Department of Health and Human Service

DEPARTMENTAL APPEALS BOARD

Civil Remedies Division

In the Case of:	)	
Texan Nursing & Rehabilitation of Amarillo, LLC (CCN: 67-6010),	)	Date: November 10, 2009
Petitioner,	)	Docket No. C-07-654
	)	Decision No. CR2024
v.	)	
Centers for Medicare & Medicaid Services.	)	

DECISION

Texan Nursing & Rehabilitation of Amarillo, LLC (Petitioner) was not in substantial compliance with Medicare participation requirements as alleged by the Centers for Medicare and Medicaid Services (CMS) based on a survey of Petitioner's facility completed on January 5, 2007, and the noncompliance continued through July 16, 2007. Therefore, CMS was required to impose a statutory denial of payment for new admissions (DPNA) effective from April 5, 2007 through July 15, 2007.

I. Background

Petitioner, located in Amarillo, Texas, is authorized to participate in Medicare as a skilled nursing facility (SNF) and in the state Medicaid program as a nursing facility (NF). Petitioner was subject to surveys by the Texas Department of Aging and Disability Services (the state agency) completed on January 5, 2007, February 6, 2007, April 19, 2007, and June 22, 2007. Joint Stipulation filed November 21, 2007 (Jt. Stip.).

The state agency sent Petitioner a notice dated January 22, 2007, advising inter alia, of the finding of noncompliance based on the January 5, 2007 survey; that Petitioner had to return to substantial compliance within three months of the last day of the survey or a

DPNA pursuant to 42 C.F.R. § 488.417(b)(1)[1] would be triggered effective April 5, 2007; and that Petitioner had until March 24, 2007 to request a hearing before an administrative law judge (ALJ). The notice stated that the DPNA would "be effectuated on [April 5, 2007] unless you demonstrate substantial compliance with an acceptable plan of correction and subsequent revisit." Petitioner's Response to CMS Motion to Partially Dismiss Petitioner's Hearing Requests and Motion for Extension of Time to File Request for Hearing filed October 16, 2007 (P. Response to Motion to Dismiss), Exhibit (Ex.) A.[2]

The state agency notified Petitioner by letter dated February 21, 2007, that another survey was completed at Petitioner's facility on February 6, 2007, which found that Petitioner no longer met state license requirements and that Petitioner was not in substantial compliance with federal participation requirements. The state agency advised that it was recommending that CMS impose alternative remedies including an optional DPNA[3] that would be effective 15 days from the date of a CMS notice of imposition of the remedy, a per instance civil money penalty (PICMP) related to one deficiency cited by the February 6 survey, and termination of Petitioner's provider agreement and participation in Medicare. The state agency specifically stated in its notice that it was not providing formal notice of imposition of a remedy and that a formal notice would be issued by CMS. The state agency did not make any reference to the statutory DPNA that was going to be triggered effective April 5, 2007, or provide Petitioner any notice of a right to appeal. P. Response to Motion to Dismiss, Ex. B.

The state agency notified Petitioner by letter dated May 2, 2007, that another survey of Petitioner's facility was completed on April 19, 2007, which found that Petitioner did not meet state license requirements and that Petitioner was not in substantial compliance with federal participation requirements. The state agency advised Petitioner that the recommendations to CMS for enforcement remedies set forth in its January 22, 2007 letter were unchanged. The state agency was in error by its reference to the January 22 letter as that letter only made one recommendation and that was that Petitioner's provider

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[1] References are to the version of the Code of Federal Regulations (C.F.R.) in effect at the time of the surveys, unless otherwise indicated.

[2] The state agency letters dated January 22, February 21, May 2, and July 9, 2007 were also submitted with the CMS Motion to Partially Dismiss Petitioner's Hearing Requests filed September 27, 2007, and they were marked as CMS Exhibits (Exs.) 1 through 4, respectively. Transcript (Tr.) 23.

[3] CMS (administers the federal Medicare program) and the state (administers the state Medicaid program) have authority to impose an "optional" DPNA pursuant to 42 C.F.R. § 488.417(a), which is not the same as the "mandatory" DPNA required by the Social Security Act (Act), section 1819(h)(2)(D), and 42 C.F.R. § 488.417(b).

agreement be terminated not later than six months from January 5, 2007, if Petitioner did not achieve substantial compliance by that date. The state agency did not give Petitioner notice of the imposition of any enforcement remedies by its letter dated May 2, 2007, or provide any advice as to appeal rights. P. Response to Motion to Dismiss, Ex. C.

The state agency sent Petitioner another notice letter dated July 9, 2007. Petitioner was advised that another survey was completed on June 22, 2007. Based upon the survey, the state agency concluded that Petitioner did not meet state license requirements and that Petitioner was not in substantial compliance with federal participation requirements. The state agency advised Petitioner that it was changing its recommendation to CMS regarding remedies based on four new deficiencies and the seriousness of the noncompliance found by the June 22, 2007 survey. The state advised in its letter that it recommended to CMS immediate imposition of termination effective August 6, 2007; an optional DPNA pursuant to 42 C.F.R. § 488.417(a) effective 15 calendar days after notice from CMS;[4] and a PICMP based upon one deficiency from the June 22 survey. The state agency specifically states in its letter that it was not providing formal notice of imposition of these remedies and that formal notice, if any, would be given by CMS. The state did include in its letter advice that Petitioner could request a hearing by an ALJ no later than September 7, 2007. P. Response to Motion to Dismiss, Ex. D.

There is no dispute that the first notice from CMS to Petitioner was a letter dated August 2, 2007. CMS Ex. 1, at 1-3. CMS advised Petitioner in its letter that the state agency found Petitioner not in substantial compliance based on the survey of Petitioner's facility completed on January 5, 2007. The letter stated further, in bold text as reproduced here:

> **On February 6, April 19, and June 22, 2007, other visits (conducted by the Survey Agency) demonstrated that your facility failed to achieve substantial compliance.[5]**

CMS Ex. 1, at 1. CMS listed the following surveys and the regulatory violations alleged by the surveyors that had the potential for more than minimal harm:

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[4] The actual language of the notice is "Continue Denial of Payment for New (Medicare/Medicaid) Admissions . . . ." However, the cited language is clearly in error as there is no evidence that an optional DPNA was ever started and there is no dispute that CMS gave no notice of the imposition of an optional DPNA.

[5] I learned at hearing that this language is extremely misleading. While it suggests that the surveys that concluded on February 6 and April 19, 2007, were revisit surveys that determined that Petitioner had not returned to substantial compliance, CMS advised me at hearing that the two surveys were actually complaint investigations that did not review whether Petitioner had corrected deficiencies from prior surveys. Tr. 23-26, 28, 32-33, 41.

Survey Completion Date	**Alleged Regulatory Violations**
January 5, 2007	42 C.F.R. § 483.25(h)(2) 42 C.F.R. § 483.25(i)(1) 42 C.F.R. § 483.35(e)
February 6, 2007	42 C.F.R. § 493.10(b)(11) 42 C.F.R. § 483.13(c)(1)-(4) 42 C.F.R. § 483.13(c) 42 C.F.R. § 483.20(k)(3)(i) 42 C.F.R. § 483.35(c) 42 C.F.R. § 483.35(i)(2) 42 C.F.R. § 483.75(l)(1)&(5)
April 19, 2007	42 C.F.R. § 483.15(h)(2) 42 C.F.R. § 483.75(f)
June 22, 2007	42 C.F.R. § 483.10(b)(11) 42 C.F.R. § 483.13(c) 42 C.F.R. § 483.13(c)(1)-(4) 42 C.F.R. § 483.20(k)(3)(i)

The CMS letter advised Petitioner that Petitioner was determined to have returned to substantial compliance with federal participation requirements effective July 22, 2007; that the termination of Petitioner's provider agreement was rescinded; that CMS was imposing a PICMP of $3000 based upon the alleged violation of 42 C.F.R. § 483.20(k)(3)(i) and a PICMP of $3100 based upon the alleged violation of 42 C.F.R. § 483.13(c), both of which were cited by both the February 6 and June 22, 2007 surveys; and that a DPNA was in effect from April 5 through July 21, 2007. CMS Ex. 1, at 2.

Petitioner requested a hearing by letter dated August 15, 2007. In its request for hearing, Petitioner specifically challenged the deficiency findings from all four surveys and all enforcement remedies based upon the alleged deficiencies. The case was assigned to me for hearing and decision on September 7, 2007. A Notice of Case Assignment and Prehearing Case Development Order (Prehearing Order) was issued at my direction on September 7, 2007.

CMS notified Petitioner by letter dated September 25, 2007, that after further administrative review, it was changing the remedies and/or penalties cited in its notice dated August 2, 2007. The two $3100 PICMPs imposed for the alleged violations of 42 C.F.R. §§ 483.13(c) and 483.20(k)(3)(i) were rescinded. However, CMS advised Petitioner that it had determined to impose PICMPs totaling $11,750 for the alleged violations of 42 C.F.R. §§ 483.10(b)(11) ($4025), 483.20(k)(3)(i) ($4725), 483.25(i)(1) ($2000), and 483.75(f) ($1000). CMS advised Petitioner that the proposed termination of its provider agreement was rescinded. CMS also advised Petitioner that the DPNA in effect April 5 through July 21, 2007, was unchanged. CMS Ex. 1, at 4. CMS notified

Petitioner by letter dated October 1, 2007, that after further administrative review, it was changing the remedies and/or penalties cited in its notice dated August 2, 2007, and that this notice superseded the notice dated September 25, 2007. CMS advised Petitioner that the two PICMPs imposed for the alleged violations of 42 C.F.R. §§ 483.13(c) and 483.20(k)(3)(i) were rescinded. However, CMS advised Petitioner that it had determined to impose PICMPs totaling $11,750 for the following alleged violations from the surveys indicated:

42 C.F.R. § 483.25(i)(1) ($2000) – January 5, 2007 Survey
42 C.F.R. § 483.10(b)(11) ($2000) – February 6, 2007 Survey
42 C.F.R. § 483.20(k)(3)(i) ($2700) – February 6, 2007 Survey
42 C.F.R. § 483.75(f) ($1000) – April 19, 2007 Survey
42 C.F.R. § 483.10(b)(11) ($2025) – June 22, 2007 Survey
42 C.F.R. § 483.20(k)(3)(i) ($2025) – June 22, 2007 Survey

CMS stated in its notice that the termination action remained rescinded and the DPNA from April 5 through July 21, 2007 was unchanged. CMS Ex. 1, at 5.

On September 27, 2007, CMS filed a "Motion to Partially Dismiss Petitioner's Hearing Request." CMS requested that I dismiss Petitioner's request for hearing to the extent that Petitioner sought review of the deficiencies that were the basis for the imposition of the statutory DPNA. On October 16, 2007, Petitioner filed its response in opposition and alternative motion for an extension of time to file its request for hearing. On November 13, 2007, I granted the CMS motion for partial dismissal as to the deficiencies alleged by the survey of Petitioner's facility completed on January 5, 2007, to the extent they were the basis for the imposition of the statutory DPNA. However, I advised the parties that I would consider whether or not Petitioner returned to substantial compliance on or before the survey completed on February 6, 2007 or any of the subsequent surveys. I further concluded in my ruling on the CMS motion that Petitioner's request for hearing was timely as to the alleged deficiencies cited by surveys completed on February 6, April 19, and June 22, 2005, and the enforcement remedies based on those surveys, because the first notice of an initial determination related to those surveys and remedies was the CMS letter dated August 2, 2007. My ruling did not dismiss the request for hearing as to one deficiency from the January 5, 2007 survey, the alleged violation of 42 C.F.R. § 483.25(i)(1) which was the basis for a PICMP, because Petitioner first received notice of that initial determination on September 25 and October 1, 2007. The alleged violation of 42 C.F.R. § 483.25(i)(1) from the January 5, 2007 survey also happened to be the only alleged deficiency not found corrected prior to April 5, 2007 (the effective date of the statutory DPNA), when the state agency finally conducted its revisit

survey on July 22, 2007.[6] P. Ex. 5, at 2. Thus, the ruling granting partial dismissal did not preclude my review of the alleged violation of 42 C.F.R. § 483.25(i)(1) as the basis for an enforcement remedy. Petitioner's January 11, 2008 motion to reconsider was denied by a ruling I issued on March 3, 2008, and in which I commented for the benefit of the parties that review of the alleged violation of 42 C.F.R. § 483.25(i)(1) from the January 2007 survey was not precluded.

On November 21, 2007, CMS filed a motion for partial summary judgment. Petitioner filed its response to the CMS motion on December 27, 2007. On January 28, 2008, I denied the CMS motion for partial summary judgment. On February 20, 2008, I denied the February 6, 2008 CMS motion for reconsideration.

On March 3, 2008, CMS moved to dismiss Petitioner's request for hearing in its entirety. CMS also notified Petitioner by letter dated March 3, 2008, that after further administrative review, CMS determined to change the remedies and/or penalties cited in its notices of September 25 and October 1, 2007. CMS advised Petitioner that the PICMPs based upon the deficiencies cited by the February 6, 2007 survey, the April 19, 2007 survey, and the June 22, 2007 survey were rescinded. CMS advised Petitioner that the statutory DPNA "imposed and effective from April 5, 2007 through July 21, 2007 is **NOW REVISED** to April 5, 2007 through July 16, 2007." (Emphasis in original.) CMS advised Petitioner that the proposed termination of Petitioner's provider agreement was rescinded and that the PICMP based upon the alleged deficiency from the January 5, 2007 survey remained. CMS Ex. 44. CMS notified Petitioner by letter dated March 4, 2008, that after further administrative review, all PICMPs previously imposed were rescinded. CMS Ex. 43. CMS filed a revised motion to dismiss on March 4, 2008, at hearing; Petitioner responded at hearing; and a lengthy discussion of the motion and the parties' positions is reflected in the transcript. Tr. 17-71. After considering the arguments of the parties and the additional evidence presented related to the motion at hearing, I modified my ruling of November 13, 2007 granting the CMS motion for partial dismissal and denied the CMS motion to dismiss. Tr. 66-71, 482-85. Although I modified my prior ruling and denied the CMS motion to dismiss, there was no change to my earlier conclusion that Petitioner preserved the right of review as to the alleged violation of 42 C.F.R. § 483.25(i)(1) from the survey that concluded on January 5, 2007.

[6] The surveyors found that the other two deficiencies cited by the survey completed on January 5, 2007, were corrected as of February 16, 2007, but that the violation of 42 C.F.R. § 483.25(i)(1) was not corrected until July 16, 2007. Petitioner's Exhibit (P. Ex.) 5, at 1.

The hearing was conducted in Amarillo, Texas on March 4 through 6, 2008. A transcript was prepared.[7] CMS Exs. 1 through 44 were admitted as evidence. Tr. 73, 105, 481. P. Exs. 1 through 10 and 14 were admitted as evidence. Tr. 80, 426. CMS called as witnesses: Barbara Courson, Nutritionist Surveyor; Delbra Edwards, Registered Nurse (R.N.) Surveyor; Cynthia Mathis, R.N. Surveyor; and Dan Osterweil, M.D. Petitioner called as witnesses: Jeffrey Reeh, President of Texan Health Care, LLC; Tammy Sundblom, Licensed Vocational Nurse (L.V.N.); TraJa Alanis, R.N.; Sandra Sweat; and Kenneth Rice, M.D., Petitioner's Medical Director. The parties filed post-hearing briefs and post-hearing response briefs.

Petitioner offered with its post-hearing response brief (P. Response) documents marked P. Ex. 15, 1-9. Petitioner argues that it assumed prior to hearing that it would not be permitted to challenge any findings from the January 5, 2007 survey; that it was surprised by CMS's proposed findings related to the alleged violation of 42 C.F.R. § 483.25(i)(1) (Tag F325); and that CMS did not present the complete record for Resident 1 related to the alleged regulatory violation. Petitioner objects specifically to proposed findings of CMS and requests that if the proposed findings are considered that I admit and consider P. Ex. 15 as evidence. P. Response at 1-3. Petitioner also attached to its response brief marked as P. Response Brief Ex. 1 an article, Stephen Sidney, M.D., et. al. "*COPD and Incident Cardiovascular Disease Hospitalizations and Mortality: Kaiser Permanente Medical Care Program*" 128 Chest 2068-75 (2005), which Petitioner requests I consider. Petitioner had no reason to assume that it would not be permitted to present evidence as to the alleged violation of 42 C.F.R. § 483.25(i)(1) from the January 5, 2007 survey, as I specifically stated in my ruling on November 13, 2007 granting the CMS motion for partial dismissal and my later ruling denying reconsideration that I would consider the alleged violation. Petitioner was provided the CMS proposed exhibits through the prehearing exchange process, Petitioner was served with the CMS prehearing brief, and Petitioner had the Statement of Deficiencies from the January 5, 2007 survey, thus, Petitioner was on notice of CMS's theory as to the alleged violation well in advance of hearing. The fact that Petitioner may not have anticipated all the arguments CMS might advance, is not justification to permit Petitioner to supplement the record after hearing. The article offered by Petitioner should have been properly marked and offered as an exhibit at hearing, not post-hearing. On June 12, 2008, CMS filed a motion to exclude P. Ex. 15 and P. Response Brief Ex. 1. No response to the CMS motion to

[7] The court reporting service advised me post-hearing that the first numbered page of Volume III, which contains the proceedings from March 6, 2008, bears the number 370 and that is the same number as the "Certification" page of Volume II, which contains the proceedings from March 5, 2008. The court reporting service offered to renumber the pages of Volume III to remedy the error. However, as the error is consistent throughout all copies of the transcript produced and it is unnecessary to cite to a certification page of the transcript, I determined that no correction was necessary.

exclude was received from Petitioner. Nevertheless, in the interest of having a complete record, P. Ex. 15 is admitted as evidence. Given my decision on the merits, I find no undue prejudice to CMS by admitting P. Ex. 15 post-hearing. The article marked as P. Response Brief Ex. 1 is not admitted. Petitioner offers the article in support of the position that a resident's death from COPD (chronic obstructive pulmonary disease) was not unusual as many people die from COPD. P. Response at 7-8. I conclude that the article is not relevant to any issue I may decide and it is excluded as evidence on that basis.

II. Discussion

A. Issues

The issue in this case is:

> Whether there is a basis for the imposition of an enforcement remedy, including the duration of the statutory DPNA.

There is no issue in this case as to whether the statutory DPNA imposed is reasonable, for if the statutory DPNA was triggered, it is reasonable as a matter of law.

B. Applicable Law

The statutory and regulatory requirements for participation by a long-term care facility are found at sections 1819 (SNF) and 1919 (NF) of the Act and at 42 C.F.R. Part 483. Section 1819(h)(2) of the Act vests the Secretary of Health and Human Services (Secretary) with authority to impose enforcement remedies against a SNF for failure to comply substantially with the federal participation requirements established by sections 1819(b), (c), and (d) of the Act.[8] Pursuant to 1819(h)(2)(C), the Secretary may continue Medicare payments to a SNF not longer than six months after the date the facility is first found not in compliance with participation requirements. Pursuant to 1819(h)(2)(D), if a SNF does not return to compliance with participation requirements within three months, the Secretary must deny payments for all individuals admitted to the facility after that date – commonly referred to as the mandatory or statutory DPNA. In addition to the authority to terminate a noncompliant SNF's participation in Medicare, the Act grants the Secretary authority to impose other enforcement remedies, including a discretionary DPNA, CMPs, appointment of temporary management, and other remedies such as a directed plan of correction. Act § 1819(h)(2)(B).

[8] Section 1919(h)(2) of the Act gives similar enforcement authority to the states to ensure that NFs comply with their participation requirements established by sections 1919(b), (c), and (d) of the Act.

The Secretary has delegated to CMS and the states the authority to impose remedies against a long-term care facility that is not complying substantially with federal participation requirements. "*Substantial compliance* means a level of compliance with the requirements of participation such that any identified deficiencies pose no greater risk to resident health or safety than the potential for causing minimal harm." 42 C.F.R. § 488.301 (emphasis in original). A deficiency is a violation of a participation requirement established by sections 1819(b), (c), and (d) of the Act or the Secretary's regulations at 42 C.F.R. Part 483, Subpart B. 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. The regulations specify the enforcement remedies that CMS may impose if a facility is not in substantial compliance with Medicare requirements. 42 C.F.R. § 488.406. The statutory DPNA is the only enforcement remedy remaining in this case.

The Act and regulations make a hearing before an ALJ available to a long-term care facility against which CMS has determined to impose an enforcement remedy. Act § 1128A(c)(2); 1866(h); 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 range of the CMP that could be imposed by CMS or impact the facility's authority to conduct a nurse aide training and competency evaluation program. 42 C.F.R. §§ 498.3(b)(14) and (d)(10)(i). CMS's determination as to the level of noncompliance "must be upheld unless it is clearly erroneous" (42 C.F.R. § 498.60(c)(2)), including the 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 subject to 42 C.F.R. § 488.438(e).

The standard of proof or quantum of evidence required is a preponderance of the evidence. CMS has the burden of coming forward with the evidence and making a prima facie showing of a basis for imposition of an enforcement remedy. Petitioner bears the burden of persuasion to show by a preponderance of the evidence that it was in

substantial compliance with participation requirements or any affirmative defense. *See Hillman Rehabilitation Center*, DAB No. 1611 (1997), *aff'd, Hillman Rehabilitation Ctr. v. United States Dep't of Health and Human Services, Health Care Fin. Admin.*, No. 98-3789 (GEB), slip op. at 25 (D.N.J. May 13, 1999); *Cross Creek Health Care Center*, DAB No. 1665 (1998); *Emerald Oaks*, DAB No. 1800; *Batavia Nursing and Convalescent Center*, DAB No. 1904 (2004), *aff'd, Batavia Nursing & Convalescent Ctr. v. Thompson*, 129 F. App'x. 181 (6th Cir. 2005); *Batavia Nursing and Convalescent Inn*, DAB No. 1911 (2004).

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

My conclusions of law are set forth in bold followed by a statement of the pertinent facts and analysis.

I have set forth in detail the history of the various notices and revisions of the remedies in the Background section of this decision. As a result of the CMS notice dated March 4, 2008, the only enforcement remedy at issue in this case is the mandatory or statutory DPNA that was triggered effective April 5, 2007, and ended on July 16, 2007. CMS Ex. 43. Only the alleged violation of 42 C.F.R. § 483.25(i)(1) (Tag F325) remains in issue from the January 5, 2007 survey. Tr. 341-42; P. Ex. 5, at 2.

I conclude that Petitioner was not in substantial compliance with program participation requirements based on the violation of 42 C.F.R. § 483.25(i)(1) as found by the January 5, 2007 survey. I further conclude based upon the violation from the January 5, 2007 survey, that Petitioner has failed to show it returned to substantial compliance prior to July 16, 2007. Accordingly, I need not consider the other surveys and their alleged deficiencies.

1. Petitioner violated 42 C.F.R. § 483.25(i)(1) (Tag 325) as found by the survey completed on January 5, 2007.

2. Petitioner did not prove that it corrected the violation of 42 C.F.R. § 483.25(i)(1) (Tag 325) prior to July 16, 2007.

3. Petitioner did not return to substantial compliance with program participation requirements within three months of January 5, 2007, and the statutory DPNA was triggered on April 5, 2007.

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

The State Operations Manual (SOM)[9] instructs surveyors that "[p]arameters of nutritional status which are unacceptable include unplanned weight loss . . . ." CMS Ex. 37, at 4. The SOM cautions surveyors that ideal body weight charts have not been validated for the institutionalized elderly and weight loss is only a guide for determining nutritional status. CMS Ex. 37, at 4. The SOM suggests parameters for evaluating the significance of unplanned and undesired weight loss:

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

CMS Ex. 37, at 4.

The SOM directs that weight loss or gain be analyzed in the context of the resident's former life style and current diagnosis, recognizing that weight loss or gain is not adequate evidence alone of a nutritional problem. CMS Ex. 37, at 4-5. Similarly, the Board has stated that weight loss alone does not support a deficiency but weight loss does trigger an inference of inadequate nutrition. *Carehouse Convalescent Hospital*, DAB No. 1799, at 21–22 (2001). If a facility shows by a preponderance of the evidence that it "provided the resident with adequate nutrition" or that the weight loss was due to non-nutritive factors, it can rebut a prima facie case based on such an inference. *Carehouse*, DAB No. 1799, at 22. The Board's interpretation of the regulation is that a facility is not strictly liable for a resident's weight loss (*Carehouse*, DAB No. 1799, at 21), but a "facility is responsible for taking all reasonable steps to ensure that the resident receives nutrition adequate to his or her needs" (*Windsor House*, DAB No. 1942, at 18 (2004)). The "clinical condition exception" is narrow and applies only when a facility demonstrates that it cannot provide nutrition adequate for the resident's overall needs so that weight loss is unavoidable. *Id*. The Board has indicated that the presence of a significant clinical condition alone does not prove that maintaining acceptable nutrition is unavoidable. *Id*. In *Windsor*, the Board found that surveyor observations that a resident was not properly assisted with eating or that the facility was slow to react to a resident's weight loss was sufficient evidence that the facility failed to provide the resident with adequate nutrition. *Id*.

[9] The SOM does not have the force and effect of law; however, 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 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.

The January 5, 2007 Statement of Deficiencies (SOD) alleges that Petitioner violated the regulation because Petitioner failed to identify and address weight loss for Resident 1. Resident 1 was an 87 year-old man admitted to Petitioner's facility on September 20, 2006, with a past medical history of bladder cancer, hypothyroidism, and Alzheimer's dementia. He was deaf and unable to communicate. CMS Ex. 6, at 1-4, 11, 14, 27, 48.

On admission to Petitioner's facility in September 20, 2006, Resident 1 was assessed as being independent for eating with setup help only, and he was 71 inches tall and weighed 150 pounds with no nutritional problems. CMS Ex. 6, at 13, 15. A subsequent Minimum Data Set (MDS) with an assessment reference date of October 3, 2006, reflects no change in weight and reflects no nutritional problems. CMS Ex. 6, at 25, 28.

A certified nursing assistant flow sheet shows that from 21 through 28 September 2006, Resident 1's consumption of meals was poor (25-50 %), except for two meals on September 26 that were rated as good (75-100 %) and fair (50-75 %). P. Ex. 15, at 1.

A care plan conference summary sheet dated October 4, 2006, identified as a dietary concern that Resident 1 weighed 150 pounds on admission on September 20, 2006 but that by October 4, 2006, only 14 days later, he weighed 142 pounds, a 5 percent weight loss. The family also expressed concern about the weight loss and indicated that they would bring Resident 1 his favorite foods. The plan was for Dietary to give finger foods and sweets. CMS Ex. 6, at 50.

A nutritional assessment on October 17, 2006 reflects that Resident 1's weight had dropped to 142 pounds. His ideal weight was listed as 155 to 189 pounds and he was assessed to require 1704 calories per day. The dietician noted that he self-fed, he ate approximately 50 percent of meals, and that his albumin and protein levels were adequate. The dietician recommended a house supplement three times per day and referral to his physician. CMS Ex. 6, at 44-45.

An ADL (activities of daily living) work sheet for October 2006 reflects that Resident 1's meal consumption was good to poor, with most meals recorded as good and fair, but with no recording on October 27, 2006. In November 2006, meal consumption was recorded ranging from refused to good, with four breakfasts refused, no recordings for November 3 and 30, and poor consumption recorded for all meals from November 20 through 25 and 27 through 29. Meal consumption was recorded as poor to good in December 2006, with all meals on December 1 through 3 and 30 being listed as poor. P. Ex. 15, at 2-4.

A height and weight form listed weights of 142 pounds on admission,[10] 142 pounds on October 1, 2006, 142 pounds on November 5, 2006, and 134 pounds on December 2, 2006. P. Ex. 15, at 5.

Resident 1's physician speculated on examination on November 29, 2006, that Resident 1 had a recurrence of transitional cell carcinoma that was multifocal but further testing was delayed. CMS Ex. 6, at 3-4; P. Ex. 15, at 7. A CT (Computed Tomography) scan of Resident 1's pelvis on December 5, 2006, revealed an abnormality in the urinary bladder wall that was characterized as "worrisome for malignancy." CMS Ex. 6, at 54-55. However, the record before me contains no evidence of a definite diagnosis that Resident 1 was suffering a recurrence of his cancer.

A physician's progress note dated December 14, 2006, shows that the physician was aware that Resident 1's weight had decreased 8 pounds to 134 pounds. However, the note includes no specific plan to address the resident's weight loss. P. Ex. 14. A physician's progress note dated November 27, 2006, does not list Resident 1's weight. CMS Ex. 6, at 2.

In December 2006, Resident 1's weights were recorded each week as 134, 129, 137 and 137. CMS Ex. 6, at 47. Laboratory results from December 8, 2006, reflect low albumin and low total protein. CMS Ex. 6, at 42. Low albumin and low protein levels are indicative of possible malnutrition. Tr. 176-77.

On January 1, 2007, Resident 1 was taken to the emergency room after being found unresponsive. He was assessed as suffering septic shock with low blood pressure, tachycardia, and hypoxia (low blood oxygen). CMS Ex. 6, at 70. The plan was for hospice care and no aggressive treatment or diagnostics as the family understood that he was dying. CMS Ex. 6, at 72. Resident 1 died on January 1, 2007, at 8:05 p.m. CMS Ex. 6, at 56, 61, 73-74. Emergency room records characterize him as thin and cachectic (physical wasting with loss of weight and muscle mass due to disease). CMS Ex. 6, at 59.

[10] This weight is not credible based upon other evidence from Resident 1's clinical record already discussed, including the MDS and nutritional assessment, which show his admission weight was 150 pounds.

Petitioner's clinical records recorded weights for Resident 1 of:

DATE	WEIGHT
September 20, 2006 (Admission)	150
October 1, 2006	142
October 17, 2006 (Nutritional Assessment)	142
November 5, 2006	142
December 2, 2006	134
December 2006 (Second Week)	129
December 2006 (Third Week)	137
December 2006 (Fourth Week)	137

Based on this data, Resident 1 lost 8 pounds between admission and October 1, 2006, a 5.3 percent loss. He lost 16 pounds between admission and December 2, 2006, a 10.6 percent weight loss. He lost 21 pounds between admission and the second week of December 2006, a 14 percent weight loss. The clinical record reflects an increase of 8 pounds between the weighing in the second week of December and the third week of December, but the recorded weight of 137 pounds reflects a loss after admission of 13 pounds or 8.7 percent. Using the guidance from the SOM, the surveyors were justified concluding that Resident 1 suffered a severe weight loss during the three months between his admission in September 2006 and December 2006. The nutritional assessment dated October 17, 2006 and physician's progress note dated December 14, 2006, support my conclusion that the weight loss was unplanned and undesired. According to the SOD, a surveyor observed Resident 1 being weighed on December 29, 2006, and his weight was actually 122 pounds. CMS Ex. 3, at 4. Other than the nutritional assessment recommending house supplements three times per day (CMS Ex. 6, at 44-45) and the care plan conference summary indicating that Dietary would give Resident 1 finger foods and sweets and that the family would bring in Resident 1's favorite foods (CMS Ex. 6, at 50), there is no other documentary evidence of a plan to address Resident 1's weight loss; there is no specific care plan document; there is no documentary evidence that the effectiveness of the interventions was assessed in light of Resident 1's continued weight loss; and there is no documentation of consultation with Resident 1's physician that considered or planned to address the weight loss. Furthermore, the evidence shows that Petitioner was not following the plan it had developed in early October 2006. The SOD records that a surveyor observed on December 29, 2006, that Resident 1 was given cottage cheese and pudding – not finger foods – and when he tried to eat a canned peach with his fingers, it fell to the floor. The surveyor also observed that Resident 1 was given a health shake that was not fully opened and he was given no straw. CMS Ex. 3, at 5-6. Petitioner does not dispute the surveyor's observations.

Petitioner argues that staff did identify Resident 1's weight loss and a plan to address the weight loss was made as early as the care planning conference on October 4, 2006. Petitioner also points out that Resident 1 was weighed weekly in the month of December 2006 when his weight fell. Petitioner asserts that Resident 1's physician was notified of the weight loss because the December progress note indicates a weight of 134 pounds and a decrease of 8 pounds. Petitioner's Post-Hearing Brief (P. Brief) at 5-7. For the reasons mentioned above, I find Petitioner's argument unpersuasive. Although there is evidence that Petitioner's staff identified the weight loss, the evidence does not show that Resident 1 was referred to his physician to address his weight loss as recommended by the dietician; the evidence does not show that his care planning team, which is supposed to include his physician, developed a specific plan to address his nutritional status and weight loss; the evidence does not show assessment of the effectiveness of the limited interventions developed in October, and the further weight loss in December permits an inference that those interventions were either not effective or not consistently implemented; the evidence does not show that the limited interventions were consistently implemented; and the evidence does not show that Resident 1's nutritional status was reassessed and new interventions considered to address the possibility of a recurrence of his cancer when that possibility was identified in late November 2006, just prior to his further weight loss in December 2006. The evidence shows that Petitioner was aware of Resident 1's weight loss; assessed his dietary needs; and developed some interventions. However, Resident 1 began to lose weight again in December and it was incumbent on Petitioner to follow up with additional interventions in order to ensure maintenance of adequate nutrition, to the extent that weight loss was not unavoidable. I conclude Petitioner did not take reasonable steps to ensure that Resident 1 maintained acceptable parameters of nutrition and thereby violated 42 C.F.R. § 483.25(i)(1). Petitioner has not shown that the weight loss was unavoidable.

Petitioner argues that, even if there was a violation of 42 C.F.R. § 483.25(i)(1), Petitioner corrected the violation and returned to substantial compliance on February 16, 2007, the date it alleged completion on its plan of correction (P. Ex. 1, at 6) and the date on which the surveyors found that the other two alleged deficiencies from the January 2007 survey were corrected (P. Ex. 5, at 2). P. Brief at 7-8; P. Response at 5. In support of its argument, TraJa Alanis, R.N., Petitioner's Director of Nursing during the January 2007 survey, was called as a witness by Petitioner. Tr. 424. R.N. Alanis testified that she participated in preparing the plan of correction for the alleged violation of 42 C.F.R. § 483.25(i)(1) found at P. Ex. 1, at 4-6. She testified that the plan of correction was fully implemented by February 16, 2007. Tr. 427-28.

Petitioner argues that:

> CMS put on no evidence whatsoever that supports a finding that F-325 was not corrected as of the date listed in its Plan of Correction, i.e., 2/16/07. Therefore, [CMS] failed to carry its burden of putting on a prima facie case that F-325 was not

> "substantially corrected" by 2/16/07, the date of completion of corrective action on the 2567 from the January 5, 2007 visit.

P. Brief at 7.

Petitioner misunderstands that it bears the burden to show by a preponderance of the evidence the date on which it achieved substantial compliance. CMS does not bear the burden of showing that Petitioner remained out of compliance. Appellate panels of the Board have held that the burden is on the facility to establish the date on which it came into compliance. *Cal Turner Extended Care Pavilion*, DAB No. 2030 (2006); *Chicago Ridge Nursing Center*, DAB No. 2151 (2008). Indeed, there is a presumption that the non-compliance continues until the facility establishes that it has corrected the deficiencies. *Regency Gardens Nursing Center*, DAB No. 1858 (2002); 42 C.F.R. § 488.308(c). Thus, the burden is with Petitioner to affirmatively establish that it came into compliance with 42 C.F.R. § 483.25(i)(1) (Tag F325) earlier than the July 16, 2007 date found by the state agency and adopted by CMS. I find that Petitioner failed to rebut the presumption and show that it returned to substantial compliance prior to July 16, 2007. Petitioner's reliance upon the testimony of its former Director of Nursing, Traja Alanis, is misplaced. R.N. Alanis' testimony is conclusory and I find her mere assertion that Petitioner's plan of correction was fully implemented by February 16, 2007 (Tr. 427-28), to be insufficient evidence to rebut the presumption in favor of the July 16, 2007 date. Petitioner offered me no evidence that shows the specific steps that were taken at its facility to complete its plan of correction (P. Ex. 1, at 4-6) in order to cure this deficiency. Accordingly, I conclude that Petitioner did not cure this deficiency prior to July 16, 2007.

> **4. CMS's imposition of the statutory DPNA is reasonable as a matter of law**.

Petitioner was not in substantial compliance with program participation requirements on January 5, 2007, and Petitioner did not show a return to substantial compliance earlier than July 16, 2007. The regulations require that the Secretary impose a DPNA against a facility that fails to return to compliance with all participation requirements within three months after the date the facility is first found to be out of compliance. Act § 1819(h)(2)(D); 42 C.F.R. § 488.417(b). The Secretary and CMS have no discretion not to effectuate a statutory DPNA. Accordingly, CMS was required to impose a statutory DPNA effective April 5, 2007 through July 16, 2007, and the statutory DPNA is reasonable as a matter of law.

III. Conclusion

For the foregoing reasons, I conclude that Petitioner was not in substantial compliance with program participation requirements from January 5, 2007 through July 16, 2007, and the statutory DPNA was triggered as a matter of law effective April 5, 2007 and continued through July 16, 2007.

/s/
Keith W. Sickendick
Administrative Law Judge