care" is identified by the situation where surveyors identify one or more deficiencies related to participation requirements established by 42 C.F.R. § 483.13 (Resident Behavior and Facility Practices), § 483.15 (Quality of Life), or § 483.25 (Quality of Care) that are found to constitute either immediate jeopardy, a pattern of or widespread actual harm that does not amount to immediate jeopardy, or a widespread potential for more than minimal harm that does not amount to immediate jeopardy and there is no actual harm. 42 C.F.R. § 488.301.

The Act and regulations make a hearing before an ALJ available to a long-term care facility against which CMS has determined to impose a CMP. Act, section 1128A(c)(2); 42 C.F.R. §§ 488.408(g); 498.3(b)(13). The hearing before an ALJ is a *de novo* proceeding. Anesthesiologists Affiliated, et al, DAB CR65 (1990), aff'd, 941 F.2d 678 (8th Cir. 1991); Emerald Oaks, DAB No. 1800, at 11 (2001); Beechwood Sanitarium, DAB No. 1906 (2004); Cal Turner Extended Care, DAB No. 2030 (2006); The Residence at Salem Woods, DAB No. 2052, (2006). 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 NATCEP. 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. Thompson, 363 F.3d 583 (6th Cir. 2003). The Departmental Appeals Board (the Board) 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).

When a penalty is proposed and appealed, CMS must make a *prima facie* case that the facility has failed to comply substantially with federal participation requirements. "*Prima facie*" means that the evidence is "[s]ufficient to establish a fact or raise a presumption unless disproved or rebutted. *Black's Law Dictionary* 1228 (8th ed. 2004); *see also*, *Hillman Rehabilitation Center*, DAB No. 1611, at 8 (1997), *aff'd Hillman Rehabilitation Center v. U.S. Dept. of Health and Human Services*, No. 98-3789 (D.N.J. May 13, 1999). To prevail, a long-term care facility must overcome CMS's showing by a preponderance of the evidence. *Batavia Nursing and Convalescent Center*, DAB No. 1904 (2004); *Batavia Nursing and Convalescent Inn*, DAB No. 1911 (2004); *Emerald Oaks*, DAB No. 1800 (2001); *Cross Creek Health Care Center*, DAB No. 1665 (1998); *Evergreene Nursing Care Center*, DAB No. 2069, at 7-8 (2007).

E. Analysis

Facilities that participate in the Medicare program are required to ensure that each resident receives care and services necessary for the resident to "attain or maintain the highest practicable physical, mental, and psychosocial well-being, in accordance with the comprehensive assessment and plan of care." 42 C.F.R. § 483.25. In this case, CMS alleges that Petitioner violated three specific requirements of 42 C.F.R. § 483.25, and that each is the basis for a PICMP of \$2500.

1. Petitioner did not violate 42 C.F.R. § 483.25(c) (Tag F314).

CMS alleges that Petitioner violated this regulation in the case of Resident 143. CMS Ex. 2, at 18-20. The regulation requires that a facility must ensure that a resident who enters the facility without a pressure sore does not develop one unless the resident's clinical condition demonstrates that development of a pressure sore is unavoidable. The regulation also requires that for a resident with a pressure sore on admission the facility must deliver care and services necessary to promote healing, prevent infection, and prevent development of new sores. 42 C.F.R. § 483.25(c).

CMS alleges that Resident 143 entered the facility without a pressure sore on his right heel, that a Stage IV (the most severe) pressure sore developed, and that Petitioner did not provide necessary care and services to promote healing, prevent infection, and prevent development of new sores, including not care planning for the sore until March 20, 2006. CMS Brief at 2-5; CMS Reply at 1-3. Petitioner argues to the contrary, that Resident 143 was readmitted to its facility on March 2, 2006, with a Stage IV pressure sore, and that there is no evidence that the pressure sore worsened while the resident was in Petitioner's care. P. Brief at 2-4.

I conclude that CMS has failed to make a *prima facie* showing of a violation. Contrary to the assertion of the surveyors and CMS, the care plan at CMS Ex. 9, at 27, is dated March 2, 2006. The care plan reflects that it was specifically developed to address a breakdown on Resident 143's heel as a Stage IV pressure sore. There is no dispute that the breakdown the resident had on his heel (characterized as a black spot/reddened area in a March 3, 2006 nutrition note and in nurse's notes (P. Ex. 5, at 9; P. Ex. 3, at 5)) should be treated as a Stage IV pressure sore. SOM, App. PP, Tag F314.

CMS's argument throughout has relied heavily upon the notion that the date on the care plan is March 20, 2006, rather than March 2, 2006. CMS Ex. 9, at 27. There is no question that the date was written over, which provides the basis for the CMS argument. However, other evidence of record is more consistent with the date being March 2, 2006, rather than March 20, 2006. Resident 143 was readmitted to Petitioner's facility on March 2, 2006, after being hospitalized for a hip fracture. A hospital note dated March 1,

2006, records the presence of a Stage I pressure sore on the resident's "left" heel. P. Ex. 2, at 3. The reference to a Stage I pressure ulcer on the left heel is likely in error. The interventions noted include a no sting barrier and film to the heels, a protective boot, and placing a pillow under the calf consistent with hospital staff having identified a pressure sore of some severity. P. Ex. 2, at 3. However, Petitioner's records show that when the resident was returned from the hospital on March 2, 2006, there was a black spot on his right heel but no reference is made to any pressure ulcer on the left heel. A nutrition note dated March 3, 2006, from Resident 143's records, reflects that Resident 143 had a black spot on his heel upon readmission from the hospital on March 2, 2006. P. Ex. 5, at 9. Nurse's notes reflect that he had a black spot on the right heel upon readmission. P. Ex. 3, at 5. The weekly pressure ulcer report shows that the black spot on the right heel was identified March 2, 2006. P. Ex. 16, at 70. I conclude that the preponderance of the evidence shows that Resident 143 was readmitted to Petitioner's facility on March 2, 2006, with a black spot on his right heel that was appropriately identified and care planned on March 2, 2006. Because Resident 143 entered with a pressure sore on readmission, CMS cannot satisfy the first alternative basis for a *prima facie* showing, i.e. that the resident entered Petitioner's facility without an ulcer and then developed one. 42 C.F.R. § 483.25(c)(1).

CMS also fails to establish a *prima facie* showing of a violation of the second prong of 42 C.F.R. § 483.25(c)(2), i.e., that Petitioner failed to deliver necessary care and treatment to promote healing, prevent infection, and prevent new sores. CMS alleges in post-hearing briefs that the pressure sore worsened, but points to no evidence in support of that position. CMS Brief at 3; CMS Reply at 1-3. CMS has to present some evidence in support of its *prima facie* case, it is not enough to simply make an allegation. The surveyors took the position that Resident 143 entered Petitioner's facility without a pressure ulcer on the right heel, and so never alleged that an existing ulcer on that right heel was treated, or how, or whether it worsened. My review of Resident 143's records, made available to me at hearing, does not reflect any worsening of the sore while Resident 143 was at Petitioner's facility, and I have found that Petitioner had a care plan in place from his admission on March 2, 2006, which included interventions with necessary care and services. CMS Ex. 9, at 27.

2. Petitioner did not violate 42 C.F.R. § 483.25(i)(1) (Tag F325).

CMS alleges that Petitioner violated this regulation in the case of Residents 9 and 60. The regulation requires that a facility must ensure that a resident "[m]aintains acceptable parameters of nutritional status, such as body weight and protein levels, unless the resident's clinical condition demonstrates that this is not possible." 42 C.F.R. § 483.25(i)(1). The Guidance to Surveyors in the SOM specifically cautions surveyors that ideal body weight charts have not been developed for institutionalized elderly residents. Thus, a resident's weight gain or loss should be considered in light of the resident's

former life style, current diagnosis, the resident's usual weight through adult life, the assessment for potential weight loss, and the care plan for weight loss. SOM, App. PP, Tag F325.

The Board discussed deficiency citations under Tag F325 in *The Windsor House*, DAB No. 1942 (2004) and Carehouse Convalescent Hospital, DAB No. 1799 (2001). In Carehouse the Board interpreted the regulation not to require that a facility maintain a resident's weight at a fixed level. The Board also determined that a facility is not strictly liable for a resident's weight loss. The Board said that the regulation requires maintenance of weight only to the extent that weight is a "parameter of nutritional status," i.e., if a resident receives adequate nutrition and weight loss is due to non-nutritive factors then the weight loss is not a "parameter of nutritional status and the weight loss alone is not a basis for a deficiency finding." Carehouse, DAB No. 1799, at 21. Nevertheless, the Board concluded that weight loss raises an inference of inadequate nutrition sufficient to be a CMS prima facie showing of a deficiency. Id. at 22. A prima facie case based upon the inference arising from weight loss is rebutted if the facility shows by a preponderance of the evidence that it "provided the resident with adequate nutrition" or weight loss was due to non-nutritive factors. Id. In Windsor, the Board used the formulation that a "facility is responsible for taking all reasonable steps to ensure that the resident receives nutrition adequate to his or her needs." Windsor, DAB No. 1942, at 18. The Board explained that if CMS makes a prima facie showing based on weight loss, the facility may rebut that showing with evidence that the resident did receive adequate nutrition or that weight loss was due to non-nutritive factors, such as the resident's clinical condition. Id. The Board commented that the "clinical condition exception" is a narrow one that applies only when the facility demonstrates that it cannot provide nutrition adequate for the resident's overall needs so that weight loss is unavoidable. Id. The Board affirmed the ALJ's findings and conclusions in *Windsor*, indicating that the ALJ correctly concluded that the presence of a significant clinical condition alone does not prove that weight loss is unavoidable. Rather, the Board noted that the ALJ correctly focused upon Windsor's own assessment of the residents' nutritional needs and whether Windsor met its own plan for how to meet those needs. *Id.* at 17-18.

CMS alleges that both residents had unplanned significant weight loss, indicating that Petitioner did not ensure that they maintained acceptable parameters of nutritional status.

I conclude that the preponderance of the evidence shows that each resident experienced unplanned weight loss. Thus, CMS has made a *prima facie* showing of a violation of the regulation. As noted by the surveyors' snapshot of the residents' weights over a several month period, Resident 9's weight fluctuated from 180.4 pounds in December 2005 to 160.4 pounds in April 2006, and Resident 60's weight fluctuated from 98.6 pounds in September 2005 to 76.4 pounds in April 2006. CMS Ex. 2, at 23, 25-26. However, although CMS has made a *prima facie* case of a violation based on weight loss, I

conclude, based on consideration of the residents' history and diagnoses, and the assessment, care planning and interventions of the facility to address the residents' weight loss, that Petitioner took all reasonable steps to provide adequate nutrition to these residents.

Both elderly residents had complicated medical conditions with many possible factors affecting their weight. Petitioner's records reflect that Petitioner's staff and the residents' attending physician were aware of the difficulty these residents had maintaining a consistent weight. CMS Exs. 6, 8; P. Exs. 38-47. The residents were assessed and monitored and various interventions were attempted to ensure the residents maintained weight. And, there is no evidence other than weight loss that suggests that either resident was malnourished.

Resident 9 was heavy at nearly 190 pounds upon her admission. A dietitian assessment shows that Resident 9's adjusted ideal body weight was 137 pounds and her daily caloric needs were calculated based upon her adjusted ideal body weight. CMS Ex. 6, at 5. This fact is consistent with a theory advanced by Petitioner that some of the resident's weight loss may be explained by less caloric intake than necessary to maintain her original weight. The resident was also being given a diuretic, Lasix 40 mg, which medication contributes to loss of water and related weight. CMS Ex. 6, at 5, 6, 8. A physician's note dated March 21, 2006, prepared by a nurse practitioner, notes Resident 9's weight had gone down to 172 pounds, but that when reviewing Resident 9's weights she noted the resident had a lot of edema when first admitted and that she had been on big doses of Lasix, which caused the nurse practitioner not "to worry so much about this [weight] loss." CMS Ex. 6, at 8. The resident's family also insisted that the resident be provided an inappropriate diet that she could not adequately swallow, which also impacted upon her ability to maintain weight and nutrition status. Tr. 843-46; CMS Ex. 6, at 11.

The facility took steps to address Resident 9's weight loss, taking into consideration her initial body weight, her diagnoses, her medication, and her family's preference for feeding her a regular diet. The facility solicited food preferences from the family in an attempt to tailor the resident's diet; monitored her weight to assess the need for supplements; provided supplements; arranged for an oral surgery consult regarding her broken teeth (which might have interfered with her eating); had staff hand-feed her, and changed the consistency of her food in the face of her difficulty consuming meals of a regular consistency (a regular consistency diet having been requested by the resident's

family). CMS Ex. 6, at 5, 6, 8, 9, 10, 11, 12, 13; Tr. 843-47. I find that considering all the factors suggested by the SOM, and the requirements of the regulation, Petitioner made reasonable efforts to ensure that Resident 9 maintained an acceptable weight and nutrition status. ⁵

I do not find persuasive the computer printouts obtained by the surveyors and which CMS introduced to show that Resident 9 missed breakfast 31 times in February and March 2006. I find credible and persuasive the testimony of the current DON, Ms. Donovan, that the computer printouts were produced by a new computer system installed shortly before the survey and that staff were not familiar with the system and made entry errors. I also find persuasive the DON's testimony that she investigated the situation and found that the resident did receive most of the breakfast meals, albeit after normal breakfast time, as the facility allowed Resident 9 to sleep-in. Tr. 847-53.

Similarly, with respect to Resident 60, the records reflect that Petitioner took reasonable steps to ensure that the resident maintained acceptable weight and nutrition. There is a record of Resident 60's weight from November 2004 through April 2006. During that time, the resident's weights varied: for instance, in April 2005, the resident weighed between 81 and 83.6 pounds, in September 2005 the resident weighed 98.6 pounds, and at the end of April 2006, the resident weighed 79.2 pounds. CMS Ex. 8, at 29-38. She was care planned for weight loss due to edema and a variable appetite needing supplements to maintain her weight. CMS Ex. 8, at 14, 17, 19. Her records show that Petitioner's staff and her physician were aware of her fluctuations in weight and that she was assessed and monitored and that there were interventions. These interventions included providing nutritional supplements, encouraging her to consume her meals, and monitoring her weight. CMS Ex. 8, at 5, 9, 11, 12, 14, 15, 16, 17, 19, 21, 22, 23-28. Some of these interventions were successful in stabilizing her weight for a while. The facility could not tube feed this resident, as comfort measures only were to be considered. CMS Ex. 8, at 14, 17, 19. It is also significant that CMS's witness, Ms. Sword, testified that, in her opinion, Petitioner provided Resident 60 adequate nutrition. Tr. 609-10.

3. Petitioner violated 42 C.F.R. § 483.25(j) (Tag F327).

This regulation requires that a facility "must provide each resident with sufficient fluid intake to maintain proper hydration and health." 42 C.F.R. § 483.25(j). According to the SOM, the intent of the regulation is to ensure that residents receive sufficient fluids based on their individual needs to prevent dehydration. SOM, App. PP, Tag F327. CMS alleges that Petitioner violated this regulation in the case of Residents CR3 and 17, by

⁵ I do not find, however, that the evidence supports Petitioner's argument that the resident suffered from the impact of cancer during the period în question.

failing to provide sufficient fluid intake to maintain proper hydration.⁶ CMS Ex. 2, at 27-29, 31-32. I find that CMS has made a *prima facie* case of noncompliance with regard to Resident CR3. However, I find that CMS has not made a *prima facie* case of noncompliance with regard to Resident 17.

Resident CR3: Resident CR3 was fed and received all fluids by feeding tube (percutaneous endoscopic gastrostomy or PEG tube) and she took no food or fluid by mouth. CMS Ex. 10, at 8, 12; P. Br. at 7. The evidence shows that Resident CR3 was dehydrated upon admission to the emergency room at Troy Community Hospital from Petitioner's facility. CMS Ex. 10, at 19-20. Specifically, the physician treating Resident CR3 in the emergency room noted clinical findings of dry oral mucosa and poor skin turgor, and an elevated BUN, which are symptoms of dehydration. The resident received IV fluids in the hospital. The ER physician noted that his impression was that the resident was dehydrated. *Id*.

CMS asserts that Resident CR3 had estimated daily fluid needs of 1250-1500 cc of fluid. CMS Ex. 10, at 8. CMS asserts that the Intake and Output record maintained by the facility from December 22, 2005 through January 16, 2006 shows her fluid needs were not being met. CMS Ex. 10, at 14-18. CMS refers to the testimony of its expert, Dr. Connors, who testified that the resident's inadequate fluid status could have been avoided, especially since she had a PEG tube, and that there was no question that the resident was clinically dehydrated. Tr. 470. CMS also refers to the testimony of its expert dietitian, Ms. Sword, who testified that the resident's hydration status was not adequately being met and that she required extra fluid due to her having a fever immediately prior to hospitalization. Ms. Sword testified that the resident's dehydration could have been prevented by adding more fluids. Tr. 578, 580. CMS then refers to the emergency room record and the emergency room physician's impression of dehydration, based on his findings of dry oral mucosa, poor skin turgor, and elevated BUN, to show that Resident CR3 was dehydrated upon arrival at the emergency room. CMS Br. at 17.

Petitioner has not shown by a preponderance of the evidence that Resident CR3 was not dehydrated. Petitioner relies on Input and Output records and Ms. Donovan's testimony to show that Resident CR3 was provided adequate fluid to maintain proper hydration. CMS Ex. 10, at 14-18; Tr. 740-830. Ms. Donovan was not the DON at the time of the survey and did not prepare the Input and Output records. Tr. 855; 861. More important, I find the Input and Output records to be unreliable due to inaccuracies in the data, and I therefore cannot rely on those documents or any of the calculations Petitioner sought to make at hearing. Tr. 784, 792, 827, 891. Further, although Petitioner implied that it

⁶ The parties stipulated that the example cited in the SOD related to Resident 158 (CMS Ex. 2, at 29-30) is no longer in issue. Tr. 9.

could not increase the fluids for this resident (referring to a frothy white discharge and the diagnosis of aspiration pneumonia at Robert Packer Hospital (P. Brief at 11-12))⁷, there is no credible evidence that this resident could not tolerate her tube feedings or that she could not have received additional hydration intravenously. *See* Tr. 905. Petitioner had nearly complete control of this resident's intake and output. Further, Petitioner did not elect to provide persuasive expert testimony to support its position that it was impossible to add more fluids for this resident.

Resident 17: CMS has not made a *prima facie* case of noncompliance with regard to Resident 17, because, even if CMS was able to make a *prima facie* case that the resident's intake was less than his calculated needs, such argument would fail based on the fact that emergency room records at Troy Community Hospital⁸ note that the emergency room physician found his "[h]ydration status is good" and that his tongue was "pink and moist." CMS Ex. 7, at 15-16. Although Resident 17's treating physician, Dr. Good, saw him at Troy Community Hospital, thought he was "dry," and ordered intravenous fluids, Dr. Good did not see the resident until hours after his admission to the emergency room. CMS Ex. 7, at 7, 12; Tr. 541-47. The emergency room physician is very credible, as he actually saw the resident, his job is to assess patients, and he assessed the resident's hydration status as "good" and his tongue as "pink and moist," and he did not order intravenous fluids administered. Even Dr. Connors agreed that lab values which she thought might indicate dehydration might be due to trauma and prescriptions. Tr. 536-40.

4. A PICMP of \$7500 is not reasonable, but a PICMP of \$1250 is reasonable.

If a facility is not in substantial compliance with program requirements, CMS has the authority to impose one or more of the enforcement remedies listed in 42 C.F.R. § 488.406, including a DPNA and a CMP. CMS may impose a CMP for the number of days that the facility is not in substantial compliance or for each instance that a facility is

⁷ On January 16, 2006, after an intravenous infusion of fluid, Resident CR3 was transferred from the Troy Community Hospital emergency room to Robert Packer Hospital, because no beds were available at Troy Community Hospital. CMS Ex. 10, at 19-20. The discharge summary from Robert Packer Hospital, dated January 24, 2007, does not note as a diagnosis or associated condition dehydration. P. Ex. 57. However, this is most likely explained by Resident CR3 having received intravenous fluids at Troy Community Hospital.

⁸ Where the resident was brought on February 28, 2006, following a fall on February 27, 2006. CMS Ex. 7, at 15.

not in substantial compliance. 42 C.F.R. § 488.430(a). There is only a single range of \$1000 to \$10,000 for a PICMP. 42 C.F.R. §§ 488.408(d)(1)(iv); 488.438(a)(2). In this case, CMS imposed a PICMP of \$2500 for each of three alleged deficiencies, an amount that is at the low end of the permissible range.

In determining whether the amount of the CMP is reasonable, the following factors specified at 42 C.F.R. § 488.438(f) must be considered: (1) the facility's history of non-compliance, including repeated deficiencies; (2) the facility's financial condition; (3) the seriousness of the deficiencies as set forth at 42 C.F.R. § 488.404; and (4) the facility's degree of culpability.

Having found Petitioner in noncompliance only for a violation of 42 C.F.R. § 483.25(j), the only PICMP at issue is the \$2500 PICMP for the violation of that section. There is no evidence that Petitioner is unable to pay the CMP. There is a history of noncompliance here, as during a prior survey conducted on April 15, 2005, there was a G level deficiency identified at Tag F327. CMS Ex. 5, at 1. However, no detail has been provided as to any of the deficiencies from that survey, just the tag identifier and the scope and severity. The violation of 42 C.F.R. § 483.25(j) here is serious. The scope and severity of G indicates actual harm that did not amount to immediate jeopardy, a characterization that is consistent with the evidence. Petitioner was culpable for failure to effect further interventions to prevent dehydration to Resident CR3. Thus, reassessing the PICMP in light of the regulatory factors, and having sustained a deficiency involving only one resident example, I find a \$1250 PICMP to be reasonable.

5. Approval of Petitioner to conduct a NATCEP program should not be withdrawn.

Petitioner's approval to conduct a NATCEP was withdrawn based upon CMS's assessment of a PICMP of not less than \$5000. However, I have concluded that, based on a single deficiency, a PICMP of only \$1250 is reasonable. Accordingly, there is no longer a requirement for the state to withdraw Petitioner's authority to conduct a NATCEP.

III. Conclusion

For the foregoing reasons, I conclude that Petitioner was out of compliance with one participation requirement involving one resident on April 28, 2006. I conclude further that a PICMP of \$1250 is reasonable. The state is not required to withdraw Petitioner's approval to conduct a NATCEP, because the PICMP upheld is less than \$5000.

/s/ Keith W. Sickendiek
Administrative Law Judge