

Department of Health and Human Service

**DEPARTMENTAL APPEALS BOARD**

Civil Remedies Division

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In the Case of:	)	Date: November 5, 2009
	)	
Valley Oaks Rehabilitation and Senior	)	
Living (CCN: 04-5173),	)	
	)	Docket No. C-08-144
	)	Decision No. CR2026
	)	
v.	)	
	)	
Centers for Medicare & Medicaid Services.	)	
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**DECISION**

Petitioner, Valley Oaks Rehabilitation and Senior Living, was not in substantial compliance with program participation requirements due to violations of 42 C.F.R. §§ 483.25 and 483.35(c) and (d)(3),<sup>1</sup> as alleged by the Centers for Medicare and Medicaid Services (CMS), based upon surveys completed at the facility on August 21, 2007 and October 18, 2007. A per instance civil money penalty (PICMP) of \$5000 and a discretionary denial of payment for new admissions (DPNA), effective October 17, 2007 through November 16, 2007, are reasonable enforcement remedies. Withdrawal of Petitioner’s authority to conduct a Nurse Aide Training and Competency Evaluation Program (NATCEP) was required.

**I. Background**

Petitioner is a long-term care facility located in Camden, Arkansas. On August 21, 2007, the Arkansas Department of Human Services, Office of Long Term Care (the state agency), completed a survey of the facility. The state agency issued a Statement of Deficiencies (SOD) dated August 21, 2007, which alleged that Petitioner was not in substantial compliance with certain requirements for participation in the Medicare and Medicaid programs. Petitioner’s exhibit (P. Ex.) 9; Joint Statement of Undisputed Facts

<sup>1</sup> References are to the Code of Federal Regulations (C.F.R.) in effect at the time of the survey, unless otherwise indicated.

filed February 20, 2008 (Jt. Stip.); CMS exhibit (CMS Ex. 12). The SOD for the August 2007 survey was amended pursuant to the findings of an informal dispute resolution hearing (IDR) conducted by the state on October 11, 2007. P. Ex. 3; P. Ex. 4. The amendment of the SOD corrected some inaccuracies with respect to Tag F365 (an alleged violation of 42 C.F.R. § 483.35(d)(3)) and removed Tag F363 (an alleged violation of 42 C.F.R. § 483.35(c)). CMS Ex. 3; P. Ex. 3; P. Ex. 4. The SOD, as amended, alleges that Petitioner was not in substantial compliance with the following requirements: 42 C.F.R. § 483.25 (Tag F309 - Quality of Care), at a scope and severity level of G; and 42 C.F.R. § 483.35(d)(3) (Tag F365 - Food) at a scope and severity level of E.

CMS notified Petitioner by letter dated October 2, 2007 that based on the August 2007 survey Petitioner was not in substantial compliance with program participation requirements. P. Ex. 1. CMS notified Petitioner that it was imposing the following enforcement remedies: termination of Petitioner's provider agreement effective January 21, 2008, if Petitioner did not achieve substantial compliance prior to that date; a PICMP of \$1000 based upon the alleged violation of 42 C.F.R. § 483.25 (Tag F309); a DPNA effective October 17, 2007 until such time as Petitioner returned to substantial compliance or its provider agreement was terminated; and withdrawal by the state of approval of Petitioner to conduct a NATCEP.

A revisit survey was performed on October 18, 2007, and Petitioner was found to be out of substantial compliance with 42 C.F.R. § 483.35(c) (Tag F363) and 42 C.F.R. § 483.35(d)(3) (Tag F365). CMS Exs. 2 and 5; P. Ex. 2. On November 14, 2007, CMS notified Petitioner that as a result of the revisit survey, it was revising the remedies initially imposed. CMS Ex. 2; P. Ex. 2. CMS increased the PICMP based on the violation of 42 C.F.R. § 483.25 (Tag F309) from \$1000 to \$5000; the remaining remedies were left unchanged. The DPNA was in effect through November 16, 2007, a total of 31 days, and the termination action was rescinded when Petitioner achieved substantial compliance. Respondent's Written Submissions and Supporting Brief (CMS Brief) at 6; CMS Ex. 10, at 4.

Petitioner timely requested a hearing by an administrative law judge (ALJ) on November 29, 2007. Jt. Stip. The case was assigned to me for hearing and decision and a Notice of Case Assignment and Prehearing Case Development Order (Prehearing Order) was issued at my direction on December 7, 2007. On February 20, 2008, I set this case for hearing in Little Rock, Arkansas beginning on March 25, 2008. On March 11, 2008, Petitioner filed an unopposed motion to waive the in-person hearing and requested that the case be decided on the pleadings and documentary evidence. On March 12, 2008, I issued an order accepting Petitioner's waiver of oral hearing and set a schedule for the parties to supplement their previously filed prehearing briefs by filing their opening and reply briefs and their documentary evidence. Petitioner filed its opening brief (P. Brief) on April 30, 2008 and its reply brief (P. Reply) on June 13, 2008. CMS filed its "Respondent's Written Submissions and Supporting Brief" (CMS Brief) on April 30,

2008 and its reply brief (CMS Reply) on June 13, 2008. CMS offered CMS Exs. 1 through 12 and Petitioner offered P. Exs. 1 through 9; no objection has been made, and these exhibits are admitted and considered as evidence. Petitioner filed the “Affidavit and Statement in Lieu of Testimony” of Nicole Pickens on April 22, 2008 with its opening brief. The affidavit was not marked as evidence but it is clear that Petitioner offered it for my consideration as evidence and I have marked the affidavit P. Ex. 10. CMS made no objection to my consideration of the affidavit of Nicole Pickens and it is admitted as P. Ex. 10. Petitioner submitted the following with its reply brief, marked as indicated: Affidavit of Dan Martin, M.D., Ex. A; Affidavit of Michelle Rainbolt, Ex. B; a document titled, “Mechanically Altered,” Ex. C; a document titled, “Dietary Services Summary of Resident Stay,” Ex. D; Affidavit of Josalyn Washington, Ex. E; a document titled, “State of Arkansas Long Term Care Facility Nursing Assistant Training Curriculum,” Ex. F; and a document titled, “July 26, 2007,” Ex. G. The documents Petitioner filed with its reply were not marked in accordance with my Prehearing Order and they are remarked P. Ex. 11 through 17, respectively. Pursuant to my Order Accepting the Waiver of Oral Hearing and Establishing Briefing Schedule dated March 12, 2008, the parties had ten days to file any objections to new evidence submitted by a party with a reply brief. CMS filed no objections to P. Ex. 11 through 17 and the exhibits are admitted and considered as evidence.

## **II. Discussion**

### **A. Issues**

The issues in this case are:

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

Whether the remedies imposed are reasonable.

### **B. Applicable Law**

The statutory and regulatory requirements for participation by a long-term care facility are found at sections 1819 (skilled nursing facilities or SNF) and 1919 (nursing facilities) of the Social Security Act (Act) and at 42 C.F.R. Part 483. Section 1819(h)(2) of the Act vests the 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.<sup>2</sup> Pursuant to 1819(h)(2)(C), the Secretary may

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<sup>2</sup> Section 1919(h)(2) of the Act gives similar enforcement authority to the states to ensure that nursing facilities comply with their participation requirements established by section 1919(b), (c), and (d) of the Act.

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, civil money penalties, appointment of temporary management, and other remedies such as a directed plan of correction. Act § 1819(h)(2)(B).

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 regulations specify that a civil money penalty (CMP) that is imposed against a facility on a per day basis will fall into one of two ranges of penalties. 42 C.F.R. §§ 488.408, 488.438. The upper range of CMP, \$3050 per day to \$10,000 per day, is reserved for deficiencies that pose immediate jeopardy to a facility’s residents and, in some circumstances, for repeated deficiencies. 42 C.F.R. §§ 488.438(a)(1)(i), (d)(2). Pursuant to 42 C.F.R. § 488.301, “*immediate jeopardy* means a situation in which the provider’s noncompliance with one or more requirements of participation has caused, or is likely to cause, serious injury, harm, impairment, or death to a resident.” (Emphasis in original.) The lower range of CMP, \$50 per day to \$3000 per day, is reserved for deficiencies that do not constitute immediate jeopardy but either cause actual harm to residents, or cause no actual harm but have the potential for causing more than minimal harm. 42 C.F.R. § 488.438(a)(1)(ii). When a CMP is imposed based upon an instance of noncompliance, as in this case, the regulation establishes a range from \$1000 to \$10,000 per instance. 42 C.F.R. § 488.438(a)(2).

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

The Act and regulations make a hearing before an ALJ available to a long-term care facility against which CMS has determined to impose 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). The CMS 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. Analysis

My conclusions of law are set forth in bold text followed by my findings of fact and analysis.

**1. Petitioner violated 42 C.F.R. § 483.35(d)(3) (Tag F365) as alleged by the survey completed on August 21, 2007; and 42 C.F.R. §§ 483.35(c) (Tag F363) and 483.35(d)(3) (Tag F365) as alleged by the survey completed on October 18, 2007.**

The first survey completed on August 21, 2007, cited Petitioner for violations of 42 C.F.R. § 483.25 (Tag F309) at a scope and severity (S/S) of G; 42 C.F.R. § 483.35(c) (Tag F363) S/S E; and 42 C.F.R. § 483.35(d)(3) (Tag F365) S/S E. P. Ex. 9. Following an IDR decision favorable to Petitioner, an amended SOD was issued without the citation of a violation of 42 C.F.R. § 483.35(c) (Tag F363) and with corrections to the allegations under Tag F365. CMS Ex. 3; P. Ex. 3; P. Ex. 4; Jt. Stip. ¶¶ 5, 8, 9, 11.

The second survey completed on October 18, 2007, cited Petitioner for violations of 42 C.F.R. §§ 483.35(c) (Tag F363) S/S E and 483.483.35(d)(3) (Tag F365) S/S E. CMS Ex. 5.

Petitioner only challenges the alleged violations of 42 C.F.R. §§ 483.25 (Tag F309) and 483.35(d)(3) (Tag F365) in its November 29, 2007 request for hearing. Petitioner concedes that it has not challenged the alleged deficiencies from the second survey completed on October 18, 2007. Petitioner's Reply Brief (P. Reply) at 14. Further, Petitioner does not advance an argument in any of its briefs for how I can conclude that it did not violate 42 C.F.R. § 483.35(d)(3) (Tag F365) as alleged by the first survey completed on August 21, 2007 and I conclude Petitioner has conceded the violation. Accordingly, I conclude that Petitioner violated: 42 C.F.R. § 483.35(d)(3) (Tag F365) as alleged by the survey completed on August 21, 2007; and 42 C.F.R. §§ 483.35(c) (Tag F363) and 483.35(d)(3) (Tag F365) as alleged by the survey completed on October 18, 2007.

## **2. Petitioner violated 42 C.F.R. § 483.25 (Tag F309).**

Petitioner challenges the alleged violation of 42 C.F.R. § 483.25 (Tag F309) that was cited by the August 21, 2007 survey. The surveyor concluded that Petitioner violated the regulation based upon record review and interviews. The surveyor alleged in the SOD that Petitioner failed: to ensure Resident 1 was assessed to determine the appropriate consistency for her food given that she had no teeth; to provide and document that Resident 1 was educated regarding the potential danger to her if she ate regular consistency food; and to monitor Resident 1's ability to safely consume regular solid food when she refused a mechanically altered diet. The surveyor alleged that Resident 1 suffered actual harm when she choked on regular food being fed to her by staff at lunch on August 14, 2007, which required her hospitalization due to aspiration and probable brain damage related to hypoxia. P. Ex. 4, at 1-2; CMS Ex. 3, at 1-2.

### **a. Facts**

Resident 1, a 60-year old female at the time of the incident, was admitted to the facility on July 11, 2006 with a diagnosis of cerebral palsy and anemia. According to her physician's order, she was admitted to the facility because she could no longer safely live independently and needed medical assistance, observation and planning. P. Ex. 5, at 14, 24.

Prior to her admission, Resident 1's home diet was mechanically altered. P. Ex. 5, at 208, 289-90; CMS Ex. 4, at 5. When Resident 1 was admitted, her doctor ordered that she receive a mechanically altered diet. P. Ex. 5, at 22-23, 47; CMS Ex. 4, at 7. The order for a mechanically altered diet continued until December 2, 2006. P. Ex. 5, at 29-30, 31; CMS Ex. 4, at 13-14, 16. On December 2, 2006, Resident 1's physician ordered that she receive a regular diet and that order was continued through August 2007. P. Ex. 5, at 31-46; P. Ex. 11; CMS Ex. 4, at 13, 15, 17, 19-25.

Resident 1's initial assessment indicated that a mechanically altered diet and assistance with eating were required. P. Ex. 5, at 290. Her initial nutritional assessment indicated that a mechanically altered diet was required, that she would sit at the restorative table where she could feed herself, she was to be monitored, assistance was to be provided, if necessary, and her meat was to be ground. P. Ex. 5, at 292-93; CMS Ex. 4, at 70-71.

Monthly summaries reflected that Resident 1 required a mechanically altered diet and that she received assistance when eating through October 2006. P. Ex. 5, at 210-35. However, Social Progress Notes entries dated July 11, 24 and October 10, 2006, indicate that Resident 1 was on a regular diet at those times. P. Ex. 5, at 282-83. Monthly summaries from January through July 2007 show that Resident 1 was receiving regular diet and feeding assistance. P. Ex. 5, at 236-53. Social Progress Notes entries dated March 22 and June 12, 2007, state that Resident 1 was on a mechanically altered diet at those times. P. Ex. 5, at 284. Petitioner offers no explanation for the inconsistency between its monthly nursing summaries and the Social Progress Notes. For purposes of this decision, I accept Petitioner's representation that its monthly summaries offer the correct information regarding the diet Resident 1 normally received as there is no dispute that Resident 1 choked on chicken that was not ground. A Dietary Progress Notes entry dated October 9, 2006, shows that Resident 1 required a mechanically altered diet with ground meat. Entries for January 2, 2007 and March 20, 2007 reflect that she was on a regular diet. P. Ex. 5, at 294-95; CMS Ex. 4, at 11-12.

A nurse's annual review progress note dated June 12, 2007, states that Resident 1 had a "few" teeth but how many is not specified. P. Ex. 5, at 324. A nutritional assessment dated June 12, 2007, states that Resident 1 had no teeth. P. Ex. 5, at 287. Surprisingly, given the fact that she had few or no teeth and was on a regular diet, her Minimum Data Set (MDS) with an assessment reference date of June 15, 2007, indicated that Resident 1 had no problem chewing. The MDS also indicates that she was on a mechanically altered diet. P. Ex. 5, at 300; CMS Ex. 4, at 76. A "Focus Statement" related to the June 2007 MDS also indicates that Resident 1 was on a mechanically altered diet. P. Ex. 5, at 305. Resident 1's MDS from her admission, with a reference date of July 24, 2006, also indicated no oral problems and a mechanically altered diet. P. Ex. 5, at 367.

Resident 1's care plan with entries dated July 24, 2006, January 3, 2007, and March 22, 2007, required assistance setting-up her meal tray and feeding. P. Ex. 5, at 374-75. Another care plan dated July 24, 2006, October 12, 2006, January 3, 2007, and March 22, 2007, indicates that Resident 1 was assessed as at risk for weight loss; she was to be given a mechanically altered diet; all meals were to be given in the dining room with supervision; and these interventions were specifically listed as being continued through March 22, 2007. P. Ex. 5, at 384; CMS Ex. 4, at 66. Resident 1's activities of daily living care plan dated June 15, 2007, required that her meal tray be set-up, that she receive assistance with meals, and that she have a certain cup with a short straw. P. Ex. 5, at 313. An undated "Nursing Assistant Care Plan" specified that Resident 1 required

special cups with lid and straw, and that she required a “mechanical soft” diet. P. Ex. 5, at 322. One Nutritional Assessment form dated June 12, 2007, indicated that Resident 1 was “spoonfed” by a CNA at the restorative table, with built-up plate and a special mug, and she had no teeth but was able to tolerate the regular consistency diet that was ordered. P. Ex. 5, at 286-87; CMS Ex. 4, at 68-69.

A “Nurses Notes” entry dated August 14, 2007 at 12:25 p.m., indicates that Resident 1 was being spoon-fed lunch when the CNA feeding Resident 1 “hollered out” that Resident 1 was choking. The Heimlich maneuver was performed in the dining room and Resident 1 coughed-up carrots. The nurse could then hear air exchange. The nurse gloved to sweep the resident’s mouth. The resident was “turning cyanotic” (blue coloration of the skin and/or mucous membrane) and she was incontinent of urine. Suctioning returned a moderate amount of dark colored mucus. The note indicates that the resident became unresponsive with no breathing and the ambulance was called. A late entry dated August 14, 2007, at 12:27 p.m., indicates that cardiopulmonary resuscitation (CPR) was started and continued until the ambulance arrived. P. Ex. 5, at 265; CMS Ex. 4, at 84.

The ambulance service report indicates that when the emergency medical service personnel arrived at 12:39 p.m. on August 14, 2007, they found Resident 1 on the floor by the nurses’ station and CPR was in progress. Resident 1 was placed on a stretcher and in the ambulance and a foreign body was removed with forceps and a laryngoscope. CMS Ex. 4, at 85-86. Vital signs are noted on the emergency room records and her admission history and physical. Her admission history and physical also reports that Resident 1 apparently choked on some chicken and that she suffered probable hypoxic induced brain injury due to aspiration and choking. CMS Ex. 4, at 86-89.

The surveyor alleges in the SOD that she interviewed the certified nurse assistant (CNA) who was feeding Resident 1 when she choked on August 14, 2007. The surveyor stated that the CNA told her that she was feeding Resident 1 a chicken thigh, that she did not cut the meat but pulled it from the bone and fed it to her, and when she gave her carrots, she heard Resident 1 gag and then yelled that Resident 1 was choking, and the nurse came and started working on Resident 1. CMS Ex. 3, at 5; CMS Ex. 9, at 7; P. Ex. 4, at 5. Petitioner does not dispute the facts reported by the CNA to the surveyor and Petitioner offered no evidence to the contrary.

Petitioner’s discharge summary indicates that Resident 1 was discharged to the hospital on August 14, 2007, and she subsequently expired. P. Ex. 5, at 10-13.

## b. Analysis

The regulation requires that a facility provide each resident with the “necessary care and services” so that the resident can “attain or maintain the highest practicable physical, mental, and psychosocial well-being in accordance with the [resident’s] comprehensive assessment and plan of care.” 42 C.F.R. § 483.25. The regulation is clear. A participating facility is required to deliver care and services necessary for a resident to attain the highest practicable state of well-being, based upon a comprehensive assessment of the resident and the plan of care based on that assessment. I conclude that Petitioner failed to deliver care and services necessary for Resident 1 to attain her highest state of well-being based upon a comprehensive assessment and care plan and Petitioner thereby violated 42 C.F.R. § 483.25.

Petitioner does not dispute that when Resident 1 was admitted in July 2006, she was assessed as requiring a mechanically altered diet including ground meat and that her physician ordered such a diet. Resident 1’s MDS from July 24, 2006, the comprehensive assessment required by the regulations (42 C.F.R. § 483.20(b)), indicated that Resident 1 required a mechanically altered diet. P. Ex. 5, at 300; CMS Ex. 4, at 76. Resident 1’s MDS from June 14, 2007, also indicated that Resident 1 required a mechanically altered diet. P. Ex. 5, at 367. A “Focus Statement” related to the June 2007 MDS also indicates that Resident 1 required a mechanically altered diet, which causes me to conclude that the assessment for a mechanically altered diet in the June 14, 2007 MDS was not a typographical error. P. Ex. 5, at 305. The regulation (42 C.F.R. § 483.20(d)) further requires that the comprehensive assessment reflected by the MDS be used to develop Resident 1’s comprehensive care plan. In fact, Petitioner’s clinical record for Resident 1 includes a comprehensive care plan initiated at the time of her admission in July 2006 and updated thereafter, that required that Resident 1 receive a mechanically altered diet with feeding assistance. P. Ex. 5, at 322, 374-75, 384; CMS Ex. 4, at 66. There is no evidence before me that Resident 1’s comprehensive care plan was ever changed to permit her to be fed a regular diet and such a change would have been inconsistent with the assessment reflected in her MDS from June 2007.

Petitioner offers the affidavit of Resident 1’s treating physician in which he testifies that he changed Resident 1 to a regular diet on December 2, 2006, based upon his review of her chart and his observations. Although I have no reason to discount the credibility of Dr. Martin, I cannot find his testimony particularly weighty as he does not specify what observations and chart entries were the bases for his opinion that a regular diet was safe for Resident 1. P. Ex. 11. Furthermore, the regulations do not permit a facility to forgo the comprehensive assessment and care planning process required by 42 C.F.R. §§ 483.20 and 483.25, in favor of relying upon conclusory opinions of a physician that may or may not be based upon a proper or complete assessment. Aside from Dr.

Martin's conclusory opinion, there is no evidence in this record that Resident 1 received a proper assessment<sup>3</sup> to determine that it was safe for her to be fed a regular diet, whether she had no teeth or just a few.

I reject Petitioner's argument<sup>4</sup> based upon the evidence in the clinical record that Resident 1 was properly assessed after December 2, 2006 and determined to be able to tolerate a regular diet, i.e. one without special preparation or presentation to accommodate the resident's lack of teeth. After reviewing all the clinical records available to me, the stated conclusions in those records that the resident tolerated a regular diet or voiced no complaint are based principally upon the fact that the resident swallowed without choking rather than an assessment of her ability to swallow various foods given her limited ability to chew. Though choking may be evidence of a resident's ability to swallow a particular item, I see no evidence that it is a proper assessment technique.<sup>5</sup>

Petitioner argues in its reply brief that "the negative outcome for Resident #1 was unavoidable." P. Reply at 7-10. Petitioner's argument turns on the facts that its records show Resident 1 had no trouble tolerating a regular diet before August 14, 2007, that her family often provided her regular foods without problems, that she ate a regular diet before admission, and that she ate regular food on a prior admission. Petitioner also argues that the evidence does not show the size of the piece of chicken on which Resident 1 choked. I conclude that Petitioner has not established a defense that the violation of 42 C.F.R. § 483.25 based on Resident 1's choking and death was unavoidable. The burden is not upon CMS to show the size of the piece of chicken. The undisputed fact that the resident choked establishes that the resident did not properly swallow the chicken and carrots. The undisputed fact that the resident had few or no teeth permits the inference that she was unable to properly chew the food prior to swallowing. The undisputed facts are sufficient to show that a proper assessment of Resident 1's chewing and swallowing ability needed to be done. Because a proper assessment was not done, Petitioner cannot establish that the choking death of Resident 1 could have been avoided by maintaining the resident on a mechanically altered diet as her June 2007 MDS and care plan required.

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<sup>3</sup> See CMS Ex. 11.

<sup>4</sup> Petitioner's Prehearing Brief at 5-6; P. Brief at 6-7; P. Reply at 3-7.

<sup>5</sup> It is not necessary to address the allegations of the survey related to failure to educate and monitor, as I have found a violation based upon Petitioner's failure to properly assess and care plan to provide necessary care and services for Resident 1.

In its request for hearing at page 4 and in P. Ex. 7, Petitioner alleges various irregularities related to the conduct of the survey and the surveyor. However, inadequate survey performance, even if true, does not relieve a participating facility of the requirement to meet all program participation requirements. 42 C.F.R. § 488.318(b). Furthermore, my determination that Petitioner violated 42 C.F.R. § 483.25 and that Petitioner was not in substantial compliance with program participation requirements, is based upon my de novo review of the evidence rather than upon the findings and conclusions of the surveyor.

**3. CMS's imposition of a \$5000 PICMP based upon the violation of 42 C.F.R. § 483.25 is reasonable.**

CMS proposed a \$5000 PICMP based upon Petitioner's violation of 42 C.F.R. § 483.25. Per-instance civil money penalties are authorized as an enforcement remedy by 42 C.F.R. § 488.438(a)(2). The amount of a PICMP authorized ranges from \$1000 to \$10,000. The criteria for determining where within this range a per-instance civil money penalty should fall are set forth at 42 C.F.R. §§ 488.438(f)(1) - (4) and 488.404 (incorporated by reference into 42 C.F.R. § 488.438(f)(3)). The criteria I must consider when assessing the reasonableness of a proposed PICMP and any other enforcement remedy, are: the seriousness of a facility's noncompliance; its compliance history; its culpability for its noncompliance; and its financial condition. *Id.*

I have no evidence of a history of noncompliance. Petitioner has not disputed the amount of the remedy or asserted an inability to pay. Petitioner's only argument is that a remedy should not apply because it was in substantial compliance. The PICMP that CMS proposed to impose is only 50 percent of the maximum allowable amount. I have concluded that Petitioner failed to properly assess and care plan for Resident 1 and she choked and died as a result. Petitioner's noncompliance was serious and Petitioner was culpable. I conclude that the \$5000 PICMP is reasonable.

**4. CMS's imposition of a discretionary DPNA is reasonable.**

**5. Withdrawal of Petitioner's authority to conduct a NATCEP was required.**

I have concluded that Petitioner violated: 42 C.F.R. §§ 483.25 (Tag F309) and 483.35(d)(3) (Tag F365) as alleged by the survey completed on August 21, 2007; and 42 C.F.R. §§ 483.35(c) (Tag F363) and 483.35(d)(3) (Tag F365) as alleged by the survey completed on October 18, 2007. These violations are a sufficient basis for the imposition of a discretionary DPNA. Based upon the regulatory factors already discussed, I conclude that a discretionary DPNA for the period October 17 through November 16, 2007, is reasonable.

