Department of Health and Human Services

DEPARTMENTAL APPEALS BOARD

Appellate Division

In the Case of:	DATE: June 16, 2008
Claiborne-Hughes Health Center,	
Petitioner,	Civil Remedies CR1687 App. Div. Docket No. A-08-45
- v. -	Decision No. 2179
Centers for Medicare & Medicaid Services.	

REMAND OF
ADMINISTRATIVE LAW JUDGE DECISION

Claiborne-Hughes Health Center (Claiborne) appealed the November 9, 2007 decision of Administrative Law Judge (ALJ) Steven T. Kessel upholding the imposition by the Centers for Medicare & Medicaid Services (CMS) of civil money penalties (CMPs) and a denial of payment for new admissions (DPNA). Claiborne-Hughes Health Center, DAB CR1687 (2007)(ALJ Decision). CMS imposed these remedies based on surveys completed on August 14, 2006 (August survey) and September 6, 2006 (September revisit) that found that Claiborne was not in substantial compliance with program participation requirements and that, for the period July 18 through September 4, 2006, Claiborne's noncompliance was at the immediate jeopardy level.

The ALJ addressed only one finding of noncompliance from each survey, although both surveys resulted in multiple findings. From the August survey, he sustained CMS's determination of noncompliance with 42 C.F.R. § 483.10(b)(11) at the immediate jeopardy level from July 18, 2006 through September 4, 2006.

From the September survey, he sustained CMS's determination of noncompliance with the same regulation from September 5, 2006 through September 17, 2006 at a lower than immediate jeopardy level. He found those determinations sufficient to support the remedies imposed: a CMP of $3,050 per day during the period of immediate jeopardy, a CMP of $100 per day during the remaining period, and a DPNA from August 20, 2006 through September 17, 2006.

For the reasons explained below, we affirm the ALJ's conclusion, based on the August survey, that Claiborne was not in substantial compliance with 42 C.F.R. § 483.10(b)(11) from July 18, 2006 through September 4, 2006; that CMS's determination as to immediate jeopardy was not clearly erroneous; and that CMS had authority to impose a $3,050 per-day CMP and a DPNA during this period. As to the September survey, however, we conclude that substantial evidence in the record as a whole does not support the findings on which the ALJ based his conclusion that Claiborne was not in substantial compliance with section 483.10(b)(11) from September 5 through September 17, 2006. We therefore reverse, vacate, and modify ALJ Findings of Fact and Conclusions of Law (FFCLS) 4, 6.b, and 6.c respectively.

Because the ALJ did not review the other deficiencies cited by CMS in the September survey, we remand this case to the ALJ to determine whether Claiborne was in substantial compliance during the period September 5 through September 17, and whether CMS had the authority to impose the proposed CMP and DPNA during this period. The ALJ may also review on remand the unresolved deficiency findings from the August survey.

Relevant background

Claiborne is a skilled nursing facility that participates in the Medicare program and is located in Franklin, Tennessee. The August survey, conducted by the state survey agency, found that Claiborne was not in substantial compliance with multiple program requirements at an immediate jeopardy level. The state survey agency conducted the September revisit and found continuing noncompliance that no longer posed immediate jeopardy.

Pursuant to the two surveys, CMS imposed a CMP of $3,050 per day from July 18, 2006 through September 4, 2004, a CMP of $100 per day from September 5, 2006 through September 17, 2006, and a denial of payment for new admissions from August 20, 2006 through September 17, 2006. ALJ Decision at 1.

Claiborne appealed CMS's determinations. The appeal of the August survey was docketed before the ALJ as C-07-31; the appeal of the September revisit was docketed as C-07-111. The August survey set forth deficiency findings under seven specific regulatory requirements, cited as "tags." 07-31 CMS Ex. 1.[1] The September revisit resulted in deficiency findings under three tags. 07-111 CMS Ex. 1.

Pursuant to the parties' agreement, the ALJ issued his decision based on their written submissions, which included briefs, written direct testimony, and exhibits. ALJ Decision at 2.

The ALJ sustained one noncompliance finding from the August survey and one from the September revisit, both cited under F Tag 157 involving 42 C.F.R. § 483.10(b)(11), for failure to consult with the residents' physicians and notify interested family members about significant changes in the residents' conditions.[2] The ALJ also concluded that CMS's immediate jeopardy determination for the period July 18, 2006 through September 4, 2006 was not clearly erroneous, that Claiborne had not corrected its noncompliance before September 18, 2006, that CMS's CMP remedy determinations were reasonable in amount, and that CMS had

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[1] We adopt the ALJ's exhibit citation convention by citing to both the exhibit number and to a docket number prefix. For example CMS Exhibit 1 in Docket No. C-07-31 is cited as "07-31 CMS Ex. 1." ALJ Decision at 2.

[2] The ALJ declined, citing judicial economy, to make any findings as to six of the seven tags cited in the August survey and two of the three tags cited in the September revisit. ALJ Decision at 3. For the August survey, the ALJ did not review noncompliance findings under F Tag 280 (42 C.F.R. §§ 483.20(d)(3), 483.10(k)(2) involving comprehensive care plans); F Tag 325 (42 C.F.R. § 483.25(i)(1) involving nutrition); F Tag 327 (42 C.F.R. § 483.25(j) involving hydration); F Tag 490 (42 C.F.R. § 483.75 involving effective administration); F Tag 497 (42 C.F.R. § 483.75(e)(8) involving regular in-service education); and F Tag 520 (42 C.F.R. § 483.75(o)(1) involving quality assurance). All of these citations were based on or involved some of the same factual allegations cited in support of the tag that the ALJ did adjudicate - Tag 157 involving notification of changes. 07-31 CMS Ex. 1. For the September revisit, the ALJ did not review the deficiencies cited under F Tag 250 (42 C.F.R. § 483.15(g)(1) involving social services) and F tag 327 (hydration). He did review F Tag 157 (notification of changes).

discretion to impose a DPNA for the period that began August 20 and continued through September 17, 2006.

Applicable law

The federal statute and regulations provide for surveys to evaluate the compliance of skilled nursing facilities with the requirements for participation in the Medicare and Medicaid programs and to impose remedies when a facility is found not to comply substantially. Sections 1819 and 1919 of the Social Security Act; 42 C.F.R. Parts 483, 488, and 498.[3]

"Substantial compliance" is defined as "a level of compliance with the requirements of participation such that any identified deficiencies pose no greater risk to resident health and safety than the potential for causing minimal harm." 42 C.F.R. § 488.301. "Noncompliance" means "any deficiency that causes a facility to not be in substantial compliance." Id. "Immediate jeopardy" is defined by 42 C.F.R. § 488.301 as a situation in which a provider's noncompliance "has caused, or is likely to cause, serious injury, harm, impairment, or death to a resident."

CMS may impose a CMP for the days on which the facility is not in substantial of noncompliance. 42 C.F.R. §§ 488.404, 488.406 and 488.408. Where the noncompliance poses immediate jeopardy, the minimum daily CMP amount that may be imposed is $3,050. 42 C.F.R. § 488.438(a)(1)(i). CMS may also impose a DPNA for each day that a facility is not complying substantially with participation requirements. 42 C.F.R. § 488.417(a).

At issue on appeal is whether Claiborne was in substantial compliance with 42 C.F.R. § 483.10(b)(11) and, if not, whether and for what period such noncompliance posed immediate jeopardy. Section 483.10(b)(11) concerns a facility's duty to consult with a resident's physician and to notify a family member of a significant change in a resident's condition.

Board precedent has established that a facility must prove by the preponderance of the evidence that it is in substantial compliance. Batavia Nursing and Convalescent Center, DAB No.

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[3] The current version of the Social Security Act can be found at www.ssa.gov/OP_Home/ssact/comp-ssa.htm. Each section of the Act on that website contains a reference to the corresponding United States Code chapter and section. Also, a cross reference table for the Act and the United States Code can be found at 42 U.S.C.A. Ch. 7, Disp Table.

1904 (2004), aff'd, Batavia Nursing & Convalescent Ctr. v. Thompson, 129 Fed.Appx. 181 (6th Cir. 2005). In order to put the facility to its proof, CMS must initially present a prima facie case of noncompliance with Medicare participation requirements. Once CMS has presented prima facie evidence as to any material disputed facts, the burden of proof shifts to the facility to show at the hearing that it is more likely than not that the facility was in substantial compliance.

Standard of review

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. Our standard of review on a disputed conclusion of law is whether the ALJ decision is erroneous. Guidelines for Appellate Review of Decisions of Administrative Law Judges Affecting a Provider's Participation in the Medicare and Medicaid Programs, www.hhs.gov/dab/guidelines/prov.html.

Substantial evidence is "more than a mere scintilla. It means such relevant evidence as a reasonable mind might accept as adequate to support a conclusion." Richardson v. Perales, 402 U.S. 389, 401 (1971), quoting Consolidated Edison Co. v. NLRB, 305 U.S. 197, 229 (1938). Under the substantial evidence standard, the reviewer must examine the record as a whole and take into account whatever in the record fairly detracts from the weight of the decision below. Universal Camera Corp. v. NLRB, 340 U.S. 474, 488 (1951).

Analysis

Claiborne challenges the ALJ's conclusions that it was not in substantial compliance with 42 C.F.R. § 483.10(b)(11) as found at both the August survey and the September revisit; that its noncompliance constituted immediate jeopardy during the period alleged by CMS; and that CMS was authorized to impose a denial of payment for new admissions. Claiborne asserts that it was in substantial compliance throughout, including with the regulatory requirements related to the noncompliance determinations that the ALJ did not address, and that the appropriate action for the Board to take, if it found the unaddressed determinations to be material, would be to remand to the ALJ for additional findings, or, in the alternative, to make such findings itself. P. Br. at 31-32.

1. Substantial evidence in the record as a whole supports the ALJ's conclusion that Claiborne was not in substantial compliance with 42 C.F.R. § 483.10(b)(11) (F Tag 157) at the August survey.

Section 483.10(b)(11) of 42 C.F.R. provides in pertinent part:

> *Notification of changes*. (i) A facility must immediately . . . consult with a resident's physician; and . . . notify . . . an interested family member when there is –
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> * * *
>
> (B) A significant change in the resident's physical, mental, or psycho-social status (i.e., a deterioration in health, mental, or psychosocial status in either life-threatening conditions or clinical complications).

The ALJ found that Claiborne was not in substantial compliance with this regulation based on its care of R4.[4]

The ALJ determined that R4 had suffered a "significant change" in his physical condition in the latter part of June and beginning of July as his food intake and weight declined. According to the ALJ, Claiborne was required under section 483.10(b)(11) immediately to consult with his physician about this change and to notify his family but failed to do so in a timely or adequate manner. As explained below, we conclude that the ALJ's findings are supported by substantial evidence in the record as whole and that his legal conclusions are without error.

The following facts about R4 are undisputed.

- R4 was admitted to Claiborne in September 2004 with diagnoses that included diabetes, dementia, and depression. He was dependent on Claiborne staff for all activities of daily living. He could not feed or hydrate himself. He could not chew solid food and had difficulty swallowing pureed food and thickened liquids.

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[4] For this deficiency, CMS also relied on findings related to R11. The ALJ did not review these findings because he concluded that CMS had not alleged that Claiborne's noncompliance as to R11 constituted immediate jeopardy. ALJ Decision at 4, n.3.

- Because of these conditions, Claiborne determined that he was at risk for malnutrition, dehydration, and weight loss. Thus, R4's care plan contained "several interventions to assure that the resident received adequate nutrition and fluids." ALJ Decision at 5. These included monitoring his intake by maintaining daily records of R4's consumption of food and fluids; spoon-feeding him all of his meals, which consisted of pureed food; and helping him to drink thickened liquids and providing nutritional supplements.

- On June 13, 2006, R4's weight was recorded as 135 pounds.

- In the later part of June and the first half of July, the R4's diet flow sheets indicate that R4's percentage of food intake decreased from the percentage recorded on the sheets for April, May and the beginning of June.

- On July 6 and July 13, his doctor visited him at Claiborne and discussed R4's condition with the staff on July 13.

- On July 18, R4 was weighed. His weight was recorded as 116.5 pounds, a loss of 18.5 pounds during this five-week period. The weight loss was reported to Claiborne's Dietary Manager, who then instructed staff to re-weigh R4.

- On the afternoon of July 19 and before he was re-weighed, the staff found R4 unresponsive and in respiratory distress. Claiborne then contacted his family and his doctor about his condition.

- R4 was immediately transferred to a hospital where his weight was recorded as 110 pounds. Early on July 20 he died.

The ALJ further found that R4's "appetite and consumption of food diminished sharply by mid-June." ALJ Decision at 5. The ALJ cited Claiborne's "diet flow sheet[s]" for June and July 2006, noting that "[i]n June, the resident consistently ate only a fraction of the food offered to him at dinner" and "[i]n July, the pattern of reduced consumption continued." Id., citing 07-31 CMS Ex. 4, at 12, 13; see also 07-31 CMS Ex. 4 at 9. This is a correct characterization of these sheets. For the 39 meals legibly recorded between June 1 and June 18, the June diet flow sheet reports that R4 ate 100% of 36 meals and never less than

75% of the three other reported meals. 07-31 CMS Ex. 4 at 12.[5] Beginning June 19 however, R4's consumption of supper declined dramatically (25% on the 19th, 45% on the 20th, 25% on the 21st, 45% on the 22nd, 20% on the 26th, 25% on the 27th, and 10% on the 28th, 29th, and 30th). Id. This pattern continues and worsens in July. Of the suppers recorded for July, R4 was reported to have eaten 30% of his supper on the 1st, 20% on the 2nd, 10% on the 5th, 100% on the 6th, 20% on the 8th, 20% on the 10th, 10% on the 11th, 12th, and 13th, and 20% on the 14th. Id. at 13. In addition by July 9, he is recorded as no longer reliably eating 100% of his breakfasts and lunches. Id. The drop off in his consumption pattern also contrasts sharply to the pattern reported in April and May in which he was almost consistently eating 100% of all meals. 07-31 CMS Ex. 4, at 11 (April); 07-31 P. Ex. 8, at 339. (May).

Finally, the ALJ relied on the testimony of Dr. Larry Johnson, M.D., a professor of geriatric medicine at the University of Arkansas. ALJ Decision at 6, citing 07-31 CMS Ex. 14. Dr. Johnson testified about the nutritional/hydration needs of elderly people and the dangers, including heightened vulnerability to infection, posed by malnutrition. 07-31 CMS Ex. 14, at ¶¶ 15-22. Dr. Johnson testified that inadequate intake posed a particular danger to R4, who had been evaluated by Claiborne as at risk for malnutrition. Id. at ¶¶ 32, 37-38. Dr. Johnson testified that R4's documented decrease in intake in June and July was "dramatic" (at ¶ 36) and "[b]y at least the end of June, it should have become apparent to the staff, based on the dietary flow records, that Resident 4 was most likely losing weight again" (Id. at ¶ 37).

Based on the undisputed facts, his finding that R4's food intake "diminished sharply" in June and July, and the testimony of the CMS expert, the ALJ concluded that R4 suffered a significant change in his intake and weight within the meaning of section 483.10(b)(11) prior to July 13, when Claiborne had a discussion with R4's doctor about his condition. ALJ Decision at 6.

Claiborne makes a number of arguments in support of its position that the ALJ erred by finding that R4 suffered a significant

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[5] Wherever possible, we cite the CMS exhibit copy of a Claiborne document because the poor quality of the reproduction of R4's records submitted by Claiborne makes them virtually unreadable. Compare 07-31 CMS Ex. 4, at 12 with 07-31 P. Ex. 8, at 340.

change prior to July 13 or 18. Below we consider Claiborne's arguments and explain why we reject them.

Claiborne's principal argument is that, prior to July 18, there was no significant change, i.e., decline, in R4's intake or weight in June and July. P. Br. at 8, 15; see also P. Reply at 2, 14. Claiborne represents:

> R4's eating habits or "loss of appetite" and weight was not a new phenomenon. The facility has always, since R4's admission, had difficulty getting him to consume foods and liquids. The records abundantly show that this was not abnormal for this resident, but was a common phenomenon for his ***entire*** stay at Claiborne.

Id. at 9 (emphasis in original); see also id. 9-12; P. Reply at 2 ("it was constant throughout R4's residence at Claiborne that his appetite and intake was poor"). Claiborne goes on to discuss the problems it had over the course of R4's residency maintaining his weight (P. Br. at 9-12) and concludes, "R4's consumption did not diminish sharply in mid-June 2006, as it had **never** been maintained consistently." Id. at 12 (emphasis in original).

The ALJ correctly rejected this argument. ALJ Decision at 8. While Claiborne's records show that it had difficulty feeding and hydrating R4, and that he lost significant weight after admission in 2004, they also show that the facility intervened with regular weighing and other actions to address his risk of malnutrition. The facility's records then show R4 regained weight and was stabilized at around 134 pounds over at least several months prior to the time at issue.[6] Specifically, while R4 had slipped to a low of 126.3 pounds as of January 4, 2006, by March 9 he weighed 134.5 pounds and stayed within two pounds of this weight

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[6] In November 2004, when R4 was admitted, he weighed 152.50 pounds. 07-31 CMS Ex. 4, at 40. In December 2004, R4 weighed 139.70 pounds; in January 2005 - 139.50 pounds; in February 2005 - 135 pounds; in March 2005 - 133.75; in April 2005 - 130.8 pounds (id.); on May 6, 2005 - 133.75 pounds; in June 2005 - 133.3 pounds (id. at 41); in October 2005 - 128.7 pounds; in November 2005 - 128.8 pounds; in December 2005 129.2 pounds (id. at 42); on January 4,2006 - 126.3; on January 24, 2006 – 132 pounds; on February 1, 2006 – 132.25 pounds, on February 20, 2006 - 131.6; on March 9, 2006 - 134.5 pounds; on April 6, 2006 – 133.1 pounds; on May 3, 2006 --135.25 pounds; on May 18, 2006 – 133 pounds; on May 31, 2006 – 135.7 pounds, and on June 13, 2006 - 135 pounds (07-31 CMS Ex. 4, at 8).

until June 13 at which time he weighed 135 pounds. 07-31 CMS Ex. 4, at 8. Further, his May and April diet flow sheets report that he ate 100% of the overwhelming majority of his recorded meals. 07-31 P. Ex. 8, at 338-339. Thus, for months prior to June 13, both R4's intake and weight had been steady.[7]

The fact that a resident has experienced a condition previously does not make the recurrence of the condition insignificant. Therefore, the fact that Claiborne had difficulty getting R4 to eat and drink, that his appetite had varied over his stay, and that he had had prior periods of weight loss did not absolve Claiborne from consulting with the doctor and notifying his family when his appetite again markedly declined in June and July. As the ALJ concluded, given R4's known vulnerability to malnutrition, if the staff was unable to reverse the decrease in intake documented in his June/July diet sheets, it should have treated the decline as a significant change and not "a mere decline in intake." ALJ Decision at 8.

Additionally, Claiborne argues that the documented decrease in intake as of June 19 did not cause a significant change in R4's weight. It asserts that "no significant weight loss was observed prior to July 18 because no significant weight loss happened before that date" (P. Reply at 14); and "there was no significant change in R4's condition until his body began evidencing signs of an acute systems failure on July 18 and 19" (P. Br. at 15; see also P. Br. at 13-14, 19).

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[7] Claiborne's schedule for weighing R4 confirms that it regarded his weight as of June 13 as stable. The SOD states that the Dietary Manager informed the surveyor as follows:

> [Claiborne's] policy for weight loss is weights every week after a significant weight loss, then bi-monthly for 2 months after adequate weight gain has been achieved, then if the weights remain stable for 2 months the Resident is only weighed every month thereafter.

07-31 CMS Ex. 1, at 3; see also 07-31 P. Ex. 24, at ¶ 6 (testimony of Dr. Kenneth Dodge (Claiborne's expert and R4's treating physician) that as of June 13, 2006 R4's "weight had remained stable for at least two months [prior to June 13]"); P. Br. at 14 (asserting that Claiborne was not required by its policy to weigh R4 more than monthly in June and July 2006 because his weight had been stable).

Claiborne relies on Dr. Dodge's and its staff's statements that R4 did not suffer significant weight loss prior to July 18. P. Br. at 13, citing P. Exs. 21, 22, 24, 26, 28. For the following reasons, the ALJ could reasonably decline to rely on these statements. First, the diet flow sheets documented a decline in intake, which Dr. Johnson stated was "likely" to result in weight loss. 07-31 CMS Ex. 14, at ¶ 37. Second, as explained below, there is no other credible explanation for R4's undisputed loss of some 18.5 pounds that was recorded on July 18. Third, the assertions that R4 suffered no visible weight loss prior to July 18 are controverted. As the ALJ pointed out, R4's daughter told a surveyor that she "noticed [R4's] weight loss about two weeks before [July 19] and brought it to staff's attention. According to this family member, the staff person to whom she spoke told her [R4] was fine."[8] ALJ Decision at 5, n.4.

Claiborne also relies on Dr. Dodge's affidavit as presenting an alternative explanation for the weight loss documented on July 18. In his declaration, Dr. Dodge explained the various stresses R4 experienced in June and July (such as shingles and infection

[8] Claiborne attempts to discredit the daughter's statement by arguing that she lived in another state and rarely visited. P. Reply at 14-15. Claiborne asserts that her last documented visit was February 16, 2006 and argues that nothing in the record shows "when [the daughter] had last seen R4, how much 'weight loss' she thought she noticed, or from what prior weight status that was based on." Id. These points do not make the ALJ's reliance on the daughter's statements error. Claiborne does not show that it had a practice of recording relatives' visits such that its assertion that its records last documented a visit by her in February 2006 in no way establishes that the daughter was not at the facility in July as she states. Furthermore, her failure to specifically estimate the amount of weight loss is not material; any observable weight loss supports the ALJ's finding that the loss occurred over the course of time between June 13 and July 18. Finally, the fact the record is not clear as to the "prior weight status" the daughter used as her frame of reference in July does not erode the credibility of the daughter's observation. Even assuming she observed R4 at his highest documented weight since February 16, 2006 (135.7 pounds on May 31), 135.7 pounds is only negligibly more than what he weighed on June 13 (135 pounds). Thus her observation as of the beginning of July supports the ALJ's finding that R4's weight was dropping beginning in mid-June, rather than plummeting in a single day.

of the scrotum and penis) and stated that, for a diabetic, such stresses --

> can result in previously well-controlled blood sugar level increasing rapidly and dramatically. This can result in diabetic ketoacidosis, which can also cause the kidneys to excrete additional fluids and exacerbate dehydration; this condition will often present with dehydration, respiratory distress, declining kidney function and impaired consciousness. These stresses apparently sent his previously well-controlled diabetes out of control, with suddenly increased glucose levels. This hyperglycemia likely caused significant volume depletion with loss of water weight (he was apparently seven liters, or 15.4 pounds, low from water loss, including diuresis from the diabetic ketoacidosis).

07-31 P. Ex. 24, at ¶ 14.

The ALJ found, as do we, Dr. Johnson's attribution of the weight loss to malnutrition more persuasive than Dr. Dodge's theory of precipitous weight loss due to ketoacidosis. ALJ Decision at 10. Claiborne's records show R4's glucose levels were recorded as normal on the afternoon of July 17. 07-31 P. Ex. 8, at 506. The nursing notes, however, reflect nothing remarkable about his condition on July 17 or 18. Thus, to adopt Claiborne's theory that the weight loss recorded on July 18 occurred precipitously as a result of a spike in R4's glucose level, the ALJ would have had to find that, in the short period between the afternoon of July 17 and the time he was weighed on July 18, R4's diabetes went out of control to the point that he lost as much as 18.5 pounds in water weight. R4 was dependent on staff for all activities of daily living; he was incontinent of bowel and bladder. 07-31 CMS Ex. 4, at 32. Therefore, it is not credible that R4 could lose such significant amounts of water weight in 24 hours without staff noticing and noting some symptoms related to fluid depletion.[9]

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[9] The Dietary Manager testified as to the facility's practice of checking for and documenting dehydration. She stated:

> [M]onitoring the resident for symptoms of dehydration is not documented in the nurse notes. Monitoring for dehydration includes a visualization of whether the resident has dry or cracked lips and/or poor skin

(continued...)

Claiborne attacks the ALJ's reliance on the CMS expert witness, Dr. Johnson. It points out that Dr. Johnson testified that "[b]y at least the end of June, it should have become apparent to the staff, based upon the dietary flow record, that Resident 4 was most likely losing weight again." P. Rely at 9 referring to 07-31 CMS Ex. 14, at ¶ 37. Claiborne focuses on the word "likely" and cites Cedar View Good Samaritan, DAB No. 1897 (2003), for the proposition that section 483.10(b)(11) "does not require a facility to notify the doctor or family of the possibility or even the likelihood that a resident's status has changed." It argues that Dr. Johnson's statement therefore does not provide a basis for finding noncompliance with that section. P. Reply at 9.[10]

We reject this argument for the following reasons. In Cedar View the facility conducted an investigation to determine whether residents had been sexually abused and found there was "no physical evidence of sexual abuse" and no "change in [mental] status from abuse or even from a perception that he or she was being abused or threatened with abuse." Cedar View at 21-22. The Board held that, in the absence of such evidence, the facility was not required by section 483.10(b)(11) to give notice to families because there had been no significant change in the residents' physical or mental status. Id. at 20-22. Here the overarching import of Dr. Johnson's testimony is that, for a compromised individual identified as at high risk of malnutrition as was R4, the documented decline in food intake was, by itself,

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[9](...continued)
turgor. I myself, as well as the staff, are constantly making rounds throughout the facility monitoring these patients. If no dry or cracked lips and/or poor skin turgor is noted with the resident, there is nothing noted in the nurses notes. On the other hand, if dry or cracked lips and/or poor skin turgor is noted, this is reflected in the nurses notes.

07-31 P. Ex. 26, at ¶ 16. Even accepting the testimony that dehydration symptoms were charted by exception as described, the ALJ could reasonably conclude that the absence of any record of such symptoms rendered implausible Claiborne's explanation that the weight loss occurred essentially overnight.

[10] We note that Claiborne's expert, Dr. Dodge, also used the qualifier "likely," stating that R4's "hyperglycemia likely caused a significant volume depletion . . . ." 07-31 P. Ex. 24, at ¶ 14.

evidence of a significant change. At a minimum, the change should have triggered an effort to determine if he was losing weight as was "likely," and, if so, to "figure out why Resident 4's consumption had reduced significantly, [and] implement on a consistent basis interventions to address this weight loss and reduction in consumption." 07-31 CMS Ex. 14, at ¶ 37. Unlike facility staff in Cedar View, Claiborne did not try to contemporaneously assess the cause or the effect of the decline in intake and rule out evidence that the lowered intake was affecting his weight. Claiborne has, therefore, no persuasive basis for asserting the change was not significant.

Claiborne argues that neither the ALJ nor CMS have pinpointed a single time or event that can be called the significant change requiring doctor consultation. P. Br. At 12; see also P. Reply at 2. The difficulty of doing so does not mean that Claiborne could simply stand by as R4 wasted away. Further, the difficulty is at least in part the effect of Claiborne's own inconsistent practices in monitoring and record keeping. Thus, Claiborne's failure to consistently record intake and failure to assess the recorded decline makes it impossible to determine the exact rate at which R4 was losing weight between June 13 and July 18, and thereby to pinpoint at what time the weight loss itself became significant. However, in view of the fact that R4 lost over 18 pounds in that period and in the absence of any other credible explanation for the loss, it was reasonable of the ALJ to rely on Dr. Johnson's testimony to find that R4's nutritional status had changed significantly at some point prior to July 13.

Claiborne repeatedly objects to the ALJ's and CMS's references to its staff's failure to consistently record R4's intake on his diet flow sheets. P. Br. at 8, n.4, at 11, n.6,at 17, n.10; P. Reply Br. at 5, 6-8, 13. It points out that there is no federal standard requiring such recording and that any failure to record is not a violation of section 483.10(b)(11). P. Br. at 8, n.4.

Claiborne's protests are of no consequence. First, Claiborne was required to complete the diet flow sheets because R4's care plan required it to "monitor and record daily intake" (07-31 CMS Ex. 4, at 62) and having and following a care plan, based on resident assessment, is a federal standard. Moreover, the monitoring and recording was adopted by the care team in furtherance of the care plan goal of "no significant weight change thru next review." Id. Consistently recording intake would have better enabled Claiborne to monitor R4's intake and to determine, on a timely basis, whether the staff needed to evaluate if he was losing weight again. Second, the ALJ did not treat Claiborne's failure to consistently record intake as a violation of section

483.10(b)(11). Rather, the ALJ referred to this failure because Claiborne asserted that R4 did not experience a significant change in his food intake and that his food intake was unrelated to the weight loss documented on July 18. The ALJ correctly observed that Claiborne's failure to comply with the care plan requirement made it "impossible to state with certainty exactly how much the resident consumed after mid-June 2006." ALJ Decision at 5.

Claiborne also points out that Dr. Johnson testified, "If R4 consumed the amount of food documented on the flow sheets, I do not think he would have lost 18 pounds in a little over one month." P. Br. at 17 referring to 07-31 CMS Ex. 14, at ¶ 38; P. Reply at 11. It argues that this statement shows that Dr. Johnson cannot explain R4's weight loss other than by suggesting that the daily flow sheets were inaccurate or that Claiborne's weighing processes were faulty. P. Br. at 17.

This argument does not provide a basis for concluding the ALJ erred in concluding that R4's decline in intake was significant. While Dr. Johnson states R4's recorded decline in intake would not have resulted in a loss of 18.5 pounds, he does not state that R4's expected weight loss from the intake recorded would have been insignificant. To the contrary, he clearly regards the intake decline as significant because he states that it should have prompted Claiborne, at that time, to weigh R4 prior to his scheduled weighing date and to assess the impact and cause of the decline. 07-31 CMS Ex. 14, at ¶ 37. It is evident that Dr. Johnson was dubious that all of the entries showing R4 eating all of a meal were actually reliable. The ALJ did not make any findings that the records were inaccurate, however, but simply concluded that even if R4 ate what was recorded, that amounted to a significant decline. Moreover, Claiborne failed to record intake for about 20% of meals in June and July. The fact that diet flow sheets are devoid of information as to what R4 ate on many days makes exact predictions about the impact of his consumption in June and July impossible. While the absence of this information is not a basis to infer R4 ate nothing on those days, neither is it is a basis for inferring that R4 ate everything on those days. We are therefore left with the facts that R4's recorded intake declined and he lost a tremendous amount of weight in a short time. The ALJ, in the absence of an alternative credible explanation, could reasonably find that the loss was primarily attributable to R4's decline in intake.

Claiborne asserts that Dr. Johnson did not review R4's Medication Administration Record (MAR), and consequently failed to take into account that R4 was receiving supplemental beverages. P. Reply

at 7, 11. This is incorrect. Dr. Johnson stated he reviewed CMS Exhibit 4. 07-31 CMS Ex. 14, at ¶ 7. CMS Exhibit 4 contains R4's MAR for July at pages 14-17. Page 16 records the administration (but not the amount consumed) of ProStat (a protein supplement) and sugar-free house shakes twice daily. Therefore, Claiborne's implication that Dr. Johnson's assessment of the inadequacy of R4's intake failed to consider the offering of those supplements is unsupported.

Claiborne argues that this decision creates an "ominous" standard for facilities because it makes any "decline in food intake consumption by any resident who is at risk for malnutrition" a significant change. P. Br. at 17, n.10, citing ALJ Decision at 8. Claiborne asks, "Should a facility consult a resident's physician every time he declines a meal? Eats only half his breakfast? 75%? Chooses not to eat dessert?" Id.

Nothing in the ALJ Decision, however, would require physician notification based on "any" decline in food intake. Only when the decline (and the inevitable accompanying weight loss) constitute a significant change under the regulation is notification required. The fact that some significant changes, like a decline in consumption or loss of weight, may not be marked by one "specific event" does not absolve a facility from monitoring a resident for daily events that cumulatively constitute or result in a significant change. Here, Claiborne adopted a care plan for R4 that called for daily recording and monitoring of food and fluid intake so that it could track whether R4 was receiving sufficient calories to prevent significant weight loss. It then failed, as Dr. Johnson observed, to address "marked decreases in Resident 4's consumption of supper" as documented on those sheets. 07-31 CMS Ex. 14, at ¶ 36. The ALJ determined that, at a minimum, prior to the time this decrease had persisted for over three weeks (i.e., before July 13), the decrease was a significant change under section 483.10(b)(11). Since substantial evidence in the record as a whole supports the ALJ's conclusion that a consultation with the doctor and notification of the family about this problem should have occurred (but did not) at least prior to July 13, it is not necessary to identify a particular day prior to July 13.

Moreover, even if one accepts Claiborne's characterization of its interaction with the doctor on July 13 as the consultation required by section 483.10(b)(11), Claiborne's failure to notify the family on the 13th was noncompliance with the regulation. Dr. Dodge testified:

> I was aware of this resident's declining condition, including his nutritional status and poor appetite. The nurses notes for this Resident indicated a decrease in appetite on July 10, 2006, and I examined him on July 13, 2006, and was informed of his recent course. I noted his condition and quality of life were both extremely poor at that time, and I felt that his condition was in its final decline. Since the family had repeatedly and steadfastly refused any more aggressive treatment, this resident was continued on antibiotics and monitored accordingly.

07-31 P. Ex. 24, at ¶ 10. Dr. Dodge goes on to say he determined that R4's clinical condition was such that "it was not possible at that stage for CHHC to continue to maintain his nutritional parameters (including weight and protein) or his hydration without a feeding tube."[11] Id. at ¶ 11. Having allegedly determined in conjunction with Dr. Dodge on July 13 that R4 was "in his final decline," Claiborne should have notified the family of this significant change. Indeed, the surveyor's notes indicate that Dr. Dodge asked staff to contact the family. The notes state that Dr. Dodge told the surveyor "I SAW HIM ON THE 13TH AND KNEW SOMETHING WAS NOT RIGHT – I KNEW HE WAS NOT EATING,

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[11] The issue of whether R4 should have had a feeding tube is raised regularly in R4's record and in Claiborne's briefing. P. Br. at 11, 16, 22; P. Reply at 7, 16, 18. In his testimony, Dr. Dodge states that, in November 2005, there was "a decline in [R4's] ability to tolerate being fed his meals" and –

> the family was first contacted about placing the resident on a feeding tube, but steadfastly refused. Repeated efforts were made over the following months to convince them of the necessity of a feeding tube, but they continued to insist they did not want one.

07-31 P. Ex. 24, at ¶ 5. As the ALJ observed, however, the family's refusal of this intervention –

> did not absolve Petitioner or its staff from taking other measures on the resident's behalf described in his plan of care nor did it relieve the staff of responsibility to notify the resident's family and consult with the resident's treating physician about the resident's anorexia and loss of weight.

ALJ Decision at 8, n.6.

DRINKING AS WELL, ETC., AND I ASKED THE FACILITY NURSE (JOANNE) TO CONTACT THE FAMILY ABOUT GETTING THE CODE STATUS CHANGED TO NO CODE." 07-31 CMS Ex. 9, at 4 (upper case in original).[12] Nothing in Dr. Dodge's testimony suggests that he had reached these conclusions any earlier than July 13, so, at a minimum, his observations that day clearly suggest that R4's condition had significantly changed.

As to a facility's responsibility where a resident is dying, Claiborne cites Park Manor Nursing Home, DAB No. 1926 (2004), in which the Board found a facility in substantial compliance with section 483.10(b)(11). P. Reply at 16. The circumstances in Park Manor were entirely different from the circumstances here. In Park Manor, the facility, the responsible family member, who was a nurse, and the doctor agreed that the resident was probably dying. The resident's care plan, in which the family member had participated, provided that the resident was "no code" (i.e., the resident did not want aggressive measures to prolong his life) and that he was to be provided "comfort measures" at the end of life. When the resident started with a urinary tract infection, the facility consulted the doctor twice on Friday and the family member and started an antibiotic; kept the family member advised of his continued deterioration over the weekend and at her visit on Sunday; and reported to the doctor again on Monday. The resident died on Tuesday. At the hearing, the family member testified that she felt that her uncle "received excellent care and was kept comfortable and allowed to die with dignity and that the facility had been diligent in keeping her informed about his status." Park Manor, DAB No. 1926, at 5. This fact pattern contrasts sharply with the situation here, in which R4 was "full code" (07-31 CMS Ex. 4, at 7) and in which Claiborne failed to consult with Dr. Dodge about R4's intake decline until July 13 and then failed to notify the family that it and Dr. Dodge had then determined that R4 was "in his final decline." Moreover, while R4's family had declined a feeding tube in the past, that does not necessarily mean that they would have continued to do so once Dr. Dodge determined (as he said he did on July 13) that "it was not possible at that stage for CHHC to continue to maintain his nutritional parameters . . . without a feeding tube." 07-31 P. Ex. 24, at ¶ 11. Furthermore, the resident's right to have

[12] We note that Dr. Dodge testified that he "had an opportunity to review and am familiar with CMS's survey, as well as CMS's report and exhibits . . . ." (07-31 P. Ex. 24, at ¶ 2) and did not deny the statement the surveyor attributed to him in her notes.

his family notified of the significant change exists regardless of what the response of the family may be. Id. at ¶ 10.

Claiborne also cites Beverly Health and Rehabilitation – Spring Hill, DAB No. 1696 (1999), aff'd sub nom. Beverly Health and Rehabilitation Services, Inc. v. Thompson, 223 F. Supp. 2d 73 (D.D.C. 2002). P. Reply at 20. In that case, the Board upheld the ALJ's determination that the facility was not required to notify a resident's doctor about a weight loss recorded on one particular day. The ALJ had found that "the weight loss recorded on April 8th was part of an ongoing decline . . . which had been observed by the physician and as to which the facility and the physician had been attempting numerous assessments and interventions in an attempt to maintain nutrition and hydration." Beverly Health, at 40. In contrast here, the ALJ found that the intake decline and weight loss were a change from a prior period of higher intake and higher weight levels. ALJ Decision at 5-6.

Finally, even when Claiborne learned on July 18 that R4 had lost 18.5 pounds (an amount Claiborne admits was a significant change), Claiborne identifies to no evidence (and we see none) that it consulted the doctor or contacted the family "immediately" as required by the regulation. Claiborne cites nursing notes at Petitioner Exhibit 8, at 209 as proof that it contacted the doctor and family on the 18th. P. Br. at 21; see also P. Br. at 2, 5; P. Reply at 20. None of the nursing notes for R4 for July 18 memorialize any contact with or attempt to contact Dr. Dodge or the family even at this late date.[13] Indeed, the notes indicate that staff did not contact the doctor or the family until July 19 when R4 was found in respiratory distress and unresponsive.

For the preceding reasons, we conclude that the ALJ's findings of fact are supported by substantial evidence in the record as a whole and that his conclusion that Claiborne was not in substantial compliance with 42 C.F.R. § 483.10(b)(11) is without error.

2. The ALJ did not err in concluding that CMS's finding that Claiborne's noncompliance posed immediate jeopardy from July 18 through September 4, 2006 was not clearly erroneous; that CMS had the authority to impose a per-day CMP of $3,050 during that

[13] Petitioner Exhibit 8, at 209, is a page of nursing notes for July 18. (A more legible copy is found at CMS Exhibit 4, at 33; other nursing notes for July 18 are found at CMS Exhibit 4, at 32.)

period; and that CMS had the authority to impose a DPNA from August 20 through September 4, 2006.

"Immediate jeopardy" is defined by 42 C.F.R. § 488.301 as a situation in which a provider's noncompliance "has caused, or is likely to cause, serious injury, harm, impairment, or death to a resident." CMS's determination that a deficiency constitutes immediate jeopardy must be upheld unless it is clearly erroneous. 42 C.F.R. § 498.60(c); see also Beverly Health Care Lumberton, DAB No. 2156, at 4 (2008), citing Woodstock Care Center, DAB No. 1726, at 39 (2000), aff'd, Woodstock Care Ctr. v. Thompson. The Board has held that section 498.60(c) "places the burden on the SNF [skilled nursing facility] – a heavy burden, in fact – to upset CMS's finding regarding the level of noncompliance." Liberty Commons Nursing & Rehab Center v. Johnston, DAB No. 2031, at 18 (2006), aff'd, Liberty Commons Nursing and Rehab Center – Johnston v. Leavitt, 241 Fed.Appx. 76 (4th Cir. 2007), quoting (with emphasis in original) Barbourville Nursing Home, DAB No. 1962 (2005), aff'd, Barbourville Nursing Home v. U.S. Dep't of Health & Human Servs., No. 05-3241 (6th Cir. April 6, 2006).

The ALJ concluded that Claiborne had not met this burden and upheld CMS's finding that immediate jeopardy existed from July 18 through September 4, 2006 and CMS's imposition of a per-day CMP of $3,050 (the minimum allowed for a per-day immediate jeopardy CMP). ALJ Decision at 10-12. Claiborne takes the position that there was no immediate jeopardy, and if there were, it was limited to R4 and ended with his death on July 20, 2006. P. Br. at 72-75. Claiborne also argues that CMS should have imposed a per-instance CMP rather than a per-day CMP. Id. at 76.

Claiborne first argues that the ALJ erred because the evidence in the record "establishes the fact that R4 had no significant change in June and July outside his condition for the prior two years . . . ." P. Br. at 73. Hence, according to Claiborne, no immediate jeopardy could exist because no violation of the regulations occurred. As discussed above, the ALJ properly rejected this argument in determining that Claiborne did not substantially comply with section 483.83(b)(11).

Claiborne argues also that "R4's condition was not due to any alleged failure by Claiborne's staff to monitor and care for R4." Id. This argument is unrelated to the deficiency at issue. Section 483.10(b)(11) looks to whether a resident suffered a significant change and whether a facility immediately consulted with his doctor and notified his family. Section 483.10(b)(11) does not look to whether the significant change is the fault of the facility. To the extent that the ALJ's discussion of

immediate jeopardy indicates that he believed R1's weight loss was attributable to the quality of care R1 received from Claiborne, we do not rely on those statements because the ALJ did not review the quality of care deficiency citations, i.e., Tag 325 (42 C.F.R. § 483.25(i)(1) involving nutrition) and Tag 327 (42 C.F.R. § 483.25(j) involving hydration).

Claiborne argues that R4's condition "was not due to any failure to substantially comply with [section 483.10(b)(11)]." Id. This argument misconstrues the requirements of section 488.301. Under section 488.301, CMS is not required to show that a facility's noncompliance caused "serious injury, harm, impairment, or death to a resident." Rather, CMS's determination must be upheld if, at a minimum, it is not clearly erroneous to conclude that the noncompliance was "likely to cause" such harm. As the ALJ pointed out, "It is not possible to say now whether more timely intervention by Petitioner's staff, including consulting the resident's physician early in the process of the resident's anorexia and weight loss, would have prolonged the resident's life." ALJ Decision at 11. As the ALJ found, however, it was not clearly erroneous for CMS to conclude that a decline in intake and weight loss for a resident at risk for malnutrition creates a likely risk of serious harm for the facility's residents and that failure to timely consult with a doctor contributes to this risk. Moreover, as the ALJ observed, Claiborne's apparent inattentiveness, as exemplified by its lack of awareness and response to the changes in R4's condition, potentially put other residents at risk of serious harm.

Claiborne also disputes the ALJ's conclusion that it failed to prove that it had corrected this deficiency and abated the immediate jeopardy before September 4, 2006. P. Br. at 73. It argues that any immediate jeopardy ended with R4's death on July 20. Id.

We reject this argument. One of CMS's concerns in these surveys was whether Claiborne staff understood what constitutes a significant change (particularly in regard to residents at risk for malnourishment and dehydration) and when staff were required to consult with a doctor or notify a family. The events involving R4 serve to illustrate the dangers facing any resident assessed as being at risk for malnutrition and whose food and liquid consumption drops off substantially or whose weight declines dramatically because the facility staff could not be relied upon to consult their physicians or notify their families immediately. This is a broader concern than the individual care of R4 and hence did not evaporate with his death. As Claiborne's

plan of correction (POC) states: "all residents are potentially affected by communication practices." 07-31 CMS Ex. 11, at 3.

Additionally, Claiborne fails to cite to any evidence in the record in support of its assertion that it abated the immediate jeopardy at any point prior to September 4, 2006. Moreover, Claiborne's POC indicates that Claiborne had not performed all of the actions listed for correcting this deficiency until at least September 5, 2006. For example, the POC states that Claiborne conducted "[m]ultiple in-services, including those on 8-11-06, 9-2-06, and 9-5-06, . . . on the facilities policies for notification of the physicians and family/LR of changes or decline in Residents' medical condition." 07-31 CMS Ex. 11, at 3. Also, the POC indicates the "completion date" for correcting the section 483.10(b)(11) deficiency was "9-5-06." Id. at 4. Since we find that R4's death alone did not necessarily remove the immediate jeopardy, and since Claiborne offered no persuasive argument proving abatement of the immediate jeopardy at a date earlier than correction of the noncompliance, we agree with the ALJ in upholding the determination that immediate jeopardy continued until September 5, 2006.

Finally, Claiborne argues that "any penalty imposed should have been only a single per-instance CMP, not the ongoing CMP imposed by CMS. P. Br. at 76. We reject this argument for the following reasons. First, Claiborne did not make this argument before the ALJ. Second, even if Claiborne did not make this argument because it did not anticipate the ALJ's circumscribed review of the cited deficiencies, prior Board cases have raised the question whether CMS's selection of a per-day CMP is a purely discretionary decision, not subject to review. See Spring Meadows Health Care Center, DAB No. 1966 (2005); Florence Park Care Center, DAB No. 1931 (2004). Claiborne offered no basis for concluding that an ALJ (or the Board) has the authority to review CMS's choice of a per-day CMP. Third, as discussed above, the staff's failure to understand the need to contact a doctor and family about a significant change in a resident's condition created jeopardy for other residents, not just R4.

Therefore, we conclude the ALJ did not err in upholding CMS's determination of immediate jeopardy and the duration of the immediate jeopardy. We affirm FFCL 2, 3, and 6.a.

3. The ALJ erred in concluding that Claiborne was noncompliant with section 483.10(b)(11) for failing to notify R1's doctor about an August 25, 2006 laboratory result.

In FFCL 4, the ALJ concluded that "[a]s of the September survey [Claiborne] failed to comply substantially with the requirements of section 483.10(b)(11)." ALJ Decision at 12. The ALJ based this deficiency finding on Claiborne's care of R1 after receiving an August 25, 2006 laboratory report that R1's Depakote level was 29.0 mcg/mL. The ALJ found that this Depakote level was sub-therapeutic. ALJ Decision at 13. He concluded that the level therefore represented a significant change in R1's condition and that Claiborne was required to consult immediately with R1's doctor but failed to do so.

We reverse this FFCL for two reasons, which we discuss below after providing relevant background information. First, Claiborne did not have adequate notice that its handling of the August 25, 2006 laboratory report was at issue in this deficiency finding. Second, even if Claiborne had had adequate notice, the record as a whole indicates that Claiborne did consult with R1's doctor on August 25 about R1's Depakote level. CMS points to no evidence (and we see none) that would support a contrary finding.

R1 was a 77 year-old woman with multiple complex medical problems including schizophrenia, diffuse cerebral atrophy, pancreatitis, anemia, Type II diabetes, congestive heart failure, hypertension, digestive neoplasm, and carcinoma of the colon. 07-111 P. Ex. 5, at ¶ 4. R1 also had a history of seizure disorder. Her doctor, Dr. Robert Hollister, had prescribed two medicines to control her seizures: Depakote and Dilantin. Id.

According to Dr. Hollister, "[d]uring the summer of 2006, . . . Resident #1 began experiencing difficulty obtaining therapeutic levels with seizure medications." Id. at ¶ 6. This difficulty coincided with other problems she was experiencing at that time including "renal failure and colon cancer which complicated issues related to her food and fluid intake, [and] absorption of her medications . . . ." Id. at ¶ 5. Dr. Hollister ordered repeated changes to her Depakote dosage. Id. at ¶ 6. On August 17, he ordered "Depakote and Dilantin level 8/18/06 and Q week," meaning he wanted her Depakote and Dilantin levels tested the next day and every week thereafter. 07-111 P. Ex. 13, at 10. Claiborne then tested R1's Depakote level on August 18, 25, 30, and September 5. 07-111 P. Ex. 13, at 56, 58, 62 and 63. All of the values for these tests were under 50 mcg/mL but showed a

gradually rising trend in the level of Depakote in her blood.[14] Id.

In the SOD, CMS alleged the following facts as grounds for this deficiency:

> Review of the laboratory values dated 8-25-06 revealed a Depakote level of 29.0 (Normal Range (NR) 50-10) and a Dilantin level of 10.9 (NR 10-20). Further review revealed another Depakote level was drawn on 9-5-06 . . . with a level that continued to be low at 44. Also noted was the lab report was received by FAX (facsimile) at the facility on 9-5-06 at 1617 (4:17 PM). Interviews on 9-6-06 at 4:40 AM with the 2nd Floor 11:00 PM to 7:00 AM Charge Nurse revealed the Charge Nurse was not aware that the abnormal lab value had been received. Interview further revealed the Charge Nurse stated "If the report has been called to the Physician the nurse would date and initial the bottom right of the report to show that it had been called to the Physician." Observation of the lab report revealed no date or nurses initial to indicate the Physician had been notified of the low Depakote level.

07-111 CMS Ex. 1, at 2-3.

Before the ALJ, Claiborne did not dispute that it failed to contact R1's doctor on September 5 about the September 5 report. Rather, it argued that the normal therapeutic range (50-100 mcg/mL) for Depakote, on which CMS relied, did not apply to R1; that a Depakote value of 44 mcg/mL did not represent a significant change in R1's condition; and that, therefore, it was not required by section 483.10(b)(11) to consult with R1's doctor on September 5.

In support of its assertions about the use of Depakote to treat R1's seizures, Claiborne relied on the written testimony of an expert witness, R1's doctor. Dr. Hollister stated that "the appropriate dose [of Depakote] is the lowest dose that stops all seizures with the fewest adverse effects regardless of blood drug level." 07-111 P. Ex. 5, at ¶ 8. Dr. Hollister agreed that the standard therapeutic range for Depakote is 50-100 mcg/mL but stated that this range is based on younger patients. Id. He

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[14] The laboratory reports indicate that the normal therapeutic range for Depakote is 50 - 100 mcg/mL. See 07-111 P. Ex. 13, at 56.

explained that, since older people metabolize the drug more slowly, they are more susceptible to side effects and, therefore, "therapeutic levels are generally considered to be lower in elderly patients." Id. Second, Dr. Hollister stated that managing R1's seizure required the use of a second anti-convulsant (Dilantin), which could alter her response to the Depakote. Id. at ¶ 6. Dr. Hollister testified that, based on these factors and R1's other complex medical conditions, he believed that R1's therapeutic range for Depakote was lower than the normal 50-100 mcg/mL range. He stated as follows:

> 10. . . . . [R1's] Depakote level on August 18 was 26.2, on August 25 it was 29.0, and on August 30 it was 35.0. . . . Her Dilantin remained within the normal range on all these checkups as well. I was made aware of all of these results, and noting that the patient remained seizure-free throughout this time, determined no new orders or dosage changes were required at that time.
>
> 11. Resident #1 then experienced another seizure on September 2, 2006. I was immediately informed and ordered another increase in her Depakote dosage. Three days later, her blood levels were tested again, and her Depakote level was 44.0. While still below the "normal" range, this was the highest level she had evidenced in over four months, and as there were no seizures or adverse effect corresponding to that blood level being manifested at the time, this did not constitute a significant change, and certainly not a deterioration in Resident #1's health, that would require my immediate notification.

07-111 P. Ex. 5, at ¶¶ 10-11.

CMS proffered no expert testimony about the use of Depakote. CMS did not point to any evidence contradicting Dr. Hollister's assertions about the management of Depakote in elderly patients who are also taking Dilantin. Indeed, CMS's submissions about Depakote support Dr. Hollister's testimony. For example, the Physician Desk Reference submitted by CMS states that "[i]f Depakote is taken with certain other drugs [such as Dilantin] the effects of either could be increased, decreased, or altered." 07-111 CMS Ex. 20, 4. An article from Clinical Geriatrics states that "there are problems in utilizing the published serum [blood] level ranges for antiepileptic medications, because these levels are based on younger patients." 07-111 CMS Ex. 18, at 7. CMS's submission from www.epilepsy.com states: "A therapeutic blood level of [Depakote] is generally considered to be 50-100 mcg/mL

(lower for seniors), but adjustments should depend on clinical response." 07-111 CMS Ex. 22, at 3.

The ALJ did not reject Dr. Hollister's testimony stating that R1's therapeutic range for Depakote was lower than the normal range and that the 44 mcg/mL on September 5 did not represent a significant change. Rather, he found that the August 25 value of 29 mcg/ML was "sub-therapeutic by any measure" and a significant change that required immediate consultation.[15] The ALJ faulted Claiborne because it "focuses entirely on the September 5 test result . . . . [but] says nothing about the failure by Petitioner's staff to consult with Dr. Hollister about the resident's Depakote level of 29.0 recorded on August 25, 2006." ALJ Decision at 13.

The ALJ's reliance on the August 25 report as the factual basis for this deficiency is error because Claiborne was given no notice that its handling of the August 25 report was at issue. In the SOD, CMS did not rely on the August 25 report as a basis for finding a deficiency under section 483.10(b)(11). 07-111 CMS Ex. 1, at 1-3. In its briefing before the ALJ on this deficiency, CMS discussed Claiborne's failure to immediately consult with the doctor about the September 5, 2006 report but did not assert that Claiborne failed to timely consult with the doctor on August 25. 07-111 CMS Br. at 2-4; 07-31 CMS Br. (in lieu of hearing) at 37-39.[16] Finally, we see nothing in the ALJ's development of the case that indicated to Claiborne that the therapeutic value of R1's August 25 Depakote level or the facility's consultation (or lack thereof) with her doctor on August 25 was at issue. Therefore, the ALJ could not rely on the August 25 report as the basis for this deficiency finding.

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[15] We not need to the reach the question of whether the 29.0 mcg/mL level was sub-therapeutic for R1. We note that the ALJ cited no evidence in support of his statement that it was "sub-therapeutic by any measure."

[16] The ALJ also stated that Claiborne "does not deny that its staff failed to consult with Resident #1's treating physician about the resident's August 25 . . . Depakote levels." ALJ Decision at 13. As discussed herein, Claiborne did submit proof that it consulted with Dr. Hollister about the August reports generally. 07-111 P. Ex. 5, at 10. However, CMS never alleged that Claiborne's staff failed to consult with Dr. Hollister about the August 25 report, and Claiborne had no reason to deny a nonexistent allegation.

Further, the undisputed evidence shows that Claiborne did immediately consult with Dr. Hollister about the August 25 value. Claiborne submitted many Depakote laboratory reports for R1. See 07-111 Ex. 13, at 42-64.[17] The printed portion of the August 25 laboratory report reflects the following: the blood was drawn August 25, the results were faxed to Claiborne at 2:22 P.M. that day, the Depakote value was 29.0; the Dilantin value was in the normal range. 07-111 P. Ex. 13, at 58. The handwritten notes on the laboratory report state "nofed HO 8/25/06" and "cont same dosage." Id. The "nofed" note is in the bottom right of the report; the dosage note is in the bottom middle of the report. The surveyor stated in the SOD that the Charge Nurse had told her that "[i]f the report has been called to the Physician the nurse would date and initial the bottom right of the report to show that it had been called to the Physician." 07-111 CMS Ex. 1, at 3. Thus, the handwritten notes on the August 25 report indicate that Dr. Hollister was "notified" about the Depakote value on August 25 and that he instructed Claiborne to continue R1's present Depakote dosage.[18] Additionally, the August 25 laboratory report, like all the others in the record, bears Dr. Hollister's handwritten initials, reflecting that he also reviewed the report when he was in the facility.[19]

Therefore, we reverse FFCL 4 and adopt the following substitute FFCL:

> 4. Substantial evidence in the record as a whole does not support findings on which to conclude that, as of the

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[17] CMS did not submit the August 25 or September 5 laboratory reports as part of its proof, based on our inspection of the record,

[18] We note that many of the laboratory reports in the record have a similar bottom right-hand notation reflecting that they were called in to Dr. Hollister. See, e.g., 07-111 P. Ex. 5, at 50, 51, 53-58.

[19] Dr. Hollister told the surveyors that he looked at all laboratory reports once a week. 07-111 CMS Ex. 4, at 8. In his written testimony, Dr. Hollister also stated that he "was made aware of all of [R1's Depakote results in August]." 07-111 P. Ex. 5, at ¶ 10. This testimony by Dr. Hollister undercuts the ALJ's conclusion that weekly blood checks "would be a meaningless exercise" unless all results were communicated "immediately" to the physician. Cf. ALJ Decision at 14.

> September survey, Claiborne failed to substantially comply with 42 C.F.R. § 483.10(b)(11) in its care of R1.

In FFCL 6.b the ALJ found that CMS had the authority to impose a per-day CMP of $100 from September 5 through September 17, 2000. ALJ Decision at 15. In FFCL 6.c the ALJ found CMS had the authority to impose a DPNA from August 20 through September 17, 2006. Claiborne challenged the basis of the per-day CMP and the imposition of the DPNA. Since CMS's authority to impose these remedies beyond September 4, 2006 rests on whether Claiborne failed to substantially comply with any participation requirement after September 4, we vacate FFCL 6.b and modify FFCL 6.c as follows:

> CMS has discretion to deny Petitioner's payment for new admissions during the period that began on August 20 and which continued through September 4, 2006.

4. Because the August survey set forth deficiency findings under two additional tags for the period September 5 through September 17, 2006, we remand this case to the ALJ.

The state survey agency concluded that Claiborne was not in substantial compliance with two additional performance standards (42 C.F.R. § 483.15(g)(1) (Tag 250) and 42 C.F.R. § 483.25(j) (Tag 327)). 07-111 CMS Ex. 1. Since the ALJ did not address these deficiency findings and since they may provide a basis for sustaining the remedies that CMS imposed from September 5 through September 17, 2007, we remand the case to the ALJ. He should review whether Claiborne was deficient during the period September 5 through September 17 and, hence, whether CMS had the authority to impose the CMP and DPNA during this period.

The ALJ may also review on remand any of the six deficiencies cited in the August 2006 that he did not reach in his previous decision.

Conclusion

For the reasons explained above, we remand this case to the ALJ for further proceedings consistent with our decision.

/s/
Judith A. Ballard

/s/
Constance B. Tobias

/s/
Leslie A. Sussan
Presiding Board Member