

Department of Health and Human Services

DEPARTMENTAL APPEALS BOARD

Civil Remedies Division

In the Case of:)
)
) Date: October 19, 2007
Ottumwa Good Samaritan Center)
(CCN: 16-5211),)
)
Petitioner,) Docket No. C-04-363
) Decision No. CR1677
v.)
)
Centers for Medicare & Medicaid)
Services.)

DECISION

Petitioner, Ottumwa Good Samaritan Center, violated 42 C.F.R. § 483.25(i)(1) in the case of five residents by failure to ensure adequate nutrition as alleged by the Centers for Medicare & Medicaid Services (CMS) based on the survey completed January 16, 2004. The violations constituted substandard quality of care. Pursuant to the Social Security Act (Act) sections 1819(f)(2)(B) and 1919(f)(2)(B) and 42 C.F.R. §§ 483.151(b)(2) and (e)(1), and 42 C.F.R. § 483.151(b)(2)(iii), the state was required to withdraw approval of Petitioner's nurse aide training and competency evaluation (NATCEP) program for a period of two years from the date of the survey.

I. Background

Petitioner is located in Ottumwa, Iowa. Petitioner is certified to participate in the Medicare program as a skilled nursing facility (SNF) and the Iowa Medicaid program as a nursing facility (NF). The Iowa Department of Inspections and Appeals (the state agency) conducted an annual survey of Petitioner on January 12 through 16, and 26 through 28, 2004. The state agency issued a Statement of Deficiencies (SOD) dated February 18, 2004, in which it alleged, based on the annual survey findings, that Petitioner was not in substantial compliance with Medicare and Medicaid participation

requirements. One deficiency cited a violation of 42 C.F.R. § 483.25(i)(1)¹ (Tag F325)² at a scope and severity level of H, which amounts to a finding of substandard quality of care. Based upon the finding of substandard quality of care, an extended survey was conducted pursuant to sections 1819(g)(2)(B) and 1919(g)(2)(B) of the Act. Pursuant to 42 C.F.R. § 483.151(b)(2)(iii), Petitioner is prohibited from operating a NATCEP for two years due to the extended survey. Joint Stipulation (Jt. Stip.).³

Pursuant to 42 C.F.R. § 498.3(b)(16), Petitioner may request a hearing before an administrative law judge (ALJ) to challenge the finding that it delivered a substandard quality of care and the resulting loss of authority to conduct a NATCEP. Petitioner was notified by the state agency, not CMS, that its NATCEP would have to be terminated due to the findings of the January 2004 survey.⁴ Jt. Stip.; Tr. 38-39; P. Ex. 11. However, Petitioner requested a hearing before an ALJ by letter dated May 28, 2004. The case was assigned to me for hearing and decision on June 24, 2004. A hearing was conducted in Des Moines, Iowa on November 4, 2004. CMS offered exhibits (CMS Exs.) 1 through 4

¹ All references are to the revision of the Code of Federal Regulations (C.F.R.) in effect at the time of the surveys, unless otherwise indicated.

² This is a “Tag” designation as used in the State Operations Manual (SOM), Appendix PP – Guidance to Surveyors for Long Term Care Facilities. The “Tag” refers to the specific regulatory provision allegedly violated and CMS’s guidance to surveyors. Although the SOM does not have the force and effect of law, the provisions of the Act and regulations interpreted clearly do have such force and effect. *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). Thus, 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.

³ Based on the survey findings, CMS had notified Petitioner that if it was not in substantial compliance on revisit survey, a denial of payment for new admissions (DPNA) would be imposed. The state agency conducted a revisit survey on March 11, 2004, and it was determined that Petitioner was again in substantial compliance and the DPNA was never effectuated.

⁴ The parties agreed at hearing that withdrawal of the approval to conduct a NATCEP was stayed pending the outcome of this appeal. Tr. 227-28; P. Ex. 11.

and Petitioner offered exhibits (P. Exs.) 1 through 11, all exhibits were admitted.⁵ CMS called one witness, surveyor Denise Gaffney. Petitioner called four witnesses, Karen Kaiser, R.N., Lisa Matthiesen, R.D., Ayesha Ahmad, M.D., and Peter J. Reiter, M.D., F.A.C.P.

Petitioner submitted a post hearing brief (P. Brief) and a post hearing reply brief (P. Reply). CMS filed a post hearing brief (CMS Brief) but elected not to file a reply brief.

II. Discussion

A. Findings of Fact

The following findings of fact are based upon the exhibits admitted. 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 is a long-term care facility located in Ottumwa, Iowa that was authorized to participate in the Medicare and Medicaid programs.
2. The state agency conducted an annual survey of Petitioner's facility from January 12 through 28, 2004.
3. The state agency determined that Petitioner was not in substantial compliance with federal program participation requirements, including 42 C.F.R. § 483.25(i)(1) (Tag F325), and that the violation of 42 C.F.R. § 483.25(i)(1) amounted to substandard quality of care that triggered an extended survey.
4. The violation of 42 C.F.R. § 483.25(i)(1) involved 5 residents and these 5 residents were found in a sample of 28 drawn from a total resident population of 138.

⁵ Petitioner objected to the CMS exhibits on the basis that they included cumulative and irrelevant material. CMS explained that it had merely submitted all documents produced to it by the state survey agency. Rather than attempt to segregate all cumulative and irrelevant documents during the hearing, I admitted the entire mass of CMS documents and have carefully avoided consideration of any irrelevant material in reaching this decision. Tr. at 21-24.

5. The state agency notified Petitioner that the extended survey required that Petitioner's authority to conduct a NATCEP be withdrawn for a period of two years, but the state also advised Petitioner that it would not withdraw the authority pending conclusion of any appeal.
6. On May 28, 2004, Petitioner requested a hearing before an ALJ.
7. Resident 3 experienced an unplanned weight loss of 11 pounds between November 2003 and January 2004.
8. Resident 3's unplanned weight loss was due to intake of inadequate nutrition.
9. Resident 3's unplanned weight loss was not unavoidable.
10. Resident 5 experienced an unplanned weight loss of 14.6 pounds between July 2003 and January 2004.
11. Resident 5's unplanned weight loss was due to intake of inadequate nutrition.
12. Resident 5's unplanned weight loss was not unavoidable.
13. Resident 6 experienced an unplanned weight loss of 39.3 pounds between October 2003 and January 2004.
14. Resident 6's unplanned weight loss was due to intake of inadequate nutrition.
15. Resident 6's unplanned weight loss was not unavoidable.
16. Resident 12 experienced an unplanned weight loss of 16.6 pounds between July 2003 and January 2004.
17. Resident 12's unplanned weight loss was due to intake of inadequate nutrition.
18. Resident 12's unplanned weight loss was not unavoidable.
19. Resident 14 experienced an unplanned weight loss of 20 pounds between December 2003 and January 2004.

20. Resident 14's unplanned weight loss was due to intake of inadequate nutrition.
21. Resident 14's unplanned weight loss was not unavoidable.

B. Conclusions of Law

1. Petitioner's request for hearing was timely and I have jurisdiction.
2. CMS made a prima facie showing of a violation of 42 C.F.R. § 483.25(i)(1) (Tag F325).
3. Petitioner failed to rebut CMS's prima facie showing of a violation of 42 C.F.R. § 483.25(i)(1) (Tag F325) either by showing by a preponderance of the evidence that the facility was in substantial compliance or with an affirmative defense.
4. Petitioner violated 42 C.F.R. § 483.25(i)(1) (Tag F325) by failing to ensure that Resident 3 maintained acceptable parameters of nutritional status.
5. Petitioner violated 42 C.F.R. § 483.25(i)(1) (Tag F325) by failing to ensure that Resident 5 maintained acceptable parameters of nutritional status.
6. Petitioner violated 42 C.F.R. § 483.25(i)(1) (Tag F325) by failing to ensure that Resident 6 maintained acceptable parameters of nutritional status.
7. Petitioner violated 42 C.F.R. § 483.25(i)(1) (Tag F325) by failing to ensure that Resident 12 maintained acceptable parameters of nutritional status.
8. Petitioner violated 42 C.F.R. § 483.25(i)(1) (Tag F325) by failing to ensure that Resident 14 maintained acceptable parameters of nutritional status.
9. Petitioner's violations of 42 C.F.R. § 483.25(i)(1) in the case of the five residents cited as examples by the SOD, presented a pattern of actual harm that amounted to substandard quality of care that required an extended survey.
10. Withdrawal of Petitioner's authority to conduct a NATCEP was required by 42 C.F.R. § 483.151(b)(2) and (e)(1).

C. Issues

The issues in this case are:

Whether Petitioner was in substantial compliance with the requirement of participation set forth in 42 C.F.R. § 483.25(i)(1), Tag F325; and,

Whether, if there was a deficiency, it constituted substandard quality of care as that phrase is defined in 42 C.F.R. § 488.301.

D. Applicable Law

The Act sets forth requirements for long-term care facility (SNF and NF) participation in the Medicare and Medicaid programs and authorizes the Secretary to promulgate regulations implementing the statutory provisions. Act §§ 1819 and 1919. The Secretary's regulations governing nursing facility participation in the Medicare program are found at 42 C.F.R. Part 483. Regulations governing survey, certification, and enforcement procedures, and regulations governing provider agreements, are found at Parts 488 and 489, respectively. Regulations governing appeals procedures are found at Part 498.

To participate in the Medicare and Medicaid programs, facilities periodically undergo surveys to determine whether they comply with applicable statutory and regulatory requirements for Medicare (SNFs) and/or Medicaid (NFs). They must maintain substantial compliance with program requirements, and, to be in substantial compliance, a facility's deficiencies may pose no greater risk to resident health and safety than "the potential for causing minimal harm." 42 C.F.R. § 488.301. If a facility is not in substantial compliance with program requirements, CMS has the authority to impose, in addition to termination, one or more of the enforcement remedies listed in 42 C.F.R. § 488.406, including a denial of payment for new admissions, directed in-service training, and imposition of a civil money penalty. *See* Act, section 1819(h).

Scope and severity levels are used by CMS and a state when selecting remedies. The scope and severity level is designated by an alpha character, A through L, selected by CMS or the state agency from the scope and severity matrix published in the SOM, 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. The matrix, which is based on 42 C.F.R. § 488.408, specifies which remedies are required and optional at each level based upon the frequency of the deficiency. *See* SOM, section 7400E.

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, a facility may not appeal the choice of remedies by CMS or the factors CMS considered when choosing a remedy. 42 C.F.R. § 488.408(g)(2). In this case, CMS imposed no remedies. Rather, the survey findings amounted to a finding of substandard quality of care which triggered the withdrawal of Petitioner’s authority to conduct a NATCEP.

Pursuant to sections 1819(b)(5) and 1919(b)(5) of the Act, skilled nursing facilities and nursing facilities may only use nurse aides who have the required training and competency evaluation. Sections 1819(e) and 1919(e) of the Act impose upon the states the requirements to specify what nurse aide training and competency evaluation programs they will approve that meet the requirements established by the Secretary and a process for reviewing and approving 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 nurse aide training and competency evaluation programs 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 nurse aide training and competency evaluation program 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(h)(2)(A)(ii) of the Act unless the survey shows the facility was in compliance with participation requirements; (2) has been assessed a CMP of not less than \$5000; or (3) that has been subject to termination of its participation agreement, denial of payment, or the appointment of temporary management.

“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. 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. *Id.* In this case, the allegation of substandard quality of care is premised upon the alleged violation of 42 C.F.R. § 483.25 at the H level, i.e., a pattern of actual harm.

As already noted, a facility is not normally entitled to ALJ review of a CMS or state agency level of noncompliance determination (also known as the “scope and severity” determination). The only two exceptions are where the amount of the CMP might be affected and where there was a finding of “substandard quality of care” that led to loss of approval of the facilities NATCEP. 42 C.F.R. § 498.3(b)14. In this case, the state agency made a finding of “substandard quality of care” that led to a partial extended survey and Petitioner’s loss of approval to conduct its NATCEP.

When a remedy is imposed or there is loss of approval to conduct a NATCEP as in this case, and there is an appeal, CMS must make a prima facie showing that the facility has failed to comply substantially with federal participation requirements. 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); *Hillman Rehabilitation Center*, DAB No. 1611 (1997), *aff’d Hillman Rehabilitation Center v. U.S. Dep’t. of Health & Human Servs.*, No. 98-3789 (D.N.J. May 13, 1999). A preponderance of evidence is “superior evidentiary weight that, though not sufficient to free the mind wholly from all reasonable doubt, is still sufficient to incline a fair and impartial mind to one side of the issue rather than the other.” Black’s Law Dictionary (7th ed. 1999) (cited by the Departmental Appeals Board (Board) in *Beechwood Sanitarium*, DAB No. 1906, at 38 (2004)).

E. Analysis

1. Petitioner received sufficient notice that its authority to conduct a NATCEP was being withdrawn for two years.

Petitioner argues in its prehearing brief that CMS and the state agency never provided “appropriate or adequate notice of its intent to prohibit continuation of Petitioner’s NATCEP program (sic).” Petitioner asserts that the notices provided Petitioner no “details associated with appeal rights relating to the loss of the NATCEP program (sic).” Petitioner argues that because it did not receive sufficient notice, approval of its NATCEP cannot be withdrawn or withheld. Petitioner’s Prehearing Brief at 10-11. In the Joint Stipulation, paragraph 11, the parties stipulated that “Petitioner has never received a letter from Centers for Medicare and Medicaid Services (CMS) notifying the facility that the

findings contained in the statement of deficiencies relating to the January 2004 survey have resulted in the loss of its NATCEP program (sic).” Petitioner renewed its objection and argument at hearing. Tr. at 38-39, 41-46. The notice Petitioner did receive was admitted as P. Ex. 11. Petitioner’s argument is not persuasive.

The Secretary’s regulations, consistent with the Act, put administration of the program for certification of nurse aides in the hands of the state subject to the regulations the Secretary promulgates establishing the details for the program. *See Act*, §§ 1819(b)(5)(A)(i)(I); 1819(b)(5)(C); 1819(f); 1919(b)(5)(A)(i)(I); 1919(b)(5)(C); 1919(f); 42 C.F.R. §§ 483.151; 483.152; 483.154; 483.156. The regulations clearly impose the duty to provide notice of withdrawal or withholding of approval to conduct a NATCEP upon the state not CMS. 42 C.F.R. § 483.151(e)(4)(i). Further, the regulation specifies that the notice from the state must indicate the “reason(s) for withdrawal of approval of the program.” *Id.* The regulation does not specify that the state must notify a provider that it has a right to appeal the loss of approval or challenge the basis for the action. Petitioner indicates in its prehearing brief that the state provided it some notice but asserts the notice is inadequate because it provides no “details associated with appeal rights.” However, Petitioner does not provide me the notices it did receive so that I might consider whether or not the notices contained sufficient detail. The stipulation of fact that Petitioner never received a notice from CMS does not support Petitioner’s position as the duty to provide notice is upon the state and not CMS. Further, while Petitioner alleges that the notice from the state was deficient, it is clear that Petitioner was on notice that approval to continue its NATCEP was withdrawn, the alleged basis for the withdrawal, and that it could appeal as Petitioner did so.

2. Petitioner violated 42 C.F.R. § 483.25(i)(1) (Tag F325).

Petitioner argues that CMS failed to make a prima facie showing of a violation of 42 C.F.R. § 483.25(i)(1) as to any of the five residents cited as examples in the SOD. In the alternative, Petitioner argues that the state agency determination of scope and severity was erroneous and that the alleged violation did not amount to substandard quality of care.

The regulation requires:

Sec. 483.25 Quality of care. 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.

* * * *

(i) Nutrition. Based on a resident's comprehensive assessment, the facility must ensure that a resident -- (1) 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;

42 C.F.R. § 483.25(i)(1).

The Guidance to Surveyors from the SOM provides that "(p)arameters of nutritional status which are unacceptable include unplanned weight loss as well as other indices such as peripheral edema, cachexia and laboratory tests indicating malnourishment (e.g., serum albumin levels)." SOM, app. P, at PP-106 (June 1995). The SOM also includes an investigative protocol for unintended weight loss which has two objectives, to determine if identified weight loss is avoidable or unavoidable and to determine the adequacy of the facility's response to the weight loss. The protocol requires surveyors to determine whether the facility properly assessed a resident for risks for unintended weight loss; whether the facility assessed the resident's nutritive and fluid requirements, need for dining assistance including need for assistive devices, food preferences, allergies, and frequency of meals; whether there is information or documentation of identified causes for the weight loss; whether a care plan was developed based on clinical conditions and risk factors identified by the assessment for the unintended weight loss and whether interventions were developed; and whether the care plan was evaluated and revised based on the response, outcomes, and needs of the resident. For a resident in end of life stage, surveyors are instructed to ensure that palliative interventions in the care plan are implemented and revised as necessary to meet the needs and choices of the resident and to maintain the resident's comfort and quality of life needs. The surveyors are instructed for all cases of unintended weight loss to make observations to determine whether interventions have actually been implemented. The protocol states that unintended weight loss may be found unavoidable if the facility properly assessed, care planned and implemented the care plan, evaluated outcomes, and revised the care plan as necessary. If the facility failed to do any of the steps, then the weight loss should be considered avoidable and the facility cited for violation of Tag F325. SOM, app. P, at P-45 to 46.1 (rev. 10).

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* 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* at 15. 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 maintaining acceptable nutrition is unavoidable rather, 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.

(a) A pattern, sufficient to support a finding of substandard quality of care, exists where violations are shown in the case of 5 residents from a sample of 28 residents.

CMS alleges, based upon the survey completed on January 16, 2004, that Petitioner failed to assess and provide and/or implement sufficient interventions for five residents (Residents 14, 12, 3, 6, and 5), who experienced significant weight loss. CMS Ex. 1, at 39; Tr. at 23. According to the SOD, the surveyors reviewed records for a sample of 28 residents out of a total resident population at the time of the survey of 138. The surveyors identified 16 residents who had recently experienced significant weight loss and five of the 16 cases allegedly amounted to violations of 42 C.F.R. § 483.25(i)(1). CMS Ex. 1, at 39. Petitioner argues that even if there are five violations, that number does not constitute a pattern, and therefore there was no basis for the state agency or CMS to conclude that there was substandard quality of care. Petitioner’s analysis is that five examples out of 138 does not constitute a pattern because the SOM defines a pattern as more than a few.

However, Petitioner ignores that the five alleged violations were not found based upon review of the records of the entire population, but rather a sample of only 28 patients. I have no difficulty concluding that five of 28 is more than a few residents and a pattern within the meaning of the SOM.

(b) Petitioner has not proven by a preponderance of the evidence that it ensured adequate nutrition was received by five residents.

Petitioner does not dispute that for each of the five residents that there was weight loss as alleged by CMS. Tr. at 33; P. Brief at 11; P. Reply at 1. Based upon the language of 42 C.F.R. § 483.25(i)(1) and the Board's analysis in *Carehouse* and *Windsor*, I conclude that the admitted weight loss, supported by the clinical records admitted as evidence, are sufficient to establish a prima facie case of a violation. Contrary to Petitioner's assertions, it is not incumbent upon CMS to show Petitioner failed to provide the five residents adequate nutrition. P. Br. at 8. Rather, the burden of persuasion by a preponderance of the evidence is upon Petitioner to show it took all reasonable steps to ensure that the residents received adequate nutrition but that weight loss nevertheless occurred or that weight loss was unavoidable. To establish that it took all reasonable steps, Petitioner must show that it complied with regulatory requirements to assess the residents' nutritional needs (42 C.F.R. § 483.20(b)), that it care planned to meet the residents' nutritional needs and followed the care plan including implementation of planned interventions (42 C.F.R. § 483.20(k)), and that it reviewed the efficacy of care planned interventions and revised as necessary (42 C.F.R. § 483.20(k)(2)(iii)). If Petitioner fails at any step in the process, it cannot show that the weight loss was unavoidable. Petitioner presented testimony from some of the residents' physicians who opined that weight loss was clinically unavoidable based on the residents' diagnosis and medical condition. However, as discussed in more detail hereafter, their opinions are conclusory and, as the Board has previously stated, the presence of a significant diagnosis alone is not sufficient to establish that weight loss was unavoidable. The physicians' testimony is also insufficient evidence that Petitioner took all reasonable steps or that weight loss was unavoidable after Petitioner took those steps, because the physicians were not regularly present to witness the delivery of care and have insufficient information regarding whether or not Petitioner implemented all care planned interventions.

The following brief summary of the evidence related to each resident reveals Petitioner's failures with regard to each and shows that Petitioner has not met its burden to establish that it took all reasonable steps to maintain adequate nutrition.

(1) Resident 14.

Petitioner called the resident's treating physician, Peter J. Reiter, M.D., to testify. Dr. Reiter testified that he was Resident 14's treating physician. He testified that Resident 14 suffered from progressive dementia, arteritis, recurring infections, osteoporosis, diverticulitis, which previously required surgery, and she had been in general decline for a number of years. She also suffered marked dependent edema which is a swelling of the lower extremities due to accumulation or retention of fluid. He opined that the edema was due to her obesity, chronic venous insufficiency, and chronic use of the corticosteroid Prednisone to treat her temporal arteritis. He testified that he administered diuretics and had her elevate her legs to try to minimize the edema. She was hospitalized from August 3 to 14, 2003 due to a blood borne infection, chronic lung disease and fluid retention. She had impairment of cognitive function and there was some evidence of aspiration of food or other materials. Her decline following hospitalization was more severe and rapid, which he attributed to dementia possibly secondary to Alzheimer's disease. He visited the resident on November 24, 2003 and observed a marked improvement in the edema in her legs from his last prior visit on September 29, 2003. He opined that the most important factor in her 20 pound weight loss between early October and early November 2003 was her reduced fluid retention. He based his opinion on the fact that during this period she was in bed more, off her legs and with them more elevated, and he was attempting to reduce the amount of Prednisone she was taking. He explained that elevating the legs more minimizes the impact of gravity, allowing circulation of the fluid and excretion by the kidneys. He also explained that Prednisone causes fluid retention and reducing the dose reduces the amount of fluid retained. He agreed with Petitioner's counsel that a significant amount of weight loss was due to mobilization of the resident's fluid. He opined that it was also clinically unavoidable for her to have some weight loss based on reduced oral intake due to end-stage dementia. He explained that dementia caused her to refuse to eat and to choke when she did eat. The resident's family had refused any mechanical means for feeding. Thus, he anticipated that there would be weight loss. He opined that supplements would not be effective to change her weight loss due to her dementia and the fluid loss. He opined that her weight loss had no connection to her development of pneumonia and readmission to the hospital in January 2004. Upon her release in January 2004, she was placed in a hospice program in which no nutrition was offered other than what she requested. He opined that the facility offered appropriate nutrition and she took whatever she chose, that her weight loss was unavoidable, and not a parameter of nutrition. Tr. at 135-45. His testimony is consistent with his letter dated March 3, 2004, which indicates that when albumin was measured it was low, consistent with malnutrition. He states that dietary supplements were not helpful. He attributes her weight loss to mobilization of fluids and poor oral intake despite interventions. P. Ex. 2, at 1-2.

Under most circumstances, I would accept a treating physician's opinion without much hesitation. However, in this case I find that Dr. Reiter's opinions are not appropriately supported. He indicated that he did not see the resident often in the facility. He testified to seeing her in the facility once in September 2003 and again in November 2003, although he apparently saw her also in the hospital in between those visits. There is no indication that he actually observed feeding of the resident at Petitioner's facility or that he reviewed Petitioner's efforts to ensure she received adequate nutrition. He did not testify that he reviewed her nutrition records or met with the dietician to develop interventions to address her resistance to feeding and other problems that interfered with her taking adequate nutrition. Rather, Dr. Reiter opined that the significant 25-pound weight loss in October and November was attributable to reduced fluid retention. He attributes the 20-pound weight loss in December 2003 and January 2004 to the fact that she was terminal. A 25-pound weight loss due to loss of fluids strains credibility, but CMS did not rebut that testimony and I do not reject it. However, the opinion that the 20-pound weight loss in December 2003 and January 2004 was acceptable because she was terminal anyway, is rejected. The fact that the resident was terminal does not relieve Petitioner of the continuing responsibility to ensure the resident received adequate nutrition. The focus is not upon whether Dr. Reiter believed that it was unnecessary to take further steps to ensure adequate nutrition because she was terminal. The focus is upon whether Petitioner has shown it took reasonable steps to ensure adequate nutrition was received by the resident, i.e., whether there was assessment, care planning, implementation of interventions, and evaluation and reassessment of the Resident's needs.

A review of Resident 14's records reveal the following weight loss during a six month period:

August 2003	192.2 lbs.
September 2003	193 lbs.
October 2003	195.8 lbs.
November 2003	170.4 lbs.
December 2003	174.6 lbs.
January 2004	154.2 lbs.

P. Ex. 1, at 19.

Resident 14's comprehensive care plan dated October 2, 2003, recognized that she had a problem with nutrition with a goal that she would accept 75 to 100 percent of three meals daily. The plan specified that meal acceptance and meal intake were to be recorded every meal. An undated, hand-written note indicates the resident was to receive Ensure, a liquid supplement, three times per day with meals. P. Ex. 1, at 22.

A registered dietician's note dated December 23, 2003, shows the resident's weight as 174.6 pounds with 11 percent weight loss in the last 180 days. The dietician noted the resident was only consuming 42 percent of meals which provided 870 calories and 35 grams of protein. The dietician recommended that the resident have her albumin checked due to potential for malnutrition. The dietician noted that at her weight, the resident required 1700 calories and 79 grams of protein. The dietician planned to continue monitoring to determine whether the resident needed supplements. P. Ex. 1, at 17-18. A note dated January 5, 2004, reflects that the dietary consultant requested that albumin level be checked because she was concerned about possible malnutrition. P. Ex. 1, at 23.

Surveyor Gaffney testified that the deficiency was cited in part because Petitioner had undertaken as part of Resident 14's care plan to record the resident's meal intake. Petitioner failed to consistently record Resident 14's meal acceptance on the forms at CMS Ex. 3, at 842-46, which made it difficult to determine the resident's actual meal intake. Surveyor Gaffney testified that knowing how much is eaten is important because, if a resident is not eating sufficiently, the resident is not getting enough nutrition and changes need to be made to increase caloric intake and avoid malnutrition. Tr. at 60-61. My review of Petitioner's records at CMS Ex. 3, at 842-46 reveals that between September 1, 2003 and January 9, 2004, Petitioner's staff failed to make any entry to reflect whether or not the resident had intake for 145 meals.

Lisa Matthiesen, Petitioner's Director of Dietary Services, testified that the intent in recording meal intake is to have every meal recorded. However, she testified that even if every meal is not recorded as in the case of Resident 14, trends may still be identified and that is helpful information. Tr. at 156-57. She also testified that snacks were sent to the wings, and if the resident was hungry, food was available. Tr. at 165. Ms. Matthieson did not testify as to whether or not snacks were actually taken to Resident 14 or whether there was any offer to assist Resident 14 or any attempt to encourage her to eat snacks. She did testify that the resident was resistive to feeding. Tr. at 163-65. According to the resident's minimum data set (MDS) with an assessment reference date of December 17, 2003, she was totally dependent on staff for eating, transferring, and locomotion on and off the unit. P. Ex. 1, at 20-21. Thus, there was no way that the resident could obtain a snack on her own and the presence of snacks on the wings, absent some evidence of staff assistance, is not evidence that she was presented with nutrition or had any intake of snacks. The resident lost 20.4 lbs in December 2003 and January 2004. This represented a 12 percent weight loss in one month and a 20 percent weight loss in 180 days. I was provided no dietician assessment for the resident's December to January weight loss nor do I find evidence that any new dietary interventions were put in place after the October 2003 care plan and the addition of a liquid supplement at that time.

CMS established a prima facie case of noncompliance with the requirements of 42 C.F.R. § 483.25(i)(1), based on the undisputed fact that there was weight loss. Petitioner has not met its burden to rebut the prima facie showing by a preponderance of the evidence. Petitioner did not document meal intake consistently as required by the resident’s care plan. Petitioner has not offered evidence that snacks were actually provided to the resident. Petitioner has not shown that interventions were developed to address the resident’s resistance to feeding. Petitioner has not shown that after October 2003 it took steps to revise the resident’s care plan and implement interventions to address the resident’s alleged lack of desire to eat food offered. Petitioner failed to take these reasonable steps even though there is clear evidence that the dietician was concerned about possible malnutrition.

(2) Resident 12.

Ms. Matthiesen testified that Resident 12 was assessed as at risk for weight loss and did sustain a loss between July and August 2003. Her supplements were increased to four times per day. Petitioner determined that the resident’s protein needs were being met through her supplement and meals and she had a slight weight gain in the late summer of 2003. The nutrition risk committee assessed her in January 2004. Her physician was contacted and a speech language pathology assessment was requested to determine whether a change in texture of her food was required. She was moved to the assisted dining room for cuing and supervision. Tr. at 167-70.

Resident 12’s MDS with an assessment reference date of November 19, 2003, shows that she required supervision in the form of oversight, encouragement or cuing with eating at least sometimes during the seven day MDS evaluation period. CMS Ex. 3, at 869-70; P. Ex. 3, at 11-12.

The facility’s weight monitoring program recorded the resident’s weights for the seven month period as:

July 2003	125.4 lbs.
August 2003	115.2 lbs.
September 2003	116.2 lbs.
October 2003	116 lbs.
November 2003	116.2 lbs.
December 2003	115.2 lbs.
January 2004	108.8 lbs.

CMS Ex. 3, at 535. The above weights reflected a total weight loss of 13.24 percent in six months. Consistent with Ms. Matthiesen's testimony, Petitioner's records show the resident lost 10.2 pounds between being weighed in July 2003 and August 2003. However, she also lost another 7.4 pounds between being weighed in November 2003 and January 2004. The correlation between changes in Resident 12's weight and her intake of nutrition is clear from her clinical record. Unlike the case of Resident 14, Resident 12's meal acceptance and intake was recorded with few gaps. CMS Ex. 3, at 864-68. These records show a decline in consumption from 46 percent on average in July to 36 percent in August 2003; an increase to 57 percent in September 2003; no record is present for October 2003; 48 percent consumption was recorded in November 2003; and an average of 42 percent consumption was recorded in December 2003. Improved intake was recorded in September but then a decline was recorded in November 2003 with further decline in December 2003, roughly matching her declines in weight.

Petitioner argues that the weight loss in July and August 2003 was addressed by the nutrition risk committee and interventions implemented were increasing her supplements; moving her to the assisted dining room; changing the texture of her food; and obtaining a speech therapy evaluation. P. Brief at 15-16. Petitioner does not specifically list the dates of the various interventions or correlate those interventions to the resident's fluctuating weights.

A quarterly nutrition note by Margaret Herman, dated September 3, 2003, shows that Resident 12 lost 10 pounds between being weighed in July and August. She recommended two interventions, that the resident be weighed in September and that her four ounces of liquid supplement be increased from three times per day to four times per day. P. Ex. 3, at 1. A nutrition note dated October 14, 2003, shows that the registered dietician, Ms. Herman, recommended adding three scoops of protein powder daily to increase the protein the resident was getting from her intake at meals and her supplement.

The dietician also recommended that Resident 12 be evaluated for the assisted dining room due to poor intake by mouth. The concern was that the resident required more protein to help heal a Stage III pressure ulcer. P. Ex. 3, at 4. The next nutrition note is the quarterly nutrition assessment dated November 20, 2003, and it was done by Ms. Matthiesen. Ms. Matthiesen recorded that she was unable to determine if the pressure ulcer had healed as there was no documentation regarding treatment since September 10, 2003, but she recorded that she believed protein intake was adequate to promote healing. Ms. Matthiesen noted Resident 12 received a regular diet with supplements, and that she consumed approximately 41 percent of three meals in the main dining room. There is no indication Ms. Matthiesen was aware of or followed-up on the recommendation of Ms. Herman from October that this resident be moved to the assisted dining facility. Ms. Matthiesen also noted that the resident's weight of 116 pounds had been stable for 180

days, which was clearly incorrect, as Petitioner's records show this resident declined from 125 pounds in July to 116 pounds in November. P. Ex. 3, at 4. Ms. Matthiesen was also apparently unaware of a progress note dated November 15, 2003, which shows that due to mental confusion the resident required assistance with eating. P. Ex. 3, at 13. A progress note dated January 2, 2004, notes that Resident 12's weight in December was 115 pounds, that her January weight was down to 108.8 pounds, and this was reported to the resident's physician who ordered a supplement if the resident desired. However, when dietary was notified they reported that the resident already had an order for a supplement. P. Ex. 3, at 14. No follow-up with the doctor is reported. A progress note dated January 3, 2004, shows that a nurse put the resident on a mechanical soft diet and moved her to the supervised dining room as a matter of "nursing judgment" until the resident could receive a speech therapy evaluation after noting the resident could not lift a glass and had difficulty chewing and swallowing. That evening, after the nurse intervened, the resident reportedly consumed 60 percent of her meal without difficulty. P. Ex. 3, at 14-15. On January 6, 2004, a speech therapy evaluation documented dysphagia and recommended that the resident be allowed extra time to eat her mechanical soft diet. P. Ex. 3, at 16.

My review of the resident's clinical records reveals that the resident was given increased supplement in September to address weight loss. A protein powder was added in October to address a serious pressure ulcer. The registered dietician recommended moving her to the assisted dining room in October but there is no evidence that was done until January when a nurse took it upon herself to do so as a matter of nursing judgment. When Ms. Matthiesen reviewed the resident in November, she was unaware of the resident's weight loss within 180 days, she did not determine the status of the pressure ulcer, and apparently did not read the prior dietician note that recommended moving the resident to the assisted dining facility. When the resident's physician was called he was unaware the resident was receiving supplements. Thus, while Petitioner did implement interventions, it took months to do so.

(3) Resident 3.

Ms. Matthiesen testified that the resident was admitted in November 2003, recovering from a fractured femur that had been surgically repaired. She testified that following a surgery it is not unusual for one to lose some weight. The resident's intake was very good at 75 to 100 percent, she could make her wants and needs known, she was not confused but alert and oriented. Petitioner's staff had no concern for her. However, she did agree that the resident experienced a significant weight loss that should trigger interventions. Tr. at 170-78

Resident 3 was admitted to Petitioner's facility on November 12, 2003, to recover from a hip fracture that was surgically repaired, possibly with a prosthesis. She was reported to have no change in her appetite upon admission. She was noted to have edema or swelling in her left hip and groin, the area of her surgery. P. Ex. 4, at 4-5. Her weight on admission was 125 pounds. P. Ex. 4, at 1. An initial nutrition note was entered on November 17, 2003 by Ms. Matthiesen. Resident 3 was approved for regular diet. She was noted to weigh 125 pounds, with good intake, and that she was nutritionally stable. P. Ex. 4, at 3. Nurses notes reflect good progress with recovery from surgery. A note dated December 1, 2003 shows she had her staples removed and that some swelling remained in the left thigh. P. Ex. 4, at 7. There is no mention of edema in the records I have after December 1, 2003.

Petitioner's records show the following weights for Resident 3:

November 13, 2003	125 lbs.
November 21, 2003	120 lbs.
November 28, 2003	118 lbs.
December 4, 2003	116 lbs.
December 11, 2003	115.2 lbs.
December 18, 2003	116.2 lbs.
January 2, 2004	114.6 lbs.
January 8, 2004	114 lbs.

P. Ex. 4, at 23; CMS Ex. 3, at 535. Resident 3's record of meal acceptance and intake shows an average intake of greater than 80% in December 2003 and January 2004. I note, however, that Petitioner's records are suspect, in their accuracy and I conclude not credible for this resident. The record of meal acceptance with intake percentages noted, lists percentages of 75 percent to 85 percent for every meal on December 4 through 6, 2003. P. Ex. 4, at 16. However, nurses notes show that the resident began vomiting on December 4 and had to be sent to the emergency room at approximately 4:00 p.m. She returned from the emergency room about 8:00 p.m. There is no indication she had dinner at the emergency room. The nurse notes also show that she refused lunch on December 4. She held her morning medication on December 5, 2003 but experienced vomiting at 6:30 a.m. She had some ice cream for lunch. She refused her evening meal on December 6, 2003 but had sips of liquid. P. Ex. 4, at 8-9, 18.

The resident had an unplanned weight loss of 11 pounds between her admission on November 12, 2003 and January 8, 2004. Petitioner argues that Resident 3 was admitted to its facility for rehabilitation following hospitalization for a fractured femur, that weight loss is not unusual following surgery due to build-up of fluids and subsequent reduction of the edema. P. Br. at 19-20. Petitioner suggests that given the resident's excellent

appetite and good intake, her weight loss was due to reduced edema following surgery. Absent some expert testimony, I find Petitioner's suggestion that the 11 pound weight loss is attributable to resolution of post-surgical swelling is not credible. Further, Petitioner continued to lose weight even after there were no longer entries in the clinical record reflecting swelling. The credible answer to why this resident lost weight is likely in her answer to a surveyor's interview question in which she stated on January 14, 2003, the food is good and that she cleaned her plate followed by the comment: "I need more because look how thin I am." P. Ex. 4, at 20. Neither the government nor Petitioner argue that any weight loss was attributable to the resident's bout of vomiting in early December 2003. I find no other credible explanations in the record for this resident's weight loss of 11 pounds other than the resident's credible assertion that she simply was not being provided enough to eat.

(4) Resident 6.

Ayesha Ahmad, M.D. testified that she had been treating physician for Resident 6 since September 2002. She testified that the resident has a history of Alzheimer's dementia, renal-vascular hypertension, a history of transient ischemic attacks (TIAs), coronary artery disease, chronic renal failure, neuropathy, and a history of aneurysm repair in 2000. The resident had a dramatic decline due to his dementia in early 2003 with gradual worsening since. He was placed in hospice care in October 2003 following hospitalization for a hip fracture, sepsis, poor appetite, and general decline. Dr. Ahmad explained that moderate to severe dementia can commonly directly affect appetite and in Resident 6's case this caused severe anorexia. She was aware that the resident was eating only 25 to 50 percent of his meals, not drinking much; in November 2003 Petitioner advised her the resident lost up to 18 pounds; and in January 2004 she was updated that he lost an additional 7.7 pounds. She believed that hospice provided an aide that assisted him with eating, she did not state how often, but characterized the aide's visits as frequent. Dr. Ahmad testified that she believed supplements were tried and that the family specified when he was in the hospital that there was to be no tube or intravenous feeding. She opined that the resident was declining from dementia, recent sepsis and hip fracture, and a lot of other co-morbidities, and that there was not much else that could have been done for him. She also opined that the resident received adequate nutrition and that his weight loss was not a parameter of nutrition. Tr. at 183-87. Her testimony is consistent with her letter to the state agency dated March 22, 2004. P. Ex. 6, at 1.

Ms. Matthiesen testified that a nutritional assessment was done in September 2003 at the hospital (P. Ex. 5, at 5) and that document and others indicated the resident had poor intake in September 2003. When Resident 6 was transferred back to Petitioner from the hospital for hospice care, the family wanted comfort measures only (P. Ex. 5, at 2). She testified that in hospice care he would be offered food, but he would only eat what he

wanted. She believed that his weight loss was an expected outcome of his disease process. Ms. Matthiesen testified that the resident's records contain almost daily entries showing the resident refused to eat, including food brought in by the family and ice cream. Tr. at 194-208.

The following weights for Resident 6, as alleged in the SOD (CMS Ex. 1, at 45-46) or as found in Petitioner's records, are undisputed by Petitioner:

August 2003	181.2 lbs.
September 2003	182.2 lbs.
September 22, 2003	165 lbs.
October 7, 2003	174.8 lbs.
November 3, 2003	156.4 lbs.
December 1, 2003	150.6 lbs.
January 2, 2004	142.9 lbs.
January 7, 2004	142.9 lbs.

P. Ex. 5, at 5, 15; CMS Ex. 3, at 536.

Dr. Ahmad's note dated June 11, 2003, shows that Resident 6 was admitted to Petitioner's facility on April 11, 2003 due to worsening Alzheimer's dementia. She could not determine why he progressed so rapidly in the last several months but speculated that it was possibly a small stroke rather than his depression, which was being treated. She listed other diagnoses including hypertension, depression, hyperlipidemia, history of lumbar stenosis with neuropathy in his legs, and degenerative joint disease. P. Ex. 5, at 1. A nutrition assessment from Ottumwa Regional Health Center, dated September 22, 2003, three days after his admission for the hip fracture (P. Ex. 5, at 9), shows the resident at approximately 165 pounds with good appetite, he required aspiration precautions, his dentures presented a chewing problem. However a note indicates, inconsistently, that the resident was not responsive and the wife reported he was not eating. Laboratory data showed his serum albumin was low, indicating a poor protein level. The problem listed is inadequate intake by mouth of less than 50 percent, due to lack of responsiveness. P. Ex. 5, at 5. Dr. Ahmad's progress note dated September 27, 2003, shows Resident 6 was admitted to Ottumwa Regional Health Center on September 18, 2003 from Petitioner due to a fall and a hip fracture that required hip replacement. The note shows the resident was suffering from pneumonia with spiking fevers for which he was being treated with antibiotics. He was delirious and hardly eating. Dr. Ahmad records that she counseled with the family and the decisions were to provide palliative care, to coax him to eat as much as possible, and transfer him back to Petitioner to die. P. Ex. 5, at 9. Dr. Ahmad's note dated October 7, 2003, shows that Resident 6 had been hospitalized for two weeks after a fall and hip fracture that was surgically repaired. During his hospital stay he

developed high temperatures and pneumonia, possibly due to aspiration, that was treated with intravenous antibiotics. His family requested comfort measures only, and he was sent back to Petitioner with an order for hospice. The doctor noted that at the facility he had not had a fever but was hardly moving or doing anything, with good and bad days for lucidity, and intake of 25 to 50 percent. Her diagnoses included anemia of chronic disease, chronic renal insufficiency, severe dementia, poor overall function and on comfort measures only. His prognosis was noted to be poor. P. Ex. 5, at 2.

Petitioner did not provide me with records reflecting meal acceptance or intake for this resident other than progress notes for the period October 2, 2003 through January 13, 2004. P. Ex. 5, at 16-37. I do not have progress notes for everyday during the period. Petitioner also did not provide me with any care plan for this resident. Progress notes show Resident 6 returned to Petitioner on October 2, 2003 and was evaluated by hospice. The notes show he refused dinner but ate ice cream, ate his medication in apple sauce, and drank water throughout the evening. I have no progress notes from October 2 through 6, 2003. A note dated October 7, shows he refused dinner but ate ice cream and drank a soda. On October 8, 2003, he refused food and drink. The note indicates the speech pathologist said he could swallow with a two to three second delay but does not say when the pathologist saw him. On October 9, hospice assisted him with breakfast and he ate nothing. At lunch, he ate some pudding and drank some milk. He ate 20 percent of his dinner. On October 10, he drank sips of water as offered, ate 20 percent of supper. On October 11, he refused breakfast, ate lunch poorly but accepted 220 cc of liquids, and for dinner ate some vegetable soup and other food, drank some water and some milk. On October 12, he ate 55 percent of his breakfast with staff assistance, for supper he ate some of the soup reheated from the day before, and around 8:00 p.m. he had ice cream and drank some water. A progress note from October 13, indicates he ate well for two meals and about one-third to one-half of his dinner drinking most of his milk and some water. A note from October 14 shows the resident ate 100 percent of his snack but does not specify whether the snack was ice cream. The remaining progress notes through January 13, 2004, reflect a similar pattern of poor intake by mouth. A note dated November 3, 2003, states that Resident 6 lost 18.4 pounds in one month and a fax was sent to Dr. Ahmad. A note dated January 5, 2004, indicates that Dr. Ahmad was notified that Resident 6 lost 7.7 pounds in December 2003. A note dated January 6, 2004, indicates that dietary recommendations were received. On January 7, 2004, Resident 6 was taken to the solarium for the evening meal, and he ate 50 percent followed by eating 100 percent of his snack. A note from January 8, 2004, includes the instruction to have hospice bring liquid supplements to give with meals. P. Ex. 5, at 16-37.

Petitioner has only produced three notes from its registered dietitians. A note dated January 7, 2004, titled "annual nutritional assessment," indicates the resident has had a 5.5 percent weight loss during the past 30 days and he was consuming only 17 percent of

a blended regular diet. The dietician ordered on January 6, 2004, that four ounces of liquid supplement be provided four times per day to aid with nutrition due to open sores and significant weight loss. She also recommended adding shakes from hospice with meals to increase calories. The next note dated January 17, 2004, is signed by Ms. Matthiesen. She notes repeated open sores and poor intake. She notes it is difficult to determine his estimated intake because he took few meals in the regular dining room, with “most food eaten brought in by family,” and “fed by hospice.” She notes he is not consuming enough calories to support healing. Due to difficulty assessing intake, she ordered additional supplements. The third note dated January 20, 2004, also signed by Ms. Matthiesen, indicates Resident 6 had significant weight loss since returning on “October 1 (sic), 2003.” He lost 6 pounds in December 2003, and had a 5 percent weight loss in 30 days in January 2004. She notes that the resident was addressed at the December 2003 and January 2004 nutrition committee meetings. P. Ex. 5, at 39-40. The nutrition risk committee meeting notes for December 2, 2003, show that the resident had a 6 pound weight loss, loss has slowed, the goal was to maintain, and the recommendation was to continue to offer foods liked, but there is no indication what those foods were. CMS Ex. 2, at 37-40; P. Ex. 9, at 5. Notes from the January 2004 meeting, show he lost another eight pounds, that hospice was in to feed him but he often refused. The plan was to add supplement, four times a day. P. Ex. 9, at 2.

Petitioner argues, relying largely upon the testimony and statement of Dr. Ahmad, that Resident 6 was provided with adequate nutrition, but that he suffered from co-morbidities resulting in his hospice care and refusal to eat, and that made his weight loss clinically unavoidable. P. Brief at 17-18. Under most circumstances, the opinions of a treating physician would be given significant weight. However, I decline to give significant weight to Dr. Ahmad’s opinions that weight loss for this resident was clinically unavoidable or that Petitioner did all that was reasonable. There is little or no evidence that Dr. Ahmad spent any time reviewing Petitioner’s care of this resident. Thus, the evidence does not show she had an adequate basis for her opinions regarding how well Petitioner attempted to meet the resident’s nutrition needs. The two times Dr. Ahmad was notified that the resident had continued weight loss, there is no evidence that she took any action. In fact, her testimony implies that she had all but given-up on this patient.

Based upon all the evidence, I conclude that Petitioner has not shown that it did what was reasonable to meet the resident’s nutrition needs. I have not received evidence of any nutrition care planning other than that which I have summarized. Ms. Matthiesen admitted that she was aware of the nutrition assessment from the resident’s hospitalization, which indicated a significant nutrition problem. Nevertheless, there is no evidence that Petitioner’s dietician did any assessment until January 2004, over three months after the resident’s readmission. The clinical records also reflect no attempt to use nutritional supplements until January 2004. Petitioner has produced no records of

continuing monitoring or assessment during the period from October 2, 2003 through January 13 or 14, 2004. There are only progress notes showing that meals were offered with poor results. Contrary to Ms. Matthiesen's testimony, the progress notes show that food brought in by the family was rare. Nursing staff made a partial record of intake in progress notes. I also recognize that the progress notes do show that individual staff members and hospice staff attempted various techniques to get the resident to eat. However, the records show a significant delay in assessing this resident's needs and do not reflect any care planned interventions to encourage eating other than staffs ad hoc attempts at coaxing.

(5) Resident 5.

Ayesha Ahmad, M.D. testified that she had been treating physician for Resident 5 since June 2002. Resident 5 suffered from Alzheimer's dementia, hypertension, a history of recurrent urinary tract infections, depression, and she had a history of a hip fracture, a seizure disorder, and a history of an upper GI bleed in June 2003. Dr. Ahmad opined that the resident's dementia and depression caused her anorexia and that her appetite was also likely affected by the upper GI bleed, which she attributed to a peptic ulcer. She was advised on July 11, 2003, that the resident had lost 20.2 pounds following a complicated hospitalization, and the resident was changed to a pureed diet due to difficulty swallowing. She approved starting the resident on liquid supplement on November 13, 2003. She testified that she could not recall discussing tube feeding with the resident's son, but she recalled that she spoke with him during the resident's June 2002 hospitalization, and she believed that the family wanted only conservative measures. She agreed with Petitioner's counsel that the decision to insert a feeding tube was to be made by the doctor and family, and the decision was not Petitioner's responsibility. She opined that other than coaxing the resident to eat there probably was not much that could be done. She opined that the resident's weight loss was related to her clinical condition and that it was unavoidable. She opined that the resident's weight loss was very likely unavoidable without extraordinary measures. She testified that the facility provided adequate nutrition and that the resident's weight loss was not a parameter of nutrition. Tr. at 187-191. Dr. Ahmad's testimony is not inconsistent with her letter dated March 23, 2004. P. Ex. 8, at 1.

Ms. Matthiesen testified that this resident was on a calorie-controlled diet due to her diabetes and difficulty maintaining acceptable blood-sugar levels. Upon admission her blood-sugar levels looked good. However, after her admission to the facility, her family started bringing in packs of snack size candy bars and that is all she would eat. She had weight gain and her blood-sugar levels were out-of-control. Around June 2003, the resident's physician put her on a tighter diabetic regimen. Family was still permitted to bring in candy, but had to leave it with the nurse who controlled distribution. Ms.

Matthiesen opined that a 30 pound weight loss between May and August 2003 was due to controlling her candy bar intake. Around July 2003, she was moved to the assisted dining room for cuing and supervision because she would refuse to feed herself. Petitioner also started providing a high calorie supplement to try to stabilize the resident's weight. The texture of her food was changed due to a jaw fracture. She was also provided a fortified cereal. Tr. at 208-15.

Records reveal the following weight loss for Resident 5:

July 2003	123.4 lbs.
August 2003	117.0 lbs.
September 2003	116.2 lbs.
October 2003	115.4 lbs.
November 2003	113.8 lbs.
December 2003	111.8 lbs.
January 2004	108.8 lbs.

CMS Ex. 3, at 538. These recorded weights reflect a loss of 14.6 pounds in seven months from July 2003 to January 2004. However, a registered dietician note signed by Margaret Herman on August 6, 2003, acknowledges that Resident 5 had a 30-pound weight loss from June to August 2003. P. Ex. 7, at 3.

Dr. Ahmad's progress note dated June 11, 2003, reflects that Resident 5 was recovering from a left hip fracture that had been surgically repaired, a GI bleed from a duodenal ulcer that had been cauterized, and seizure activity attributed to her Alzheimer's dementia that was controlled with Dilantin. The doctor noted a decline in the resident's activity level, her ability to perform activities of daily living, and that she was not eating well. She was also noted to have a history of recurrent falls. P. Ex. 7, at 2. She was admitted to Ottumwa Regional Health Center from July 25 through 29, 2003, for treatment of a urinary tract infection with intravenous antibiotics. Her admission note indicated a history of a mandibular fracture due to a fall. P. Ex. 8, at 14-17. A nutrition assessment from Ottumwa Regional Health Center dated July 28, 2003, indicates that Resident 5's appetite was poor, she had inadequate caloric intake due to increased dementia as evidenced by a loss of 23.6 pounds in one month. Laboratory values showed a low serum albumin indicating a poor protein level. P. Ex. 7, at 6. Petitioner's registered dietician's note dated August 6, 2003, shows that the resident was started on a medication for her diabetes on May 30, 2003, that she had a poor appetite, and that she complained that

chewing hurt her mouth.⁶ The dietician, Ms. Herman, recommended a change to a liquified diet and increasing her liquid supplement to four times per day to help prevent further weight loss. She noted the last laboratory report indicated low serum albumin, which indicates a poor protein level. P. Ex. 7, at 3. A dietician note by Ms. Herman dated September 9, 2003, shows the resident's weight was 116.2 pounds but states she was stable over the last month. The resident continued a blended diet with supplement twice per day with a multivitamin. P. Ex. 7, at 4. There is no indication that Ms. Herman reviewed her prior recommendation for a liquified diet or to increase the supplement, and there is no indication she requested an assessment to determine the cause for the resident's complaint of pain when chewing. Resident 6 was admitted to Ottumwa Regional Health Center on November 10, 2003, for administration of intravenous antibiotics to treat a urinary tract infection, and she was discharged back to Petitioner on November 16, 2003. P. Ex. 8, at 9. A history of mandibular fracture was noted on admission. P. Ex. 8, at 10. A nutrition assessment on an Ottumwa Regional Health Center form completed by Margaret Herman on November 11, 2003, records a weight of 122 pounds (clearly at odds with other clinical records of this resident), a low serum albumin, and notes that Resident 5 has an inadequate feeding route due to a mandibular fracture as evidenced by past weight loss. P. Ex. 7, at 8. A quarterly nutrition assessment was completed by Ms. Matthiesen on November 26, 2003. Resident 5's weight is listed as 113 pounds. Ms. Matthiesen notes the resident refused to eat in July 2003 due to the fact she could not chew, and she was changed to a blended texture diet. She notes that weight loss is expected because of intake of only 35 percent. She indicated that weight loss had stabilized, that the resident was under good diabetic control, and that the present plan for nutrition would continue. P. Ex. 7, at 5. A nutrition data sheet dated November, 26, 2003, shows that Ms. Matthiesen directed the addition of fortified cereal to the resident's diet. P. Ex. 7, at 10. A note from Dr. Ahmad's record's dated January 21, 2004, indicated that Resident 6 was on a pureed diet due to her jaw fracture several months ago. P. Ex. 8, at 5.

Only two pages from Resident 5's MDS with an assessment reference date of November 24, 2003, were provided. The partial MDS shows that she had moderately impaired decision-making skills, required supervision for eating, and had a chewing problem. The assessment reflected the resident was 60 inches tall, weighed 113 pounds, and had a significant weight loss. P. Ex. 7 at 12-13.

⁶ The date on which Resident 5 suffered the jaw fractured is not indicated in the records submitted for my review. I also find no assessment contemporaneous with the dietician's note that indicates whether or not the pain complained of was due to the jaw fracture.

Petitioner argues that Resident 5 was on a planned weight change program and that the resident was always in the range of her ideal body weights. P. Br. at 9, 20. Petitioner also argues that the facility implemented interventions to address the resident's weight loss including, moving the resident to the assisted dining room for closer staff supervision and cuing, use of liquid supplements, and change of texture. P. Br. at 20; P. Reply at 8. Petitioner's third-line of defense is that the resident's physician testified that the resident's weight loss was clinically unavoidable due to her dementia and multiple comorbidities. P. Br. at 20; P. Reply at 8.

According to Ms. Matthiesen, upon admission to Petitioner's facility, Resident 5's blood sugar levels were good. However, the resident's family started bringing in bags of small candy bars, and the resident would eat the entire bag. Ms. Matthiesen did not indicate in her testimony that the resident was prevented by physical or other reasons from eating whatever she liked, including bags of candy. Because her diet was not controlled and she was able to eat an entire bag of candy bars, her blood sugar levels were uncontrolled. According to Ms. Matthiesen, this provoked the weight control program to which Ms. Matthiesen attributed the 30 pound weight-loss the resident experienced between May and August 2003. Tr. at 208-09. This testimony is inconsistent with her November 26, 2003, nutrition note which indicated that in July 2003 the resident refused to eat because she could not chew. P. Ex. 7, at 5. Further, the only specific element of the weight-control plan that I have discerned from the evidence is that a nurse kept the candy bars and limited their distribution to the resident, and this is based only upon Ms. Matthiesen's testimony. A loss of 30 pounds in four months precipitated by reducing the number of candy bars eaten by the resident, suggests that she was eating a lot of candy bars before the intervention.

Petitioner's evidence does not clearly indicate whether or not the weight control program Ms. Matthiesen testified to, continued after August 2003. Because Resident 5 was diabetic and her blood sugar needed to be in a stable range, I will assume that candy bar control continued as part of good medical management of her diabetes. However, the evidence does not show that the resident's continuing weight loss from 117 pounds in August 2003 to 108.8 pounds in January 2004, is attributable in whole or part to any planned weight control program. In fact, the summary of dietician and other clinical notes I have set out clearly show that the dieticians, Ms. Herman and Ms. Matthiesen, were not satisfied that the resident was experiencing a planned weight loss. Rather, Petitioner admits interventions were undertaken in an effort to stabilize the resident's weight. In fact, as early as August 2003, Ms. Herman recommended changing food texture and doubling the resident's liquid supplement to stop weight loss.

Petitioner elicited Dr. Ahmad's opinion that weight loss for this resident was unavoidable. Dr. Ahmad qualified her opinion by stating that short of coaxing the resident, or insertion of a feeding tube, or other extraordinary measures, weight loss was unavoidable. Dr. Ahmad also implied that Petitioner had done all it could do to ensure the resident received good nutrition. I have already noted that my inclination is to give heavy weight to a treating source's opinion but only if that opinion has a sound basis. There is no evidence that Dr. Ahmad spent any time observing the delivery of nutrition to Resident 5 by Petitioner's staff. The frequency of Dr. Ahmad's visits to the facility so that she might have occasion to observe and what she observed during visits is not established. The evidence also does not show to what extent Dr. Ahmad participated in care planning for the resident with Petitioner's staff or that she otherwise communicated, except through orders, with either nutritionist, Ms. Herman or Ms. Matthiesen. Thus, I cannot conclude that Dr. Ahmad had an adequate basis for her opinion regarding the quality of the delivery of nutrition to Resident 5. While I do not question Dr. Ahmad's opinion that the resident's dementia and "co-morbidities" contributed to decreased appetite and weight loss, I do not find credible her opinion that the weight loss was clinically unavoidable given her lack of information about what efforts to nourish the resident were undertaken by Petitioner's staff, including information that showed the quality and consistency of those efforts.

I find no fault with the nutritionist's decision to use supplemental nutrition such as liquid supplements and fortified cereal. However, the evidence shows that the nutritionists were not diligent about ensuring such interventions were implemented. Ms. Herman recommended in August 2003, that the resident be placed on a liquified diet and that her liquid supplement be increased to four times per day to prevent further weight loss.

However, Ms. Herman's September 2003 note shows that the resident continued on a blended diet with liquid supplement only twice per day. There is evidence that Ms. Matthiesen added fortified cereal on November 26, 2003, but the evidence does not show that Ms. Herman's recommendation to double the resident's supplements was ever acted upon.

I find no fault with the decision to move the resident to the assisted dining room for cuing and supervision around July 2003. However, Petitioner has not shown that this intervention had any effect because there is no evidence that cuing, supervision, or feeding were provided by staff to this or any resident. In fact, a note from Petitioner's record with the title "Nutrition Risk Committee Meeting" December 2, 2003, shows that Ms. Matthiesen, Petitioner's registered dietician, expressed concern that the speech language pathologist had identified that Petitioner's aides were not using proper technique to feed residents. Ms. Matthiesen called for an assessment of what feeding training was being provided, what training needed to be provided, and what was

necessary to hold aides accountable to use proper feeding techniques. CMS Ex. 2, at 37. Thus, the fact that the resident was moved to the assisted dining room does not alone establish that she was receiving cuing, supervision, or actual assistance with eating. Dr. Ahmad opined that coaxing the resident might have been effective, but Petitioner has presented no evidence that its aides used coaxing when assisting residents in the assisted dining room. Simply placing nourishment before a resident is not sufficient to ensure a resident receives adequate nutrition. Rather, Petitioner needs to establish that it took all reasonable steps to ensure adequate nourishment was actually ingested. Any interpretation of the regulatory requirement that imposes a lesser requirement upon a long-term care facility, would render meaningless the requirement of the regulation.

The evidence shows that in June 2002, Dr. Ahmad considered placement of a feeding tube to ensure the resident received the appropriate level of nutrition, but that intervention was rejected by the resident's family. There is no question that the decision to place a feeding tube is made by a physician in consultation with the family. However, in this case, the consultation and refusal by the family was nearly a year before evidence of malnutrition, as evidenced by weight loss, developed. Although Petitioner could not have had a feeding tube placed without consent of the family and direction of the doctor, Petitioner should have ensured that the option was again discussed with the family when evidence of malnutrition developed.

The examples of the five residents show that CMS established a prima facie case of noncompliance with the requirements of 42 C.F.R. § 483.25(i)(1). The discussion for each resident also demonstrates that Petitioner has failed to show by a preponderance of the evidence that it was in substantial compliance or that it had an affirmative defense. The examples show that in one or more cases, Petitioner failed to assess unplanned weight-loss promptly, failed to care plan, failed to develop interventions, failed to implement proposed interventions, failed to assess the effectiveness of interventions and to modify interventions as necessary. Petitioner's failures resulted in continuing weight loss over periods of months, and I have no difficulty concluding that this amounted to actual harm.

III. Conclusion

For the foregoing reasons, Petitioner violated 42 C.F.R. § 483.25(i)(1) in the case of five residents as alleged by CMS. The state was required to withdraw approval of Petitioner's NATCEP for a period of two years from the date of the survey because the violations amounted to substandard quality of care that required an extended or partial-extended survey.

/s/

Keith W. Sickendick
Administrative Law Judge