**Department of Health and Human Services**
**DEPARTMENTAL APPEALS BOARD**
**Appellate Division**

Oaks of Mid City Nursing and Rehabilitation Center
Docket No. A-11-24
Decision No. 2375
March 31, 2011

# FINAL DECISION ON REVIEW OF ADMINISTRATIVE LAW JUDGE DECISION

Oaks of Mid City Nursing and Rehabilitation Center (Oaks), a Louisiana skilled nursing facility (SNF), appeals the September 29, 2010 decision of Administrative Law Judge (ALJ) Steven T. Kessel, *Oaks of Mid City Nursing and Rehabilitation Center*, DAB CR2254 (2010) (ALJ Decision). Based largely on evidence concerning the nursing care provided to an insulin-dependent diabetic resident identified as Resident 2, the ALJ determined that Oaks was noncompliant with Medicare participation requirements in 42 C.F.R. §§ 483.20(b), 483.20(k)(3)(ii), 483.25, and 483.75. The ALJ also sustained the enforcement remedies that the Centers for Medicare & Medicaid Services (CMS) had imposed on Oaks for that alleged noncompliance. The remedies imposed by CMS included per-instance civil money penalties (CMPs), a denial of payment for new Medicare and Medicaid admissions (DPNA), and the termination of Oaks's participation in the Medicare program.

We affirm the ALJ's conclusion that Oaks was noncompliant with 483.20(k)(3)(ii), 483.25, and 483.75 but reverse his conclusion that Oaks was noncompliant with section 483.20(b). Because we reverse the noncompliance finding under section 483.20(b), we vacate the $3,500 per-instance CMP that was based on that finding. We affirm the ALJ's conclusion that the other two per-instance CMPs (imposed for Oaks's noncompliance with sections 483.25 and 483.75) were lawful and reasonable in amount. We also sustain the DPNA. Finally, we affirm the ALJ's conclusion that CMS lawfully terminated Oaks's participation in the Medicare program.

## Legal Background

In order to participate in Medicare, a SNF must comply with the participation requirements in 42 C.F.R. §§ 483.1-483.75. Compliance with these requirements is verified by nursing home surveys conducted by state health agencies. 42 C.F.R. Part 488, subpart E. Survey findings are reported in a document called a Statement of Deficiencies (SOD). A "deficiency" is "any failure to meet a participation requirement." 42 C.F.R. §

488.301. The SOD identifies each deficiency under its regulatory requirement and a corresponding "tag" number used by surveyors for organizational purposes.

CMS may impose enforcement "remedies" on a SNF if it determines, on the basis of survey findings, that the facility is not in "substantial compliance" with one or more participation requirements. 42 C.F.R. §§ 488.400, 488.402(b), (c). A SNF is not in substantial compliance when it has a deficiency that creates the potential for more than minimal harm to one or more residents. 42 C.F.R. § 488.301 (defining "substantial compliance" to mean the "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"). Under the regulations, the term "noncompliance" means "any deficiency that causes a facility to not be in substantial compliance." *Id*.

In choosing an appropriate remedy for a SNF's noncompliance, CMS considers the "seriousness" of the deficiencies and may consider other factors, including the SNF's history of noncompliance. 42 C.F.R. § 488.404(a), (c). The seriousness of a SNF's noncompliance is a function of its "severity" (whether the noncompliance has created a "potential" for "more than minimal" harm, resulted in "actual harm," or placed residents in "immediate jeopardy") and "scope" (whether the noncompliance is "isolated," constitutes a "pattern," or is "widespread"). 42 C.F.R. § 488.404(b); State Operations Manual (SOM), CMS Pub. 100-07, Appendix P – *Survey Protocol for Long-Term Care Facilities*, sec. IV.[1]

The most severe noncompliance is that which puts one or more residents in "immediate jeopardy." *See* 42 C.F.R. §§ 488.404 (setting out the levels of severity and scope that CMS considers when selecting remedies), 488.438(a) (authorizing the highest CMPs for immediate jeopardy); SOM § 7400.5.1. Immediate jeopardy is defined as a situation in which the noncompliance "has caused, or is likely to cause, serious injury, harm, impairment, or death to a resident." 42 C.F.R. § 488.301.

The remedies that CMS may impose for a SNF's noncompliance include termination of the SNF's Medicare participation. Social Security Act (Act) §§ 1819(h)(2)(A)(i), 1866(b)(2); 42 C.F.R. § 488.412. In lieu of, or in addition to, terminating a SNF's program participation, CMS may impose other, "alternative" remedies, including a CMP "for either the number of days a facility is not in substantial compliance with one or more participation requirements *or for each instance* that a facility is not in substantial compliance[ .]" 42 C.F.R. §§ 488.330(b)(2), 488.406(a), 488.430(a) (italics added).

A SNF's appeal rights with respect to a CMS enforcement action are specified in 42 C.F.R. Part 498. A SNF has a right to an administrative law judge hearing (and subsequent review of the judge's decision by the Departmental Appeals Board (Board))

[1] The SOM is available on CMS's website at http://www.cms.hhs.gov/Manuals/IOM/ list.asp.

concerning a termination of its Medicare provider agreement and any "finding of noncompliance that results in the imposition of a remedy specified in" 42 C.F.R. § 488.406 (except the "State monitoring" remedy). 42 C.F.R. §§ 498.3(b)(8), (13); *see also* 42 C.F.R. § 498.5 (specifying the appeal rights of providers with respect to the CMS initial determinations listed in section 498.3(b)); 42 C.F.R. § 488.408(g)(1) (stating that "a facility may appeal a certification of noncompliance leading to an enforcement remedy").

## Case Background[2]

On February 4, 2010, the Louisiana Department of Health and Hospitals (state survey agency) completed a compliance survey of Oaks (February 4th survey).[3] *See* CMS Ex. 48, at 7. The February 4th survey found Oaks noncompliant with nine participation requirements, but none of the cited deficiencies was judged to be at the level of immediate jeopardy. *Id*.

On March 5, 2010, in response to a complaint, the state survey agency conducted another survey (the March 5th survey), focusing on Oaks's management of Resident 2's diabetes and nutritional needs. CMS Ex. 24; CMS Ex. 48, at 4, 7. As a result of the March 5th survey, the state survey agency issued a SOD containing the following four citations: *tag F272* (alleging noncompliance with sections 483.20 and 483.20(b)); *tag F282* (alleging noncompliance with section 483.20(k)(3)(ii)); *tag F309* (alleging noncompliance with section 483.25); and *tag F490* (alleging noncompliance with section 483.75). The state survey agency determined that the noncompliance cited under tags F272, F309, and F490 placed residents in immediate jeopardy. *Id*. at 7-8.

In a letter dated March 30, 2010, CMS notified Oaks that it concurred with the February 4th and March 5th survey findings. CMS Ex. 48, at 7-8. CMS also notified Oaks that it had decided to impose the following per-instance CMPs: (1) $3,500 for the noncompliance cited under tag F272; (2) $3,500 for the noncompliance cited under tag F309; and (3) $3,000 for the noncompliance cited under tag F490. *Id*. at 8. In addition, CMS advised Oaks that another remedy – a DPNA – would take effect on April 15, 2010. *Id*. at 8-9. Finally, CMS notified Oaks that its participation in Medicare would be terminated unless it came back into substantial compliance prior to August 4, 2010. *Id*. at 8.

CMS revised its remedy notice shortly thereafter. In a letter dated April 9, 2010 and signed by CMS employee Gerardo Ortiz, CMS notified Oaks that its Medicare and

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[2] The information in this section is drawn from the ALJ Decision and the record before the ALJ, and is presented to provide a context for the discussion of the issues raised on appeal. Nothing in this section is intended to replace, modify, or supplement the ALJ's findings of fact or conclusions of law.

[3] The February 4th survey actually consisted of two distinct surveys: a "standard" health survey; and a Life Safety Code survey. See CMS Ex. 48, at 7.

Medicaid participation would terminate on May 9, 2010 (instead of August 4, 2010) and that "no revisits [would] be authorized prior to the termination date." CMS Ex. 48, at 11. CMS stated that this revision had been made "[a]fter consideration of [Oaks's] history of non-compliance and selection as a Special Focus Facility (SFF) by the State of Louisiana Department of Health and Hospitals[.]" *Id*. CMS also notified Oaks that the DPNA would take effect on April 14, 2010 and continue until Oaks's provider agreement with Medicare was terminated. *Id*. at 12.

Oaks filed requests for hearing to contest the February 4th and March 5th survey findings as well as the remedies imposed by CMS following the March 5th survey. The ALJ consolidated the hearing requests. The ALJ also consented to Oaks's request to expedite the hearing in view of its pending request to a United States District Court for a preliminary injunction to bar implementation of CMS's remedies.

On May 21, 2010, the ALJ issued a pre-hearing order directing the parties to file pre-hearing briefs, exchange proposed exhibits, and submit written direct testimony of their witnesses by June 11, 2010 (for CMS) and July 2, 2010 (for Oaks). The May 21 pre-hearing order also directed each party to make available for cross-examination any witness whose written direct testimony was submitted in the party's pre-hearing exchange.

CMS subsequently submitted, as written direct testimony, the declarations of CMS employee Daniel McElroy, R.N. and medical expert Larry Johnson, M.D., as well as the affidavits of three state surveyors – Deborah Franklin, R.N., Sandra Mizell, R.N., and Hedra Dubea, R.N. – who participated in the March 5th survey.

As its written direct testimony, Oaks submitted the declarations of Shirley Barbara Anthony, R.N. (a consultant) and Charles Cefalu, M.D. (who testified as a medical expert). Oaks also filed the transcript of the judicial preliminary injunction proceeding, and a transcript of the deposition of Gerardo Ortiz, which was taken in connection with that judicial proceeding. In its pre-hearing brief, Oaks urged the ALJ to rule that CMS was "estopped from terminating its provider agreement with CMS as a result of [CMS's] deceptive misconduct" in rescinding Oaks' opportunity to correct the alleged noncompliance. Pet.'s Pre-Hearing Br. (July 12, 2010) at 23. Oaks also contended that, by terminating its Medicare participation, CMS had treated it differently than other SNFs with equal or worse compliance histories. *Id*. at 15. In addition, Oaks contended that its designation as a Special Focus Facility violated its constitutional right to due process and equal protection. *Id*. at 15-18.

When it submitted its pre-hearing exchange, Oaks informed the ALJ that it needed "additional discovery" from CMS's proposed witnesses – specifically, depositions of Mr. McElroy, Dr. Johnson, and the three state surveyors. *See* July 12, 2010 letter from Attorney Rabalais to the ALJ. The ALJ denied this discovery request during a pre-hearing conference, stating that the regulations governing hearings involving CMS (i.e.,

42 C.F.R. Part 498) do not authorize discovery and that he "had no authority to order depositions." July 26, 2010 Pre-Hearing Order at 3. The ALJ also ruled that the February 4th survey findings were "largely irrelevant" because the remedies imposed by CMS were "either based exclusively" on the March 5th survey findings or because the remedies could be sustained "based solely on" those findings. *Id*. at 2. In addition, the ALJ ruled that he had no authority to hear or adjudicate Oaks's estoppel and constitutional claims. *Id*. at 3. Finally, the ALJ scheduled the in-person evidentiary hearing for August 11, 2010. *Id*. at 1.

On August 9, 2010, the ALJ held another pre-hearing conference during which CMS informed the participants that one of its witnesses, Daniel McElroy, would be unable to attend the hearing because of his wife's illness. The ensuing discussion resulted in CMS withdrawing Mr. McElroy's declaration. *See* Tape Recording of August 9 Pre-Hearing Conf.; Tr. at 8.

The ALJ convened the evidentiary hearing on August 11, 2010 as scheduled. At the hearing's outset, the ALJ excluded from the record various exhibits relating to the February 4th survey. Tr. at 7, 19, 23-24. He also excluded the deposition of Gerardo Ortiz. Tr. at 37-39. Afterward, Oaks cross-examined Surveyors Dubea, Mizell, and Franklin as well as Dr. Johnson. Oaks also elicited brief rebuttal testimony from Dr. Cefalu. CMS did not cross-examine any of Oaks's witnesses.

**The ALJ Decision**

Based largely on the evidence concerning Resident 2, the ALJ concluded that Oaks was not in substantial compliance with sections 483.25, 483.20(k)(3)(ii), 483.75, and 483.20(b) during the March 5th survey. ALJ Decision at 3-19. The most notable deficiency, said the ALJ, was Oaks's "fail[ure] to test [Resident 2's] blood sugar to assess the effects of insulin on her" – a failure that occurred "even after [Oaks] knew that the resident was prone to suffering from episodes of life-threatening low blood sugar." *Id*. at 1. The ALJ also found that Oaks's nursing staff had failed to consult with Resident 2's physician (or the facility's medical director) about the need for blood glucose monitoring, about a February 6, 2010 episode of hypoglycemia, or about dietary issues that potentially affected her blood glucose levels. *Id*. at 5, 7, 8, 13-14, 17.

The ALJ further held that Oaks's noncompliance was sufficient to justify CMS's decision to terminate its Medicare participation. ALJ Decision at 19-20. In addition, he concluded that the CMPs levied by CMS were reasonable in amount. *Id*. at 20. Finally, the ALJ rejected Oaks's due process claims and reiterated his prior rulings denying Oaks's equal protection and estoppel claims and request for pre-hearing discovery. *Id*. at 22-25.

## Standard of Review

Our standard of review on a disputed conclusion of law is whether the ALJ decision is erroneous. *Guidelines - Appellate Review* of *Decisions* of *Administrative Law Judges Affecting* a *Provider's Participation in the Medicare and Medicaid Programs (Guidelines),* http://www.hhs.gov/dab/ divisions/appellate/guidelines/index.html. Our standard of review on a disputed finding of fact is whether the ALJ decision is supported by substantial evidence on the record as a whole. *Id*.

## Oaks's Contentions on Appeal

Oaks objects to all of the ALJ's findings of noncompliance, focusing on the evidence concerning Resident 2. Oaks contends that Resident 2 received adequate nursing care under the circumstances and that the ALJ failed to consider or give proper weight to the opinions of its two witnesses concerning that care. RR at 14-16, 23-29. Oaks also contends that whatever noncompliance may have occurred did not justify an immediate jeopardy finding or CMPs of the magnitude imposed. RR at 13, 38-45. Finally, Oaks contends that it was denied due process and equal protection and that CMS should be estopped from terminating its Medicare participation. RR at 45-46.

We address these contentions in the sections below, beginning with Oaks's challenge to the ALJ's findings of noncompliance.

## Discussion

1. *The ALJ's conclusion that Oaks was noncompliant with 42 C.F.R. § 483.25 in caring for Resident 2 is legally correct and supported by substantial evidence.*

Title 42 C.F.R. § 483.25 states that "[e]ach 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" of the resident "in accordance with [the resident's] comprehensive assessment and plan of care." The Board has held that section 483.25, among other things, "requires long-term care facilities to furnish the care and services set forth in a resident's care plan; to monitor and document the resident's condition; and to implement physician orders." *Embassy Health Care Center*, DAB No. 2327, at 6 (2010) (citing cases); *see also Cedar Lake Nursing Home*, DAB No. 2344, at 8 (2010). Section 483.25 also "implicitly imposes on facilities a duty to provide care and services that, at a minimum, meet accepted professional standards of quality 'since the regulations elsewhere [in section 483.20(k)(3)(i)] require that the services provided or arranged by the facility must meet such standards.'" *Sheridan Health Care Center*, DAB No. 2178, at 15 (2006) (quoting *Spring Meadows Health Care Center*, DAB No. 1966, at 17 (2005)).

Discussing events that occurred between February 4 and March 2, 2010, the ALJ concluded that Oaks was not in substantial compliance with section 483.25 because it "failed to provide [Resident 2] with care that was critical to protecting her from life threatening medical complications" of diabetes. ALJ Decision at 3; *see also id*. at 6 (stating that staff "fail[ed] to protect Resident # 2 from the adverse consequences of her diabetes" and "from unmonitored administration of insulin"). The ALJ identified two areas of concern with Oaks's management of Resident 2's diabetes: blood glucose monitoring (i.e., periodic measurement of blood glucose levels, sometimes referred to as "accuchecks"), and nutrition. For clarity's sake, we address these concerns separately.

(a) Blood glucose monitoring

The ALJ found that Oaks had failed to: (1) "clarify gaps and ambiguities" in a physician order to monitor Resident 2's blood glucose; and (2) "regularly" monitor or check Resident 2's blood glucose levels, "even after it became apparent that the resident was suffering from potentially life threatening episodes of hypoglycemia." ALJ Decision at 3, 4, 6. In support of these findings, the ALJ made the following additional findings of fact:

- On February 4, 2010, Resident 2 was admitted to Oaks following a hospitalization. ALJ Decision at 3. Although she was only 58 years old, Resident 2 had more than one potentially life-threatening medical condition, including end stage renal failure (for which she received periodic dialysis), chronic obstructive pulmonary disease, and insulin dependent diabetes. *Id*.

- When Resident 2 was admitted on February 4, Oaks received physician orders that were contained on a form known as a Statement of Medical Status (SMS). ALJ Decision at 3 (citing CMS Ex. 28, at 139). The SMS for Resident 2's February 4th admission "contains a form completed by [Resident 2's] physician in which a box entitled 'Glucose Monitoring' was checked." *Id*. at 4. The SMS is "ambiguous," however, "in that it does not . . . tell Petitioner's staff how frequently, or at what times of the day, to monitor the resident's blood glucose level, nor does it tell the staff for how long such monitoring should continue[,] . . . [n]or does the SMS contain any instructions telling the staff what to do in the event the resident's blood sugar became abnormally high or low." *Id*.

- Despite the SMS's ambiguity, Oaks's nursing staff "failed to seek clarification about how and when to monitor [Resident 2's] blood glucose level." ALJ Decision at 5. "It was *critically important* that the staff have – and that it followed – precise directions to monitor Resident # 2's blood glucose level." *Id*. at 4 (italics in original). "Without such directions, the staff was without guidance as to how often, and under what circumstances, to perform blood glucose monitoring. Failure to monitor the resident's blood glucose rigorously would put

the resident at risk of developing potentially life-threatening hypo- or hyperglycemia." *Id*.

- On February 6, 2010, the third day of Resident 2's stay, the nursing staff checked her blood glucose and found that it had dropped to a level consistent with hypoglycemia. ALJ Decision at 5. Thus, the nursing staff "knew no later than February 6, 2010 that Resident # 2 had a labile[4] blood glucose level and that she was prone to developing hypoglycemia that could be life threatening if not detected and treated effectively." *Id*. (footnote added).

- Oaks's nursing "staff did not consult with [Resident 2's] physician concerning the [February 6] decline in [her] blood glucose level nor did they investigate the reasons for the sudden drop." ALJ Decision at 5.

- Following the February 6 episode, the nursing staff "failed completely to monitor and document the resident's blood glucose level" from February 7 through February 16, 2010. ALJ Decision at 5. In effect, "[t]he staff continued to administer insulin to the resident without assessing whether the insulin was effective in controlling the resident's blood sugar, or whether the insulin was producing adverse or even potentially lethal effects." *Id*. at 5-6.

- Oaks's failure to systematically monitor Resident 2's blood glucose from February 7 through February 16, 2010 violated the facility's own internal policy governing care of diabetic residents. ALJ Decision at 5 (citing CMS Ex. 28, at 141, 143, and CMS Ex. 7, at 8). That failure also violated "the professionally recognized standard of nursing care governing" the care of a diabetic individual who is admitted to a SNF. *Id*. at 4, 5 (citing Tr. at 159-60). That standard obligated Oaks in these circumstances to monitor Resident 2's blood glucose "regularly." *Id*.

- On February 17, 2010, Oaks's staff found Resident 2 unresponsive. ALJ Decision at 6. Her blood glucose was found to be 24 mg/dl, "a potentially lethal level of hypoglycemia." *Id*. She was transferred to and revived at the hospital. *Id*.

- On March 1, 2010, Resident 2 was readmitted to Oaks. ALJ Decision at 6. "Once again, no specific orders were given to monitor the resident's blood glucose level, and, once again, [Oaks's] staff failed to request clarification from the resident's physician." *Id*. In addition, the nursing staff did not measure Resident 2's blood glucose on March 1. *Id*. The next day, March 2, Resident 2 "showed neurological signs consistent with hypoglycemia," prompting the staff to check her blood glucose. *Id*. The testing found her to be "dangerously hypoglycemic with a reading of 32 mg/dl." *Id*. While the staff attempted to reverse that condition,

[4] See Dorland's Illustrated Medical Dictionary (28th ed.), defining "labile" to mean, among other things, "unstable" or "fluctuating."

> Resident 2 became unresponsive and her blood sugar dropped to a "lethal reading of 10 mg/dl." *Id*. She was transferred to the hospital, where she died. *Id*.

On their face these findings suffice to establish that Oaks was noncompliant with its regulatory obligation to provide Resident 2 with the "necessary care and services" required by section 483.25. As we indicated, the obligation to provide "necessary care and services" includes a duty to implement physician orders. *Embassy Health Care Center* at 6; *Cedar Lake Nursing Home* at 8. That obligation also includes the duty to consult with a resident's physician to clarify treatment orders. *Greenbrier Nursing and Rehabilitation Center*, DAB No. 2335, at 7-8 (2010). The ALJ's findings clearly establish that Oaks did not perform those duties in caring for Resident 2.

The ALJ found that Resident 2 was admitted to Oaks with a physician order for blood glucose monitoring, an order reflected in Resident 2's Statement of Medical Status (SMS). ALJ Decision at 3-4, 10. Substantial evidence supports that finding. That evidence includes the SMS itself, which was signed on February 3 by the physician who sent Resident 2 to the facility. *See* CMS Ex. 24, at 12; CMS Ex. 28, at 139. In a section of the SMS entitled "Special Care Procedures," the physician checked the box for "Glucose Monitoring." CMS Ex. 28, at 139. Other evidence clearly demonstrates that Oaks regarded the SMS as containing a physician's admission order for glucose monitoring. Especially probative is the unrebutted report of a survey interview of Oaks's director of nursing (DON) and the testimony of surveyor Franklin. CMS Ex. 24, at 12; CMS Ex. 40, at 4. The DON acknowledged to surveyor Franklin during her interview that Resident 2 had entered the facility with a SMS signed by a physician on February 3; that the facility's nurses obtained Resident 2's admission orders from the SMS; and that Resident 2's SMS reflected an order for blood glucose monitoring. CMS Ex. 24, at 12. Surveyor Franklin testified that Oaks's nursing staff treated the SMS as containing a physician's admission orders for the resident. Tr. at 115.

Oaks asserts in this appeal that Resident 2 did not, in fact, have a physician's order for blood glucose monitoring when she was admitted on February 4. RR at 14. However, Oaks does not address the above-mentioned evidence of such an order and points to no contrary evidence. Moreover, our review of the record indicates that Oaks did not (1) specifically dispute Surveyor Franklin's testimony or the accuracy of her report of the DON's interviews; (2) submit testimony or statements from employees stating they did not interpret or regard the SMS as containing a physician's order for blood glucose monitoring; or (3) submit evidence of a facility policy or practice contrary to the one described by the DON and surveyor Franklin.

In addition, Oaks ignores the ALJ's finding that the glucose monitoring order's lack of specificity obligated the nursing staff to contact the physician who signed the SMS (or Resident 2's treating physician) for precise instructions about when or under what circumstances the monitoring should be performed. Oaks submitted no evidence that its nursing staff contacted a physician to obtain such clarification. And it is undisputed that

Oaks's nursing staff did not check Resident 2's blood glucose during the 10 days between her February 6th and February 17th episodes of hypoglycemia. Finally, Oaks's expert did not rebut testimony by Dr. Johnson and surveyor Franklin that a nursing staff is duty-bound to clarify incomplete or confusing physician orders. *See* CMS Ex. 50, at 2; P. Exs. 1-2; Tr. at 110, 157, 201-203.

In short, substantial evidence supports the ALJ's finding that Oaks did not implement or clarify a physician's order for blood glucose monitoring. That failure alone justified CMS's determination that Oaks was not in substantial compliance with section 483.25.

Substantial evidence also supports the ALJ's finding that Oaks's failure to monitor Resident 2's blood glucose violated professional standards of quality, and that evidence also demonstrates noncompliance with section 483.25. As indicated, the Board held in *Sheridan Health Care* that section 483.25 imposes on a SNF the duty to meet professional standards of quality. *Accord Greenbrier Nursing and Rehabilitation Center* at 5. "Professional standards of quality" mean "services that are provided according to accepted standards of clinical practice." SOM, Appendix PP (guidelines for tag F281).

Oaks maintains that it complied with accepted standards of clinical practice by observing Resident 2 for signs and symptoms of hypoglycemia prior to administering insulin to her. RR at 13-15. According to Oaks, it was medically unnecessary for staff to regularly check Resident 2's blood glucose because she was, in Oaks's words, a "stabilized diabetic with no prior history of hypoglycemic episodes." *Id*. In support of this argument, Oaks relies principally on the declaration of its expert, Dr. Cefalu (Petitioner's Exhibit 2).

This argument is not supported by the record as a whole. First, the argument's factual premise – that Resident 2 was a "stabilized" diabetic – is belied by the evidence of Resident 2's episode of hypoglycemia on February 6, only two days after her initial admission to the facility. Neither of Oaks's witnesses sought to minimize the clinical significance of this event or claim that Resident 2's diabetic status was stable while she was a resident at Oaks, and neither clearly or satisfactorily explained why the February 6 episode should not have triggered at least a temporary period of blood glucose monitoring given Resident 2's generally fragile condition.[5]

Second, Dr. Cefalu did not provide the source of his opinion concerning the applicable standard of care. Dr. Cefalu testified: "It is the applicable standard of care in the nursing home setting that nurses provide regular accuchecks only on the written order of the

[5] Oaks asserts that Resident 2's physician "was aware of" the February 6 hypoglycemia episode but "elected not to order" regular blood glucose checks. RR at 14-15. However, Oaks did not present any testimony from Resident 2's physician, facility employees, or other individuals with relevant personal knowledge to support that claim. The available nursing records do not support the claim either. Indeed, there is no evidence that staff consulted with Resident 2's physician about her diabetes prior to February 17, 2010, the date she was hospitalized.

attending [physician] unless an acute episode of hypoglycemia is suspected and as represented by clinical symptoms of the resident." P. Ex. 2, at 2-3. Dr. Cefalu did not support this statement with references to published medical literature or published professional standards. *See* SOM, Appendix PP (guidelines for survey tag F281) (stating that the sources of "accepted standards of clinical practice" include nursing manuals or textbooks or guidelines published by professional medical organizations).
In contrast, CMS's expert, Dr. Johnson, provided a source for his opinion on the applicable standard of care. He testified that guidelines published by the American Medical Directors Association (AMDA) obligate a SNF to check the blood glucose of a newly admitted diabetic resident regularly, whether or not a physician has issued an order for such monitoring, until the staff is reasonably assured that the blood glucose level is stable on the patient's nutrition and treatment regimen. CMS Ex. 50, at 2; Tr. at 159-68.

Contrary to Oaks's claim, the ALJ considered Dr. Cefalu's testimony and gave specific reasons for discounting his opinion on the standard of care. In the ALJ's view, Dr. Cefalu's suggestion that SNFs do not routinely check a diabetic resident's blood glucose level unless there is a physician's order for such testing was "belied by the fact that Petitioner's staff did check Resident # 2's blood glucose level on several occasions," and that Oaks did not "explain[ ] why the staff would have done this if nursing standards or Louisiana law actually prohibited them from doing so in the absence of an express physician's order." ALJ Decision at 10. These were plainly legitimate reasons to reject Dr. Cefalu's opinion, and Oaks has not shown otherwise. We note also that none of the surveyors who testified (all of whom are registered nurses) indicated that the nursing staff needed a physician's order in order to check Resident 2's blood glucose under the circumstances. In fact, two surveyors, Sandra Mizell and Deborah Franklin, testified that a nurse could check a resident's blood glucose without a physician's order in appropriate circumstances. Tr. at 83-84, 123.

Oaks contends that the ALJ's reliance on Dr. Johnson's testimony is misplaced for several reasons. First, it argues that Dr. Johnson was not qualified by licensure, knowledge (case-specific or otherwise), or professional experience to give his opinions. RR at 24-25. However, the ALJ gave sound and well-supported reasons for rejecting that argument. *See* ALJ Decision at 9. We find particularly persuasive, as the ALJ did, the evidence of Dr. Johnson's academic credentials and experience as a medical director of a SNF.

Oaks further contends that Dr. Johnson's testimony rests on an erroneous assumption that Resident 2 had a diagnosis of hypoglycemia upon her initial admission to the facility on February 4, 2010. Reply Br. at 15. However, Dr. Johnson never stated or suggested that his opinion was contingent on that assumption. *See* CMS Ex. 50. In fact, he expressly rejected that proposition on cross-examination. Tr. at 156-57.

Oaks further contends that Dr. Johnson's opinions failed to take into account information, particularly concerning the cause of Resident 2's death on March 2, 2010, that was

"important" to the determination of when or whether "nursing judgment" came into play. RR at 28. This contention is also unconvincing. If Oaks doubted that Dr. Johnson's opinions failed to account for "important information," it should have asked Dr. Johnson on cross-examination to account for that information.[6] Oaks is also vague about what it means by "nursing judgment," and it fails to explain precisely how Dr. Johnson's opinion should have incorporated that concept. Whatever the term's meaning, Dr. Johnson's testimony clearly suggests that nurses are not supposed to exercise judgment untethered from accepted standards of nursing practice or in contravention of valid physician orders or a facility's resident care policies. Tr. at 181-82, 190-92. In any event, as we discuss later in this section, whether or not the deficiencies identified by CMS actually caused Resident 2's death is immaterial in determining whether the ALJ's findings of noncompliance are legally correct and supported by substantial evidence.

Oaks also argues that the ALJ should have disregarded Dr. Johnson's testimony because CMS failed to produce copies of the AMDA guidelines Dr. Johnson cited during cross-examination. Oaks asserts that although Dr. Johnson "express[ed] opinions as to the standard of care on several issues, Dr. Johnson could never cite directly by name, page number or specific identifiable reference to support his opinion . . . ." RR at 25. This assertion is baseless since Dr. Johnson named a specific AMDA-authored document containing the relevant guidelines ("Management of Diabetes in the Long-Term Care Setting"). Tr. at 166. This citation was more than adequate to put Oaks on notice of the source of Dr. Johnson's opinion. Moreover, Oaks did not ask the ALJ for leave to obtain and offer the relevant AMDA document or to submit rebuttal evidence concerning its contents.

Oaks's critique is particularly unpersuasive because Oaks failed to provide *any* reference to support its claims about the applicable standard of care, even though it had the ultimate burden of persuasion. Under the Board's well-established framework for allocating the burden of proof, if Oaks disputed the standard of care articulated by CMS's witnesses (including its physician expert), then it was Oaks's burden to produce evidence, documentary or testimonial, showing a different standard of nursing care. In an administrative law judge proceeding, "CMS has the burden of coming forward with evidence related to disputed findings that is sufficient (together with any undisputed findings and relevant legal authority) to establish a prima facie case of noncompliance with a regulatory requirement." *Evergreene Nursing Care Center*, DAB No. 2069, at 4 (2007); *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). Once CMS has made a prima facie showing of noncompliance, however, the SNF "must carry its ultimate burden of persuasion by showing, by a preponderance of the evidence, on the

[6] To the extent that Dr. Johnson was asked on cross-examination to reconsider his opinions in light of information that Oaks deemed important, we see no indication that Dr. Johnson revised those opinions to support Oaks's views.

record as a whole, that it was in substantial compliance during the relevant period." *Evergreene Nursing Care Center* at 4.

As noted, during the in-person hearing, Dr. Johnson described what he understood to be the standard of care for a resident like Resident 2 and further testified that AMDA guidelines were the source for that standard. This testimony, standing alone, was adequate to permit a finding in favor of CMS on the applicable standard of care. Thus, the burden shifted to Oaks to demonstrate by a preponderance of evidence that Dr. Johnson's description of the standard was erroneous, either by offering the relevant guidelines, eliciting contradictory testimony from its own witnesses, or cross-examining Dr. Johnson on the issue. Oaks did none of these things and even now does not claim that Dr. Johnson inaccurately characterized the AMDA guidelines.

In short, we find no improper reliance by the ALJ on Dr. Johnson's opinion. The Board defers to the findings of an administrative law judge on the relative weight and credibility of testimony unless there are "compelling" reasons not to defer. *Carrington Place at Muscatine*, DAB No. 2321, at 19 (2010). As the foregoing discussion makes clear, Oaks has not articulated compelling reasons why we should overturn the ALJ's decision to give greater weight to Dr. Johnson's opinion than to Dr. Cefalu's.

Finally, Oaks asserts that Resident 2 "had more hypoglycemic episodes in the hospital with accuchecks, meal consumption monitoring and intake and output monitoring than while she was [at] the Oaks." RR at 16. Even assuming that claim is factually accurate, it only reinforces the ALJ's finding that Oaks's nursing staff should have been performing regular blood glucose checks. Oaks posits no credible reason why regular blood glucose checks were less necessary for Resident 2 in its facility than in the hospital.

(b) Nutrition

The ALJ found that Oaks had "failed to clarify admission orders concerning the nutrition that Resident # 2 was to receive, failed to assess and monitor the resident's nutritional status, and failed to adjust the resident's diet, when it became evident that the resident was not only eating poorly but that she rejected the diet that had been given." ALJ Decision at 6, 14. The ALJ found that these nutrition-related failures were "significant" because a controlled diet was necessary to manage Resident 2's "labile" blood glucose. *Id*. at 6, 14. In support of these findings, the ALJ made the following additional findings of fact:

- Upon Resident 2's admission to Oaks on February 4, 2010, Resident 2 had an order that she receive a 2,200 calorie American Diabetic Association (ADA) diet consisting of pureed food. ALJ Decision at 7 (citing CMS Ex. 28, at 108, 111). The order also referred to feeding the resident through a "PEG" or feeding tube – which allows nutrition to flow directly into the digestive tract – at 200 ccs per hour. *Id*. (citing CMS Ex. 28, at 111, 140).

- The nursing staff did not seek to reconcile the order for a 2,200 calorie pureed diet (which implied feeding by mouth) with the order that Resident 2 receive nutrition through a PEG tube. ALJ Decision at 8. "The quantity of food that was ordered administered by PEG tube greatly exceeded that which Resident # 2 would have been able to tolerate." *Id*. at 7 (citing Tr. at 172-73). "An experienced nurse should have noticed the error and sought clarification of the order from the physician who issued it," but "[n]o one on Petitioner's staff sought immediate clarification" of the tube feeding order. *Id*.

- "The errors and ambiguities in the resident's nutrition orders were compounded by the instructions that Petitioner gave its own staff for feeding Resident # 2. The staff was instructed that the resident be fed by 'PEG – nothing by mouth' even though the resident had been prescribed a 2,200 calorie diet of pureed food. CMS Ex. 28, at 120. The staff evidently disregarded this instruction without attempting to reconcile it with conflicting instructions." ALJ Decision at 8.

- On February 8, 2010, Oaks's nursing staff notified Resident 2's treating physician that Resident 2, who had told the staff that she did not like pureed food, had been eating poorly since admission. ALJ Decision at 8 (citing CMS Ex. 28 at 106). "The physician responded by instructing [Oaks's] staff to contact the resident's nephrologist for orders concerning tube feeding the resident." *Id*. Although Resident 2 saw a nephrologist on February 9, 2010, "there is no evidence that this visit was the product of, or prompted, a consultation between the nephrologist and Petitioner's staff or with Petitioner's medical director." *Id*. (citing Tr. at 177).

- The record is "devoid of evidence of any ongoing systematic assessment by Petitioner's staff of the resident's nutritional status." ALJ Decision at 8. Oaks's nursing staff was specifically instructed to monitor food consumption and fluid intake and output. *Id*. (citing CMS Ex. 28, at 120). However, "[n]o monitoring was done aside from monitoring on two shifts on February 4, 2010, the date of the resident's admission to the facility." *Id*. (citing CMS Ex. 28, at 112). The nursing staff also "did not document whether [Resident 2] actually was fed by PEG tube." *Id*. In failing to monitor Resident 2's intake and output, "[t]he staff not only contravened the instructions that they had been given, but they violated [Oaks's] policy requiring measurement of intake and output of a resident such as Resident # 2, an individual whose meal consumption needed to be assessed on an ongoing basis." *Id*. (citing CMS Ex. 37, at 9, and CMS Ex. 50, at 3).

- "[Oaks's] failure to clarify orders concerning the resident's nutritional regime, to monitor and assess the resident's eating behavior and her intake and output, to adjust her diet in order to encourage her to eat more, and to consult with the resident's nephrologist about her diet, all put the resident at great risk for harm" from hypoglycemia. ALJ Decision at 6-7 (citing CMS Ex. 50, at 3).

With one immaterial exception (discussed in the following paragraphs), Oaks does not challenge these detailed findings, which collectively show a failure to provide necessary nutrition-related services. Moreover, our record review confirms that the unchallenged findings are supported by the evidence cited by the ALJ, including testimony by Dr. Johnson that Oaks failed to have clear and complete tube feeding and diet orders, and failed to "adequately monitor Resident #2's diet and respond appropriately to her poor dietary intake while she received insulin." CMS Ex. 50, at 4.

Oaks disputes the ALJ's finding that it failed to reconcile an order for an ADA diet (by mouth) with an order for tube feeding. *See* RR at 32-35. According to Oaks, there was no tube feeding order on the admission document cited by the ALJ, and, thus, no reason for the nursing staff to seek clarification from the physician. RR at 35. However, substantial evidence supports the ALJ's finding that Resident 2 had a physician's order for tube feeding on admission. The admission document in question, a single-page form entitled "Physician Admission and Order Form" (PAOF), has two sections. *See* CMS Ex. 28, at 140. Section I, which covers roughly the top half of the page, instructs the physician to specify orders for a patient who will receive "adult day health care." At the bottom of section I, immediately following the space for writing or typing treatment orders, is a line for the physician's name and signature. Section II occupies the bottom half of the page. It provides space for the physician to communicate treatment orders "for nursing facility admission only." Below the space reserved for nursing facility orders is another physician's signature line. In this case, although Resident 2's physician wrote orders in section II, including an order for "PEG tube feeds @ 200 cc's/hour," she signed on the line for section I.

Since Resident 2 was not in adult day-care, section I of the PAOF contained no orders for adult day-care, and the physician's signature on the PAOF was dated only four days prior to her admission to Oaks, the ALJ reasonably construed the PAOF as containing the physician's nursing facility admission orders for Resident 2. It seems clear that the physician simply put her signature on the wrong line of the form, and Oaks provided no contrary evidence, such as a statement from the physician. Had any nurse actually construed the form as Oaks does in this appeal, the nurse's minimum obligation would have been to clarify whether the physician actually intended to issue the tube feeding order. *Cf. Greenbrier Nursing and Rehabilitation Center* at 7-8 (holding that the nursing staff had an obligation to contact physician to obtain a lab testing order). Incidentally, Oaks does not allege that it actually disregarded – or had reason to disregard – the *other two orders* that appear in section II of the PAOF (for dialysis and physical and occupational therapy), nor does Oaks point to evidence that its staff regarded the PAOF as something other than a document containing Resident 2's admission orders.

In fact, contrary to Oaks's contention that the PAOF did not contain a physician's tube feeding order, it appears that Oaks initially regarded the PAOF as calling for tube feeding to *supplement* Resident 1's oral intake when necessary. *See* CMS Ex. 28, at 108 (section entitled "Eating Pattern/Nutritional Problems"). A February 5, 2010 nursing note states

that the author was "unable to contact Dr. Stan May for verification of peg tube feeding to supplement diet" but that the assistant director of nursing (ADON) was aware of the problem and would take care of it. P. Ex. 3, at 47. However, we see no evidence that the ADON promptly followed up to verify or clarify the order.

Oaks contends that it "did in fact monitor meal consumption and monitor intake and output correctly." Reply Br. at 13. However, the record contains no evidence of regular, consistent monitoring, such as documentation of meal consumption patterns and fluid intake and output measurements. Oaks also suggests that the hospital's "Discharge and External Transfer" sheet – which Resident 2's physician signed on February 4 and which states that Resident 2's diet was "2200 cal ADA diet" but makes no mention of tube feeding – superseded any physician order for tube feeding on the PAOF. Reply Br. at 13-14 (citing CMS Ex. 28, at 138). Even if that is true, the fact remains that the nursing staff was still unsure, as of February 5, what the physician intended concerning tube feeding, as the nursing note discussed in the previous paragraph reveals. It took three additional days, or until February 8, for the nursing staff to contact the physician to attempt to clarify the order, at which time the staff was instructed to contact Resident 2's nephrologist to obtain nutrition orders. CMS Ex. 28, at 106. As the ALJ found, there is no evidence that the nursing staff followed the physician's instructions to consult with the nephrologist. *See* Tr. at 177.

Finally, Oaks asserts that there is no evidence that Resident 2 did not receive her pureed diet or had poor appetite, claiming that "[a]ny reduction in consumption of any portion of [her] meals can easily be explained by her documented lack of preference for pureed foods." Reply Br. at 14. However, Oaks's own records show that Resident 2 displayed poor appetite during her first week in the facility. *See* P. Ex. 3, at 40. Oaks's claim that there is *no evidence* that Resident 2 *did not receive* her pureed diet is beside the point. The critical issue is not whether the facility provided, or the resident "received," the pureed diet. The issue is whether that diet actually met Resident 1's nutritional needs. Oaks admits that Resident 2 did not like the diet she was receiving but provides no evidence that the nursing staff took appropriate alternative steps to ensure that she received adequate nutrition.

(c) Harm and causation

Oaks contends that "[n]o accu checks, meal consumption monitoring or intake and output monitoring would have prevented [Resident 2's] hypoglycemic episodes as she was septic." RR at 16. In a related vein, Oaks contends that CMS may not find noncompliance with section 483.25 **"**unless there is a factual finding that a negative resident outcome" resulted from its failure to meet accepted standards of nursing practice. RR at 35.

Oaks's position here appears to be that CMS failed to establish a causal link between the facility's noncompliance and Resident 2's death. The ALJ correctly held that CMS was

not required to prove such a link. *See* ALJ Decision at 11. The dispositive compliance issue here is not whether Oaks caused harm to Resident 2 but whether its care of the resident fell below the quality standard enunciated in section 483.25 and whether that care, if deficient, posed *a potential for more than minimal harm* to the resident (and other similarly situated residents). CMS's regulations do not require a finding that the noncompliance caused actual harm, even for immediate-jeopardy level violations. *See* 42 C.F.R. § 488.301 (defining the terms "substantial compliance" and "noncompliance"); *NHC Healthcare Athens*, DAB No. 2258, at 2 (2009); *Somerset Nursing & Rehabilitation Facility*, DAB No. 2353, at 19 (2010). The regulations permit a finding of noncompliance based on evidence of a "potential" for more than minimal harm, and they permit a finding of immediate jeopardy based on evidence that the deficiency is "likely to cause" serious harm (or death). 42 C.F.R. § 488.301.

(d) Conclusion

For all the reasons set out above, we affirm the ALJ's conclusion that Oaks was not in substantial compliance with section 483.25 in its care of Resident 2.[7]

2. *The ALJ's conclusion that Oaks was noncompliant with 42 C.F.R. 483.20(k)(3)(ii) is legally correct and supported by substantial evidence.*

Title 42 C.F.R. § 483.20(k)(3)(ii) requires that a SNF's services "[b]e provided by qualified persons in accordance with each resident's written plan of care." CMS's "interpretive guidelines" for this requirement instruct surveyors to consider whether any "problems" relating to quality of care, quality of life, or resident life are attributable to either the "qualifications of the facility staff" or "inadequate or incorrect implementation of the care plan." SOM, Appendix PP (tag F282 guidelines).

Based on evidence concerning Residents 1, 2, 3, and 6, the ALJ found that "[t]he evidence establishes a pattern of failure by Petitioner's staff to provide care consistent with these diabetic residents' plans of care and physician orders." ALJ Decision at 15. In support of that finding, the ALJ further found that Oaks:

- failed on two occasions during February 2010 to check Resident 1's blood glucose as directed by the resident's physician;

- "frequently failed to administer insulin" to Resident 1 as ordered by the resident's physician;

[7] Oaks's appeal briefs contain other arguments regarding its compliance with section 483.25 that are not specifically addressed in this decision. We have carefully considered those arguments but have determined that they are adequately addressed in the ALJ Decision or are immaterial.

- failed on one occasion during February 2010 to check Resident 3's blood glucose "as directed";

- failed to administer insulin to Resident 3 on four occasions during February 2010 "as prescribed"; and

- failed to administer insulin to Resident 6 on six instances during January and February 2010, or to check the resident's blood glucose level, "as had been directed."

ALJ Decision at 15. In addition, the ALJ found that Oaks was noncompliant with section 483.20(k)(3)(ii) because, as discussed in the previous section, its nursing staff failed to clarify physicians' orders for Resident 2, thereby precluding development of a "meaningful plan of care" for that resident. *Id*. at 15. "Failure by [Oaks] and its staff to obtain clarification" of the physician orders, said the ALJ, "constitute[s] noncompliance with . . . [section] 483.20(k)(3)(ii), because it meant that [Oaks] could not possibly prepare and implement a meaningful plan of care for the resident." *Id*. at 16.

Pointing to section 483.20(k)(3)(ii)'s requirement that services be provided by "qualified persons," Oaks objects to the ALJ's finding of noncompliance on the ground that none of the evidence discussed by the ALJ speaks to the nursing staff's professional qualifications or knowledge. RR at 31-32, 35, 36. According to Oaks, "[t]he surveyors admitted at trial that none of the [employees] were unqualified or lacked licensing to perform the tasks required by the care plan."[8] RR at 32.

This argument overlooks the regulation's requirement that a SNF furnish services "in accordance with each resident's written plan of care." Regardless of whether members of Oaks's nursing staff were professionally qualified to administer the services that Residents 1, 2, 3, and 6 required, the ALJ could find Oaks noncompliant with section 483.20(k)(3)(ii) if the employees did not carry out instructions in those residents' plans of care. The ALJ concluded that Oaks failed to meet this plan-of-care requirement for Residents 1, 2, 3, and 6, and Oaks does not take issue with that conclusion.

Oaks contends that to the extent there was any noncompliance with section 483.20(k)(3)(ii), CMS incorrectly determined that its scope was "widespread." RR at 32-33. We decline to address the merits of that contention because CMS's finding concerning the severity and scope of this deficiency is not reviewable. A finding regarding a deficiency's severity or scope is reviewable only if the finding would affect: (1) the applicable range of CMP amounts that CMS could impose for the noncompliance;

[8] The surveyors did not positively assert or confirm that members of the nursing staff were qualified to provide the nursing care required by Residents 1, 2, 3, and 6. The surveyors merely testified that the relevant deficiency citation was not based on a finding that Oaks's nurses were unqualified. See Tr. at 56-57, 93, 131-32.

or (2) a finding of substandard quality of care that results in the loss of approval of a SNF's nurse aide training program. *See* 42 C.F.R §§ 498.3(b)(14), (b)(16), and (d)(10)(i); *Plum City Care Center*, DAB No. 2272, at 16 (2009).
Neither of these conditions exists here. CMS did not impose a CMP for Oaks's noncompliance with section 483.20(k)(3)(ii). And the finding that Oaks's noncompliance was widespread in scope did not lead – and could not have led – to a finding of substandard quality of care. "Substandard quality of care" means "one or more deficiencies related to" requirements in sections 483.13 (resident behavior), 483.15 (quality of life), and 483.25 (quality of care). 42 C.F.R. § 488.301. The participation requirement discussed here is found elsewhere – in section 483.20 – and for that reason could not, as a matter of law, support a substandard quality of care finding.

For the reasons stated above, we affirm the ALJ's conclusion that Oaks was not in substantial compliance with section 483.20(k)(3)(ii).

3. *Substantial evidence in the record before us does not support the ALJ's conclusion that Oaks was noncompliant with 42 C.F.R. 483.20(b).*

The ALJ concluded that Oaks was noncompliant with section 483.20(b), which requires that a SNF "conduct initially for each of its residents and periodically a comprehensive, accurate, standardized, reproducible assessment of that resident's functional capacity."[9] ALJ Decision at 18-19. The "comprehensive" assessment envisioned by section 483.20(b) is performed using a "resident assessment instrument (RAI) specified by the State." 42 C.F.R. § 483.20(b)(1). To comply with section 483.20(b), facilities use the "CMS-designated" RAI, which has three components: the Minimum Data Set Version (MDS), a standard form on which a SNF enters information about a resident's clinical status and functional capacity; the RAI Manual, which contains guidelines and instructions on how to use the RAI effectively; and the Resident Assessment Protocols (RAPs), which are guidelines that help a SNF identify, evaluate, and develop plans of care for clinical or functional problems that become apparent in the process of gathering information for the MDS. 42 C.F.R. § 483.15; *see also Park Manor Nursing Home*, DAB No. 2005, at 36 (2005); *Maine Veterans Home – Scarborough*, DAB No. 1975, at 14 & n.11 (2005); *Northern Montana Care Center*, DAB No. 1930, at 13 (2004). A comprehensive assessment must be conducted "promptly upon (but no later than 14 days after the date of)" the resident's admission and within other timeframes not relevant here. *See* Act § 1819(b)(3)(C)(i); 42 C.F.R. § 483.20(b)(2)(i)-(iii).

CMS contended before the ALJ that Oaks was not in substantial compliance with section 483.20(b) because it had "failed to assess and monitor the glucose levels of Residents 1,

[9] The ALJ's formal "finding" cites to both section 483.20 (in its entirety) and to paragraph (b) of section 483.20, which relates specifically to "comprehensive assessments." ALJ Decision at 18-19. It is clear from his analysis, however, that the ALJ found Oaks noncompliant with the comprehensive requirement in section 483.20(b) and not with any other provision of section 483.20.

2, and 6" and "also failed to assess and monitor Resident 2's meal consumption and intake and output." CMS's Post-Hearing Br. at 9. CMS further stated that "comprehensive assessment" is "*an on-going process* which must be done in order to provide the 'appropriate care and services for each resident and to modify the care plan and care/services based upon the resident's status.'" *Id*. (italics added, quoting SOM, Appendix PP (guidelines for tag F272)).

Responding directly to this contention, the ALJ began his analysis by stating that "[t]here is a difference between the requirement that a resident's needs and condition be assessed on an ongoing basis and the requirement that a facility perform a 'comprehensive assessment' of that resident." ALJ Decision at 18. According to the ALJ, the "ongoing assessment" requirement is "subsumed within the regulation governing quality of care at a facility" (namely, section 483.25), whereas the "comprehensive assessment" involves "*a formal document* that embodies the facility's staff's overall evaluation of a resident." *Id*. at 18-19 (italics added). The ALJ then observed that Resident 2 "was in [Oaks's] facility for barely enough time to trigger the comprehensive assessment requirement" and that it was "unclear . . . whether [Oaks's] staff even met and considered writing the document that the regulation required." *Id*. at 19.

Notwithstanding his distinction between the "ongoing assessment" requirement in section 483.25 and the comprehensive assessment requirement in section 483.20(b), the ALJ found Oaks noncompliant with the latter. He made that finding "not because [Oaks] failed to dot all of the i's and cross all of the t's in the comprehensive assessment form required by 42 C.F.R. § 483.20" but because it "would have been impossible for [Oaks] ever to have prepared a document that complied with regulatory requirements, given its failure to perform basic assessment and monitoring of Resident #2." *Id*. In support of this finding, the ALJ stated:

> The staff's continuous and ongoing failures to monitor [Resident 2's] blood glucose level and her nutrition mean that the staff was not collecting any of the *information that they needed to write a comprehensive assessment*. Consequently, any document that the staff prepared for Ressident # 2, or that it could have have prepared for this resident, would have been effectively meaningless where it addressed the resident's diabetes or the status of her nutrition.

*Id*. (italics added).

Our difficulty with this analysis is that it omits any reference to the RAI. The ALJ found that staff "was not collecting any of the information they needed" to make the "comprehensive assessment." That finding begs the question: what information was needed to complete the comprehensive assessment envisioned under section 483.20(b)? Because the RAI is the regulation's specified tool for conducting a comprehensive assessment, *see* 42 C.F.R. § 483.20(b)(1), a finding that a SNF could not have completed

the comprehensive assessment should logically specify what information the MDS and the RAPs required the nursing staff to collect. The ALJ's findings imply that Oaks needed (and lacked) information about blood glucose levels and nutritional intake and output in order to complete the comprehensive assessment. It is true, as we discussed in the section upholding the finding of noncompliance with section 483.25, that Oaks did not regularly check Resident 2's blood glucose and failed to monitor or assess Resident 2's nutrition status. However, the ALJ did not point to any portion of the MDS, or to any RAP, which required a SNF to collect or use periodic blood glucose levels or data on her nutritional status for the purpose of completing the comprehensive assessment.

CMS, for its part, did not allege a connection between the RAI and Oaks's failure to monitor Resident 2's blood glucose and nutritional status, and did not place into evidence any of the documents which constitute the RAI. CMS's brief on appeal also completely ignores Oaks's complaint, *see* RR at 29, about the lack of any "reference to the MDS or RAI process in any of the surveyor findings or testimony." CMS merely defends the ALJ's reasoning without linking its finding of noncompliance to specific information-gathering requirements in the RAI, and without commenting on the legal distinction drawn by the ALJ between the requirement of "ongoing assessment" and the requirement to perform a "comprehensive assessment." *See* Response Br. at 14-16. We note also that neither the relevant SOD (CMS Ex. 24, at 1-19) nor the surveyors' affidavits (CMS Exhibits 40, 42, and 46) indicate that the March 5th survey evaluated – or identified shortcomings in – Oaks's process for timely completing the MDS and RAPs.[10]

We, thus, conclude that the record, as discussed by CMS and the ALJ in reference to section 483.20(b), is insufficient to support the ALJ's finding that it would have been impossible for Oaks to complete the comprehensive assessment required by section 483.20(b) and reverse his conclusion that Oaks was not in substantial compliance with that regulation. *Cf. Northern Montana Care Center* at 20-21 (finding that CMS did not make a prima facie showing of noncompliance with the comprehensive assessment requirement because it did not show that the MDS called for information about the presence or history of edema, or that the SNF failed to include information about edema on any RAI-related document that required that information). We emphasize that our reversal of the ALJ in this case should not be construed as a holding that it is legally impossible for a SNF to *ever* violate section 483.20(b) prior to expiration of the 14-day deadline for completing the initial comprehensive assessment. We also note that the evidence of record regarding the facility's failure to consult Resident 2's physician(s) to clarify orders for glucose monitoring and nutrition might arguably have supported a finding of noncompliance with section 483.20(a), which states that the facility "must have physician orders for the resident's immediate care." However, CMS did not

[10] The applicable regulation states that "[t]he assessment process must include direct observation and communication with the resident, as well as communication with licensed and nonlicensed direct care staff members on all shifts." 42 C.F.R. § 483.20(b)(1).

specifically allege a violation of section 483.20(a), and the ALJ did not consider that provision's relevance or applicability.

4. *The ALJ's conclusion that Oaks was noncompliant with 42 C.F.R. § 483.75 is legally correct and supported by substantial evidence.*

Section 483.75 states in its prefatory paragraph that a SNF "must be administered in a manner that enables it to use its resources effectively and efficiently to attain or maintain the highest practicable physical, mental and psychosocial well-being of each resident." The Board has held that, in appropriate circumstances, a finding that a SNF was noncompliant with section 483.75 may be derived from findings of noncompliance with other participation requirements. *Stone County Nursing and Rehabilitation Center*, DAB No. 2276, at 15-16 (2009) (citing cases).

The ALJ held that Oaks was not in substantial compliance with section 483.75 because the evidence showed that its noncompliance with other requirements – namely, sections 483.20 and 483.25 – stemmed from "failures by [its] management to develop and implement policies and procedures to assure efficient and effective operation of the facility." ALJ Decision at 17. There was, said the ALJ,

> an obvious failure on the part of Petitioner's management to assure that the staff operated effectively and efficiently. The deficient care that Petitioner gave to Resident # 2 is graphic proof of the ineffectiveness with which Petitioner was managed. As I have stated, the failure by Petitioner's staff to monitor this resident's blood glucose level – both as a matter of protocol governing a newly admitted insulin dependent diabetic resident, and as a matter of urgency in the face of the resident's labile blood glucose level – is a shocking dereliction of the duty of care that Petitioner owed to the resident. That misfeasance persisted over a period of several weeks. At no time during this period did Petitioner's supervisory staff notice anything untoward in the care that was being given to the resident. No review took place, no corrections were made, and no protocols were determined to have been violated. This is an obvious failure by Petitioner's management to have in place *meaningful supervision* of its staff or systems that would detect and stop improper care.

*Id*. (italics added). The ALJ also found that management failure was "evident in the staff's lack of comprehension of what was required by professionally recognized standards of nursing care." *Id*. According to the ALJ, Oaks's management was "clueless" about "repeated breaches" of accepted standards of nursing care and "had no system in place to detect and correct them." *Id*.

We find the ALJ's analysis persuasive. We agree with the ALJ that the nursing staff's failure to monitor Resident 2's blood glucose level, along with the other lapses discussed

earlier, support an inference that Oaks lacked supervisory and other administrative mechanisms to ensure that Resident 2 received care that met accepted standards of nursing care and helped her to attain or maintain the highest practicable level of functioning, as required by the general quality of care regulation (section 483.25). Oaks's response to this finding of noncompliance largely restates or summarizes arguments regarding the merits of the ALJ's other noncompliance findings – arguments that we have rejected. *See* RR at 37-38 (asserting that its nursing staff exercised proper "nursing judgment" in caring for Resident 2 (and other residents), did not deviate from accepted standards of nursing practice, and otherwise provided nursing care that complied with section 483.25). Moreover, Oaks does not respond to the ALJ's finding that it failed to provide "meaningful supervision" of its staff.

For these reasons, we affirm without further discussion the ALJ's conclusion that Oaks was not in substantial compliance with section 483.75.

5. *CMS's immediate jeopardy determination is not appealable.*

Oaks urged the ALJ, and urges us, to overturn CMS's determination that the noncompliance cited under tag F309 (the violation of section 483.25) and tag F490 (the violation of section 483.75) was serious enough to place one or more residents in "immediate jeopardy." RR at 13, 44. According to Oaks, CMS's immediate jeopardy determination is unfounded because CMS did not prove that the nursing staff's lapses directly caused Resident 2's death or other harm. *Id*. at 13, 36.

In response to this argument, the ALJ held:

> I find it unnecessary to address the question of immediate jeopardy, because a finding of immediate jeopardy is not necessary to deciding whether any of the three [civil money] penalties is reasonable. There is no requirement that noncompliance be at the level of immediate jeopardy to justify a per-instance civil money penalty. And, . . . a finding of immediate jeopardy level noncompliance also is unnecessary to deciding whether CMS is authorized to terminate Petitioner's participation in Medicare.

ALJ Decision at 21.

The ALJ correctly applied the law to the facts of this case. As we have indicated, a SNF may appeal CMS's finding about the severity and scope of its noncompliance (such as an immediate jeopardy finding) only if a successful challenge to that finding would affect either: (1) the range of the CMP that CMS could collect; or (2) a finding of substandard quality of care that "results in the loss of approval for a SNF . . . of its nurse aide training program." *See* 42 C.F.R §§ 498.3(b)(14), (b)(16), and (d)(10)(ii). Neither of these conditions is satisfied with respect to the immediate jeopardy finding at issue here.

First, because CMS imposed "per instance" CMPs, and because per-instance CMPs are imposed within a single dollar range ($1,000 to $10,000), *see* 42 C.F.R. § 488.438(a)(2), a successful challenge to CMS's immediate jeopardy finding would not have affected the range of the CMP that could be imposed but only the amount of the CMP within the range for per-instance CMPs. *Aase Haugen Homes, Inc.*, DAB No. 2013, at 3 (2006).

Second, although the state survey agency made a substandard quality of care finding in this case that, as a matter of law, removed any authority Oaks may have had to conduct a nurse aide training and competency evaluation program (NATCEP), *see* CMS Exhibit 48, at 1, Oaks does not allege in this appeal – or claim during the ALJ proceeding – that it even had a NATCEP when CMS issued its notices of noncompliance (on March 30 and April 9, 2010), much less that it lost such a program because of a substandard quality of care finding.[11]

Because review of the immediate jeopardy finding would not affect the applicable CMP range, and because there is no assertion (much less evidence) that a substandard quality of care finding resulted in Oaks losing approval of a nurse aide training program, Oaks does not have a right to an administrative law judge hearing or Board review concerning CMS's immediate jeopardy determination. *Cf. Aase Haugen Homes, Inc.* at 17-19 (2006) (upholding an administrative law judge's decision not to reach the merits of the SNF's challenge to an immediate jeopardy finding because the SNF did not allege during the hearing that it was entitled to review of the immediate jeopardy determination based on the loss of a NATCEP).

In any event, an administrative law judge or the Board may not overturn CMS's immediate jeopardy finding unless it is clearly erroneous. 42 C.F.R. § 498.60(c)(2); *Maysville Nursing & Rehabilitation Facility*, DAB No. 2317, at 11 (2010). As the Board has long held, this is a heavy burden. *Maysville* at 11. Were we to reach the issue, we would have no trouble concluding that the record before us strongly supports a finding of immediate jeopardy based on a likelihood of serious harm to Resident 2 from Oaks's failure to clarify and implement a physician's order to monitor her blood glucose and to consult with her doctors to ensure that she received adequate nutrition.

For these reasons, we decline to disturb CMS's immediate jeopardy determination.

6. *CMS lacked sufficient grounds to impose a per-instance CMP for the deficiency cited in the SOD under tag F272; the CMPs imposed for the deficiencies cited under tags F309 and F490 were legally valid and reasonable in amount.*

[11] We note that a facility can also lose authority to conduct a NATCEP for other reasons that include imposition of a CMP of $5,000 or more or a denial of payment for new admissions. Act § 1819(f)(2)(B)(iii)(I).

As indicated, CMS imposed a $3,500 per-instance CMP for the deficiency citation under tag F272 (alleging noncompliance with section 483.20(b)); a $3,500 per-instance CMP for the citation under tag F309 (alleging noncompliance with section 483.25); and a $3,000 per-instance CMP for the citation under tag F490 (alleging noncompliance with section 483.75). Because we affirm the ALJ's conclusion that Oaks was noncompliant with sections 483.25 and 483.75, we hold that CMS was authorized to impose a per-instance CMP for the citations under tags F309 and F490. *See* 42 C.F.R. § 488.408(d)(3)(i) (indicating that CMS may impose a CMP when a SNF is not in substantial compliance). However, because we reverse the ALJ's conclusion that Oaks was noncompliant with section 483.20(b) (*see* section 3, above), a basis no longer exists to impose an enforcement remedy based on tag F272. Accordingly, we reverse the portion of the ALJ Decision which sustained the $3,500 per-instance CMP associated with that deficiency citation. We next consider whether the two remaining per-instance CMPs were reasonable in amount.

When CMS elects to impose a per-instance CMP for a SNF's noncompliance, the penalty amount must be in the range of $1,000 to $10,000 per instance, regardless of whether the noncompliance constitutes immediate jeopardy. 42 C.F.R. § 488.438(a)(2), 488.408(d)(1)(iv). In appealing a finding of noncompliance, a SNF may contend that the amount of a CMP imposed for that noncompliance is unreasonable. *See, e.g., Lutheran Home at Trinity Oaks*, DAB No. 2111, at 21 (2007). In deciding whether the CMS-imposed penalty amount is reasonable, an administrative law judge (or the Board) may consider only those factors specified in section 488.438 of CMS's regulations. *See* 42 C.F.R. § 488.438(e), (f); *Senior Rehabilitation and Skilled Nursing Center*, DAB No. 2300, at 19-20 (2010). Those factors are: (1) the SNF's history of noncompliance; (2) the SNF's financial condition; (3) factors specified in 42 C.F.R. § 488.404 (i.e., the severity and scope of the noncompliance, and "the relationship of the one deficiency to other deficiencies resulting in noncompliance"); and (4) the SNF's degree of culpability, which includes neglect, indifference, or disregard for resident care, comfort or safety. 42 C.F.R. §§ 488.438(f), 488.404. An administrative law judge (or the Board) reviews the reasonableness of the CMP de novo, based on the facts and evidence contained in the appeal record. *Emerald Oaks*, DAB No. 1800, at 13 (2001); *CarePlex of Silver Spring*, DAB No. 1683, at 17-18 (1999).

Citing two of the relevant regulatory factors, the ALJ concluded that the per-instance CMPs imposed by CMS for Oaks's noncompliance with section 483.25 and 483.75 were "justified by the seriousness of Petitioner's noncompliance," and that Oaks had not shown an inability to pay those penalties. ALJ Decision at 21.

We agree with the ALJ that the CMPs were reasonable. Even though the underlying deficiencies were found to be at the highest level of severity, each penalty represents only 30 to 35 percent of the maximum allowed for the corresponding "instance" of noncompliance. Oaks maintains that CMS's immediate jeopardy determination is

erroneous, RR at 44, but, as we explained earlier, that finding is not reviewable (though the record would support it in any event).[12]

Oaks contends that the ALJ overlooked evidence of its financial condition, citing the federal court testimony of Joseph Delpit, president of Oaks's corporate owner, D&W Health Services, Inc. ("D & W"). RR at 40 (citing P. Ex. 10, at 24, 26, and 27). According to Oaks, that testimony established that CMS's enforcement action would "put [Oaks] out of business," leave it "destitute," and thus render it unable to pay the penalties. *Id*.

Before the ALJ, Oaks had the burden of demonstrating (by a preponderance of the evidence) its inability to pay the CMPs. *Gilman Care Center*, DAB No. 2357, at 7 (2010). Furthermore, the Board has long held that "the correct inquiry" in evaluating such a claim is "whether the facility has adequate assets to pay the CMP without having to go out of business or compromise resident health and safety." *Id*.

Oaks did not meet its burden of proof on the issue of its financial condition. While Mr. Delpit testified that income or cash flow from Oaks's operations would evaporate upon termination of its Medicare and Medicaid participation (*see* P. Ex. 10, at 24-26), and that D & W had incurred substantial legal expenses to challenge the enforcement action, he provided no appraisal of D & W's *overall* financial condition, claim that either the facility's or D & W's assets were inadequate to pay the CMPs, or claim that the CMPs would, in themselves, cause the facility to go out of business or compromise resident health or safety. In addition, Oaks proffered no financial statements or business records to back up its claim of destitution. Given the scant evidence submitted by Oaks, we cannot find that it was unable to pay the two rather modest penalties (totaling $6,500).

Oaks also contends that the magnitude of the per-instance CMPs is unjustified because CMS failed to present any evidence of a history of noncompliance (prior to the March 5th survey). RR at 39. Oaks also contends that "CMS has failed to establish any degree of culpability on the part of The Oaks and presented no evidence at the hearing as to any neglect by the nursing home or indifference or disregard for resident care, comfort or safety." RR at 41. However, CMS was not required to establish that Oaks was culpable for its noncompliance or that it had a poor compliance history. The Board has held that "there is a presumption that CMS has considered the regulatory factors [in section 488.434(f)] in setting the amount of the CMP and that those factors support the CMP amount imposed by CMS." *Coquina Center*, DAB No. 1860, at 32 (2002). Accordingly, the burden is not on CMS to present evidence bearing on each regulatory factor, but on the SNF to demonstrate, through argument and the submission of evidence addressing the

[12] The Board has held that the regulations which permit an administrative law judge to consider the seriousness of a SNF's noncompliance in assessing the reasonableness of a CMP amount do not authorize the judge (or the Board) to entertain a dispute about the merits of a finding by CMS about the severity and scope of the noncompliance if that finding is non-appealable under 42 C.F.R. Par 498. See NHC Healthcare Athens at 16-17.

regulatory factors, that a reduction is necessary to make the CMP amount reasonable. *Id.; The Windsor House*, DAB No. 1942, at 62 (2004). In this case, evidence submitted by Oaks – a judicial hearing transcript of the testimony of, among others, CMS Associate Regional Administrator David Wright – indicates that Oaks's compliance history was not a good one. P. Ex. 10, at 129 (Wright's testimony that from November 2007 until the March 5, 2010 survey, Oaks received 10 immediate jeopardy citations). In addition, Oaks has not presented evidence that it lacked any culpability,[13] and, in fact, the evidence regarding Resident 2 shows at least some degree of disregard of Resident 2's needs by Oaks's nursing staff.

Finally, Oaks contends that

> because the state surveyors and CMS refused to return to The Oaks to determine whether The Oaks came within substantial compliance, the Secretary should be limited in its imposition of penalties to the least amount allowed by law, that is $50 per day or only a single day for each of the 3 tag[s] levied, for a total of $150.00 in civil money penalties, if any are to be sanctioned against The Oaks. Certainly, because CMS refuses to allow a return visit to the facility, it should not be able to reap the benefit of imposing a per instance sanction which is at the highest level and/or exceeds the level for less serious deficiencies.

RR at 44-45. In essence, Oaks is arguing that a per-day CMP would have been a more appropriate remedy than the per-instance CMPs actually imposed. However, CMS's decision to impose a per-instance CMP, as opposed to any other type of remedy (including a per-day CMP), is a choice committed to CMS's discretion and not subject to review by an administrative law judge or the Board. 42 C.F.R. § 488.404(g)(2); *Alexandria Place*, DAB No. 2245, at 8 n.25 (2009). To the extent that Oaks contends that the circumstances described in the above-quoted passage support a reduction in the amount of the per-instance CMPs, we reiterate that we are precluded from reducing a CMP based on any factors other than those specified in the regulations. Those regulatory factors do not include the degree, if any, to which CMS has permitted a SNF to correct its noncompliance.[14]

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[13] Even if Oaks had presented evidence that it had no culpability, we could not rely on that evidence to reduce the CMPs because CMS's regulations expressly provide that the "absence of culpability is not a mitigating circumstance in reducing the amount of the penalty." 42 C.F.R. § 488.438(f)(4).

[14] Oaks also asserts that the DPNA should be reversed, suggesting, without further explanation, that CMS could enforce the DPNA only if it did a revisit and found continuing noncompliance prior to the date the DPNA went into effect (April 15, 2010). That a DPNA might not be effective immediately after a survey that found noncompliance, however, does not mean that a revisit finding of continuing noncompliance is a prerequisite for imposing the DPNA. Oaks cites no support for such a proposition, and we find no basis for it.

For all of these reasons, we affirm the ALJ's conclusion that the amounts of the per-instance CMPs were reasonable.

7. *Oaks's arguments about the ALJ's ruling on the findings of the February 4th survey have no merit.*

During a July 21, 2010 pre-hearing conference, the ALJ ruled that the February 4th survey findings were "irrelevant" in this proceeding because CMS did not impose any remedies based on those findings and because the enforcement remedies he upheld were justified based on the March 5th survey findings. *See* ALJ Decision at 2-3. Oaks now contends, as it did below, that it had a right to a hearing concerning the February 4th survey findings. RR at 21-22. Oaks also contends that it should have been permitted to introduce evidence relating to the February 4th survey in order to: (1) "show that there was no widespread problem as suggested inaccurately" in the SOD for the March 5th survey; (2) establish that its compliance history did not support the size of the CMPs; and (3) challenge the "credibility and competency of the surveyors" who gathered the evidence that CMS relies upon to support its enforcement action. RR at 22.

The regulations at 42 C.F.R. Part 498 provide hearing rights for specified determinations by CMS that affect a provider's participation in the Medicare and Medicaid programs. Contrary to what Oaks suggests, section 498.5 does not set out an unqualified right to appeal a finding of noncompliance. The appeal rights specified in section 498.5 are afforded only with respect to "initial determinations" (or initial determination that are "reconsidered" by CMS). *See, e.g.*, 42 C.F.R. § 498.5(b) ("Any provider dissatisfied with an *initial determination* to terminate its provider agreement is entitled to a hearing before an ALJ."). Section 498.3 identifies the types of actions considered "initial determinations" subject to administrative review. These initial determinations include, "[w]ith respect to a SNF . . ., a finding of noncompliance that results in the imposition of a remedy specified in section 488.406 of this chapter, except the State monitoring remedy." 42 C.F.R. § 498.3(b)(13); *see also* 42 C.F.R. § 488.408(g) ("A facility may appeal a certification of noncompliance leading to an enforcement remedy.").

The ALJ found that the February 4th survey did not result in the imposition of any enforcement remedies. ALJ Decision at 2-3; Tr. at 208. Oaks disputes that finding, asserting that CMS's March 30, 2010 notice letter states that CMS had chosen to terminate its participation based on the findings of both the February 4th and March 5th surveys. Reply Br. at 7. This is not a wholly accurate characterization of the March 30 letter, however. While the letter informed Oaks of the noncompliance found during both surveys, it stated that the termination remedy was imposed based on the "Statement of Deficiencies" (singular) without specifying the survey to which the Statement of Deficiencies related. CMS Ex. 48, at 17-18. In any event, as Oaks implicitly acknowledges, the March 30 letter was superseded by CMS's April 9, 2010 notice letter, which expressly states, in its first paragraph, that CMS chose to terminate Oaks's participation based on the March 5th survey findings. CMS Ex. 48, at 11.

The other issue raised by Oaks concerning the February 4th survey is whether the ALJ should have permitted it to introduce evidence about the survey for purposes such as establishing that its compliance history did not support the size of the CMPs. However, we find no evidence that Oaks even asked the ALJ to admit evidence relating to the February 4th survey for those other purposes. *See* August 6, 2010 letter from Attorney Rabalais to ALJ at 2 (objecting to the ALJ's ruling concerning the relevance of the February 4th survey findings but not indicating that those findings were relevant to remedy, credibility, or other issues). Furthermore, we see no basis for concluding that the results of the February 4th survey would have made a difference with respect to the amount of the CMPs we have upheld. As we note elsewhere in this decision, Oaks submitted evidence from the federal court injunction hearing indicating that it had 10 immediate jeopardy citations between November 2007 and the March 5, 2010 survey. P. Ex. 10, at 129. This evidence reflects history that clearly supports the CMP amounts at their current levels and arguably would support greater amounts.

In any event, CMS would likely have been entitled to judgment on the February 4th survey findings. Despite filing a hearing request to challenge the February 4th survey findings, Oaks exhibited no intention during the ALJ proceeding to litigate those findings on the merits. Unlike CMS's pre-hearing exchange, Oaks's pre-hearing exchange – which was filed *before* the ALJ issued his ruling barring consideration of the February 4th survey – included no evidence or argument opposing the February 4th survey findings. The ALJ's May 21, 2010 pre-hearing order, which set out the rules for submission of the pre-hearing exchange, did not bar Oaks from submitting evidence to challenge those findings. Moreover, even on appeal, Oaks does not specify the evidence it would have introduced, nor does it explain how or why that evidence would have altered the proceeding's outcome.

For these reasons, we reject Oaks's arguments about the February 4th survey.

8. *CMS may lawfully terminate Oaks's participation in the Medicare program based on the noncompliance found during the March 5th survey.*

Because we affirm the ALJ's conclusion that Oaks was not in substantial compliance with Medicare participation requirements during the March 5th survey, we also affirm his holding that CMS may terminate Oaks's participation in Medicare. The Medicare statute and regulations permit CMS to terminate a SNF's participation based on one or more deficiencies constituting noncompliance, regardless of the noncompliance's severity or scope, and without first giving the SNF an opportunity to remove the noncompliance. Act § 1866(b)(2); 42 C.F.R. §§ 488.412(a), 488.456(b)(i); *Rosewood Living Center*, DAB

No. 2019, at 9 (2006); *Beverly Health and Rehabilitation – Spring Hill*, DAB No. 1696, at 11, 15-16 (1999).[15]

Oaks suggests that CMS's decision to terminate its participation immediately was unlawful because CMS had earlier, in its March 30, 2010 notice letter, indicated that Oaks would have an opportunity to avoid termination by removing the noncompliance. *See* RR at 20. CMS's March 30, 2010 notice letter does not affirmatively state that CMS was giving Oaks an opportunity to correct its noncompliance prior to terminating its Medicare participation. Rather, the letter states, "Unless your facility achieves substantial compliance before August 4, 2010, CMS will terminate your facility's provider agreement in accordance with the statutory provisions at § 1819(h)(2)(C) . . . ." The statute cited by CMS requires the Secretary to terminate a facility's Medicare participation if it has not achieved substantial compliance within six months after the noncompliance was found. In this case, Oaks was first found noncompliant on February 4, 2010. Thus, CMS was providing notice that termination would be mandatory if Oaks did not correct its noncompliance within six months. However, as previously stated, the statute gives CMS *discretion* to terminate a SNF's provider agreement whenever the SNF is not in substantial compliance, without an opportunity to correct. Thus, nothing in the statute, or the regulations, prevented CMS from terminating immediately, after giving the proper notice, which it did, without regard to whether CMS previously provided notice of the six-month mandatory termination date.

9. *Oaks's collateral contentions are meritless or beyond the scope of the hearing authorized by CMS's regulations.*

a. The ALJ properly refused to entertain Oaks's equal protection and estoppel claims.

Oaks asserts that CMS's decision to terminate its Medicare participation without giving it an opportunity to correct its noncompliance was "arbitrary" and violated its constitutional right to equal protection of the law. RR at 45-46. Oaks also contends that CMS should be estopped from enforcing its remedies "due to its arbitrary actions against the appellant." RR at 46. Oaks asserts that the ALJ erred in refusing to adjudicate or admit evidence regarding these contentions. RR at 12 (item XI).

Because an administrative law judge is bound by applicable statutes and regulations, he or she may not ignore or refuse to apply those laws on any ground, even a constitutional one. *Experts Are Us, Inc.*, DAB No. 2322, at 10 (2010); *see also Sentinel Medical Laboratories, Inc.*, DAB No. 1762, at 9 (2001), *aff'd sub nom., Teitelbaum v. Health Care Financing Admin.*, No. 01-70236 (9th Cir. Mar. 15, 2002), *reh'g denied*, No. 01-

[15] Section 1819(h)(2)(A) of the Act makes it clear that if the Secretary of Health and Human Services (or her delegate, CMS) finds that a SNF's deficiencies "immediately jeopardize the health or safety of its residents," as CMS found here, then she may terminate a SNF's Medicare participation regardless of whether she also chooses to impose one or more of the alternative remedies in section 1819(h)(2)(B).

70236 (9th Cir. May 22, 2002). "Consistent with the applicable regulations and statutes," an administrative law judge or the Board may, however, "take steps to ensure procedural fairness . . . and consider constitutional claims challenging the manner in which a statute or regulation is interpreted or applied in a particular case . . . ." *Experts Are Us* at 10 (internal quotations omitted).

Applying these principles, we agree with the ALJ that Oaks's equal protection claim was beyond the scope of the administrative hearing. That claim concerns neither the procedural fairness of the hearing nor the manner in which CMS has interpreted the applicable statute and regulations. Instead, the equal protection claim directly challenges a discretionary enforcement action that was, in these circumstances, plainly authorized by the Medicare statute and regulations. The statute and regulations provide that when CMS makes (as it did here) a valid finding that a SNF is not in substantial compliance, CMS may – in its discretion – terminate the SNF's Medicare participation (without first giving the facility an opportunity to correct its noncompliance). Act §§ 1866(b)(2), 1819(h)(2)(A); 42 C.F.R. §§ 488.412(a), 488.456(b)(i). In addition, the regulations expressly preclude an administrative law judge or the Board from reviewing that discretionary enforcement decision. 42 C.F.R. § 488.408(g)(2). As we said, neither the Board nor an administrative law may refuse to comply – for any reason, including a constitutional one – with that legally binding limitation. *Experts Are Us, Inc.*

For similar reasons, we sustain the ALJ's refusal to entertain Oak's equitable estoppel claim, which is, at its root, a request that we decline to apply binding and applicable statutory provisions and regulations governing Oaks's participation in Medicare. In general, neither the Board nor an administrative law judge is authorized to provide equitable relief. *See, e.g.*, *US Ultrasound*, DAB No. 2302, at 8 (2010). Moreover, the government cannot be estopped absent, at minimum, a showing that the traditional requirements for estoppel are present (i.e., a factual misrepresentation by the government, reasonable reliance on the misrepresentation by the party seeking estoppel, and harm or detriment to that party as a result of the reliance) and that the government's employees or agents engaged in "affirmative misconduct." *Office of Personnel Management v. Richmond*, 496 U.S. 414, 421 (1990); *Linkous v. United States*, 142 F.3d 271, 277-78 (5th Cir. 1998); *Pacific Islander Council of Leaders*, DAB No. 2091, at 12 & n.11 (2007). Oaks has not alleged or shown that it met these requirements.

b. The ALJ properly denied Oaks's pre-hearing discovery requests.

During the July 21, 2010 pre-hearing conference, the ALJ denied Oaks permission to take the depositions of Daniel McElroy, Dr. Johnson, and the three state surveyors whose affidavits CMS submitted. The ALJ explained his reasons for that ruling in his decision on the merits, stating that "[t]here is nothing in the [Social Security] Act, or in the regulations governing hearings in 42 C.F.R. Part 498, that allows a party to take discovery." ALJ Decision at 23. He further held that "[t]here is no constitutional or statutory right to take discovery in a case involving CMS," and that "[t]he regulations [in

Part 498] expressly define the rights of the parties." *Id*. Finally, the ALJ stated that, even were he authorized to permit pre-hearing discovery, he would not have permitted the requested depositions, finding that the information purportedly sought by Oaks was "irrelevant" and related to an estoppel claim that he had no authority to hear and decide. *Id*. at 24.

We agree that there is no constitutional right to pretrial discovery in administrative proceedings." *Kelly v. U.S. E.P.A.*, 203 F.3d 519, 523 (7th Cir. 2000). In addition, "[t]he Administrative Procedure Act contains no provision for pretrial discovery in the administrative process and the Federal Rules of Civil Procedure do not apply to administrative proceedings." *Id*.; *see also Guardian Health Care Center*, DAB No. 1943, at 15 (2004) (stating that the Federal Rules of Civil Procedure do not control in a Part 498 proceeding). Furthermore, the regulations that govern hearings on CMS program determinations – 42 C.F.R. Part 498 – do not expressly provide for the use of depositions or other pre-hearing discovery tools available under the Federal Rules of Civil Procedure (FRCP).[16]

Oaks nonetheless contends that administrative law judges are legally obligated to permit depositions and other pre-hearing discovery when they choose to apply FRCP 56 when ruling on motions for summary judgment. RR at 17-18; Reply Br. at 2-3. This argument is unpersuasive partly because the Board has made clear that FRCP 56 "does not apply by its own terms to administrative proceedings under 42 C.F.R. Part 498." *Cedar Lake Nursing Home* at 2 (2010); *see also Tri-County Extended Care Center*, DAB No. 2060, at 8 (2007). Furthermore, the Board and its administrative law judges look to FRCP 56 only for guidance in applying its well-established standards for evaluating and adjudicating summary judgment motions. *See Cedar Lake Nursing Home* at 2. In any event, FRCP 56 says nothing about what discovery tools a trier of fact must allow or may permit.

Oaks further contends that discovery was necessary in this case to identify evidence that the surveyors neglected to gather, consider, or report concerning the adequacy of the nursing care provided to Resident 2 and other residents. Reply Br. at 5. Oaks asserts that "[a] legal proceeding without the ability to conduct depositions prior to trial simply creates a trial by ambush of a government agency upon individuals, corporations and other legal entities, depriving those parties of their due process rights before trial." RR at 18.

These contentions assume, of course, that the ALJ had discretion to grant its discovery requests. Regarding that assumption as true for purposes of this discussion, Oaks has not shown that it needed the discovery it sought. Oaks's contention that it needed discovery to help prove that it provided adequate nursing care overlooks a critical fact: evidence

[16] The Part 498 regulations give the ALJ one and only one tool – namely, the subpoena – for compelling the production of relevant evidence that the parties have not voluntarily produced. See 42 C.F.R. § 498.58.

about the adequacy of its nursing care, if any existed, was largely within its control and ability to gather. That evidence includes the clinical records maintained by its nursing staff, the recollection and opinions of employees involved in providing or supervising the care furnished to Resident 2 and others, and expert testimony about whether the nursing staff met accepted standards of clinical practice. Indeed, the record consists largely of such evidence. Oaks makes no claim that it was prevented from gathering or producing that evidence at the hearing.[17] Moreover, the quality of the surveyors' information gathering or thought processes is immaterial because the compliance issues presented are ones that the ALJ decides de novo based on the evidence presented by the parties to the administrative law judge. "As the Board has stated, an ALJ hearing is not a review of how or why CMS decided to impose remedies, nor is it "restricted to the facts or evidence that were available to CMS when it made its decision. Rather, the ALJ hearing provides a fresh look by a neutral decision-maker at the legal and factual basis for the deficiency findings underlying the remedies." *Britthaven of Chapel Hill*, DAB No. 2284, at 6 (2009) (citations and internal quotations omitted).

Upon careful review of the entire record, we find that Oaks received a full and fair opportunity to litigate the issues properly before the ALJ: (1) whether Oaks was noncompliant with various participation requirements in caring for Resident 2 and others; and (2) whether the CMP amounts were reasonable (assuming that the ALJ sustained the underlying noncompliance findings) in light of the applicable regulatory factors. Oaks had the opportunity to present documentary evidence and witness testimony – and to cross-examine CMS's witnesses – about those issues, an opportunity communicated to the parties in the ALJ's May 21, 2010 pre-hearing order. Contrary to Oaks's characterization, the hearing was not a "trial by ambush" because Oaks received CMS's exhibits and written direct testimony before the in-person hearing and was permitted to cross-examine CMS's witnesses about their written direct testimony. Oaks does not claim that it had inadequate time to prepare its cross-examination, nor does it claim that the ALJ permitted CMS to introduce evidence at that hearing that was not included in CMS's pre-hearing exchange.[18]

c. <u>The ALJ committed no error in allowing CMS to withdraw the declaration of Daniel McElroy</u>.

During the August 9, 2010 pre-hearing conference, Oaks objected to CMS's withdrawal of Daniel McElroy's declaration, claiming that Mr. McElroy would have given testimony favorable to its case on cross-examination. *See* Tape Recording of August 9, 2010 Pre-Hearing Conf. Oaks also asserted during that conference that Mr. McElroy had been

[17] To the extent that Oaks required the testimony of an uncooperative employee, it could have requested a subpoena pursuant to section 498.58.

[18] The Board has affirmed the legality in general of requiring parties to submit their direct testimony in writing, see Life Care Center of Tullahoma, DAB No. 2304, at 48-51 (2010), and Oaks does not object to that procedure as such

involved in CMS's decision to terminate its Medicare participation and would have been able to testify about the reasons for that decision. *Id*. Finally, Oaks asserted that it needed to question Mr. McElroy because he had rendered an opinion that was reflected in Dr. Johnson's written direct testimony. *Id*.

The ALJ overruled Oaks's objection, noting that he was not empowered to inquire about the thought processes that Mr. McElroy (and other CMS officials) used to arrive at the termination decision, and that he (the ALJ) was merely authorized to inquire about whether evidence relating to the survey findings was sufficient to conclude that Oaks was noncompliant with Medicare participation requirements and, if so, whether that noncompliance justified the remedies imposed. *See* Tape Recording of August 9, 2010 Pre-Hearing Conf.; August 9, 2010 Pre-Hearing Order at 1. In addition, the ALJ stated that he found nothing in Dr. Johnson's declaration indicating that his opinions were based on statements in Mr. McElroy's declaration. *Id*. Although the ALJ permitted CMS to withdraw Mr. McElroy's declaration, and "declined to order that Mr. McElroy appear as a witness," he invited Oaks's attorney "to make an offer of proof on the record of the in-person hearing concerning what he believed that Mr. McElroy might say if called to testify." August 9, 2010 Pre-hearing Order at 2. Despite that invitation, Oaks did not make an offer of proof or formally request a subpoena pursuant to section 498.58(a). Oaks now asserts that the ALJ should have postponed or continued the hearing to allow Mr. McElroy to appear (either voluntarily or under subpoena), *see* Reply Br. at 5, but we see no indication that Oaks asked the ALJ for a postponement or continuance for that purpose.

Oaks has also failed to show that Mr. McElroy's testimony was "reasonably necessary for the full presentation" of its case on the issues properly before the ALJ. 42 C.F.R. § 498.58(a) (setting out the necessity standard for issuance of a subpoena). We note, as the ALJ did, that Mr. McElroy, a CMS employee, did not participate in the on-site survey at issue. His declaration alleged no personal knowledge of Oaks's facility or the noncompliance found there. The apparent main purpose of his declaration was to identify what CMS regarded as the proper factual bases for the state survey agency's findings of noncompliance as well as CMS's reasons for imposing particular remedies, matters that are addressed in the SOD and in testimony of the surveyors and CMS's medical expert. Moreover, during the August 9, 2010 pre-hearing conference, the ALJ found that Mr. McElroy's declaration was at best "cumulative" of testimony offered by CMS, a finding that Oaks does not dispute.

For all these reasons, we decline to overturn the ALJ's rulings concerning Mr. McElroy.

d. The ALJ committed no error in refusing to admit the deposition and correspondence of CMS employee Gerardo Ortiz.

Oaks contends that the ALJ erred in refusing to admit the deposition of CMS employee Gerardo Ortiz. RR at 23. Mr. Ortiz, who signed the April 9, 2010 letter which notified

Oaks of CMS's decision to terminate its Medicare participation, gave the deposition in connection with the federal court injunction proceeding. *See* P. Ex. 11; Tr. at 37-38. The ALJ sustained CMS's objection to the deposition's admission, ruling that it "really doesn't relate to what I have the authority to hear and decide." Tr. at 38. We decline to overturn this ruling because Oaks has not alleged or shown that Mr. Ortiz's testimony in the judicial injunction proceeding was, in fact, relevant and material to the legal and factual issues that the ALJ was required and authorized to address – most notably, the validity of the March 5th survey's findings of noncompliance, and the reasonableness of the per-instance CMPs.

Oaks also contends that the ALJ improperly excluded an April 20, 2010 letter written by Mr. Ortiz and addressed to United States Congressman Bill Cassidy (Petitioner's Exhibit 7). RR at 23. The ALJ found the letter irrelevant because it had been offered to support Oaks's estoppel claim, *see* Tr. at 30-31, a claim that we have already held was beyond the scope of the hearing. Oaks does not deny that the letter was offered to support an estoppel claim, nor does it contend that the letter was material to any issue properly before the ALJ. Oaks merely asserts that Mr. Ortiz's letter "bears on CMS's credibility in its decision to terminate the Medicare and Medicaid provider agreements and whether CMS abused its discretion in this case by Mr. Ortiz's inappropriate comments communicated in said writing." RR at 23. As previously stated, the ALJ had no authority to review CMS's choice of remedy, and Mr. Ortiz's comments in a letter to a member of Congress, whether appropriate or not, had nothing to do with the issues before the ALJ on de novo review.

e. The ALJ committed no error in his other evidentiary rulings.

Oaks asserts that the ALJ admitted "irrelevant hearsay evidence" and "evidence without a foundation." RR at 23. We reject this contention because Oaks does not point to the evidence it believes was improperly admitted. Moreover, Oaks had an opportunity to subpoena any declarant but did not do so. In any event, it is well-settled that hearsay is admissible in an evidentiary hearing affecting a provider's participation in Medicare, and may constitute substantial evidence supporting a noncompliance finding if it has sufficient indicia of reliability. *Beatrice State Developmental Center*, DAB No. 2311, at 17 (2010); *Florence Park Care Center*, DAB No. 1931, at 10 (2004); *cf.* 42 C.F.R. § 498.61 ("Evidence may be received at the hearing even though inadmissible under the rules of evidence applicable to court procedures"). Oaks makes no claim here that any particular documents admitted by the ALJ lacked sufficient indicia of reliability.

f. The ALJ's comments during the cross-examination of Deborah Franklin were not inappropriate or prejudicial.

Oaks contends that the ALJ engaged in "inappropriate leading" of surveyor Deborah Franklin's in-person testimony, and that he "appeared to be attempting to shape" her testimony with his "comment[s]" on the evidence. RR at 34-35; Reply Br. at 16. In

support of this contention, Oaks cites passages of the transcript in which surveyor Franklin is asked about whether Resident 2 had a physician order for tube feeding and, more specifically, about whether such an order was contained or reflected in the Physician Admission and Order Form (PAOF) that Oaks received when Resident 2 was first admitted on February 4, 2010. *See* RR at 34-35; CMS Ex. 28, at 140; Tr. at 111-27.

We carefully reviewed the transcript passages cited by Oaks. They indicate that the ALJ interjected to clarify the witness's answer (Tr. at 112-13), clarify the purpose or identity of an exhibit (Tr. at 114-15), advise Oaks's counsel that the factual premise of his question was erroneous (Tr. at 115-16), rule on an objection by CMS that a question contained irrelevant information (Tr. at 119-22), caution Oaks's counsel about the phrasing of a question (122-23), and disagree with counsel's characterization of a passage in surveyor Franklin's declaration (Tr. at 124-26). Administrative law judges have broad leeway in conducting their hearings as is necessary to assure a clear, well-documented record for decision. We see nothing improper in this judge's conduct of the hearing, and we certainly see nothing that could reasonably be regarded as "leading" or "shaping" the witnesses' testimony. While the ALJ discussed before the parties possible inferences he could draw from the face of the PAOF and whether the document did, in fact, contain or constitute a physician's order, the ALJ made no finding about that issue but, instead, indicated that the parties could argue about it in their post-hearing briefs and that the PAOF would "speak for itself." *See* Tr. at 116-18. In sum, we see no indication that the ALJ's comments and interruptions had any undue influence on the witness's testimony or were anything more than permissible interjections by a trial judge in the course of a hearing.

**Conclusion**

For the reasons stated above, we reverse the ALJ's conclusion that Oaks was not in substantial compliance with 42 C.F.R. § 483.20(b), as well as the portion of the ALJ Decision which sustained the $3,500 per instance CMP associated with tag F272. We affirm the ALJ Decision in all other respects.

_____/s/_____
Judith A. Ballard

_____/s/_____
Leslie A. Sussan

_____/s/_____
Sheila Ann Hegy
Presiding Board Member