Department of Health and Human Services

DEPARTMENTAL APPEALS BOARD

Civil Remedies Division

In the Case of:	)	
	)	
Universal Healthcare/King,	)	Date: May 6, 2008
(CCN: 34-5449),	)	
	)	
Petitioner,	)	
	)	
- v. -	)	Docket No. C-06-227
	)	Decision No. CR1784
Centers for Medicare & Medicaid	)	
Services.	)	
	)	

DECISION

I sustain the imposition by the Centers for Medicare & Medicaid Services (CMS) of remedies against Petitioner, Universal Healthcare/King (Petitioner or facility) consisting of the following civil money penalties (CMPs):

- $4,000 per day for the period of immediate jeopardy, which ran from November 3, 2005 through December 9, 2005; and

- $300 per day for the period of noncompliance that was not immediate jeopardy, which ran from December 10, 2005 through January 26, 2006.

I. Background

Petitioner is a skilled nursing facility in King, North Carolina. It participates in the Medicare program. Its participation in that program is governed by sections 1866 and 1819 of the Social Security Act (Act). It is also governed by regulations at 42 C.F.R. Parts 483 and 488.

Petitioner was surveyed by the North Carolina State Survey Agency (State survey agency) for compliance with Medicare participation requirements in a complaint survey that ended on November 22, 2005 (November survey). The surveyors found that Petitioner had failed to comply substantially with two participation requirements, 42 C.F.R. § 483.25 (Tag F309) and 42 C.F.R. § 483.60(a) (Tag F426), with respect to one of the residents, "Resident 1." The surveyors cited both violations at the "G" level of scope and severity, which indicated an isolated occurrence involving actual harm that does not amount to immediate jeopardy.

On December 16, 2005, CMS sent a notice letter to Petitioner advising that, as a result of the deficiencies found at the November survey, CMS was imposing a CMP in the amount of $250 per day effective November 22, 2005, as well as other remedies that are not at issue in this appeal. P. Ex. 3; *see* P. Br. at 2.

The surveyors conducted another survey of Petitioner that ended on December 10, 2005 (December survey). They found that Petitioner was not in substantial compliance with three participation requirements, 42 C.F.R. § 483.10(b)(11) (Tag F157), 42 C.F.R. § 483.13(c) (Tag F224), and 42 C.F.R. § 483.25 (Tag F309), with respect to another resident who was also identified as "Resident 1." I note that this resident is not the same "Resident 1" who was at issue in the November survey. The surveyors cited these three violations at the "J" level of scope and severity, which indicated an isolated occurrence that constituted immediate jeopardy to resident health or safety.

Following the December survey, CMS sent Petitioner a notice letter dated December 29, 2005. In this notice, CMS advised Petitioner that it was imposing a CMP in the amount of $4000 per day effective November 3, 2005 through December 9, 2005, and a CMP in the amount of $300 per day effective December 10, 2005. CMS advised Petitioner that it would be disqualified from operating a nurse aide training and competency evaluation program (NATCEP) for two years as a result of CMS's finding that Petitioner's noncompliance constituted substandard quality of care. CMS's notice imposed other additional remedies, which are not at issue here. P. Ex. 4; *see* P. Br. at 3.

On January 26, 2006, the State survey agency conducted a recertification and revisit survey of Petitioner. CMS sent Petitioner a notice letter dated February 10, 2006, which advised Petitioner that it was in substantial compliance with participation requirements, effective January 26, 2006. P. Ex. 5. However, CMS then sent Petitioner a notice letter dated February 13, 2006, which was meant to be an "amended letter" to the February 10,

2006 notice. P. Ex. 6. In this notice, CMS stated that the January 26, 2006 revisit survey revealed that Petitioner continued to be out of substantial compliance, and was reducing the CMP to $50 per day effective January 26, 2006. P. Ex. 6.[1]

Petitioner requested a hearing, and the case was assigned to me for a hearing and a decision. I held a hearing on April 24-25, 2007, in Greensboro, North Carolina. At the hearing, I received exhibits into evidence consisting of CMS Exhibits (CMS Exs.) 1-12, and 14-16, and Petitioner's Exhibits (P. Exs.) 1-46.[2] Sharon Myers and Manay Gunter testified on behalf of CMS. Elizabeth Lancaster, Dr. Richard Aronson, Dr. Sam Newsome, Annette O'Brien, and Dr. Stephen South testified on behalf of Petitioner. CMS and Petitioner submitted posthearing briefs (CMS Brief and P. Brief, respectively) and reply briefs (CMS Reply and P. Reply, respectively).

II. Issues

The issues in this case are:

- Whether there is a basis for the imposition of an enforcement remedy;
- whether CMS's finding of immediate jeopardy is clearly erroneous, and;

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[1] In its posthearing brief, Petitioner stated "[s]ince Petitioner has not appealed the deficiencies cited following the January 26, 2006 annual survey, or the relatively small CMP imposed as a result, the inconsistency in CMS' Notices does not seem to be material to this appeal." P. Br. at 3-4 n.3. Consequently, there is no dispute that the end date of the CMP at issue in this case is January 26, 2006.

On March 14, 2006, the State survey agency conducted a second revisit survey of Petitioner. On March 21, 2006, CMS sent Petitioner another notice letter, which provided that, as a result of the March 14, 2006 survey, it was increasing the CMP to $100 per day effective March 14, 2006. P. Ex. 7. This survey is not at issue, and I do not discuss it in this decision.

[2] CMS withdrew its proposed Ex. 13. Transcript (Tr.) 2.

- whether the remedies imposed, a CMP of $4,000 per day for the period of immediate jeopardy, November 3, 2005 through December 9, 2005, and a CMP of $300 per day for December 10, 2005 through January 26, 2006, are reasonable.

III. Applicable Law

Petitioner is a long-term care facility participating in the federal Medicare program as a skilled nursing facility and in the state Medicaid program as a nursing facility. The statutory and regulatory requirements for participation by a long-term care facility are found at sections 1819 and 1919 of the Act and at 42 C.F.R. Part 483. Sections 1819 and 1919 of the Act vest the Secretary of Health and Human Services (Secretary) with authority to impose CMPs against a long-term care facility for failure to comply substantially with federal participation requirements.

Pursuant to the Act, the Secretary has delegated to CMS and the states the authority to impose remedies against a long-term care facility that is not complying substantially with federal participation requirements. Facilities that participate in Medicare may be surveyed, on behalf of CMS, by state survey agencies in order to determine whether the facilities are complying with federal participation requirements. 42 C.F.R. §§ 488.10-488.28, 488.300-488.335. Pursuant to 42 C.F.R. Part 488, CMS may impose a per instance or per day CMP against a long-term care facility when a state survey agency concludes that the facility is not complying substantially with federal participation requirements. 42 C.F.R. §§ 488.406; 488.408; 488.430.

The regulations at 42 C.F.R. Part 488 also give CMS a number of other remedies that can be imposed if a facility is not in compliance with Medicare requirements. *Id.* Pursuant to 42 C.F.R. § 488.301, "*(i)mmediate jeopardy* means a situation in which the provider's noncompliance with one or more requirements of participation has caused, or is likely to cause, serious injury, harm, impairment, or death to a resident." (Emphasis in original). Further, "*(s)ubstantial compliance* means a level of compliance with the requirements of participation such that any identified deficiencies pose no greater risk to resident health or safety than the potential for causing minimal harm." *Id.* (emphasis in original).

The regulations specify that a CMP, which is imposed against a facility on a per day basis, will fall into one of two ranges of penalties. 42 C.F.R. §§ 488.408, 488.438. The upper range of CMP, from $3,050 per day to $10,000 per day, is reserved for deficiencies that constitute immediate jeopardy to a facility's residents, and in some circumstances, for

repeated deficiencies. 42 C.F.R. §§ 488.438(a)(1)(i), (d)(2). The lower range of CMP, from $50 per day to $3,000 per day, is reserved for deficiencies that do not constitute immediate jeopardy, but either cause actual harm to residents, or cause no actual harm, but have the potential for causing more than minimal harm. 42 C.F.R. § 488.438(a)(1)(ii).

The Act and regulations make a hearing before an administrative law judge (ALJ) available to a long-term care facility against whom CMS has determined to impose a CMP. Act, section 1128A(c)(2); 42 C.F.R. §§ 488.408(g), 498.3(b)(13). The hearing before an ALJ is a *de novo* proceeding. *Anesthesiologists Affiliated, et al.*, DAB CR65 (1990), *aff'd*, 941 F.2d 678 (8th Cir. 1991). A facility has a right to appeal a "certification of noncompliance leading to an enforcement remedy." 42 C.F.R. § 488.408(g)(1); *see also,* 42 C.F.R. §§ 488.330(e), 498.3. However, the choice of remedies by CMS or the factors CMS considered when choosing remedies are not subject to review. 42 C.F.R. § 488.408(g)(2). A facility may only challenge the scope and severity level of noncompliance found by CMS if a successful challenge would affect the amount of the CMP that could be collected by CMS or impact upon the facility's nurse aide training program. 42 C.F.R. §§ 498.3(b)(14), (d)(10)(i).

CMS's determination as to the level of noncompliance "must be upheld unless it is clearly erroneous." 42 C.F.R. § 498.60(c)(2). This includes CMS's finding of immediate jeopardy. *Woodstock Care Center*, DAB No. 1726, at 9, 38 (2000), *aff'd, Woodstock Care Center v. Thompson*, 363 F.3d 583 (6th Cir. 2003). The Departmental Appeals Board (the Board) has long held that the net effect of the regulations is that a provider has no right to challenge the scope and severity level assigned to a noncompliance finding, except in the situation where that finding was the basis for an immediate jeopardy determination. *See, e.g.*, *Ridge Terrace*, DAB No. 1834 (2002); *Koester Pavilion*, DAB No. 1750 (2000). Review of a CMP by an ALJ is governed by 42 C.F.R. § 488.438(e).

The Act prohibits approval of a NATCEP at any facility participating in the Medicare program "which, within the previous 2 years – . . . has been subject to an extended (or partial extended) survey," which would be triggered by any finding of substandard quality of care. Section 1819(f)(2)(B)(iii)(I) of the Act; see also section 1919(f)(2)(B)(iii)(I) (the same provision for facilities participating in the Medicaid program).

When a penalty is proposed and appealed, CMS must make a *prima facie* case that the facility has failed to comply substantially with federal participation requirements. "*Prima facie*" means that the evidence is "[s]ufficient to establish a fact or raise a presumption unless disproved or rebutted." *Black's Law Dictionary* 1228 (8th ed. 2004); *see also*,

Hillman Rehabilitation Center, DAB No. 1611, at 8 (1997), *aff'd*, *Hillman Rehabilitation Center v. U.S. Dept. of Health and Human Services*, No. 98-3789 (G.E.B.), slip op. at 25 (D.N.J. May 13, 1999). To prevail, a long-term care facility must overcome CMS's showing by a preponderance of the evidence. *Batavia Nursing and Convalescent Center*, DAB No. 1904 (2004); *Batavia Nursing and Convalescent Inn*, DAB No. 1911 (2004); *Emerald Oaks*, DAB No. 1800 (2001); *Cross Creek Health Care Center*, DAB No. 1665 (1998) *Hillman Rehabilitation Center*, DAB No. 1611 (1997).

IV. Findings and Discussion

The findings of fact and conclusions of law noted below in italics are followed by a discussion of each finding.

A. Petitioner was not in substantial compliance with federal requirements applicable to nursing homes participating in the Medicare and Medicaid programs.

1. The facility failed to provide prescribed, scheduled pain management medication for Resident 1A (R1A) on November 19, 2005, at 5:00 a.m. (Tags F309 and F426).

The applicable regulation at 42 C.F.R. § 483.25, entitled Quality of Care, provides that each resident must receive and the facility must provide the necessary care and services to attain or maintain the highest practicable physical, mental, and psychosocial well-being, in accordance with the comprehensive assessment and plan of care.

42 C.F.R. § 483.60(a) (Pharmacy Services) requires that a facility provide pharmaceutical services (including procedures that assure the accurate acquiring, receiving, dispensing, and administering of all drugs and biologicals) to meet the needs of each resident.

This case concerns deficiencies cited by CMS at two different surveys. At the November 22, 2005 survey, the surveyors cited deficiencies under Tags F309 and F426 with respect to Resident 1.[3] At the December 10, 2005 survey, the surveyors cited deficiencies under Tags F157, F224, and F309 relating to the care and treatment of a different Resident 1.[4]

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[3] I will refer to this resident as R1A.

[4] I will refer to this resident as R1B.

R1A

A summary of the surveyor findings as reflected in the Statement of Deficiencies (SOD) from the November survey reveals that:

R1A was admitted to the facility on August 18, 1998, with multiple diagnoses of hyper carbonic respiratory failure, obstructive sleep apnea, cervical stenosis, and diabetes. Record review of the facility's Medication Administration Record (MAR) for R1A, dated November 1, 2005 through November 21, 2005, showed that on October 22, 1999, a physician had ordered Cafergot pain tablets to be administered to the resident every day at 5:00 a.m. P. Ex. 1, at 3, 5.

The SOD alleges that in an interview on November 21, 2005, R1A stated that he did not receive Cafergot on November 19, 2005 at 5:00 a.m. R1A related that the nurse did not have any Cafergot in her medication cart for his headache. According to R1A, he received Cafergot at 5:00 a.m. each morning after his continuous positive airway pressure (CPAP) mask was removed. R1A said he had a headache, and the nurse offered him another type of pain reliever. He told the nurse that nothing else worked for his headache after the mask was removed. The resident also stated that he finally accepted another type of pain reliever, and did not understand why he did not get his regularly scheduled Cafergot until 4:30 p.m. on November 19, 2005. P. Ex. 1, at 5-6.

According to the SOD, R1A's MAR contained an order dated November 19, 2005, to "hold Cafergot for the 5:00 A.M. dose on 11/19/05." The SOD states that the nurse's medication notes on the backside of the MAR indicated that, on November 19, 2005, at 5:00 a.m., "DCN [Darvocet]" was given for "pain," and it was described as "effective" and initialed by a nurse. There was nothing written as to the strength of Darvocet or number of tablets given, or what time it was effective. The MAR showed further that, on November 19, 2005, at 10:40 a.m., R1A was given two tablets of Ultram, a pain reliever, for his complaint of headache. The Ultram was documented as decreasing R1A's headache at 12 noon on November 19, 2005. P. Ex. 1, at 5.

> The SOD relates that the surveyors interviewed Nurse #1, who was responsible for R1A's care on November 18, 2005, from 7:00 p.m. to 7:00 a.m. According to the SOD, on November 19, 2005, at 5:00 a.m., Nurse #1 found that Cafergot was not in the medication cart. She looked in the backup medication room and no Cafergot was available. Nurse #1 stated that she obtained an order to hold Cafergot until 5:00 p.m. on November 19, 2005. She told Nurse #2 at 7:00 a.m. that more Cafergot needed to be obtained for R1A. P. Ex. 1, at 6. The SOD also states that Nurse #1 expected Nurse #2 to obtain more Cafergot and administer the missed 5:00 a.m. dose by mid-morning when the local and facility pharmacies were open.
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> The SOD recites further that R1A rated his headache on November 19, 2005, as a "5" on a scale of "1 to 5" ("1" being minimal pain and "5" being most severe pain), and that he told the nurse that he had to have Cafergot and that nothing else would work. R1A stated that the alternative pain reliever he took did not help his headache. He stated that he was "miserable all day" and "finally got relief 2 hours after receiving the Cafergot at 4:30 PM on 11/19/05." P. Ex. 1, at 7.

In response to these allegations in the SOD, Petitioner contends in its brief that its staff responded appropriately to "an ordinary non-emergency operational issue" (P. Br. at 6) and that its staff "had no regulatory obligation to administer the Resident's preferred medication, as opposed to a substitute actually ordered by his physician." P. Reply at 7. Petitioner claims that its nurse discovered that Cafergot was not in the medication cart during the early morning hours of November 19; she "immediately contacted" R1A's attending physician (P. Br. at 6); the physician "ordered that the morning dose of Cafergot be held, and a substitute pain medication be administered while the pharmacy refilled the order; and the nurse followed the physician's order." P. Reply at 7-8; *see also* P. Br. at 6.

As I discuss below, Petitioner misrepresents the evidence of record in describing the sequence of events. I find that CMS has made a *prima facie* showing that Petitioner was in violation of 42 C.F.R. § 483.25 as a result of Petitioner's failure to provide Cafergot as prescribed to R1A. Petitioner has not rebutted CMS's *prima facie* case with credible evidence.

Petitioner would have me believe that its nurse called R1A's physician prior to 5 a.m. on November 19, and received a telephone order to hold Cafergot since Petitioner was out of it, and administered Darvocet instead at the 5 a.m. dosage time.[5] *See* Tr. 89, 93. In

[5] I harbor serious doubt that a nurse would call the treating physician at such an early hour of the morning to inform him that staff failed to timely re-order R1A's pain medication.

support of these assertions, Petitioner points to a document titled, "Nurse's Medication Notes" (P. Ex. 20, page 2), and to a copy of a telephone order dated November 19, 2005 (P. Ex. 21). I note that the pertinent line on the "Nurse's Medication Notes" (P. Ex. 20, at 2) relating to R1A's receipt of Darvocet is basically illegible.[6] However, based on Surveyor Myers' testimony and what is set forth in the SOD, these notes apparently indicate that Darvocet ("DCN") was administered at 5:00 a.m. on November 19, 2005, for "pain," and was noted as effective. *See* P. Ex. 1, at 5.

From my review of these medication notes, I myself cannot with any certainty state whether Darvocet was given on November 19, 2005, and, if so, at what time it was given, other than that it appears that something was given for "pain" on November 19. P. Ex. 20, at 2. Nevertheless, there is apparently no dispute that R1A was given Darvocet as an alternative pain reliever. With respect to the November 19, 2005 telephone order, P. Ex. 21, this order has a handwritten note stating "Hold Cafergot for 5 am dose on 11/19." No time is stated on this order.

Despite Petitioner's assertion that the record "clearly shows" that the nurse received an order for Darvocet from the physician before R1A's morning medication was due (P. Br. at 6), there is no documentation in the record to support Petitioner's alleged version of the facts or sequence of events. The November 19, 2005 telephone order instructs only that the 5 a.m. dosage of Cafergot is to be held; it does not mention Darvocet at all. Moreover, since there is no time stated on the order, it is not clear when this order was given. Petitioner has offered no evidence to support its claim that the nurse contacted R1A's physician *before* 5 a.m., and received *an order before 5 a.m.* to administer Darvocet instead of Cafergot. I note that, interestingly, there is no order for Darvocet,

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[6] At the hearing, the following exchange took place on cross-examination:

> Q (Petitioner's counsel): Directing your attention to the entry for 5 a.m. on November 19, and the handwriting is – the copying is light, but do you see where it says a Darvocet was administered at 5 a.m. to Resident [1] on the 19th?
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> A (Surveyor Myers): Honestly, I can't read this. But I know he was given a Darvocet.

Tr. 89.

dated November 19, 2005, in the record.[7] Furthermore, an order from the treating physician directing that Cafergot be withheld is not a cure for the facility's failure to timely re-order the resident's medication. It is evident that the Cafergot was not withheld for a legitimate clinical purpose, but rather as a ploy to legitimize the facility's failure.

At the hearing, Surveyor Myers testified that she interviewed two nurses that completed the medication pass for R1A. Tr. 41. According to Surveyor Myers, the first nurse was not aware of the November 19, 2005 order that Cafergot be held at 5:00 a.m., and the nurse believed the reason for R1A not receiving Cafergot was because she was out of it. Tr. 41-42. Surveyor Myers stated that the second nurse she interviewed also was not aware of the order to hold Cafergot at 5:00 a.m. Tr. 42.

In addition to receiving Darvocet, the record shows that R1A received an additional pain reliever, Ultram, around 10:40 a.m. According to the nurse's medication notes, Ultram was effective in reducing his headache. P. Ex. 20, at 3. I infer that had the Darvocet been effective in relieving the resident's headache, the 10:40 a.m. dosage of Ultram would not have been necessary. In fact it is evident from the record that neither medication was effective inasmuch as R1A did not experience relief until Cafergot was administered at approximately 4:30 p.m. on November 19.

According to the SOD, Petitioner's pharmacist stated that she received a call on November 19, 2005[8], between 10:00 a.m. and 11:00 a.m., from a nurse requesting Cafergot for R1A.[9] *See* P. Ex. 1, at 6. The pharmacist stated that the nurse did not tell her that R1A's Cafergot was needed right away, and had she stated this, she would have ordered the Cafergot from the local pharmacy, and facility staff could have picked it up

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[7] Darvocet is one of the medications listed on R1A's MAR. However, the date next to Darvocet is "03/18/05," and the MAR notes that Darvocet was to be given as needed for pain in R1A's left hand/arm. P. Ex. 20, at 1. Inasmuch as Petitioner is claiming that R1A's physician gave an order for Darvocet on **November 19, 2005**, the fact that R1A's MAR lists Darvocet is irrelevant.

[8] November 19, 2005 was a Saturday.

[9] The SOD states that the pharmacist received a call from a nurse at the facility requesting Cafergot for R1A on "11/19/95 between 10:00 AM and 11:00 AM." The "95" in the date appears to be a typo. P. Ex. 1, at 6.

within an hour. *See* P. Ex. 1, at 6.[10] According to the pharmacist, the on-call pharmacist for the weekend is available by telephone and comes in the late morning, and fills faxed and telephone medication requests from Petitioner. Then, a courier would deliver the medications to the facility in the mid to late afternoon of the same day. *See* P. Ex. 1, at 6-7.

I am not persuaded by Petitioner's efforts to minimize the seriousness of this deficiency by stating that "[t]he gist of the deficiency is that Petitioner somehow ran out of the Resident's favorite pain medication." P. Br. at 6. Prescription pain medication for the level of pain described by R1A (level 5 on a scale of 1 to 5), is not susceptible to being described as the "resident's favorite medication." It is not as if the staff had failed to turn the resident's television to his favorite channel. Such loose description of the situation borders on being flippant. Moreover, it is disingenuous to say that the facility "somehow" ran out of Cafergot. It is obvious that the facility utterly failed to comply with its own policies and procedures, which required that medications be re-ordered "three to four days in advance of need to assure an adequate supply on hand." CMS Ex. 16, at 7; *see* P. Ex. 1, at 3, 4.

It is clear that Petitioner's staff failed to reorder Cafergot in "advance of need," in accordance with its policy. Moreover, after discovering that Cafergot was out of stock on the medication cart, Petitioner's staff failed to act with a sense of urgency to have Cafergot replenished. According to the pharmacist, there was a method by which Petitioner's staff could have obtained more Cafergot by prompt dispatch. When Petitioner's nurse contacted the pharmacist, she could have requested that the order be expedited, which would have caused the pharmacist to contact the local pharmacy, where facility staff could then have picked up the Cafergot within an hour. Instead, Petitioner's staff waited at least five hours before calling the pharmacist, and then failed to impress upon the pharmacist that Cafergot was needed right away for a resident.

Further, in reviewing the evidence, I find Petitioner's alleged version of the sequence of events unpersuasive. Petitioner has suggested that the physician's telephone order to hold the 5:00 a.m. dosage of Cafergot was given prior to 5:00 a.m. on November 19, 2005. I find this claim to be specious as there is no evidence to support this. I note that staff did inform R1A that he would not be receiving Cafergot, and, according to him, the explanation he received was that they were out of the medication. Tr. 39-40; *see* P. Ex. 25. Further, the two nurses interviewed by the surveyor both stated they were unaware of an order to hold Cafergot at 5 a.m. Had there been an actual order from R1A's physician to hold Cafergot, I would have expected the nurses completing R1A's medication pass to

[10] Petitioner does not have a pharmacy on site. Tr. 43.

have been aware of such an order. The simple, unvarnished reason R1A did not receive Cafergot at 5:00 a.m. is because the facility staff had failed to place a timely order to replenish the medication.

Moreover, the lack of evidence undermines Petitioner's unfounded assertion that R1A's physician, prior to 5:00 a.m., gave an order to administer Darvocet to the resident. The record contains no documentation of any physician's order for Darvocet given on November 19, 2005. While R1A did receive Darvocet at some point during the morning of November 19, 2005, the details surrounding the order and when it was administered, remain vague.

R1A had informed Petitioner's nursing staff that Cafergot was the only pain medication that relieved his headache after he came off the CPAP mask. *See* Tr. 44, 97. The record shows that R1A suffered a headache pain that he would not have experienced, had he received Cafergot at 5:00 a.m. Petitioner points out that R1A experienced relief after he received Ultram around 10:40 a.m. However, as stated earlier, the record indicates that his headache pain decreased – his pain did not go away completely.

Petitioner points out that R1A was a difficult patient, noting his mental health problems, his obsessive-compulsive disorder, and the numerous complaints he filed with the State. P. Br. at 5-6; Tr. 96-97. That R1A may have displayed difficult and/or demanding behavior is irrelevant to the issues of this deficiency, and I do not address these arguments.

Because of the facility's failure to timely re-order Cafergot, and to obtain a refill expeditiously for R1A after discovering they were out of the medication, R1A experienced a lengthy period of headache pain. The facts show that his situation was far from "border[ing] on frivolous." P. Br. at 1.

Based on the foregoing, I conclude that Petitioner was not in substantial compliance with 42 C.F.R. § 483.25 and 42 C.F.R. § 483.60(a) inasmuch as Petitioner's facility failed to provide necessary care and services, as well as pharmaceutical services, to R1A as a result of its failure to provide him with his prescribed pain reliever, Cafergot, as ordered by his physician.

2. The facility failed to notify the physician and responsible party of R1B's change in condition (Tag F157).

A facility must immediately inform the resident; consult with the resident's physician; and if known, notify the resident's legal representative or an interested family member when changes occur, including, but not limited to:

> a. A significant change in the resident's physical, mental, or psychosocial status (i.e., a deterioration in health, mental, or psychosocial status in either life-threatening conditions or clinical complications); 42 C.F.R. § 483.10(b)(11)(i)(B);
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> b. A need to alter treatment significantly (i.e., a need to discontinue an existing form of treatment due to adverse consequences, or to commence a new form of treatment) 42 C.F.R. § 483.10(b)(11)(i)(C).

R1B

The deficiencies under Tags F157, F224, and F309 in the SOD from the December 10, 2005 survey all stem from the same facts relating to the care of R1B.

CMS asserts that, based on record review, interviews with Petitioner's staff, R1B's physician, Emergency Medical Service staff, and R1B's family, Petitioner failed to notify the physician and responsible party that R1B experienced a significant change in condition. CMS alleges that Petitioner's failure constituted a deficiency at the level of immediate jeopardy, which began on November 3, 2005, and continued through December 9, 2005. P. Ex. 2, at 4-5.

According to the SOD, R1B was admitted to Petitioner's facility on July 6, 2004. His diagnoses included right subdural hematoma, craniotomy, schizophrenia, seizure disorder, hypertension, and cerebral vascular accident. The Minimum Data Set (MDS) dated September 16, 2005, revealed that R1B had no short term memory impairment, but had long term memory impairment. The MDS indicated that R1B was able to make independent decisions for tasks of daily living, and was independent with activities of daily living and continent of urine and stool. P. Ex. 2, at 6; *see* CMS Ex. 7, at 47-51; P. Ex. 31.

A summary of the surveyor findings as reflected in the SOD reveals that:

> In an interview with the surveyor, Nursing Assistant # 4 stated that, on November 3, 2005, between 7:00 a.m. and 8:00 a.m., she found R1B confused and incontinent of urine. She stated that R1B was pushing a chair and walking around his room randomly. The nursing assistant said she had never seen him do that before. She said that he told her that he "did not feel good and was hungry." The nursing assistant went to the dining room to get R1B's breakfast tray and stated that she

found him lying in his bed on his back and his whole body was shaking. According to the nursing assistant, the resident was talking, but she could not understand him because he was shaking so much. The nursing assistant took R1B's vital signs, and his blood pressure was 190/120. P. Ex. 2, at 6.

In an interview with the surveyor, Nurse # 1, who was responsible for the care of R1B on the 7:00 a.m. to 7:00 p.m. shift on November 3, 2005, stated that his blood pressure was "up a little bit." She said she called the physician (Dr. Newsome), and told him that the resident was "acting strange, shaking, blood pressure was elevated and complaining (R1B) that his roommate was tearing his nerves up." Nurse # 1 stated that Dr. Newsome ordered Valium for R1B, and she administered it at 10:15 a.m. on November 3, 2005. P. Ex. 2, at 8-9.

In another interview, Nurse # 1 noted that R1B's blood pressure was 190/120 before he took the Valium at 10:15 a.m. She said that she and the nursing assistants tried to sit him up in the bed, and he "flopped" back down. P. Ex. 2, at 9.

In an interview with the surveyor, Nursing Assistant # 2 stated that shortly after 3:00 p.m. on November 3, 2005, Nursing Assistant # 1 called her to R1B's room to help her move him. Nursing Assistant # 2 found R1B lying horizontally across the end of his bed with his feet on the floor. She said that he was '"unresponsive"' and his shorts and underwear were down around his feet. Nursing Assistant # 2 said that R1B's underwear was completely soaked and smelled of urine. She said that he had never been incontinent of stool or urine in the past.[11] She and Nursing Assistant # 1 tried to sit the resident up in his bed, but he fell back down. P. Ex. 2, at 7-8.

Describing the same incident above, Nursing Assistant # 1 related that she and Nursing Assistant # 2 were making rounds after coming on shift at 3:00 p.m., and found R1B lying down horizontally at the foot of his bed with his feet on the floor. She stated that R1B's eyes were closed and she could not get him to talk to her.

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[11] I note that whereas MDS assessments performed in January and April 2005 reflect that R1B was occasionally incontinent (P. Exs. 28, 29), assessments performed in June and September 2005 show that he was continent of bowel and bladder. P. Exs. 30, 31. It may be that the Nursing Assistant who made the comment was new to the facility, but nonetheless, the notations in the more recent MDS assessments evince that the episodes of incontinence experienced by the resident on November 3, 2005, constituted a change in condition that warranted consideration along with other changes exhibited.

Nursing Assistant # 1 said that R1B was "pretty wet." She noted that his lunch tray was untouched. The nursing assistant said she told Nurse # 1 that R1B had been incontinent of urine and was not responding to her verbally. P. Ex. 2, at 8.

In an interview with the surveyor, Nurse # 2, who was responsible for R1B's care on November 3, 2005, from 7:00 p.m. to 7:00 a.m., said Nurse # 1 told her that R1B's blood pressure had been elevated when he was taken to the shower room that morning. Nurse # 2 said that Nurse #1 told her that the Valium "knocked [R1B] out" and that he had been sleeping all day. She stated that Nursing Assistant # 5 came to her after taking R1B's vital signs and reported that he had a high temperature. Nurse # 2 said she obtained an acetaminophen suppository for R1B's elevated temperature. When she prepared to administer the suppository, she noticed that R1B had been incontinent of stool. P. Ex. 2, at 9-10.

In an interview with the surveyor, Nursing Assistant # 5 stated that she observed R1B shortly after shift change at 7:00 p.m. on November 3, 2005. According to her, R1B's head of the bed was at a 90 degree angle, and he was "slumped down in the bed," his eyes were closed, and his face was "red." P. Ex. 2, at 10.

A family member of R1B was interviewed by a surveyor and stated that the family was not contacted about R1B's change in condition during the day on November 3, 2005. The family member stated that they were contacted when R1B was transported from Petitioner's facility to the hospital. P. Ex. 2, at 10.

In an interview with the surveyor, R1B's physician, Dr. Newsome, stated that he had seen R1B on November 2, 2005, and he seemed fine. Dr. Newsome said he vaguely remembered a nurse calling on the morning of November 3, 2005, regarding the resident. He could not recall the conversation with the nurse, but knew that R1B was agitated with his new roommate. According to Dr. Newsome, another nurse called him on the evening of November 3, 2005. He remembered it sounded like R1B was having an '"acute episode"' such as a '"stroke."' P. Ex. 2, at 10.

The surveyors found no documentation about R1B in the nurses' notes for the 7:00 a.m. to 7:00 p.m. shift on November 3, 2005. P. Ex. 2, at 10.

Nursing notes dated November 3, 2005, at 8:45 p.m., stated "Res found unresponsive↑temp 102.4 BP 150/88, 78 [pulse], 18 [respirations]102.4. [Left] side flaccid. Then notified MD & EMS. Rectal suppository given acetaminophen 650 mg at 2030." P. Ex. 2, at 8; *see* CMS Ex. 7, at 107.

> In an interview with the surveyor, an EMS staff member who transported R1B to the hospital on November 3, 2005, stated that he observed R1B being "unresponsive, taking very shallow breaths, and 02 running via nasal cannula." He stated that R1B's "right pupil was 3 millimeters and the left pupil was 10 millimeters and blown (dilated)." P. Ex. 2, at 11.
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> In another interview with the surveyor, R1B's physician, Dr. Newsome, said that he expected nursing staff to check the resident's vital signs at least every hour for an acute change. He stated that he would have expected a head to toe and neurological assessment, and a blood glucose check with results provided to him within two hours. P. Ex. 2, at 11.

I find that the foregoing facts establish that R1B's condition deteriorated during the day on November 3, 2005. His decline was significant enough to require immediate notification and consultation of his physician, Dr. Newsome, and notification of a family representative. Although Dr. Newsome was notified on the morning of November 3, 2005, that R1B had undergone a change in condition, he was not subsequently notified of a deterioration in his condition until 8:45 p.m.[12] That notification occurred many hours after the resident had shown signs of significant decline. The family, on the other hand, was not notified at all except when the resident was finally sent to the hospital for evaluation.[13] The significance of the failure to notify the family immediately when a change in the resident's status occurred cannot be overlooked. Oftentimes it is the family's intervention that prompts the facility to provide residents with the necessary care. In this particular case, I infer that had the family been notified of R1B's change in condition on the morning of November 3rd, it is unlikely that he would have been treated with almost total abandon, as is disclosed by the record before me. Moreover, the staff would not have been allowed to dismiss the resident's weakened and unresponsive state as merely "playing possum." P. Ex. 2, at 18-19, 20-21.

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[12] Dr. Newsome's recollection of having been called by the facility staff is vague, and there is no contemporaneous documentation of any notification of him on the morning of November 3, 2005, regarding R1B. However, even accepting that there was notification of the resident's physician on the morning of November 3rd, (albeit based on very weak evidence), the evidence that there was more than sufficient reason to contact him again concerning the resident's deteriorated condition is robust.

[13] R1B later died at the hospital. The hospital death summary indicates more than one cause of death, with hyperosmolar coma and new onset diabetes type 3 listed as #1, and #2 on the list, respectively. P. Ex. 38, CMS Ex. 7, at 117.

Petitioner argues that its staff assessed R1B often throughout the day. Allegedly, after Nurse Coburn's (Nurse #1 in the SOD) morning telephone call to R1B's physician, and prior to 8:45 p.m., there were no changes in the resident's condition during the rest of the day that would have necessitated further notification of R1B's physician.

Further, Petitioner relies on the testimony of its expert witnesses, who opined that R1B did not exhibit any signs and symptoms during the morning and afternoon of November 3, 2005, that could have been viewed as a significant change in condition. Petitioner asserts that its experts testified that the first significant change in condition experienced by R1B did not occur until around 8:45 p.m. I disagree. The resident's state of almost complete stupor, incontinence, absence of appetite (when he was known to be a good eater), and debilitated state did constitute a significant deterioration in the resident's condition to warrant notification of his physician.[14] Moreover, the facility staff finally decided to call the treating physician in the evening only after R1B was noted to be running a high temperature at 8:45 p.m. They also noted him to be unresponsive and flaccid, but that is the way he had been for several hours prior to 8:45 p.m. on November 3, 2005. Had the staff assessed the resident's vitals on an hourly basis as expected by Dr. Newsome, the increased temperature may have been discovered sooner. In fact, it was the nurse that entered on duty at the 7:00 p.m. shift on November 3rd who realized that "something was not right" (Nurse # 2). P. Ex. 2, at 9. After she was given an oral briefing regarding R1B's condition and events of the day, and a nursing assistant reported to her that the resident had an elevated temperature, Nurse # 2 decided to administer an acetaminophen suppository. It was at that time, when in the process of administering that treatment, that she noted R1B to be incontinent, and concluded that something was wrong. *See* P. Ex. 2, at 10. The opportunity to assess the resident and realize that the unresponsiveness he had displayed all day was not a ploy to gain attention was available to the staff responsible for his care prior to the 7:00 p.m. shift, but they did not avail themselves of such an opportunity.

Nurse Coburn was R1B's attending nurse on November 3, 2005, during the 7:00 a.m. to 7:00 p.m. shift. Petitioner asserts that "according to her report, Nurse Coburn personally assessed [R1B] at least eight times in about twelve hours." P. Br. at 13. As support for this claim, Petitioner relies on her written statement dated December 13, 2005 (P. Ex. 42, at 1-3). I note that this statement is Nurse Coburn's after-the-fact reconstruction of the events that took place on November 3, 2005, and thus is deserving of less weight than had she written it contemporaneously during her shift on November 3. Additionally, a reconstruction of the events after the facility was cited for noncompliance with

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[14] It has been established that notification was not given to the family until the resident was taken to the hospital. This evidence has not been refuted by Petitioner.

participation requirements is no substitute for the contemporaneous notes that should have been entered in the resident's chart. In fact, the inference that I draw is that on November 3, 2005, R1B was not clinically assessed until 8:45 p.m. when he was found to be running a temperature as was documented in the nurse's notes.

According to Nurse Coburn's December 13, 2005 written statement, around 8 a.m. on November 3, 2005, she went into R1B's room to give him his medication and he was dressed and sitting in his chair. P. Ex. 42, at 1. Nurse Coburn stated that the certified nursing assistant (CNA) who took R1B to the shower room noticed that "he was unsteady on his feet and shaking." P. Ex. 42, at 1. A CNA went to get a wheelchair, and another nurse took R1B's blood pressure, which was 190/120.[15] When asked if he was hurting, R1B said no. They decided that the resident should go back to his room. *Id.*

Nurse Coburn's statement relates that she contacted Dr. Newsome and told him that R1B's blood pressure was elevated, and he was unsteady and shaking.[16] Dr. Newsome told her he had seen R1B the previous night and that he had been very upset over his new roommate. Pursuant to Dr. Newsome's instructions, Nurse Coburn administered Valium to R1B at 10:15 a.m. According to her statement, around 11:30 a.m., Nurse Coburn passed by R1B's room, and went in. She woke him up to take his blood pressure, which was 170/90, and noted that he was sleepy and not shaking. P. Ex. 42, at 1. Nurse Coburn described R1B as being "very sleepy acting" around 2:00 p.m. when she woke him up to take his medicine. P. Ex. 42, at 2. According to her statement, around 4:30 p.m., when she passed by R1B's room, she saw that he was sitting at the end of his bed with his pants

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[15] No entry for blood pressure can be found at 8:00 a.m. in the nurse's notes for the day in question.

[16] The SOD notes that the Assistant Director of Nursing (ADON) stated in an interview with the surveyor that, in the morning hours between 9:00 a.m. and 10:00 a.m. on November 3, 2005, the nursing assistants were taking R1B to the shower room and he began "shaking, not acting right and was flushed." P. Ex. 2, at 34-35. She said that she asked him if he was hurting, and he said he wasn't. The ADON said R1B stated he did not feel well, but had no complaints of pain. The ADON said she told Nurse Coburn to call R1B's physician. P. Ex. 2, at 35. She stated that she told the nursing assistants to take R1B back to his room and lay him down in his bed. The ADON stated that she did not check back with Nurse Coburn or check on R1B during the rest of the day. P. Ex. 2, at 35-36.

down by his feet. R1B told her he needed to go to the bathroom. Nurse Coburn told him not to get up because he was too sleepy, and she called the CNA to help clean him up. R1B lay back down in the bed. Nurse Coburn stated she helped the CNAs get him back up to a sitting position, and then she left the room to continue doing her medication pass.

According to Nurse Coburn's statement, at dinner time, the CNAs told her that R1B was not eating his dinner and that he continued to be very sleepy. Nurse Coburn went into R1B's room, and noted that he was very sleepy. She stated he was not shaking. Nurse Coburn asked him if he wished to eat, and R1B said no. She stated that he drank two cups of orange soda, and then he fell back asleep. According to Nurse Coburn, "[h]e was not shaking, resp. were even and not labored his skin was warm and dry to the touch. At this point I felt he was sleeping soundly from not having much sleep for a couple of days before and being so upset over his roommate and having taken the Valium." P. Ex. 42, at 2.

It is apparent from Nurse Coburn's after-the-fact statement that her involvement in R1B's care consisted mainly of *observations* of R1B. Her own interview statements also confirm that she failed to perform assessments of R1B. According to the SOD, Nurse Coburn stated that she did not do an assessment of R1B. P. Ex. 2, at 43; *see* P. Ex. 2, at 19. She stated that she "popped her head" in R1B's room two other times during the afternoon, but could not remember the time, and that R1B was "breathing and his color was okay." P. Ex. 2, at 41. The SOD further notes that when the resident was lying horizontally at the foot of the bed, and attempts to sit him up were unsuccessful because he flopped back down, Nurse Coburn stated she left the room and did not take his blood pressure or do an assessment. P. Ex. 2, at 43.

Nurse Coburn's observations cannot take the place of performing actual, meaningful assessments. Had she performed actual assessments of R1B in the true sense of that word, I would have expected to see documentation in the form of contemporaneous nursing notes written by her.[17]

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[17] At the hearing, Petitioner's counsel himself made the comments that "the documentation in this case is not terrific" and "the nursing notes are not particularly great." Tr. 265-66. Petitioner's witness, Annette O'Brien, agreed with Petitioner's counsel's assessment ("the documentation is just not good") and commented that the notes were not contemporaneous. Tr. 265, 268, 271. In his report dated January 13, 2006, Dr. Aronson, one of Petitioner's expert witnesses, stated that "nursing notes are not documented early in the day" on November 3, 2005, and that "nursing documentation on 11/3/05 is not satisfactory." P. Ex. 41. In the absence of nursing notes, Dr. Aronson indicates that he reviewed other documents. *Id.*

Petitioner concedes that Nurse Coburn "did not contemporaneously document most of her observations through the afternoon," but notes that she did not see anything that she considered noteworthy. Petitioner states, "one would not expect *unremarkable* observations to be documented in such circumstances." P. Br. at 14 (emphasis included). A resident that is being closely monitored should be assessed periodically, and the findings need to be documented, regardless of how remarkable the findings may be. Merely "eyeballing" a resident is no substitute for a clinical nursing assessment. Moreover, properly documented *unremarkable* findings may be as important as positive findings when the overall clinical picture is being scrutinized for arriving at a diagnosis and treatment approach. Petitioner's unsupported assertions ignore accepted standards of proper nursing practice. Moreover, the nursing staff would not know if the resident's condition was *remarkable* or *unremarkable* unless they performed proper nursing assessments, which they did not do. Thus, there is no basis for concluding that R1B's condition was *unremarkable.*

I note that, as recited in the SOD, Petitioner's Director of Nursing stated in an interview with the surveyor that she expected the nurses to do an assessment of R1B, continue monitoring, and document findings in the nurses' notes. The Director of Nursing stated that an assessment would include taking R1B's vital signs, and doing a visual and cognitive check. She stated that she would have expected a nurse to check R1B's vital signs at least two times between 1:00 p.m. and 7:00 p.m. for a change in condition. P. Ex. 2, at 48.

Other than taking R1B's blood pressure around 11:30 a.m., Nurse Coburn did not take R1B's vital signs hourly or at any other time during her shift (according to her own after-the-fact statement), nor did she instruct the nursing assistants to do so.[18] P. Ex. 42. R1B's "T.P.R. Chart," which was used to record his temperature, pulse, respirations, blood pressure, and weight, does not contain an entry dated "November 3, 2005," nor any notations of vital signs for this date. P. Ex. 36; *see* Tr. 62-63.

Further, Nurse Coburn failed to create any nursing notes with respect to R1B during her 7:00 a.m. to 7:00 p.m. shift. From the interviews the surveyors held with the nursing assistants, it appears that Nurse Coburn did not even take R1B's condition seriously. When the nursing assistants were unable to sit R1B up because he kept falling backward, and was verbally nonresponsive with eyes closed, Nurse Coburn accused R1B of

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[18] When interviewed by a surveyor, an EMS staff member who arrived at the facility on November 3, 2005, at 9:01 p.m. to transport R1B to the hospital stated that it was his understanding from one of Petitioner's nurses that R1B had not been checked on since 11:00 a.m. that day. P. Ex. 2, at 47.

"playing possum" and trying to get attention. When the nursing assistants questioned R1B's behavior, Nurse Coburn continued to say that he was "faking it." P. Ex. 2, at 18-19, 20-21. One can hardly say that Nurse Coburn was closely monitoring and checking on R1B's status during her shift. Petitioner's claim that Nurse Coburn assessed R1B "at least eight times in about twelve hours" has absolutely no basis in the record.[19] Ms. Coburn's after-the-fact explanation that she thought R1B was sleeping soundly from not having had much sleep for a couple of days, and being so upset over his roommate, and having taken the Valium, is unconvincing in view of her comments that the resident was "playing possum" and "faking it." P. Ex. 42, at 2.

In its posthearing brief, Petitioner argues:

> [R1B] was not reported to be gasping for breath, bleeding, vomiting, complaining of pain, suffering the symptoms of some new infection, or the like. Instead, he was sleepy and lethargic. Significantly, even lay common knowledge indicates that sleepiness and lethargy can have many causes, including many that are benign. In this case, the evidence is unrebutted that the Valium administered to [R1B] commonly causes this effect, and that this was the intended and expected effect of administering the medication to [R1B] to address his sleepiness[20] and agitation.

P. Br. at 30-31.

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[19] I note that the only place where Petitioner's staff contemporaneously recorded some information about R1B on November 3, 2005, is in a document titled "Nurses Report Sheet," also known as a "24-hour report." CMS Ex. 7, at 60; *see* Tr. 122. According to Surveyor Myers, this is a communication tool used by the nurses to communicate with the next shift nurse and is not part of a resident's record or part of the nursing notes. Tr. 122-23, 124, 127. Surveyor Myers testified that she looked at this document, and it showed some blood pressure notations for R1B, without any corresponding times. Tr. 125; *see* CMS Ex. 7, at 60. Surveyor Myers stated that this document was the only place where she was able to obtain any information about R1B. Tr. 126; *see* CMS Ex. 7, at 60.

[20] I am puzzled by Petitioner's suggestion that R1B was prescribed Valium to address his sleepiness.

Petitioner makes much of the fact that each of its expert witnesses testified that the intended and expected effect of taking Valium, a long-acting drug, would be sedation and sleepiness. P. Br. at 10. In Petitioner's view, CMS has chosen to disregard the obvious – that the drowsiness and lethargy exhibited by R1B were simply induced by the Valium he was given.

Petitioner's argument here lacks merit. When facility staff reported to Dr. Newsome on the morning of November 3, 2005, that R1B was shaking and had elevated blood pressure, he instructed them to administer the Valium he had prescribed the prior evening because the resident had been upset about his roommate. For some unknown reason, Dr. Newsome associated the shakiness and increased blood pressure with R1B's unhappiness with his roommate. As has been pointed out, Dr. Newsome prescribed the lowest dosage available in the hope that the resident would calm down. Thus, 2mg. of Valium for a 210 lb., ambulatory 69-year-old resident (*see* Tr. 254, P. Ex 31) who required minimal assistance with activities of daily living, was not intended as a chemical restraint. The anticipated result was not that R1B would be totally unresponsive and "knocked out." Moreover, Petitioner's experts' testimony that the staff could have reasonably concluded that sedation and sleepiness was caused by the Valium administered to the resident is not persuasive. It was not appropriate for the nurse to surmise that Valium, either singly or in combination with other medications or because he was sleep deprived, would cause him to lose appetite, become incontinent, and unresponsive. The nursing staff had a duty to periodically assess the resident and notify the treating physician of the resident's significant change. Only by conducting proper assessments and notifying the physician could a determination be made as to the underlying cause of R1B's altered state. That determination could not have been made by merely "eyeballing" the resident or construing him to be a "fake." The clinical conclusions arrived at by a medical expert testifying at the hearing are not available to the nursing staff caring for a resident who presents himself with a sudden change in condition in real time. Additionally, any rationale that the nursing staff may have for following a particular course of action must be documented in the nursing notes. Such explanations in the aftermath, are of little probative value.

When R1B spoke to the Social Services Director, Ms. Lancaster, around 7:15 a.m. that morning regarding his roommate problem, he was "calm, alert . . . answered questions appropriately . . . seemed normal as usual with no apparent confusion." P. Ex. 42, at 4; *see* Tr. 165-68. However, when he was being taken to the shower room around 9:30 a.m., R1B exhibited unsteadiness on his feet, shakiness, and high blood pressure. Thus, it is evident that R1B was already manifesting signs of debilitation. These symptoms, which led to Nurse Coburn's notification of Dr. Newsome on the morning of November 3, 2005, obviously cannot be attributed to Valium, which R1B did not receive until

around 10:15 a.m.[21] The Valium that was afterwards administered may have compounded the underlying problem, and even clouded, the clinical picture, but was not the cause of the signs and symptoms that prompted notification of the treating physician.

Dr. Newsome, R1B's physician, stated in an interview with the surveyor that 2 mg. of Valium was not likely to make R1B unresponsive. P. Ex. 2, at 50. Consistent with that opinion, at the hearing, he testified that the two milligrams of Valium he prescribed was a "small dose" Tr. 214. Dr. South, Petitioner's expert witness, expressed the opinion that two milligrams is a "modest dose." However, he added that one milligram is a "low" dose and five milligrams is a "modest" dose. Tr. 304. Based on that scale, two milligrams would fall in the low end of what constitutes a small dose, which is in keeping with Dr. Newsome's opinion.[22]

Notwithstanding his opinion that two milligrams was a small dose, Dr. South felt that two mg. of Valium would have justified the kind of lethargy and sleepiness exhibited by R1B.[23] As stated earlier, Dr. Newsome, the treating physician, held a differing view inasmuch as he told the surveyor that 2 milligrams of Valium was not likely to make R1B unresponsive. According to Nurse O'Brien, "the peak of [the Valium] would probably be three hours, and the maximum benefit of the Valium then would decline if it's an every six-hour medication." Tr. 264.

Petitioner asserts, moreover, that R1B's baseline condition did not change until around 8:45 p.m. on the day in question, when Petitioner's staff found him unresponsive, flaccid on his left side, and with a temperature of 102 degrees, and called his physician and 911. As for R1B's condition during the day, Petitioner argues that R1B experienced only "subtle – i.e., insignificant – signs and symptoms that were *consistent with* his complex baseline and the expected effects of the Valium." P .Br. at 31. (Emphasis in original).

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[21] Dr. Newsome had seen R1B on the night of November 2, 2005, and had written an order that R1B receive two milligrams of Valium by mouth every six hours as needed for anxiety. CMS Ex. 7, at 106. R1B's MAR shows that he did not receive any Valium on the night of November 2, 2005. CMS Ex. 7, at 110.

[22] Although Dr. South indicated that he considered one milligram of Valium to be a low dose, the medical literature reflects that Valium is administered in three dosages: two mg., five mg., and 10 mg. *Physicians' Desk Reference* 1829 (44th ed. 1990).

[23] I note that R1B was a 69-year-old male who weighed 210 lbs. Tr. at 254; *see* P. Ex. 31.

It is true that Resident 1B's baseline shows an individual with numerous medical problems. However, based on the record, which includes surveyors' interviews with staff, it is evident that R1B exhibited changes in his appearance and behavior during the day of November 3, 2005, that could be characterized as more than "subtle." These changes clearly signaled a deterioration in R1B's status which triggered Petitioner's duty under the regulation to immediately notify and consult R1B's physician, Dr. Newsome.

One nursing assistant stated in an interview that when she went to R1B's room shortly after 3:00 p.m. to help another nursing assistant move R1B, he was lying horizontally across the end of his bed with his feet on the floor and he was "unresponsive." P. Ex. 2, at 7; *see* CMS Ex. 1, at 2; CMS Ex. 7, at 4. R1B's shorts and underwear were down around his feet, and his underwear was urine-soaked. The nursing assistants tried to sit him up in his bed, but he fell back down, still unresponsive. P. Ex. 2, at 7-8; *see* CMS Ex. 1, at 2; CMS Ex. 7, at 4. According to the interview, one of the nursing assistants told Nurse Coburn about R1B's condition, and Nurse Coburn chastised R1B for "playing possum." Nurse Coburn allegedly told the nursing assistants that R1B's nonresponsiveness was a ploy for attention because he did not like his roommate. *See* CMS Ex. 1, at 2; CMS Ex. 7, at 4. The nursing assistants noted that Nurse Coburn walked out of the room and said that R1B was "faking it." *See* CMS Ex. 1, at 2.

In another interview, a nursing assistant stated that, around 7:00 p.m., she noticed that R1B's head of the bed was at a 90 degree angle and he was "slumped down in the bed," his eyes closed and his face was "red." P. Ex. 2, at 10. These accounts of R1B's condition, as related to the surveyors, clearly indicate that he was undergoing a decline in his condition, and hence, a departure from his baseline status that was sufficiently anomalous as to necessitate physician notification.

Even Dr. Newsome stated in an interview with the surveyor that he would have expected nursing staff to have checked R1B's vital signs at least every hour for an acute change, and that he would also have expected a neurological evaluation and a blood glucose check with results provided to him within two hours. P. Ex. 2, at 11. At the hearing, Dr. Newsome acknowledged having made such statements. Tr. 220-21. However, he then suggests that his comments to the surveyor were not meant as criticism of the actions the nursing staff actually did take:

> I don't think that a prudent nurse without the knowledge needed to do anymore than was done. Looking back, could other things have been done? Sure. But could/would a prudent nurse have done those beforehand? I don't think so.

Tr. 221.

Dr. Newsome is apparently of the view that there is a justifiable distinction between what ought to have been done *hypothetically* by Petitioner's staff in terms of R1B's care and treatment, and what, in fact, occurred with R1B. *See* P. Reply at 5. However, rather than acting as a defense of the staff's actions, his testimony instead puts their actions under a harsher light. Is Dr. Newsome suggesting by his testimony that R1B was deserving of less care and less monitoring than what should generally have been given? Frankly, I am not impressed by Dr. Newsome's attempt to suggest that he had only been speaking in hypothetical terms to the surveyor.

The lack of monitoring R1B received was also commented on by Petitioner's own expert witnesses. Both Dr. South and Dr. Aronson testified that they would have performed some testing of R1B during the day. Dr. South stated that he probably would have ordered "some more lab work" during the morning of November 3, 2005, at the time Dr. Newsome was called by staff. Tr. 309. In the report he prepared for Petitioner, Dr. South noted that R1B had had a blood sugar level of 377 on October 11, 2005, and expressed his opinion that there probably should have been orders to follow up on this with further testing. P. Ex. 40. Similarly, Dr. Aronson, in his report for Petitioner, stated, "The only diagnostic intervention that would have potentially changed this course and allowed an earlier intervention would have been a glucose level and there was no indication for this in the facility." P. Ex. 41, at 1. At the hearing, Dr. Aronson testified that he "would have been a little more concerned about diabetes. I would have initiated some laboratory monitoring more aggressively from a physician's standpoint." Tr. 199.

I am also not persuaded by Petitioner's argument that, according to its expert witnesses, no one could have had any inkling that R1B was exhibiting signs of a hyperosmolar coma. This argument is not relevant to the issue before me. Implicit in the suggestion that R1B's condition displayed no red flags at all that would have warranted physician notification is the assumption that staff was looking out for red flags in the first place, via monitoring of R1B's vital signs and other assessments. As the record indicates, there was no such careful monitoring or assessments of R1B carried out by staff. Given those circumstances, to say that no red flags were recognized in R1B's case is both specious and meaningless.

Along the same lines, Petitioner notes also that Dr. South opined that R1B's ailment was irreversible, and that nothing could have been done during the six or seven hours at issue. Tr. 312; *see* P. Br. at 20. The assessment of R1B's survival chances is wholly irrelevant to the issue of whether Petitioner complied with the physician notification requirement of 42 C.F.R. § 483.10(b)(11). It may be that R1B would have expired no matter what efforts Petitioner's staff made on his behalf. But, the fact that he was likely to die anyway is not a justification for the failure of Petitioner's staff to discharge its duty to him. The staff had no way of knowing with any certainty what was likely to happen to

R1B on November 3, 2005. It was obligated to monitor him for any significant clinical changes, and notify his physician immediately about those changes so that a medical evaluation could be made.

I find that R1B exhibited significant signs of decline during the day on November 3, 2005, prior to 8:45 p.m., and these signs were warnings that physician intervention was required. Petitioner failed to fulfill its regulatory duty to immediately notify and consult R1B's physician and notify a family representative of R1B's deteriorating status, in violation of 42 C.F.R. § 483.10(b)(11).

In view of the foregoing, it is my finding that CMS has established a *prima facie* case that Petitioner was in violation of 42 C.F.R. § 483.10(b)(11). Petitioner has not overcome CMS's showing by a preponderance of the evidence.

3. Petitioner failed to comply substantially with the requirements of 42 C.F.R. § 483.13(c) (Tag F224).

The regulation at 42 C.F.R. § 483.13(c) provides:

> The facility must develop and implement written policies and procedures that prohibit mistreatment, neglect, and abuse of residents and misappropriation of resident property.

Under this alleged deficiency, which arises under the same facts related above under Tag F157, CMS contends that Petitioner neglected to assess, monitor, and notify R1B's physician of his significant change in condition. CMS alleged that this deficiency was at the immediate jeopardy level. P. Ex. 2, at 14-27.

CMS submitted into the record Petitioner's Abuse and Neglect Prohibition Policy, which states the following:

> Each resident has the right to be free from mistreatment, neglect, abuse, involuntary seclusion and misappropriation of property.
>
> ***
>
> ***Neglect*** means failure to provide goods and services necessary to avoid physical harm, mental anguish or mental illness.

CMS Ex. 6, at 1. (Emphasis in original).

I note that Petitioner's definition of "neglect" matches the definition of "neglect" contained in 42 C.F.R. 488.301:

> failure to provide goods and services necessary to avoid physical harm, mental anguish, or mental illness.

As I have discussed above, Petitioner's staff failed to monitor and assess R1B during the day on November 3, 2005, thus allowing his decline to go unchecked. Petitioner's failure to provide R1B with the care and services he needed in the face of his deteriorating status constitutes neglect, in violation of 42 C.F.R. § 483.13(c). Moreover, Petitioner's failure to carry out its affirmative duty under the regulation to immediately notify and consult with R1B's physician and notify his family representative when he exhibited signs of decline during the day, also constitutes neglect.

> ***4. Petitioner failed to comply substantially with the requirements of 42 C.F.R. § 483.25 (Tag F309).***

The regulation at 42 C.F.R. § 483.25 provides:

> Each resident must receive and the facility must provide the necessary care and services to attain or maintain the highest practicable physical, mental, and psychosocial well-being, in accordance with the comprehensive assessment and plan of care.

Under this alleged deficiency, which arises under the same facts related above under Tag F157, CMS contends that Petitioner failed to provide the necessary care and services to R1B, who had a significant change in condition, by failing to assess and monitor physical and neurological changes. CMS alleged that this deficiency was at the immediate jeopardy level. P. Ex. 2, at 27-53.

To attain or maintain his highest practicable physical, mental, and psychosocial well-being, R1B required an attentive staff who recognized his signs of deterioration during the day of November 3, 2005, and reported these changes in his condition to his physician. Inasmuch as I have found that Petitioner violated 42 C.F.R. § 483.10(b)(11) and 42 C.F.R. § 483.13(c), I find that Petitioner also failed to provide him the care and services that he needed and therefore violated 42 C.F.R. § 483.25.

B. CMS's finding of immediate jeopardy was not clearly erroneous.

CMS determined that the deficiencies under Tags F157, F224, and F309 presented immediate jeopardy to R1B. CMS's determination as to the level of noncompliance "must be upheld unless it is clearly erroneous." 42 C.F.R. § 498.60(c)(2). This includes CMS's finding of immediate jeopardy. *Woodstock Care Center*, DAB No. 1726, at 9, 38 (2000), *aff'd, Woodstock Care Center v. Thompson*, 363 F.3d 583 (6th Cir. 2003).

Immediate jeopardy exists if the facility's noncompliance has caused or is likely to cause "serious injury, harm, impairment, or death to a resident." 42 C.F.R. § 488.301. The Board has observed repeatedly that the "clearly erroneous" standard imposes on facilities a "heavy burden" to show no immediate jeopardy, and has sustained determinations of immediate jeopardy where CMS presented evidence "from which '[o]ne could reasonably conclude' that immediate jeopardy exists." *Barbourville Nursing Home*, DAB No. 1962, at 11 (2005); *Florence Park Care Center*, DAB No. 1931, at 27–28 (2004), *citing Koester Pavilion*, DAB No. 1750 (2000).

Petitioner's failure to monitor and assess R1B during the day on November 3, 2005, and its failure to immediately notify and consult his physician and to notify his family representative of the signs of his deteriorating condition jeopardized the resident's health and life. Moreover, Petitioner should have foreseen that a failure to appropriately monitor and assess the resident for significant changes in his condition as well as the failure to notify and consult with his physician and notify his family was likely to cause serious injury, harm, impairment, or death. CMS's immediate jeopardy determination for each of the three deficiency tags at issue, Tags F157, F224, and F309, is therefore not "clearly erroneous."

C. The amount of the CMP imposed by CMS is reasonable.

The burden is on Petitioner to produce evidence that it corrected its deficiencies sooner than January 26, 2006. Petitioner has produced no such evidence, and in fact, does not dispute the period of the CMP at issue.

Having found a basis for imposing a CMP, I now consider whether the amount imposed is reasonable, applying the factors listed in 42 C.F.R. § 488.438(f). *Emerald Oaks,* DAB No. 1800, at 10 (2001); *CarePlex of Silver Spring*, DAB No. 1683, at 16–17 (1999); *Capitol Hill Community Rehabilitation and Specialty Care Center*, DAB No. 1629 (1997).

CMS imposed a CMP in the amount of $4,000 per day from November 3, 2005 through December 9, 2005 (immediate jeopardy period), and a CMP in the amount of $300 per day from December 10, 2005 through January 26, 2006. *See* P. Ex. 6; P. Br. 3-4. In the notice of remedies sent by CMS on December 29, 2005, Petitioner was advised that, in imposing the CMP, the factors identified at 42 C.F.R. § 488.438(f) were considered. CMS Ex. 11, at 6. Aside from its claims regarding compliance, Petitioner offers no argument as to the reasonableness of the CMP amount, stating only that the CMP is "in excess of $160,000, a substantial amount for any nursing facility." P. Reply at 9. Thus, Petitioner has not refuted the reasonableness of the CMP.

I determine whether the amount of a CMP is reasonable by applying the factors listed in 42 C.F.R. § 488.438(f): 1) the facility's history of noncompliance; 2) the facility's financial condition; 3) factors specified in 42 C.F.R. § 488.404; and 4) the facility's degree of culpability, which includes neglect, indifference, or disregard for resident care, comfort or safety. The absence of culpability is not a mitigating factor. 42 C.F.R. § 488.438(f). The factors in 42 C.F.R. § 488.404 include: 1) the scope and severity of the deficiency; 2) the relationship of the deficiency to other deficiencies resulting in noncompliance; 3) the facility's prior history of noncompliance in general and specifically with reference to the cited deficiencies.

I have before me no evidence regarding facility history or financial condition. With respect to the other factors, however, I find that the deficiencies were serious. Petitioner's staff jeopardized R1B's health and safety by failing to monitor and assess the resident's condition and by failing to notify and consult with his physician and notify his family representative of his decline in status during the day on November 3, 2005. For this, Petitioner was culpable. I therefore find reasonable the amount of the CMP.

D. Petitioner was properly subject to the prohibition on conducting a NATCEP for two years.

In addition to the CMP, I conclude that the State survey agency was required to prohibit Petitioner from conducting a NATCEP for two years. Pursuant to section 1819(f)(2)(B)(iii)(I)(b) and (c) of the Act and 42 C.F.R. § 483.151(b)(2) and (e)(1), a state may not approve and must withdraw any prior approval of a nurse aide training and competency evaluation program offered by a skilled nursing or nursing facility that: (1) has been subject to an extended or partial extended survey under sections 1819(g)(2)(B)(i) or 1919(g)(2)(B)(i) of the Act; (2) has been assessed a CMP of not less than $5,000; or (3) that has been subject to termination of its participation agreement, denial of payment, or the appointment of temporary management. CMS imposed a CMP, the total amount of which satisfies the regulatory requirement, thus triggering the two-year prohibition in this case.

V. Conclusion

For all of the reasons discussed above, I uphold CMS's determination that, from November 3 through January 26, 2006, Petitioner was not in substantial compliance with program participation requirements. I also find that, from November 3, 2005 through December 9, 2005, Petitioner was not in substantial compliance at the immediate jeopardy level. I sustain, as reasonable, the $4,000 per day CMP for the period of immediate jeopardy. I also sustain, as reasonable, the $300 per day CMP imposed from December 10, 2005 through January 26, 2006.

/s/
Jose´ A. Anglada
Administrative Law Judge