Department of Health and Human Services

DEPARTMENTAL APPEALS BOARD

Civil Remedies Division

In the Case of:	)	
	)	
Premier Living and Rehab Center, (CCN: 34-5185)	)	Date: May 29, 2007
	)	
Petitioner,	)	
	)	
- v. -	)	Docket No. C-06-199
	)	Decision No. CR1602
Centers for Medicare & Medicaid Services.	)	
	)	

DECISION

Premier Living and Rehab Center (Petitioner or facility) is a nursing facility located in Raleigh, North Carolina, that is certified to participate in the Medicare program as a provider of services. On multiple occasions, members of Petitioner's nursing staff administered to one of its residents (R1) excessive doses of morphine sulphate. Staff subsequently misrepresented the incidents, and the facility inadequately investigated. Based on these findings, the Centers for Medicare & Medicaid Services (CMS) charges that, from September 24 through December 15, 2005, the facility was not in substantial compliance with program participation requirements; specifically, its services did not meet professional standards of quality (42 C.F.R. § 483.20(k)(3)(i)) and R1 was not free from unnecessary drugs (42 C.F.R. § 483.25(l)(1)). CMS also claims that, from September 24 through November 20, 2005, the facility's deficiencies posed immediate jeopardy to resident health and safety. CMS has imposed a civil money penalty (CMP) of $178,150 ($3,050/day for 58 days of immediate jeopardy plus $50/day for 25 days of substantial noncompliance).

For the reasons set forth below, I sustain CMS's determinations.

I. Background

The Social Security Act (Act) sets forth requirements for nursing facility participation in the Medicare program, and authorizes the Secretary of Health and Human Services (Secretary) to promulgate regulations implementing the statutory provisions. Act, section 1819. The Secretary's regulations are found at 42 C.F.R. Part 483. To participate in the Medicare program, a nursing facility must maintain substantial compliance with program requirements. To be in substantial compliance, a facility's deficiencies may pose no greater risk to resident health and safety than "the potential for causing minimal harm." 42 C.F.R. § 488.301. 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 Secretary contracts with state survey agencies to conduct periodic surveys to determine whether skilled nursing facilities are in substantial compliance with program participation requirements. Act, section 1864(a); 42 C.F.R. § 488.20. The regulations require that each facility be surveyed once every twelve months, and more often, if necessary, to ensure that identified deficiencies are corrected. Act, section 1819(g)(2)(A); 42 C.F.R. §§ 488.20(a), 488.308.

Here, responding to a complaint, the North Carolina Department of Health and Human Services (State Agency) surveyed the facility on November 14 - 15 and November 21, 2005. CMS Exhibit (Ex.) 2; CMS Ex. 36, at 2 (Benson Decl. ¶ 4). The surveyors concluded that the facility was not in substantial compliance with two Medicare requirements: 42 C.F.R. § 483.20(k)(3)(i) (services must meet professional standards of quality) and 42 C.F.R. § 483.25(l)(1) (residents must be free from unnecessary drugs). They also concluded that, from September 24, 2005, through November 21, 2005, the facility's deficiencies posed immediate jeopardy to resident health and safety. CMS Exs. 1, 2.

Thereafter, following a January 9, 2006 survey, the State Agency determined that the facility achieved substantial compliance as of December 16, 2005, the date it identified in its plan of corrections as the date it would achieve substantial compliance. P. Ex. 3.

CMS has concurred with the State Agency, and imposes a CMP of $3,050 per day for 58 days of immediate jeopardy (September 24 through November 20, 2005) ($176,900), and $50 per day for 25 days of substantial noncompliance that was not immediate jeopardy ($1,250). The total CMP is $178,150. CMS Ex. 28; P. Exs. 2, 3.

Petitioner timely requested a hearing. The hearing convened on October 25, 2006, in Raleigh, North Carolina. Mr. Joseph Bianculli appeared on behalf of Petitioner, and Ms. Leslie A. Connery appeared on behalf of CMS. In the absence of objection, I admitted into evidence CMS Exhibits 1- 36 and Petitioner Exhibits (P. Exs.) 1- 44. Hearing Transcript (Tr.) 1.

II. Issues

The issues before me are:

1. Whether, from September 24 through December 15, 2005, the facility was in substantial compliance with program participation requirements, specifically, 42 C.F.R. §§ 483.20(k)(3)(i) and 483.25(l)(1);

   and

2. If the facility was not in substantial compliance from September 24 through November 20, 2005, did its deficiencies then pose immediate jeopardy to resident health and safety?

With respect to the amount of the penalty imposed, if I find immediate jeopardy from September 24 through November 20, 2005, I must sustain the $3,050 per day CMP, because that is the statutory and regulatory minimum for deficiencies that pose immediate jeopardy. 42 C.F.R. § 488.438. Similarly, if I find that the facility was not in substantial compliance from November 21, 2005, through December 15, 2005, I must sustain the $50 per day CMP because that is the statutory and regulatory minimum. 42 C.F.R. § 488.438(a)(1)(ii).

III. Discussion

A. From September 24 through December 15, 2005, Petitioner was not in substantial compliance with 42 C.F.R. §§ 483.20(k)(3)(i) and 483.25(l)(1) because: 1) its nursing staff repeatedly administered excessive doses of morphine to a vulnerable resident; 2) its staff repeatedly misrepresented their actions; and 3) the facility inadequately investigated the incidents.[1]

Services provided or arranged by the facility must meet professional standards of quality. 42 C.F.R. § 483.20(k)(3)(i).

Under the statute and the "quality of care" regulation, each resident must receive, and the facility must provide, the necessary care and services to allow a resident to attain or maintain the highest practicable physical, mental, and psychosocial well-being, in accordance with the resident's comprehensive assessment and plan of care. Act, section 1819(b)(2); 42 C.F.R. § 483.25. Among other quality of care requirements, each resident's drug regimen must be free from unnecessary drugs. Unnecessary drugs include any drug used: i) "in excessive dose (including duplicate drug therapy)"; ii) for excessive duration; iii) without adequate monitoring; iv) without adequate indications for its use; v) in the presence of adverse consequences indicating the dose should be reduced or discontinued; or vi) any combination of the reasons above. 42 C.F.R. § 483.25(l)(1).

Nearing the end of her life, R1 was an 82-year old hospice patient admitted to the facility on September 21, 2005. She was recovering from sepsis, and had diagnoses of metastatic colon cancer, Alzheimer's disease, and diabetes. CMS Ex. 6, at 32, 61; CMS Ex. 36, at 3 (Benson Decl. ¶ 6). Among other medications, her physician prescribed morphine sulphate, 2 milligrams by mouth every two hours. P. Ex. 24, at 1; CMS Ex. 36, at 3 (Benson Decl. ¶ 6). Morphine sulphate is a potentially dangerous and closely-regulated narcotic, used primarily for pain control and/or to induce sedation. It can be lethal, especially if used improperly in an excessive dose. CMS Ex. 35, at 3-4, 6 (Guay Decl. ¶¶ 6, 9); CMS Ex. 36, at 3, 4 (Benson Decl. ¶¶ 7, 9).

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[1] I make findings of fact and conclusions of law to support my decision in this case. I set forth each finding below, in italics and bold, as a separate heading.

The hospice supplied R1's morphine. It came in a highly concentrated form: 20 milligrams per milliliter. At this concentration, the physician order of 2 milligrams was equivalent to ***0.1*** milliliter (or one cubic centimeter) of morphine sulphate, which, the parties agree, is a very small amount. CMS Ex. 24, at 1; CMS Ex. 36, at 4, 7 (Benson Decl. ¶¶ 8, 14). The morphine came in a 30-milliliter bottle that had a clear strip down the side, marked at intervals, so, after administering a dose, staff could determine the amount of liquid remaining in the bottle. CMS Ex. 24, at 1; CMS Ex. 36, at 7 (Benson Decl. ¶ 14). With the bottle was a small syringe capable of holding just one milliliter of liquid, and divided into very small increments of measurement. P. Ex. 42, at 2 (Morlan Decl.); CMS Ex. 36, at 7 (Benson Decl. ¶ 14).

Federal and state law require that facilities closely monitor their narcotics. Facilities that dispense morphine are required to keep it under double lock and key, and to maintain accurate, contemporaneous records of the amount of medication received, administered, and remaining. CMS Ex. 35, at 6 (Guay Decl. ¶ 9). Accordingly, facilities maintain a log, called the individual narcotic record (INR), which is separate from the individual patient's medication administration record (MAR). The INR lists the patient's name, the strength and ordered dosage of his/her medication, the amount of medication initially provided, and the amount remaining after each administration. CMS Ex. 35, at 8 n.6 (Guay Decl.); CMS Ex. 36, at 4 (Benson Decl. ¶ 9). The administering nurse consults the INR for the patient's name, medication, route of administration and dosage. The nurse notes the amount of medication before the dose is given. After administering the ordered dose, the nurse measures and records the amount remaining. P. Ex. 35; Tr. 32.

Standards of nursing practice also require that licensed nurses perform a narcotic count at each shift change, when the narcotic keys change hands. The facility policy reflected this standard, requiring that the nurse coming on duty and the nurse going off duty make the count together, and document and report to the Director of Nursing (DON) any discrepancies. CMS Ex. 36, at 4 (Benson Decl. ¶ 9); CMS Ex. 19; Tr. 105. The DON was then responsible for investigating the discrepancy to determine its cause, and providing the facility administrator with a written report of her findings. CMS Ex. 19, at 2.

R1's Individual Narcotic Record. According to R1's INR, on ten separate occasions, nurses gave her ten times more morphine sulfate than ordered by her physician. P. Ex. 35; CMS Ex. 36, at 7-8 (Benson Decl. ¶ 15). The document shows:

- At 6:30 p.m. on September 24, 2005 (a Saturday), Registered Nurse (RN) Barbara Godwin administered a ***1.0*** milliliter dose instead of a ***0.1*** milliliter dose, as ordered by R1's physician. RN Godwin recorded that 25 milliliters remained in the bottle after she had administered the dose (down from 26 milliliters in the bottle *before* she administered the 6:30 p.m. dose).

- At 10:00 p.m., RN Godwin administered a second 1.0 milliliter dose and recorded that 24 milliliters remained in the bottle.

- On September 25, a second nurse (Nurse 2) administered ***three*** consecutive 1.0 milliliter doses, and indicated that 23, 22, and 21 milliliters, respectively, remained.

P. Ex. 35, at 1; CMS Ex. 6, at 27.

- During the late afternoon and evening of September 25, a third nurse administered ***three*** consecutive 1.0 milliliter doses. This nurse recorded that 20, 19, and then 18 milliliters remained in the bottle.

- The following morning, September 26, Nurse 2 again administered ***two*** 1.0 milliliter doses and recorded that 17 and then 16 milliliters remained.

- At 8:30 p.m. that evening, a different nurse, LeeAnn Harrelson, administered the correct dosage, 0.1 milliliter. She recorded that 15.9 milliliters remained.

P. Ex. 35, at 2; CMS Ex. 6, at 28. In all, the INR shows that three nurses administered a total of ten consecutive drug overdoses to R1.

By itself, the INR evidence should be sufficient to establish that the nurses' actions did not meet professional standards of quality and that R1's drug regime was not free from unnecessary drugs. Ten times the ordered amount must be considered an "excessive dose," and administering the excessive dose on multiple occasions must be considered "for excessive duration." Thus, on its face, the documentary evidence shows that the facility was not in substantial compliance with 42 C.F.R. § 483.25(l)(1) .

If, as the record shows, nursing staff were administering ten times the ordered dosage, they were obviously not following the physician's order, and failure to follow a physician's order in administering medication violates professional nursing standards. CMS Ex. 36, at 8 (Benson Decl. ¶ 16). Professional standards also require that nurses follow specific procedures to insure that residents receive the correct dosage of the

correct medication. In addition to the requirements for the administration of narcotics, discussed above, nursing standards require that, prior to administering *any* medication, a nurse must verify that the dosage he/she intends to administer is consistent with the dosage on the medication's packaging, the dosage on the MAR and the dosage on the physician's order. If any doubt remains as to the appropriate dosage, the nurse should not administer it, but should consult others, including supervisory nursing staff and/or the treating physician, to resolve those questions. CMS Ex. 36, at 6 (Benson Decl. ¶ 12). The glaring errors documented in the INR suggest that these procedures were not followed. Indeed, as discussed below, Petitioner admits that its nursing staff did not follow them. The facility was therefore not in substantial compliance with 42 C.F.R. § 483.20(k)(3)(i).

Petitioner nevertheless asks that I disregard the INR, claiming that, with one exception, the INR record entries are in error.[2] I decline to do so. First, as CMS correctly points out, federal regulations require that medical records be "complete" and "accurately documented," so "it does not help [the facility]'s case to impugn its own medical recordkeeping practice." *Britthaven of Goldsboro*, DAB No. 1960, at 10 n.8 (2005). Moreover, corroborating evidence confirms that the INR accurately reflects that three nurses administered the excessive doses of morphine, and that they failed to follow standard nursing practices designed to prevent the mis-administration of narcotics.

The Facility's Investigations. At the time of these incidents, Registered Nurse Crystal Coleman was the Unit Manager on R1's unit. On September 26, 2005 (Monday), RN Coleman told the facility's DON, Lia Morlan, that the count of R1's narcotic medication appeared to be "off." P. Ex. 42, at 2 (Morlan Decl.). Apparently unaware of the September 24 – 26 entries in R1's INR, DON Morlan claims that "a nurse apparently had administered a dose of '1.0' rather than '0.1' ml; but the Resident suffered no adverse effects."[3] P. Ex. 42, at 2 (Morlan Decl.) According to DON Morlan, no one suggested to her that more than one nurse was involved in over-medicating the resident. DON Morlan determined (by a means she does not explain) that R1 had not been harmed, and

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[2] If I agreed that nursing staff were recording wildly inaccurate medication entries, I would find that such practice violated professional standards of quality.

[3] As discussed *infra*, contrary to DON Morlan's assertion of no harm, staff contemporaneously reported to R1's physician that R1 suffered decreased respirations and became extremely lethargic as a result of the medication errors. P. Ex. 34.

instructed RN Coleman "to conduct a further investigation, to reconcile the Resident's narcotic record, and to complete the medication error report initiated by [Nurse] M. McAllister." P. Ex. 42, at 2-3 (Morlan Decl.) DON Morlan also claims that, when she subsequently followed up, all was in order:

> A day or two later, I asked Nurse Coleman whether she had completed her investigation, and she said that she had, and that everything was OK. Nurse Godwin apparently had been unaware of her error, and was not scheduled back in the building (being PRN staff) until Oct. 5th, so plans were made to bring it to her attention at that time and inservice/counsel her regarding it. So far as I was concerned, that was the typical, and appropriate, way to deal with a medication error that caused no harm, and was the end of the matter.

P. Ex. 42, at 3 (Morlan Decl.). DON Morlan now says that, in fact, RN Coleman did not reconcile the medication count, as she had claimed. P. Ex. 42, at 4 (Morlan Decl.) RN Coleman supposedly completed a medication error report, but that document has been destroyed. CMS Ex. 36, at 10 n.4 (Benson Decl.); Tr. 82, 83; *but see* 42 C.F.R. § 483.75(l) (Clinical records must be retained, and the facility must safeguard their contents against loss or destruction); Tr. 105 (destroying a medication error report is not in accordance with the standard of care).

About a week after the over-dosing, on October 4, 2005, R1's son filed a written complaint, alleging that staff failed to give his mother sufficient pain medication. Specifically, he alleged that a nurse had signed out his mother's pain medication, but went to lunch "and may not have administered it." P. Ex. 42, at 3 (Morlan Decl.). Under standards of practice, nurses should not pre-sign for narcotics or any other medications. Tr. 106. DON Morlan claims that she had already addressed the problem when the complaint was filed; she instructed the weekend supervisor to counsel the errant nurse not to sign out meds unless ready to administer them.[4] Nevertheless, according to DON Morlan, because R1's son had sent a copy of his complaint to the state, the facility's administrator, Linda Parnell, "was eager to ensure that all of our narcotic records were in order, if, in fact, a complaint team came in to investigate his allegation." P. Ex. 42, at 3

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[4] This medication irregularity, like R1's overdosing, occurred on the weekend, which suggests that the facility might have been well-advised to examine more carefully the practices of its weekend staff. But it seems that the facility did not make that connection, possibly because it was not aware that the earlier R1 medication errors spanned an entire weekend.

(Morlan Decl.); *see also* P. Ex. 43, at 2 (Parnell Decl.).[5] To that end, Administrator Parnell directed a team of registered nurses to audit R1's narcotic record, as well as the narcotic records of other residents. P. Ex. 42, at 3-4.

The nurses completed their purported audit on October 4, 2005, and RN Coleman reported to DON Morlan that R1's morphine sulfate count was not accurate: the reconciliation was off by 0.9 milliliter. According to DON Morlan, who had never, apparently, looked at the INR, "[t]his made sense to me at the time, believing that only one med error had actually been made." P. Ex. 42, at 4. DON Morlan goes on to assert that, by October 6,

> the audits had been conducted by 5 registered nurses, the nurses making the med error and documentation errors had been counseled by the administrative nurse on call (Becky Hewitt, RN, MDS Coordinator), and the inservices had been scheduled. The entire investigation had been completed under the direction of the administrator with the assistance/advice of the corporate nurse consultant. I felt sure that all was in order, and [turned my attention] to many pressing issues that took precedence over a med error that had caused no injury and had been investigated *thoroughly*.

P. Ex. 42, at 4-5 (Morlan Decl.) (emphasis added).

But the medication errors had not been "investigated thoroughly" or even adequately. The nurses' conclusions were plainly wrong, as shown by review of the INR and some simple arithmetic. After the 123rd dose had been administered, the nurse auditors measured the remaining morphine sulfate and discovered a discrepancy.[6] According to the INR entry for the dose administered at 6:30 a.m. on October 4, 2005 (which was the

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[5] Administrator Parnell has a slightly different recollection. She says that DON Morlan expressed the concern that the state probably would investigate, and DON Morlan wanted to be sure that all narcotic administration records were complete and accurate. P. Ex. 43, at 2 (Parnell Decl.)

[6] The individual doses are not all numbered consecutively on the INR. The 40 doses listed on the first page of the INR (P. Ex. 35, at 1) are not numbered at all. The next page contains 60 doses (the 41st through 100th doses administered to R1), numbered 60 down to 1. P. Ex. 35, at 2. The next 36 doses administered to R1 are on the third page of the INR, and are numbered 120 down to 83. (At space 96, no dose was given; in that space, staff wrote that they found a 0.9 milliliter discrepancy). P. Ex. 35, at 3.

123rd dose administered from the bottle) 8.3 milliliters remained. But, at 7:20 a.m. staff measured only 7.4 milliliters remaining in the bottle. They concluded that the dosage was off by 0.9 milliliter.[7] P. Ex. 35, at 3.

In fact, the discrepancy was far more significant than 0.9 milliliter. Staff began to administer the medication on September 21, 2005, starting with 30 milliliters.[8] Had they consistently administered the medication properly, by the 123rd dose, staff would have administered about 12.3 milliliters of morphine. (123 x 0.1 = 12.3). ***17.7*** milliliters should have been left in the bottle. (30 – 12.3 = 17.7). The discrepancy was ***9.4*** milliliters, not 0.9, as the DON has claimed. (17.7 – 8.3 = 9.4). That's almost a third of the bottle. This count is absolutely consistent with the finding that ten excessive doses had been given. *Accord* CMS Ex. 35, at 15 (Guay Decl. ¶ 20); Tr. 146; CMS Ex. 36, at 11 (Benson Decl. ¶ 22).

The facility's medication error report indicates that staff advised R1's physician (and the facility medical director), Ray Thigpen, M.D., that from September 24, 2005 through September 26, 2005, three different nurses administered nine excessive doses ("1 cc instead of 0.1 cc") of morphine sulfate to R1. P. Ex. 34; CMS Ex. 8. The facility administrator signed the report on October 6. The pharmacist signed it on November 20,

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[7] In a written statement she provided to the surveyors at the time of the survey, DON Morlan claimed that the nurse auditors inaccurately subtracted and the discrepancy was 0.7 rather than 0.9. She does not explain how she came up with that figure. CMS Ex. 13, at 1.

[8] Petitioner posits, without any supporting documentation, that the vial may not have contained 30 milliliters of morphine. Citing rules for drug labeling (21 C.F.R. § 201.51(g)) for the proposition that liquid drugs must state on their labels the *minimum* volume contained therein and may otherwise vary as much as 10%, Petitioner suggests that the vial may have contained as few as 27 milliliters. P. Posthearing Br. at 13 *et seq.* But this does not follow. Assuming the hospice complied with federal labeling regulations – and no evidence suggests that it did not – the vial contained at least 30 milliliters, and as many as 33 milliliters, of morphine sulphate. That up to three additional milliliters might be unaccounted for hardly furthers Petitioner's case. In any event, since *all* of the records that mention an initial amount of morphine sulfate say that the facility received 30 milliliters, and *no* record suggests any other amount, I can reasonably conclude that the facility received 30 milliliters of morphine sulfate. *See* P. Exs. 5, 35; CMS Ex. 6, at 26, 27. Ultimately, the facility nurses are responsible for verifying the amount of medication received (Tr. 104), and they consistently recorded receipt of 30 milliliters. P. Exs. 5, 35; CMS Ex. 6, at 26.

2005. P. Ex. 34. Although she was the individual charged with overseeing the investigation, DON Morlan did not sign the report at all, which suggests that she did not review it and is consistent with her apparent ignorance as to its contents.

In a separate note dated September 26, 2005, at 11:25 p.m., Matresse McAllister, the nurse who "initiated" the medication error report (P. Ex. 42, at 3 (Morlan Decl.)), wrote:

> [indecipherable] Dr. Thigpen in regards to medication error found on [R1]. Morphine Sulfate 2 mg po q 2° for pain (terminal cancer) was given at 1 cc instead of 0.1 cc as ordered starting on 9/24/05 ending on 9/26/05 at 4:30 am X 9 [indecipherable].
>
> Weekend supervisor aware. Med error report filled out left [with] DON.

CMS Ex. 8, at 2.[9]

Notwithstanding this compelling documentary evidence – generated contemporaneously by its own staff – Petitioner concedes only that one nurse administered one overdose. On November 14, 2005, both the facility's DON and its MDS coordinator (Becky Hewitt) told Surveyor Benson that, notwithstanding the documentation of ten errors, only one dosage error occurred ("I know it looks like nine errors to you, but it was really only one."). CMS Ex. 36, at 12 (Benson Decl. ¶ 23). In support, Petitioner points out that only RN Godwin admitted making a medication error.[10] The other two nurses insisted

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[9] The contemporaneous documents thus show that staff reported to Dr. Thigpen multiple instances of overdosing throughout the weekend of September 24 – 26. I therefore find unconvincing Dr. Thigpen's declaration that:

> As I understood it, a nurse reconciling the patient's narcotic count on Monday morning September 26 discovered a discrepancy, and determined that a weekend nurse apparently had administered 1.0 rather than 0.1 milliliters of morphine.

P. Ex. 44, at 3 (Thigpen Decl.).

[10] RN Godwin complained that she had difficulty reading the label on the box of morphine sulfate because it was "smeared" and she thought that it read "***2*** mg/ml" – a much less concentrated formulation (CMS Ex. 35, at 5 (Guay Decl. ¶ 8)) – rather than "***20***

that they gave the correct dosage, but, in recording the dosage, put the decimal point in the wrong place, and, according to DON Morlan, "I had no way at that time to determine whether they were telling the truth or not." P. Ex. 42, at 5; CMS Ex. 13, at 2.

Had the DON followed up on her staff's denials, she would have realized how inconsistent their claims were with all of the other evidence. As the above discussion shows, the amount of morphine remaining on October 4 is consistent with the finding of ten overdoses. DON Morlan overlooks the October 4 count, and argues that, by the time she learned the extent of the problem – which was not until the time of the survey – it was "impossible" to determine how much medication was administered in excess of the ordered amount since, "we were unable physically to measure the amount of medication remaining in the vial, because the vial was used up on October 5, and discarded at that time." P. Ex. 42, at 5 (Morlan Decl.). But this assertion is also wrong. It would have been very easy to "measure" and reconcile at any time, with or without the vial. Facility staff knew how much medication they started with; they knew the number of doses given; and they knew the amount of medication left in the vial as of October 5 – none. On that day it was "used up."[11]

Another obvious problem with the nurses' claims that their sole errors were in misplacing a decimal point: how to account for their entries under the amount remaining, which they invariably recorded as 1.0 milliliter less than the amount they started with. P. Ex. 35, at 1, 2; CMS Ex. 6, at 26, 27. Petitioner now concedes that staff made *no* effort to measure independently the amount of medication remaining in the vial, and that they simply

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mg/ml." CMS Ex. 10; CMS Ex. 36, at 8 (Benson Decl. ¶ 17). Of course, inability to read the label does not justify administering the wrong dosage, and I agree with CMS's expert pharmacologist, Dr. David Guay, that for a nurse to administer a medication without verifying the correct dosage deviates from the most basic standards for medication administration. CMS Ex. 35, at 10 (Guay Decl. ¶ 14).

[11] DON Morlan asserts in her declaration that the morphine was "used up" on October 5, which I accept. I note, however, that the final entries on the INR show that at 6:30 a.m. a nurse administered 0.5 milliliter (in accordance with an October 4 physician's order), leaving 2.2 milliliters of morphine sulfate. At 8:30 p.m., another nurse administered 0.5 milliliters, although the "amount left" entry has been crossed out. The INR contains no other entries. Presumably, 1.7 milliliters, or approximately 3 more doses would have remained, which, following the physician's order, would have depleted the morphine that day. P. Ex. 35, at 3. On October 7, two days after the vial of morphine was "used up," R1's physician discontinued the morphine and ordered the Fentanyl. P. Ex. 23, at 4.

subtracted the "incorrectly recorded" (1.0 milliliter) dosage from the amount previously recorded. P. Pre-hearing Br. at 13-14. This certainly explains how the narcotic medication count could be off by 9.4 milliliters without the staff's noticing. But it is no defense. The practice is wholly inconsistent with standards of quality for dispensing and tracking narcotics, and therefore violative of 42 C.F.R. § 483.20(k)(3)(i).

Further, if these nurses were telling the truth, which I find highly unlikely, then the facility still had a significant and uninvestigated problem – almost a third of R1's morphine disappeared. Where did it go?

I reject Petitioner's poorly supported suggestion that the "viscosity" of the drug rendered it impossible to measure (thus justifying staff's failure to measure the amount remaining after they administered a dose), and explains the 9.4 milliliter discrepancy. I note that no one who was actually charged with administering the medication testified. I see no complaints from staff that they could not measure the amounts remaining in the vial. The only support for Petitioner's argument is DON Morlan's description of the medication as "a thick syrup, similar to common children's medicines." P. Ex. 42, at 2 (Morlan Decl.). On the other hand, Dr. Guay, who would know, testified that the morphine sulphate is *not* a thick, viscous liquid. "[I]t's a thin, aqueous – that is, water-based liquid – this is not difficult to draw up. It doesn't cling exceedingly to glass or to syringes." Tr. 149.

I recognize that the ordered dosage was small, and staff might have difficulty distinguishing 0.1 milliliter increments. However, this difficulty does not entitle staff to ignore the requirement that they independently verify and record the amount remaining. As Dr. Guay points out, had any nurse done so from September 24 through 26, 2005, (s)he would have noticed a very perceptible change in the level of liquid in the bottle, which should have alerted him/her to the excessive dosing. CMS Ex. 35, at 11 (Guay Decl. ¶ 16). Further, even if the individual nurses failed to verify the amount remaining after they administered the medication, staff responsible for counting narcotics at each shift change should have done so, leading to earlier detection of the overdosing.

Dr. Guay acknowledged, and I accept, that some waste is inevitable, but it would be small. Tr. 151-152. *See, e.g.*, P. Ex. 35, at 1. For example, at 10:30 p.m. on September 23, a nurse administered 0.1 milliliter, but recorded that the amount decreased from 27.3 to 27.1. This was likely a reasonable adjustment based on the loss of 0.1 milliliter after 27 doses had been administered. That reasonable degree of "waste" is a far cry from almost ten milliliters. It strains credulity to conclude that one-third of this powerful narcotic was lost because it clung to the syringe or to the sides of the vial.

Thus, compelling evidence establishes that three nurses administered to R1 ten consecutive morphine overdoses. Because staff were not adequately monitoring the remaining amount of the narcotic, the errors went undetected. When confronted, the nurses denied responsibility, and the facility did not follow up. Ironically, DON Morlan asserts that "owning up to our mistakes is one of the most important facets of nursing." CMS Ex. 13, at 2. I agree that owning up to mistakes is critically important, but conclude that the facility's nursing staff did not do so.

In other respects, the facility's investigation fell short of standards of quality. Facility policies made DON Morlan responsible for investigating and reporting medication errors. When the error was initially brought to her attention on September 26, 2005, she delegated that task to the Unit Manager, "which is my usual practice." P. Ex. 42, at 7 (Morlan Decl.). It seems that RN Coleman conducted no real investigation. She may have asked the responsible nurses whether they had given the correct dosages, but she made no effort to reconcile the amount of medication left in the bottle with the amount listed on the INR at that time. DON Morlan concedes the inadequacy of the investigation, but characterizes it as "inconsequential":

> As it happens, the nurse reported to me that she had conducted a complete investigation when she really had not, but I had no reason to doubt her report to me at the time. While it obviously would have been better for the nurse to have completed her investigation, even in retrospect, her failure to do so seems inconsequential, since my nursing staff did promptly identify and address the cause of the error, and we promptly took appropriate corrective action.

P. Ex. 42, at 7 (Morlan Decl.).

The facility's failure to investigate was hardly "inconsequential." Given the serious risks posed by a narcotic overdose, and the number of nurses involved, standards of practice dictate an immediate narcotic medication count. CMS Ex. 36, at 11 (Benson Decl. ¶¶ 21, 22); Tr. 98. ("[W]ith a narcotic like morphine and overdosing at that level, there should have been an immediate response.") That she delegated this responsibility does not absolve the DON, or the facility, from its obligation to ensure that the action was taken. *See Emerald Oaks*, DAB No. 1800, at 7 n.3 (2001) (The facility "cannot disown the consequences" of inadequate care by the simple expedient of pointing the finger at staff, who are agents of the facility, "empowered to make and carry out daily care decisions.")

Additional findings. Although the most serious, R1's overdosing was not the only problem the surveyors found with respect to narcotics administration. The incident that led to R1's son complaining about staff's failure to administer medication to his mother was not isolated. On October 1, 2005, facility auditors found that a nurse had "pre-signed for all narcotics for the shift." CMS Ex. 26, at 3.

The surveyors found another overdosing incident of which the facility seemed unaware. R4's physician ordered Lorazepam (Ativan), a controlled substance, one tablet, twice a day, at 8:00 a.m. and 8:00 p.m. CMS Ex. 14, at 5. R4's INR shows that on October 28, 2005, staff administered to her at least three tablets, at 7:30 a.m., 2:00 p.m., and 8:00 p.m. *Id.* at 6.[12]

While Petitioner concedes that its staff made mistakes, it argues that the facility should not be held accountable for those errors. Petitioner points out that "every nurse is trained and drilled to record medications properly, and it is not clear how Petitioner, or any nursing facility, could prevent this sort of error." P. Posthearing Br. at 38. In Petitioner's view, the problem was "the result of human error" rather than some systemic breakdown. P. Br. at 2. As pointed out in *Barn Hill Care Center*, DAB No. 1848, at 18 (2002), the regulatory requirements offer no "human error" exception:

> Indeed, it is difficult to imagine any deficiency that is not, at its core, attributable to "human error." A facility, therefore, puts in place systems that minimize the chance for "human error."

Id. at 18, *citing* DAB CR902, at 10 (2002).

Here, those systems failed. The individual nurses administering the medication did not follow appropriate protocols, and administered narcotics overdoses. Narcotic counts at shift change should have picked up the errors, but did not. When someone finally noticed, the person charged with investigating conducted no real investigation, but represented that she had. Staff's purported eventual reconciliation of the narcotics was inadequate; they did not consider how much medication should have been administered

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[12] In fact, the INR contains four entries dated October 28. The first (found on line 2) says that a tablet was given at 8:00 p.m. Staff probably made a mistake in entering the date, since the next entry shows that a tablet was administered at 7:30 a.m. on October 27. CMS Ex. 14, at 6.

and how much should have remained. These shortcomings mean that the facility was not in substantial compliance with program requirements, specifically 42 C.F.R. §§ 483.20(k)(3)(i) and 483.25(l)(1).

B. CMS's determination that the facility's deficiencies posed immediate jeopardy to resident health and safety is not clearly erroneous.

I next consider whether CMS's immediate jeopardy finding was "clearly erroneous."

CMS's determination as to the level of a facility's noncompliance – which includes its immediate jeopardy finding – must be upheld unless it is "clearly erroneous." 42 C.F.R. § 498.60(c). The Departmental Appeals 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, *citing Koester Pavilion*, DAB No. 1750 (2000).

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 parties have debated at some length whether the morphine overdoses caused R1 actual harm. CMS points to evidence of her reduced respiratory rate, periods of sleep apnea, and episodes of Cheyne-Stokes breathing, to establish serious harm attributable to the overdosing. CMS Ex. 35, at 6-7, 12 (Guay Decl. ¶¶ 10, 11, 17); CMS Ex. 36, at 5, 13 (Benson Decl. ¶¶ 10, 24); P. Ex. 26, at 4; Tr. 66, 75. Petitioner argues that these problems were instead attributable to R1's underlying conditions, and that the overdosing caused her no harm. P. Ex. 42, at 2, 3, 6, 7 (Morlan Decl.); P. Ex. 44, at 3 (Thigpen Decl.). I note that Petitioner's position is inconsistent with the surviving medication error report. That document indicates that, as a result of the excessive dosing, R1 suffered decreased respirations and became "extremely lethargic." According to the report, her morphine was subsequently withheld (likely subjecting her to increased discomfort) until these problems resolved. P. Ex. 34.

In any event, the regulation does not require that a resident suffer actual harm; the *likelihood* of serious injury or harm creates immediate jeopardy. Morphine is widely known to have life-threatening side effects if administered in excessive amounts. CMS Ex. 36, at 13 (Benson Decl. ¶ 24). Even Dr. Thigpen agrees that an overdose of a narcotic medication potentially can be a serious matter. P. Ex. 44, at 3 (Thigpen Decl.) Here, on multiple occasions, facility nurses administered to a vulnerable resident

massively excessive doses of that narcotic. Their errors "related to some of the most basic concepts of nursing practice." CMS Ex. 36, at 13 (Benson Decl. ¶ 24). The facility then failed to investigate adequately. Indeed, facility administration was not even aware of the seriousness of the overdosage until the time of the survey.

In light of these significant facts, I do not find "clearly erroneous" CMS's immediate jeopardy determination.

C. The duration of the penalty is consistent with statutory and regulatory requirements.

The Board has repeatedly explained that, under the regulatory scheme, any deficiency that has a potential for more than minimal harm is necessarily indicative of problems in the facility that need to be corrected. *Barn Hill Care Center* at 12-18; *Lake City Extended Care Center*, DAB No. 1658, at 14 (1998). Since I found that the deficiencies cited have the potential for more than minimal harm, I must also find that the facility was out of compliance "from the date of the completion of the survey in which [these deficiencies] were cited until the date of the resurvey in which substantial compliance was established." *Lake City* at 14-15. Substantial compliance means not only that the specific cited instances of substandard care were corrected, and that no other instances have occurred, but also that the facility has implemented a plan of correction designed to assure that no such incidents occur in the future. No findings that the facility violated the standard of care between these dates are required in order to find the facility out of substantial compliance, nor can evidence of other incidents in which the facility met the standard of care change the fact that it was out of substantial compliance. *Barn Hill Care Center; Lake City* at 15; s*ee also Hermina Traeye Memorial Nursing Home*, DAB No. 1810, at 19 (2002) ("The burden is on the facility to prove that it has resumed complying with program requirements, not on CMS to prove that deficiencies continued to exist after they were discovered."); *Asbury Center at Johnson City*, DAB No. 1815, at 20 (2002) ("[A] facility's return to substantial compliance must usually be established through a resurvey, and in a situation involving inadequate supervision, requiring such a resurvey appears wise."); *Cross Creek Care Center*, DAB No. 1665 (1998).

Petitioner has not established that an effective plan of correction had been implemented any earlier than CMS has found. In fact, additional violations of the standards of care occurred. The surveyors found that on October 28, 2005, R4 had received an additional dose of Lorazepam, an error that was never noted or investigated. CMS Ex. 14, at 5. In Dr. Guay's opinion:

> [T]he situation involving [R4] reflects many of the same problems with medication administration that were evident in the facility's administration of morphine sulphate to [R1]. The fact that [R4] received a dose of Lorazepam that was not ordered by her physician strongly suggests that the nurse providing the medication failed to review the MAR, INR, and physician order prior to giving the medication. Moreover, it is my understanding that facility staff were not aware of the extra dose until the surveyors brought it to their attention. In my opinion, the nursing staff should have identified this error at the next scheduled medication time through review of the MAR, INR, and physician's order. The fact that the situation occurred approximately one month after staff administered excessive doses of morphine sulfate to [R1] suggests that this facility continued to evidence significant problems with fundamental aspects of medication administration.

CMS Ex. 35, at 16 (Guay Decl. ¶ 22).

At the time of the survey, no effective investigation of R1's overdosing had occurred. Administrative staff were not even aware of the extent of the facility's problem. In its plan of correction, the facility promised closer DON oversight in the administration of liquid narcotics. But on November 16, 2005, the DON learned for the first time of a November 11 order for a liquid narcotic. She later learned that the bottle created difficulty for staff in counting the drug, and returned it to the pharmacy, asking that it be repackaged in a container "that allowed for easier visualization." CMS Ex. 36, at 14 (Benson Decl. ¶ 25); Tr. 56-57.

On November 21, 2005, the facility's risk manager finally trained the nurses and the Administrator on the proper procedures for investigating medication errors. I agree that such training was "a necessary predicate to the removal of immediate jeopardy because the facility's handling of the events involving Resident # 1 demonstrated that administrative staff did not understand the importance of conducting a thorough investigation." CMS Ex. 36, at 15 (Benson Decl. ¶ 26). However, training alone does not ensure that the cited deficiencies will not recur. The facility must then follow-up with staff to verify that they have understood and implemented the practices taught.

D. The facility's per day CMP for the period of noncompliance at the immediate jeopardy level must be at least $3,050, and the CMP for each day of noncompliance that is not immediate jeopardy must be at least $50.

The statute and regulations limit my authority to review the amount of the CMP. In situations such as this, where the deficiencies constitute immediate jeopardy, CMS may impose a CMP in the range of $3,050 to $10,000 per day. 42 C.F.R. § 488.438. Where a CMP of $3,050 per day is imposed, the daily amount must be sustained unless the nursing home establishes that the determination of immediate jeopardy is clearly erroneous. *Hermina Traeye Memorial Nursing Home*, DAB No. 1810, at 16 (2002).

With respect to the days of substantial noncompliance that was not immediate jeopardy, the minimum penalty must be at least $50 per day. 42 C.F.R. § 488.438.

IV. Conclusion

For all of the reasons discussed above, I uphold CMS's determination that from September 24 through December 15, 2005, the facility was not in substantial compliance with program participation requirements, specifically 42 C.F.R. §§ 483.20(k)(3)(i) (services must meet professional standards of care) and 483.25(l)(1) (residents must be free from unnecessary drugs). I uphold CMS's determination that, from September 24 through November 20, 2005, the facility's deficiencies posed immediate jeopardy to resident health and safety.

The CMP imposed is the statutory minimum and is therefore reasonable as a matter of law.

/s/
Carolyn Cozad Hughes
Administrative Law Judge