Department of Health and Human Services

DEPARTMENTAL APPEALS BOARD

Appellate Division

In the Case of:	DATE: December 17, 2008
Universal Healthcare/King,	
Petitioner,	Civil Remedies CR1784 App. Div. Docket No. A-08-107
	Decision No. 2215
- v. -	
Centers for Medicare & Medicaid Services.	

FINAL DECISION ON REVIEW OF ADMINISTRATIVE LAW JUDGE DECISION

Universal Healthcare/King (Universal or Petitioner) appealed the May 6, 2008 decision of Administrative Law Judge (ALJ) José A. Anglada. The ALJ concluded that Universal was not in substantial compliance with Medicare participation requirements and upheld the imposition by the Centers for Medicare & Medicaid Services (CMS) of a prohibition on conducting nurse aide training, and of a civil money penalty (CMP) of $4,000 per day from November 2, 2005 through December 9, 2005 and $300 per day from December 10, 2005 through January 26, 2006. Universal Healthcare/King, DAB CR1784 (2008) (ALJ Decision).

For the reasons explained below, we affirm the ALJ Decision.

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.[1]

A "deficiency" is defined as a nursing facility's "failure to meet a participation requirement specified in the Act or [42 C.F.R. Part 483]." "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 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." 42 C.F.R. § 488.301.

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, CMS may impose a penalty in the range of $3,050 to $10,000 per day. 42 C.F.R. § 488.438(a)(1)(i). Where CMS finds, as here, that a facility's noncompliance constitutes substandard quality of care, the facility is disqualified from operating a nurse aide training and competency evaluation program (NATCEP) for two years. 42 C.F.R. § 483.151(b)(2).

Under the statute and regulations, CMS has the initial burden of going forward, but the facility has the ultimate burden of persuasion to prove by the preponderance of the evidence that it is in substantial compliance. Batavia Nursing and Convalescent Center, DAB No. 1904 (2004), aff'd, Batavia Nursing & Convalescent Ctr. v. Thompson, 129 Fed. Appx. 181 (6th Cir. 2005).

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

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[1] 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.

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).

Relevant background

Universal is a skilled nursing facility located in King, North Carolina that participates in the Medicare program. Based on surveys completed by the North Carolina State Survey Agency (State survey agency) that ended on November 22, 2005 and December 16, 2005, the state agency determined that Universal was not in substantial compliance with multiple federal requirements.

Following the November survey, CMS notified Universal that it was imposing a CMP in the amount of $250 per day effective November 22. P. Ex. 3. Following the December survey, CMS notified Universal that it was imposing a CMP in the amount of $4,000 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 also advised Universal that it would be disqualified from operating a NATCEP for two years. In both notices, CMS imposed additional remedies that are not at issue here. P. Ex. 4.

On January 26, 2006, the State survey agency conducted a recertification and revisit survey. On February 13, 2006, CMS sent Universal a notice letter stating that the January 26, 2006 revisit survey revealed that Universal continued to be out of substantial compliance but that CMS was reducing the CMP to $50 per day effective January 26, 2006. P. Ex. 6. The CMP imposed as of January 26, 2006 is not at issue in this case. ALJ Decision at 3.

The ALJ held an in-person hearing on April 24-25, 2007, in Greensboro, North Carolina. He received into evidence CMS Exhibits (CMS Exs.) 1-12, and 14-16, and Petitioner's Exhibits (P. Exs.) 1-46. Two surveyors testified on behalf of CMS. Universal's Social Service Director, its Medical Director, the

Medical Director of its management company, another physician affiliated with that management company, and one unaffiliated nurse testified on behalf of Universal.

Analysis

Universal raised a number of arguments on appeal. Most of those arguments, while facially appealing, are based on misstatements about the relevant issues, the ALJ's findings, or Board precedent. Below, we first discuss Universal's major arguments on appeal related to the ALJ's finding that Universal failed to provide prescribed, scheduled pain management medication for Resident 1A (R1A). We then discuss Universal's major arguments related to the ALJ's findings that Universal failed to meet notification requirements when Resident 1B (R1B) underwent a significant change in status, failed to assess R1B as required to meet quality of care standards, and failed to implement its policy on neglect. Finally, we discuss Universal's general arguments related to the standard of review in CMP cases such as this one.

Since Universal's brief frames the same issues in multiple ways, we do not repeat and discuss each iteration separately, but we have considered all of the arguments and find them without merit. Thus, we uphold the ALJ's conclusions that Universal was not in substantial compliance with Medicare requirements. Universal did not appeal the level of noncompliance found or the amount or duration of the CMP.

1. Substantial evidence in the record as a whole supports the ALJ's findings that Universal failed to provide prescribed, scheduled pain management medication for R1A on November 19, 2005 at 5:00 A.M. and that this failure caused actual harm to R1A.

CMS cited Universal for noncompliance with 42 C.F.R. §§ 483.60(a) (pharmacy services) and 483.25 (quality of care) because the surveyors found that Universal had failed to provide R1A with prescribed, scheduled pain management medication, a failure that resulted in actual harm to R1A.

Section 483.60(a) requires a facility to "provide pharmaceutical services (including procedures that assure the accurate acquiring, receiving, dispensing, and administering of all drugs . . .) to meet the needs of each resident." (Emphasis added.)

Section 483.25 requires that --

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

R1A had resided at Universal since 1998. CMS Ex. 16, at 1. He had multiple diagnoses, including hyper carbonic respiratory failure, obstructive sleep apnea, cervical stenosis, diabetes, and obsessive compulsive personality disorder. Id.; P. Ex. 10, at 4.

The following relevant facts, set out in the ALJ Decision at 6-12 with record citations, are undisputed:

- On October 22, 1999, R1A's physician had ordered Cafergot pain tablets to be administered to R1A every day at 5:00 A.M. R1A received the Cafergot to prevent headaches after his continuous positive airway pressure (CPAP) mask was removed each morning.

- Around 5:00 A.M. on November 19, 2005, Nurse # 1, who was responsible for R1A's care from 7 P.M. the previous evening to 7 A.M., found that R1A's Cafergot was not on the medication cart and that no Cafergot was available in the backup medication room. R1A told Nurse # 1 that he had a headache, and Nurse # 1 offered him another pain reliever (Darvocet). He told the nurse that nothing but Cafergot worked for his headache after the mask was removed but he finally took the Darvocet that the nurse offered him.

- Nurse # 1 told the surveyors that she told Nurse # 2, who came on duty at 7:00 A.M., that Cafergot needed to be obtained for R1A and that she expected Nurse # 2 to obtain it and administer the missed dose by mid-morning.

- At approximately 10:40 A.M., after complaining again of a headache, R1A was given and took a second pain reliever (Ultram). He told the administering nurse that he would be in pain all day if he did not get his Cafergot.

- The facility pharmacist told the surveyors that a nurse ordered Cafergot for R1A between 10 and 11:00 A.M. but did not tell her that it was needed right away. The

pharmacist said that, had the nurse done so, the Cafergot could have been picked up within an hour. Instead, R1A did not get his regularly scheduled Cafergot until 4:30 P.M. that afternoon.

- R1A told the surveyor that on November 19 he had a severe headache all day and that he was miserable until about two hours after receiving the Cafergot.

- Universal's policies 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.

The ALJ correctly found that these undisputed facts established noncompliance with section 483.60(a) because they showed that Universal failed, under its own policies, to timely acquire and administer a prescribed drug, and, as result, R1A suffered actual harm - a severe headache.

The ALJ found that the facts also establish noncompliance with section 483.25. R1A did not receive and Universal did not provide a necessary prescribed drug for R1A's physical, mental, and psychosocial well-being, in accordance with his plan of care. See P. Ex. 13, at 8, 9 (R1A's plan of care providing "ADMINISTER ROUTINE AND PRN PAIN MEDS AS ORDERED - NOTE EFFECTIVENESS").

On appeal, Universal makes a number of arguments, none of which are persuasive. First, Universal argues that its staff did not fail to provide R1A with a prescribed medicine. Request for Review (RR) at 27. It asserts that "there was a *superceding* order to suspend the Cafergot and replace it with Darvocet for the dose in question" and that the nurse gave R1A the Darvocet in accordance with this order. Id. at 29.

The evidence does not support this assertion, much less compel the ALJ to have made such a finding. The record contains a telephone order form on which a handwritten entry states that Dr. Newsome instructed staff to "hold Cafergot for 5 am dose on 11/19." P. Ex. 21. The form is signed by Nurse Jenkins, who was identified as Nurse # 1 for the relevant survey. P. Ex. 1, at 12. The form provides a place to enter "TIME" after the signature space for "NURSE RECEIVING ORDER," but no time was entered. The only other evidence as to a doctor's order for the dose in question are statements by Nurse # 1 recorded by the surveyors:

> Nurse #1 stated on 11/19/05 at 5:00 A.M. she found that Resident #1 did not have his prescribed Cafergot in the

> medication cart. Nurse #1 stated she looked in the backup medication room and no Cafergot was available. Nurse #1 stated she obtained an order to hold Cafergot until 5:00 P.M. on 11/19/05.

CMS Ex. 16, at 5.

The ALJ correctly rejected Universal'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." ALJ Decision at 9, citing P. Br. at 6. The ALJ wrote:

> 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, dated November 19, 2005, in the record.

ALJ Decision 9-10.[2] Based on the record before him, the ALJ reasonably concluded that -

> [i]t is evident that the Cafergot was not withheld for a legitimate clinical purpose, but rather as a ploy to legitimize the facility's failure [to timely reorder the Cafergot].

Id.

Second, Universal argues that staff met R1A's need for pain medication by giving him Darvocet and was not required to meet

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[2] The ALJ noted that Darvocet was listed in R1A's Medication Administration Record (MAR) as having been ordered in March 2005 to be given as needed for pain in R1A's left hand/arm. ALJ Decision at 10, n.7, citing P. Ex. 20, at 1. Dr. Newsome testified but said nothing about the "hold" order or any order for Darvocet. Tr. at 207-222. Further, neither Nurse # 1 nor any other witness with personal knowledge of the events of November 19 testified at the hearing. A short handwritten statement from Nurse # 1 is in the record, but says nothing about her administration of medication on November 19 or her call to Dr. Newsome. P. Ex. 24, at 5.

his preference for a particular type of pain medication (the Cafergot). RR at 27 (stating that "the regulation requires that a facility meet a resident's *needs*, not his preferences" (emphasis in the original)).

Substantial evidence in the record as a whole supports the ALJ's finding that Universal did not meet R1A's need for pain medication. First, it is reasonable to infer from the fact that a doctor prescribed morning Cafergot for some six years that the Cafergot was needed to meet R1A's need for headache prevention after removal of the CPAP mask. The surveyor explained that, because R1A suffered from sleep apnea, he wore a CPAP mask. The purpose of a CPAP mask is to force oxygen into the body, and consequently, brain. Tr. at 36. When the mask is removed, "the brain perceives oxygen deprivation," which for R1A resulted in a "very severe headache" for which Cafergot was prescribed. Id. She also stated that "it's not uncommon with residents to have [such headaches]." Id.

Second, while Darvocet is a pain medication, there is no evidence indicating that it (in the unknown strength R1A received) was equivalent to the prescribed dose of Cafergot. That is, no doctor prescribed Darvocet as an alternative to Cafergot for preventing such headaches; no doctor (or nurse) testified that the drugs have equivalent results.

Third, R1A said he suffered a severe headache that morning and staff gave him a second type of pain medication, which indicates that they did not treat the Darvocet as equivalent.

Universal argues that "CMS offered no evidence to establish any cause and effect relationship between the Resident's headache and the receipt of Darvocet (and Ultram) rather than his favorite pain medication." RR at 29. This argument is not persuasive. First, Cafergot was prescribed, indicating that a doctor had determined it was effective to prevent R1A's headaches. CMS Ex. 16, at 3. Second, R1A repeatedly told the nurses and the surveyors that other medications did not prevent this type of headache. Id. at 3, 5; P. Ex. 24, at 5 (statement from the nurse who gave R1A the Ultram). Third, R1A missed the Cafergot and got a headache. Id. These facts are sufficient to establish causation. Finally, if the Darvocet R1A received was medically equivalent to Cafergot, Universal could have offered testimony to that effect from Dr. Newsome, R1A's treating doctor, who testified at the hearing, but Universal did not do so.

Universal does not deny that R1A made the statements on which the ALJ relied, but argues that R1A should not be believed for the

following reasons, none of which are persuasive. RR at 30.

- Universal asserts that R1A's "record shows that the medication he did receive was effective to reduce his pain." RR at 30. Presumably, Universal is referring to an entry on the MAR indicating that, as of 12 noon, R1A's headache pain decreased after taking the Ultram at 10:40 A.M.. P. Ex. 20, at 3. However, the entry does not establish that the headache was gone. Moreover, for the hours between 5 A.M. and 12 noon, it supports the ALJ's finding that R1A was in pain.

- Universal asserts that "it is medically unlikely that the Resident could have suffered a serious headache after administration of *two* narcotic pain killers." RR at 30. Again, this statement fails to address the issue of pain R1A suffered between 5:00 A.M. and 12 noon. Moreover, this assertion is mere conjecture, unsupported by any evidence.

- Universal asserts that "the record shows the Resident attended a social event with his family the same day without complaint." Id. This assertion is not supported by Universal's citations - Petitioner Exhibits 20, at 18 (which does not exist) and 24. Further we see no reference to any social event, much less the time of the event, elsewhere in the record.

- Universal asserts there are "unrebutted written statements by staff familiar with the Resident that he did not complain of unusual pain at the time." RR at 30, citing P. Ex. 24. Petitioner Exhibit 24 contains five short handwritten statements from staff, four of which are undated. While four statements say that the staff members do not recall R1A complaining of a headache or pain, the nurse who gave him the Ultram at 10:40 A.M. stated that he asked her for "his headache [Cafergot] pill" and told her that "if he didn't get it he would have a headache all day" and she offered him Ultram, which he took. Therefore, Universal's own evidence shows that as of 10:40 at least one staff member was aware that R1A was complaining of a headache and that she responded with an action that indicates that she gave credence to his assertions of pain.

Universal also contends that R1A had obsessive compulsive disorder (OCD) that resulted in a "profound fixation on his ailments, real or imagined, and certain aspects of his care,

including certain medications." RR at 8. Universal argues that "the cited deficiency must be evaluated against this context." RR at 8. Universal does not explain the specific relevance of its allegations, however. To the extent Universal is relying on the resident's history of OCD as undercutting the finding of actual harm, we disagree. Even if R1A's history is read as calling into question the reliability of his complaint of physical harm (which it does not clearly do), it can also be read as showing that he would be anxious if he did not receive the Cafergot in a timely manner (and still had not received it many hours later). Such emotional distress can also support a finding of noncompliance.

In sum, the ALJ correctly concluded Universal was not in substantial compliance with 42 C.F.R. §§ 483.25 and 483.60(a).

2. Substantial evidence in the record as a whole supports the ALJ's findings that Universal failed to comply substantially with the requirement at 42 C.F.R. § 483.10(b)(11).

CMS cited Universal for noncompliance with 42 C.F.R. § 483.10(b)(11) because the surveyors found that Universal had failed to immediately notify R1B's family and consult with R1B's physician after R1B suffered significant changes in his condition on November 3, 2005. Section 483.10(b)(11) provides in pertinent part:

> (11) *Notification of changes.* A facility must immediately . . . consult with the resident's physician; and if known, notify the resident's legal representative or an interested family member when there is -
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> * * *
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> (B) 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);
>
> (C) 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).

R1B was a 69-year old man who had resided at Universal since July 2004. CMS Ex. 10, at 1. He had multiple diagnoses, including right subdural hematoma, craniotomy, schizophrenia, seizure disorder, hypertension and cerebral vascular accident. Id. R1B weighed 210 pounds. Tr. at 254; P. Ex. 31.

The following facts, most of which are set out in the ALJ Decision with record citations, are undisputed.

- The Minimum Data Set (MDS) dated September 16, 2005, indicated that R1B had long term but no short term memory impairment, was able to make independent decisions for tasks of daily living, was independent with activities of daily living, and was continent of urine and stool.

- On November 2, 2005, R1B's treating physician, Dr. Newsome, saw R1B because he had been exhibiting "agitation," seemingly associated with difficulties adjusting to a new roommate. P. Ex. 37, at 2. Dr. Newsome wrote that "we are going to try a little Valium 2mg [every six hours as needed]" and "check a lithium and Depakote level tomorrow."[3] Id. (emphasis added).

- A certified nursing assistant (CNA # 4) told the surveyor as follows. The next day (November 3) between 7:00 A.M. and 8:00 A.M., she went to look for R1B because he was not at breakfast, which was not characteristic for him. P. Ex. 2, at 6. She found him confused, incontinent of urine, and pushing a chair around his room randomly. This was behavior she had never seen before.[4] R1B told her that he "did not feel

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[3] Laboratory results on November 3, 2005 showed that R1B's Lithium and Depakote levels were within a normal range. P. Ex. 34.

[4] Universal says that the SOD "alleges that [R1B] was incontinent of urine between 7 and 8 A.M., apparently based on the statement of a certified nursing assistant during the survey," but "there is no evidence in the Resident's chart to support such a statement, and Nurse Coburn and the Center's Social Worker, Elizabeth Lancaster both denied seeing the Resident wet during that time." RR at 14, citing P. Ex. 42, at 4. The ALJ reasonably found R1B had been incontinent as described by the CNAs. ALJ Decision at 13. The cited statement by Ms. Lancaster merely says that, when she saw R1B at about 7:15, "there was no evidence of odor or of any incontinence episodes." This statement does not rule out incontinence some time between 7:15 and 8 A.M., and no statement by Nurse Coburn denies this episode of incontinence. Also, CNA # 4 told the

(continued...)

good and was hungry." She went to the dining room to get him a breakfast tray. When she returned he was on his back in his bed and his whole body was shaking. She could not understand what he was saying because he was shaking so much. She told Nurse Coburn, who was the nurse responsible for R1B's care on the 7:00 A.M. to 7:00 P.M. shift, about R1B's condition, including his incontinence. P. Ex. 2, at 16.

- The Assistant Director of Nursing (ADON) told the surveyor as follows. Between 9:00 A.M. and 10:00 A.M. on November 3, 2005, after the CNAs had found R1B "shaking, not acting right and [] flushed", she asked him if he was hurting and he said no. P. Ex. 2, at 34-35. He told her he did not feel well, but had no complaints of pain. Id. at 35. R1B's vital signs were taken and were "up a tad." Id. The ADON told Nurse Coburn to call R1B's physician and saw Nurse Coburn do so later. Id. She did not check back with Nurse Coburn or check on R1B during the rest of the day. Id. at 36. She told the CNAs to take R1B back to his room and "lay him down in his bed." Id. at 35.

- Nurse Coburn told the surveyors as follows. She called Dr. Newsome and told him that the resident was "acting strange, shaking, blood pressure was elevated and complaining that his roommate was tearing his nerves up." P. Ex. 2, at 8-9. Dr. Newsome told her to give R1B the 2 mg. of Valium, which she administered at 10:15 A.M. Id. She took his blood pressure between 11 A.M. and 12 P.M.. Id. at 41.

- Dr. Newsome told the surveyor the following. R1B had seemed fine when Dr. Newsome had seen him the evening before, but he had prescribed 2 mg. Valium PRN (as needed) because R1B was upset over a new roommate. He vaguely remembered a nurse calling on the morning of November 3, 2005 about R1B.

- CNA # 1 told the surveyor as follows. Shortly after 3:00 P.M., she found R1B lying horizontally across the

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[4](...continued)
surveyor that she told Nurse Coburn about the morning incontinence. P. Ex. 2, at 16. Finally, since Nurse Coburn documented none of R1B's symptoms that day in the nurses' notes, the lack of documentation of this episode is meaningless.

end of his bed with his feet on the floor. P. Ex. 2, at 39. His lunch tray was untouched. Id. He was "pretty wet" with urine. Id. She asked Nurse Coburn to come see him because he had been incontinent of urine and was not responding to her verbally. Id. With Nurse Coburn, she and CNA # 2 tried to sit R1B up, but he "kept falling backward onto the bed, his eyes closed with no verbal response." Id. Nurse Coburn told R1B to "stop playing possum" and told CNAs # 1 and # 2 that R1B was "trying to get attention so the other guy [roommate] would get out of the room." Id. at 40.

- CNA # 2 told the surveyor as follows. Shortly after 3:00 P.M. CNA # 1 called her to R1B's room to help her move him. He was "unresponsive" and his shorts and underwear, completely soaked and smelling of urine, were down around his feet. Id. at 17. He had never been incontinent of stool or urine in the past. Id. Nurse Coburn told the CNAs that R1B was playing possum, trying to get attention, and, as she left the room, said he was "faking it." Id. The CNAs checked on R1B several times and asked Nurse Coburn about him at least two or three more times between that incident and 7 P.M. His condition did not change during this time.

- No neurological check was performed on R1B by Universal staff at any time on November 3 before 8:45 P.M. His blood pressure was taken before the 9:30 A.M. call to the doctor, at which time it was 190/120. P. Ex. 2, at 6. Nurse Coleman told the surveyor that she took his blood pressure between 11 A.M. and 12 P.M.. P. Ex. 2, at 41. A second blood pressure reading was entered on the "Nurses Report Sheet" as 170/90. CMS Ex. 7, at 60. No time was recorded on the Nurses Report Sheet for either reading. Id. No other vital signs are recorded for the day shift on November 3.

- Nurse # 2, who was responsible for R1B's care on November 3, 2005, from 7:00 P.M. to 7:00 A.M., told the surveyor that at the shift change Nurse Coburn told her that R1B's blood pressure had been elevated that morning, that the Valium "knocked [R1B] out," and that he had been sleeping all day. P. Ex. 2, at 9.

- CNA # 5 told the surveyor that she observed R1B shortly after 7 P.M. shift change, that the head of his bed was

at a 90 degree angle, that he was "slumped down in the bed," his eyes were closed, and his face was "red." P. Ex. 2, at 10.

- Nurse # 2 told the surveyor that CNA # 5 came to her after taking R1B's vital signs and reported that he had a high temperature. Nurse # 2 obtained an acetaminophen suppository for R1B's elevated temperature. When she prepared to administer the suppository, she found that R1B had been incontinent of stool. P. Ex. 2, at 9-10. She knew "something was not right." Id.

- Nurses' notes by Nurse # 2 for 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 [Emergency Medical Services]. Rectal suppository given acetaminophen 650 mg at 2030." P. Ex. 2, at 8; *see* CMS Ex. 7, at 107.

- An EMS staff member who took R1B to the hospital told the surveyor that R1B was "unresponsive, taking very shallow breaths" and that his "right pupil was 3 millimeters and the left pupil was 10 millimeters and blown (dilated)." P. Ex. 2, at 11. The EMS report stated, "Nursing staff advise they gave PT a valium approx. 11:00 A.M. this morning. PT was not checked on since then." Id. at 54.

- R1B died at the hospital the next morning. The hospital death summary lists multiple causes of death, with hyperosmolar coma and new onset diabetes type 3 listed as # 1 and # 2 respectively. P. Ex. 38, CMS Ex. 7, at 117.

- The family was contacted about R1B's condition when he was sent to the hospital but not before. P. Ex. 2, at 10.

- There was no documentation about R1B or care provided to R1B in the nurses' notes for the 7:00 A.M. to 7:00 P.M. shift. P. Ex. 2, at 10.

These undisputed facts are sufficient to support the ALJ's determination that Universal failed to timely notify R1B's family and to timely consult with his physician after R1B suffered a significant change in his physical, mental, or psychosocial status and that Universal was not in substantial compliance with section 483.10(b)(11).

Universal makes a number of arguments as to why the ALJ's findings are not supported by substantial evidence in the record as a whole or why the ALJ committed error. As discussed below, these arguments have no merit.

> *R1B's symptoms prior to 9:30 A.M. are not irrelevant under the regulations, merely because his physician was called at that time.*

Universal asserts that any analysis of its actions must begin after the 9:30 A.M. call that Nurse Coburn made to Dr. Newsome. It argues that its staff complied with section 483.10(b)(11) for symptoms prior to the call and that the symptoms arising after the call did not require further contact with the doctor. RR at 11, 30, 34. We reject this argument for the following reasons.

The 9:30 A.M. call may have constituted notification to the physician, as required by section 483.10(b)(11), but Universal does not deny it failed to contact the family (or a legal representative) at that time. The ALJ discusses the "significance of the failure to notify the family immediately when a change in the resident's status occurred." ALJ Decision at 16. Had the family been contacted, they might have protested Nurse Coburn's dismissal of R1B's symptoms (unresponsiveness, failure to eat, shakiness, incoherence, and incontinence) as faking, playing possum, and attention seeking.

Universal's argument that only signs and symptoms occurring after 9:30 are relevant is inconsistent with the regulation. The significance of signs and symptoms may not be clear until others also appear. Universal's nurse expert, Nurse O'Brien, acknowledged that signs or symptoms might have to be "evaluate[d]" over a period of time before their significance is clear. Tr. at 242. In other words, the significance of the symptoms after 9:30 must be evaluated in light of the prior symptoms.

While Dr. Newsome tried Valium to address the initial report about R1B, his statement to the surveyor indicates he expected the nurse to monitor R1B for symptoms that might indicate that R1B was suffering from something more than anxiety over his new roommate or an imbalance in his Depakote or Lithium levels. The surveyor reported that Dr. Newsome said that he expected the nursing staff to check R1B's vital signs at least every hour for

an acute change, conduct a head to toe and neurological assessment, check his blood glucose, and provide results to him within two hours.[5] P. Ex. 2, at 11.

Thus, at a minimum, the symptoms occurring after the call to Dr. Newsome must be evaluated in light of the symptoms occurring before the call.

The ALJ's findings regarding R1A's baseline are supported by substantial evidence in the record.

Universal also argues that any analysis of a change in condition must start with the resident's baseline and that ALJ "got many of the central facts regarding the Resident's clinical *baseline* wrong." RR at 11. These arguments lack merit, for the following reasons.

Universal asserts that, while the ALJ treated R1B's incontinence as a departure from his baseline, R1B had "a history of at least occasional incontinence." Id. In fact, while R1B's care plan reflects R1B was incontinent when he came to Universal in June 2004, December 29, 2004 entries state that he was "now continent of B & B." P. Ex. 33, at 9, 10. Additionally, the entries on his Minimum Data Sets (MDS) for June and September of 2005 also state that he was continent of bowel and bladder. P. Exs. 30, at 4; 31, at 2. Finally, the CNAs who regularly cared for R1B told the surveyor that they viewed the incontinence they witnessed on November 3 as a change for R1B.

Universal also asserts that R1B "had a history of significant fluctuations in blood pressure" so that his high blood pressure (190/120) on the morning of November 3 should not have been treated as a "significant change." RR at 12. Universal overstates the ALJ's reliance on the blood pressure. The ALJ noted it as one symptom, along with the incontinence, confusion, shaking, and loss of appetite, that R1B displayed early in that morning; it was not the sole basis for concluding R1B was experiencing a significant change. Moreover, R1B's TPR Chart, which documented his blood pressure for the prior year, shows that the five highest recorded measurements were between 164/90 and 160/98. P. Ex. 36. These were the only measurements with a high in the 160s. Thus, Nurse Coburn's characterization of his blood pressure to the surveyor as "up a little bit" (P. Ex. 2, at 8) is inaccurate.

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[5] We discuss below Dr. Newsome's subsequent qualification of his statement as reported by the surveyor.

Universal further asserts that the ALJ failed to account for the fact that R1B had "schizophrenia (i.e., disordered thinking), short term memory problems, impaired decision making ability, and other mental issues." RR at 12, citing care plan at P. Ex. 33, 4, 7, 9. The ALJ did not disregard any of these problems. The record clearly shows that, in spite of these problems, R1B was usually alert, oriented, pleasant and cooperative. See, e.g., P. Ex. 33, at 7 (care plan entry stating he was "pleasant and cooperative"); Tr. at 164 (Universal social worker describing R1B's "ordinary demeanor" as "very friendly, always spoke, was very sociable, enjoyed talking to residents and staff members there, very alert, always pleasant"); P. Ex. 2, at 22 (Registered Nurse who cared for R1B told surveyor that she had never known R1B to be lethargic or to sleep for long periods of time).

Thus, contrary to Universal's assertions in its brief, the ALJ's findings as to R1B's baseline are supported by substantial evidence in the record as a whole.

> *The regulation requires neither a discrete, significant event nor identification of a particular point in time when a change becomes significant.*

Citing ALJ cases and one Board decision, Universal argues that section 483.10(b)(11) applies only to situations in which a resident experiences "some 'significant' clinical event such as sudden respiratory distress" and not to situations where there is a "slow or subtle alleged deterioration of a resident's overall condition from an established 'baseline.'" RR at 32. Universal also asserts that the ALJ's conclusion is wrong because CMS was unable to identify any particular point in time after 9:30 A.M. that the facility was required to recontact the physician and to show that physician intervention would have "reversed the inexorable progression of the Resident's developing fatal malady." RR at 34.

This is not correct. While sudden dramatic changes are more easily recognized as significant, the accumulation of slow or subtle changes may, a some point, become significant. For example, Claiborne-Hughes Health Center, DAB No. 2179 (2008) involved a resident whose appetite declined, resulting in a significant weight loss over a five-week period. The Board held that the facility's failure to notify the doctor or family about this change on a timely basis constituted noncompliance with section 483.10(b)(11). Since some nursing judgment is involved (as CMS and the Board have recognized), CMS may be unable to identify any particular point in time when the requirement applies, but still be able to conclude that waiting until the

facility did was not consistent with any reasonable nursing judgment about whether a resident was experiencing a significant change in status.[6] Also, Universal's assumption that the notification requirement is meaningless if a physician's intervention would not make a difference ignores the following: 1) part of the requirement is to notify the legal representative (usually a family member) and that notification may be even more important if the resident is apt to die; 2) judgment about whether anything can be done should be the physician's not the nurse's, which is why the resident has a right to the notification; and 3) even if the physician may not have been able to save R1A, the physician may have been able to address the symptoms to make the resident more comfortable, reduce pain, etc.

This case is distinguishable from Georgian Court Nursing Center v. CMS, DAB Dec. No. 1866 (2003), the only Board case cited by Universal. RR at 32-33. In that decision, the Board found that notification was required under section 483.10(b)(11)(A) because the facility was aware of circumstances indicating that the resident had been injured in a transfer. It does not stand for the proposition for which Universal cites it.

> *Substantial evidence supports the ALJ's finding that an additional call to the physician was required after the Valium was administered.*

Universal speculates that "[i]f the material question is whether a reasonably competent nurse should have identified the Resident's sleepiness, slurred speech and inability to swallow following administration of Valium under these circumstances as [] a "significant change in condition" from his baseline that required an *additional* call to his attending physician after 9:30 A.M., the answer is obviously no." RR at 34. Universal argues that its expert testimony proved that after 9:30 A.M. R1B "experienced only subtle - i.e., *insignificant* - signs and symptoms that were *consistent with* his complex baseline and the expected effects of the Valium." RR at 35. According to Universal, the ALJ "simply rejected that expert testimony in favor of his subjective conclusion to the contrary. See Aronson, Tr. 196-197." Id.

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[6] As in Claiborne-Hughes, the difficulty in identifying a particular time by which Universal should have given notice of a significant change resulted in part from its staff's failure to conduct any timely clinical assessments, such as vital signs or neurological checks.

As discussed above, the issue here is not limited to the symptoms Nurse Coburn says she observed after she administered Valium. Some of the symptoms on which the ALJ relied had manifested themselves before the Valium was administered, so they could hardly be attributed to it. Contrary to what Universal suggests, moreover, the ALJ could reasonably determine based on the evidence in the record that the resident remained "unresponsive" (and not just "sleepy"), long after he received a modest dose of Valium, the effect of which would have been expected to peak at about 1:15 P.M. See, e.g., Tr. at 264 (Nurse O'Brien's testimony that the "peak" effectiveness of the dose "would probably be three hours, and . . . then would decline"); P. Ex.2, at 50 (Dr. Newsome's statement that 2 mg. of Valium was not likely to make R1B unresponsive).[7] The evidence of Nurse Coburn's dismissive attitude toward the resident also undercuts Universal's assertion that she in fact thought that his state resulted from the Valium and lack of sleep the night before.

More important, Nurse Coburn acknowledged that she did no "assessment" of the resident. P. Ex. 2, at 19. Thus, she had no reasonable basis on which she could make a judgment that his unresponsiveness, which persisted, was not significant because it was solely due to tiredness and the Valium.

The ALJ did not, as Universal asserts, merely substitute his own subjective judgment for that of Universal's experts. The ALJ said he found the experts' opinions unconvincing and gave some reasons why. ALJ Decision at 17-26. Based on our review of the experts' testimony, we conclude that the ALJ reasonably determined that the testimony was not probative, given the facts as he determined them to be, for the following reasons, among others:

- Unlike the ALJ, Universal's experts accepted as true the facts reported by Nurse Coburn in an "addendum" to the nurses' notes. The addendum allegedly described her care and observations of R1B on November 3 and seeks to compensate for the fact that she made no nurses' notes on that day. The addendum is dated December 13, 2005,

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[7] The Valium was administered at approximately 10:15 A.M., but some five hours later R1B "kept falling backward onto the bed, his eyes closed with no verbal response" when the CNAs tried to rouse him. P. Ex. 2, at 39. Moreover, according the CNAs, he remained that way through the end of the shift at 7 P.M. (Id. at 38-39) and was found that way by the CNA coming on the 7 P.M. shift (id. at 44).

after the December survey and after Nurse Coburn had been terminated by Universal. CMS Ex. 7, at 105. Under these circumstances, Nurse Coburn may have misremembered facts and had considerable motive to present the facts in a self-serving way. Indeed, many of her assertions in the addendum conflict with facts reported by multiple CNAs.[8] Finally, since she did not testify at the hearing, her assertions were not subject to cross-examination. The ALJ properly determined the addendum was "deserving of less weight than had she written it contemporaneously during her shift on November 3." ALJ Decision at 17.

- In particular, it was key to Nurse O'Brien's general opinion regarding the care R1A received that he was "sleepy but rousable" at 6:30 P.M. Tr. at 254. See also Tr. at 296 (Dr. South stating that R1B was able to drink orange soda at 5:30). For example, Nurse O'Brien says that, at 6:30, Nurse Coburn reports that R1B actually drank "two big glasses of water." Tr. at 254. Nurse Coburn did not, however, document contemporaneously that she gave any liquid to him, much less the amount or type of any such liquid or his mental status at the time. Nurse Coburn first told the surveyor that he drank some juice, then later asserted in her addendum that he drank water with a pill at 2:00 P.M. and at 5:30 he drank two cups of orange soda. P. Ex. 2, at 42. The ALJ reasonably gave this after-the-fact assertion little to no weight, however, especially given that CNA # 2 who said she delivered his dinner tray around 5:30 described him as unresponsive both when she delivered the tray and when she picked it up at 6 or 6:30. Id. at 37. CNA # 1 also told the surveyor that R1B was unresponsive during this period. Id. at 38-39.

- Unlike the ALJ, Universal's experts appeared to have not believed (or been unaware of) the multiple statements by

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[8] For example, Nurse Coburn wrote that she found R1B at 4:30 P.M. sitting up at the end of his bed, the pants were "a little bit wet" ("wetness . . . the size of a baseball"), and she called the CNAs to help. P. Ex. 42, at 41. CNAs # 1 and 2 told the surveyor that they found R1B lying horizontally at the end of his bed with his feet on floor, his pants down, and "pretty wet" or "completely soaked" with urine about 3:00 P.M. and that they went to Nurse Coburn and asked her to come see about him. P. Ex. 2, at 17, 39.

the CNAs about R1B's condition over the course of the day (e.g., that he was nonresponsive, that he could not be roused, that he was repeatedly incontinent), about their repeated attempts to bring his condition to Nurse Coburn's attention, and about Nurse Coburn's attitude that R1B was "faking." Thus, while the experts assumed that Nurse Coburn had been properly checking on R1B and RIB was merely "sleepy" (Tr. at 181, 215, 216, 254, 307), the ALJ found that he was treated with "almost total abandon" and remained in "almost a complete stupor" (ALJ Decision at 17) long after he received a modest dose of Valium.

- The ALJ reasonably found not credible the testimony of Dr. Newsome, who was Universal's Medical Director and R1B's attending physician. His testimony that the staff acted properly conflicts with his earlier statement to the surveyor that he expected the nursing staff to check R1B's vital signs at least every hour for an acute change, conduct a head to toe and neurological assessment, check his blood glucose, and provide results to him within two hours. P. Ex. 2, at 11.

- Neither of the other physicians had personal knowledge of R1B, and all of the physicians were affiliated with Universal or the company that managed Universal. Tr. at 176-177, 222, 289. Much of the physicians' testimony goes to irrelevant issues, such as at what point R1B's condition was irreversible.

- None of the experts specified which parts of the record (or any other documents) they reviewed in formulating their opinions. The ALJ could reasonably conclude that lack of clarity of foundation for each of these opinions diminishes their persuasiveness.

- Counsel's questions asking for Nurse O'Brien's nursing opinion were very carefully and narrowly framed. Many of them go only to whether an individual symptom would of itself raise a "red flag" for a nurse. See, e.g., Tr. at 257, 262, 263. Also, when the ALJ asked if there would be observable symptoms from the resident's condition, counsel reframed the question, asking for an opinion based on her "review of the record, given what the nurses saw in this case . . ." Tr. at 248 (emphasis added); see also Tr. at 265 (opinion based on nurse's responses to what she saw). This phrasing asks for an opinion that would not take into account signs or

symptoms that were only reported to Nurse Coburn and assumes that Nurse Coburn correctly reported what she did see.

- None of the experts addressed the fact that from 11 or 12 A.M. until after 7:00 P.M., no staff, including Nurse Coburn, took R1B's vital signs or conducted a neurocheck. They further failed to discuss whether a reasonable nurse would make a judgment that R1B's stupor was due to Valium and prior sleeplessness, as Nurse Coburn did, without such assessments.

- Nurse O'Brien's reading of the record either was not complete or was not particularly careful. For example, she said that, to best of her knowledge, the resident was not incontinent before taking the Valium (Tr. at 276-277), and the record indicates otherwise (P. Ex. 2, at 6, 16). She referred to the resident as having drunk two glasses of water at 6:30 P.M. (Tr. at 254), for which there is no support whatever. She testified that a blood pressure reading of 170/90 is not dangerously high and that she had noted that he was agitated, shaky, and with a blood pressure of 170/90 in the morning when the physician was notified. Tr. at 253, 278. The blood pressure recorded before the physician was called, however, was 190/120. P. Ex. 2, at 6. Similarly, Dr. South stated that he did not know what strength Valium was administered at 10:15 A.M. Tr. at 298. Yet, the ALJ's decision relied on testimony that the 2 mg. dose was small, or at most, modest.

- Nurse O'Brien characterized the morning call to Dr. Newsome as simply a nurse being conservative," and speculated that people were probably thinking the resident was "sleep-deprived" in the morning, saying "we all get shaky when we're tired." Tr. at 279-281. This speculation does not, however, comport with the ADON's directive to Nurse Coburn to call the doctor or with the facility's "alert" form about his status, which describes him as "sick." CMS Ex. 7, at 5. Moreover, as mentioned, Nurse O'Brien was unaware that R1B also was incontinent before the first call. Tr. at 276-277.

Finally, it was not improper, as Universal suggests, for the ALJ to cite to those parts of the expert testimony that support his conclusions. Such citation is not inconsistent with his finding that their testimony as a whole was unconvincing.

Nurses are not required to "diagnose" residents' conditions.

Universal argues that CMS's position requires nurses to diagnose conditions. RR at 21, 33-34. That is not correct. CMS agrees that, because only physicians can diagnose, the physician must be notified of a significant change in status so the physician can diagnose the problem or gather further information. Thus, the nurses here are not being faulted for failure to determine whether R1B's unresponsiveness was due to blood sugar crisis or some other cause, but for failure to monitor for signs and symptoms and report those signs and symptoms when they indicated a significant change.

The ALJ reasonably relied on Universal's failure to document.

Universal describes this case as "the latest in a series of cases where CMS attacks the (widely misunderstood) practice of 'documentation by exception.'" RR at 37, n. 10. Universal goes on to describe what this means and to argue that, since "there really is no dispute that [R1B's] lethargy was an expected and unremarkable effect" of the Valium, the nurse did not need to document it. Id.

This argument ignores the fact that there was a dispute about what effect the Valium the resident received would have. It also assumes that Universal had a practice of "documentation by exception." There is no evidence that Universal had such a practice, though, and the nurses' notes we do have are not consistent with how that practice is described in Universal's brief.

Universal concedes, moreover, that "documentation is required for every assessment" even if a facility has adopted documentation by exception. Id. Indeed, the facility's own policy and forms called for documenting. CMS Ex. 3 (re documenting vital signs in circumstances such as those present here). Universal's own nurse expert, as well as others, acknowledged that Universal's "documentation is just not good." Tr. at 271.

Finally, in addition to the lack of contemporaneous documentation here, there is no testimony by anyone with firsthand knowledge of R1A's status on November 3, and statements made by staff to the surveyors undercut Universal's assertions about that status.

In sum, the ALJ's conclusion that Universal was not in substantial compliance with section 483.10(b)(11) is supported by

substantial evidence in the record and free of legal error.

3. Substantial evidence in the record supports the ALJ's conclusions that Universal failed to comply substantially with quality of care and anti-neglect requirements.

CMS also found Universal failed to comply substantially with 42 C.F.R. §§ 483.13(c) and 483.25. Section 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.

Section 488.301 defines neglect as the "failure to provide goods and services necessary to avoid physical harm, mental anguish or mental illness. Universal's neglect policy uses the same definition. CMS Ex. 6, at 1.

Section 483.25 requires that -

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

Universal argues that, for these citations, "the essential question . . . is whether Petitioner's staff provided care appropriate to the needs of the Resident." RR at 36. It argues that the ALJ improperly rejected the conclusions of its experts that Universal did provide such care. Id.

As discussed above, the ALJ's treatment of the experts' testimony was reasonable. Moreover, substantial evidence in the record supports his finding that Universal failed to provide R1B with needed care and services by failing to assess R1B over the course of the day. This evidence includes the following:

- The Director of Nursing (DON) told the surveyor that she expected "nurses to do an assessment, continue to monitor residents with a change in condition and document the findings in the nurses' notes." P. Ex. 2 at 48. She stated further that such an assessment "would include vital signs, a visual and cognitive check of Resident # 1's condition." Id. The DON "would have expected a nurse to check Resident # 1's vital signs at

least two times between the hours of 1:00 P.M. and 7:00 P.M. for a change in condition." Id.

- Dr. Newsome told the surveyor that, after the initial call on November 3, "he expected nursing staff to check Resident # 1's vital signs at least every hour for an acute change" and conduct "a head to toe and neurological assessment, blood glucose check with results being called to the Physician within 2 hours." P. Ex. 2, at 11. While Dr. Newsome later tried to qualify this statement (Tr. at 120-121), the surveyor testified that she was certain that she had asked him what he expected the staff to do for R1B. Tr. at 131-132. The ALJ, who observed Dr. Newsome testify, found Dr. Newsome's first statement more credible. ALJ Decision at 24-25.

- Unrebutted evidence shows that Nurse # 2 "was upset about finding [R1B] unresponsive . . . because she felt first shift . . . should have done more" for R1B. P. Ex. 2, at 48. She stated that "would have [gone] to [R1B's] room first, if [Nurse Coburn] had told her he was not doing well." Id. at 47.

Universal provided no expert opinion directly stating that Nurse Coburn's failure to assess R1B during the relevant time period was consistent with nursing standards.

While Universal did have policies to prevent neglect, such as a policy for taking vital signs (CMS Ex. 3) and for contacting physicians about changes in residents' conditions (CMS Ex. 7, at 99-101), staff did not follow these policies.

Thus, the ALJ reasonably concluded that Universal failed to comply substantially with these two additional requirements.

4. Universal's general arguments have no merit.

In addition to challenging the ALJ's specific findings related to R1A and R1B, Universal makes a number of general allegations. None of these arguments has merit.

For example, under the heading "Standard of Review," Universal raises arguments suggesting that the ALJ erroneously applied either a "presumption" that CMS's factual allegations were enough to sustain the remedies imposed, or a "strict liability" standard that would impose a remedy "whenever a resident dies or suffers injury, even as a result of the disease process." RR at 22-23.

Universal also suggests that there are inconsistencies in how an SOD is treated in Board decisions and that the burden of proof standard adopted by the Board is inconsistent with the federal Administrative Procedure Act (APA). In the course of these arguments, Universal cites a number of Board and ALJ decisions that it says stand for propositions with which it takes issue and which it claims are inconsistent with court decisions.

As is clear from our discussion above, neither the ALJ's nor our analysis "presumes" that CMS's factual allegations are true or relies solely on the outcomes for the residents to infer noncompliance. Instead, our conclusions and the ALJ's findings are based largely on the undisputed facts, on statements that Universal does not dispute were made to the surveyors by facility staff, and on the lack of any documentation in the nurses' notes or elsewhere or any testimony from first-hand witnesses to support the allegations on which Universal relies.

Moreover, Universal's arguments misrepresent Board precedent on burden of proof and on other issues. For example, in discussing burden of proof, Universal cites the Board's decision in Hillman Rehabilitation Center, DAB No. 1611 (1997), aff'd Hillman Rehabilitation Center v. United States, No. 98-3789 (GEB) (D.N.J. May 13, 1999), but ignores the Board's decision in Batavia, *supra*. In that decision (at 15-20), the Board thoroughly addressed and rejected an argument that the APA requires that CMS have the ultimate burden of persuasion in a CMP action such as this one. Universal asserts that "since the Medicare Act itself does not contain any specific burden of proof rule, traditional APA burdens of proof ought to apply" and cites 5 U.S.C. § 704 as standing for the proposition that "the 'proponent' of a rule or order, in this case the Secretary, has the burden of proof to sustain the order." RR at 25. The Board concluded in Batavia, however, that it is the long-term care facility that is seeking an order from the Secretary certifying it to be in substantial compliance with the requirements, and, alternatively, that the applicable statute and regulations place the ultimate burden of persuasion on the facility. Universal provides no reason for us to reconsider that analysis.

Universal's description of what the Board has held CMS is required to do to meet its initial burden of going forward is also inaccurate. Universal takes a statement in Hillman out of context to suggest that CMS must present evidence to support every finding in an SOD. The Board has not, however, required CMS to present evidence with respect to survey findings that are undisputed. See, e.g., Batavia at 7; Florence Park Care Center, DAB No. 1931, at 13 (2004). Universal also mistakenly relies on

U.S. Steel Mining Co. v. Director, Office of Workers's Compensation, 187 F.3d 384, 389 (4th Cir. 1999) as standing for the proposition that the "party with the initial burden of proceeding" must "offer evidence on 'each element of a claim' in order to meet the *evidentiary* standard of 'preponderance of the evidence,' and, if the agency fails to do so, then the 'preponderance-of-the-evidence standard cannot be satisfied' and the agency action cannot stand." RR at 26. The cited decision, however, discusses only the evidentiary standard that applies to a claimant in a Black Lung disability case, who the court said had the ultimate burden of persuasion. The decision contains no discussion whatsoever of the initial burden of going forward.

In support of its argument that the Board has "begun to hold that a Statement of Deficiencies is only a 'notice' document that informs a facility that it has violated *some* regulations," Universal cites an ALJ decision, Hillcrest Health Care Center, DAB CR1579 (2007). In Hillcrest, the facility argued that CMS is strictly constrained by the allegations in an SOD and may not rely on additional supporting evidence without amending that SOD. The ALJ rejected this argument based on the Board's decisions in Pacific Regency Arvin, DAB No. 1823, at 9-10 (2002) and Northern Montana Care Center, DAB No. 1930, at 26 (2004); aff'd Montana v. Leavitt, No. 04-00097-GF-SEH, 2006 WL 2700729 (D.Mont. Sept. 18, 2006). The ALJ mentioned the role of the SOD as a notice document, but did not state it was only a notice document. Board decisions have concluded that an SOD is both a notice document and evidence of the findings therein. See, e.g., Oxford Manor, DAB No. 2167 (2002); Jennifer Mathews Nursing & Rehabilitation Center, DAB No. 2192 (2008).

Universal also misrepresents the Board's decision in Cal Turner Extended Care Pavilion, DAB No. 2030 (2006), taking statements in that decision out of context to suggest that the decision has led the ALJs to hold that "they may summarily affirm sanctions if they find even a scrap of evidentiary support for that result, without having even to review Petitioner's evidence." RR at 24-25. In Cal Turner (at 7), the Board rejected the claim that no remedy can be sustained in the absence of express findings by CMS on all of the regulatory factors used to determine the amount of a CMP. The cited statements were in this context, not in the context of findings of CMS based on which it determines that it has authority to impose a CMP. The Board's decisions as a whole make clear that it reviews an ALJ decision to see whether it is supported by substantial evidence in the record as a whole and that an ALJ may not simply disregard evidence in the record.

Finally, Universal asserts that the "undisputed clinical evidence illustrates no deviation from any clinical or regulatory standard of care" and that in neither case did Universal's staff "do anything wrong." RR at 37. The first assertion ignores what the regulations and Universal's own policies provide and is based on Universal's unfounded premises, such as that only events occurring since the last physician notification should be considered in determining whether there has been a significant change in a resident's status. It also relies on testimony from Nurse O'Brien regarding "minimum standards of care" that is not probative because it was based on assumptions about what occurred that are inconsistent with the facts found by the ALJ.

The second assertion, even if true, is irrelevant since the bases for finding lack of substantial compliance with federal requirements were what Universal's staff failed to do, not what they did.

Conclusion

For the reasons stated above, we uphold the ALJ Decision and affirm and adopt the ALJ's findings of fact and conclusions of law.

/s/
Leslie A. Sussan

/s/
Constance B. Tobias

/s/
Judith A. Ballard
Presiding Board Member