Department of Health and Human Services

DEPARTMENTAL APPEALS BOARD

Civil Remedies Division

In the Case of:	)	
	)	
Centerclair, Inc.,	)	Date: March 10, 2008
	)	
Petitioner,	)	
	)	Docket No. C-07-47
- v. -	)	Decision No. CR1747
	)	
Centers for Medicare & Medicaid Services.	)	
	)	

DECISION

Petitioner, Centerclair, Inc., is a long-term care facility located in Lexington, North Carolina, that is certified to participate in the Medicare program as a provider of services. Surveyors from the North Carolina Department of Health and Human Services, Division of Facility Services (State Agency) completed a complaint investigation survey on August 1, 2006. As a result of their findings, the Centers for Medicare & Medicaid Services (CMS) determined that, from June 1, 2006, through August 18, 2006, the facility was not in substantial compliance with program requirements, and, from June 1, 2006, through July 31, 2006, its deficiencies posed immediate jeopardy to resident health and safety. CMS imposed civil money penalties (CMPs) of $3050 per day for 61 days of immediate jeopardy, and $100 per day for 18 days of substantial noncompliance that was not immediate jeopardy ($187,850 total). Petitioner here challenges those determinations.

For the reasons set forth below, I find that the facility was not in substantial compliance with program requirements for the period in question, and that, from June 1 through July 31, 2006, its deficiencies posed immediate jeopardy to resident health and safety. Petitioner has not challenged the reasonableness of the CMP, so that issue is not before me.

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 to promulgate regulations implementing those statutory provisions. Act § 1819. The Secretary's regulations are found at 42 C.F.R. Part 483 (2006). 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.

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 § 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 § 1819(g)(2)(A); 42 C.F.R. §§ 488.20(a); 488.308.

In this case, the surveyors found that a facility resident, identified as at high risk for injury from choking and/or aspiration, was nevertheless allowed to suck on foreign objects (disposable oral swabs called toothettes) and had, at least twice, ingested foreign objects. Based on the surveyor findings, CMS determined that the facility was not in substantial compliance with the following federal requirements for nursing homes participating in the Medicare program:

- 42 C.F.R. § 483.13(c) (Tag F224 – failure to implement policies and procedures that prohibit mistreatment, neglect and abuse of residents, at scope and severity level J – isolated instance of immediate jeopardy);[1]

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[1] Although the state surveyors did not cite a deficiency under section 483.13(c), CMS subsequently determined that the surveyors' factual findings supported the conclusion that the facility was also not in substantial compliance with the requirement that it implement policies and procedures that prohibit resident neglect. Such action is well within CMS's discretion, and Petitioner has been provided ample notice of CMS's determination. *See* 42 C.F.R. § 498.56(a); *Alden Town Manor Rehab & HCC*, DAB No. 2054, at 17-19 (2006) (While fairness requires that facilities know, prior to hearing, what they must answer to, the Statement of Deficiencies is not the sole source of notice, which may be provided during the pre-hearing development of the case.).

- 42 C.F.R. § 483.25(h)(1) and (2) (Tags F323 and F324 – quality of care, failure to prevent accidents, at scope and severity level J); and

- 42 C.F.R. § 483.75(l)(1) (Tag F514 – failure to maintain clinical records in accordance with accepted professional standards, at scope and severity level D – isolated instance presenting no actual harm, with the potential for more than minimal harm).

CMS (Exhibit) Ex. 2; CMS Pre-hearing Br. at 3, 7-13.

CMS has imposed CMPs of $3050 per day for 61 days of immediate jeopardy, and $100 per day for 18 days of noncompliance that was not immediate jeopardy.

The facility timely requested a hearing, and the matter was assigned to me. I held a hearing in Raleigh, North Carolina on September 25, 2007. Mr. Kenneth L. Burgess appeared on behalf of Petitioner, and Ms. J. Lori Kee appeared on behalf of CMS. I admitted into evidence CMS Exs. 1-28 and Petitioner's (P.) Exs. 1-18. Tr. 3.
The parties have filed initial briefs (Br.) and closing briefs (Cl. Br.). CMS has filed a reply brief (CMS Reply).

II. Issues

This case presents the following questions:

- Whether, from June 1 through August 18, 2006, the facility was in substantial compliance with requirements for facilities participating in the Medicare program, specifically 42 C.F.R. §§ 483.13(c) (neglect); 483.25(h)(1) and (2) (failure to prevent accidents); and 483.75(l)(1) (clinical records)?

- If the facility was not in substantial compliance from June 1 through July 31, 2006, did its deficiencies then pose immediate jeopardy to resident health and safety?

III. Discussion

A. The facility was not in substantial compliance with 42 C.F.R. §§ 483.13(c) (neglect), 483.25(h)(1) and (h)(2) (quality of care), and 483.75(l)(1) (clinical records), because its staff allowed one of its residents to engage in dangerous behavior, and, when confronted with evidence of that behavior, did not properly document, investigate nor intervene.[2]

Regulatory requirements. "Neglect" means failure to provide goods and services necessary to avoid physical harm, mental anguish, or mental illness. 42 C.F.R. § 488.301. A facility must develop and implement written policies and procedures that prohibit resident neglect. 42 C.F.R. § 483.13(c). This regulation governing staff treatment of residents "addresses a deficiency related to lack of an effective policy as opposed to one directed at the occurrence of neglect itself." *Emerald Oaks*, DAB No. 1800, at 12 (2001). However, the drafters of the regulation characterized as "inherent in § 483.13(c)" the requirement that "each resident should be free from neglect as well as other forms of mistreatment." 59 Fed. Reg. 56,130 (November 10, 1994). The drafters also deliberately rejected the suggestion that the regulations require evidence of a negative outcome to support the finding of neglect:

> We do not accept this comment because neglect may be determined even if no apparent negative outcome has occurred. The potential for negative outcome must be considered.

Id.

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 § 1819(b); 42 C.F.R. § 483.25. Among other requirements, the facility must ensure that the resident environment is as free of accident hazards as possible, and that each resident receives adequate supervision and assistance devices to prevent accidents. 42 C.F.R. § 483.25(h)(1) and (2).

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[2] My findings of fact and conclusions of law are set forth, in italics and bold, in the discussion captions.

The facility is also required to maintain clinical records on each resident in accordance with accepted professional standards and practices. These records must be complete and accurate. 42 C.F.R. § 483.75(1)(1).

In this case, Resident 3 (R3) was a 90-year old woman admitted to the facility on March 10, 2006, with diagnoses of Alzheimer's-type dementia, cerebrovascular accident (stroke), congestive heart failure, and history of failure to thrive. She was entirely dependent on staff. But, although she required total care, she also resisted care. Nursing notes describe some of the difficulties staff had in caring for her. She was confused, unable to make her needs known, was "constantly babbling," and became "very anxious" when care was given. CMS Ex. 4, at 15 *et seq*.; P. Ex. 2, at 2-3 (Morton Decl. ¶ 6); Tr. 79.

R3 had severe oral/pharyngeal dysphagia (very serious difficulty chewing and swallowing solids and liquids) and was therefore at risk for choking and aspiration. She could take nothing by mouth (referred to as NPO), and received nourishment by means of a gastric-tube. CMS Ex. 4, at 9, 14, 38, 40, 58-62, 66-68; CMS Ex. 27, at 2-3 (Lesesne Decl. ¶¶ 4, 5). Although the testimony of R3's treating doctor is silent on the reason for the NPO (P. Ex. 4), CMS's expert, Dr. A. Jefferson Lesesne, M.D., explains that a physician usually orders NPO status because the patient faces a substantial risk of injury caused by choking. CMS Ex. 27, at 3 (Lesesne Decl. ¶ 6).[3]

The parties agree that R3 could not safely take anything by mouth. Yet, facility staff concede that, contrary to the facility's policies and procedures, at least one nurse gave her oral swabs to suck on in order to keep her calm while the nurse provided care. The evidence also establishes that, with staff's knowledge, R3's visiting family members provided her with swabs to suck on, but staff took no action to stop the practice nor to educate the family as to the risks. Further, compelling evidence establishes that on two occasions – June 1 and June 12, 2006 – foreign objects (including the sponge tips from oral swabs) were found in R3's bowel movements, strongly suggesting that she ingested them while at the facility. Facility staff did not adequately document or investigate either of these occurrences, again in contravention of facility policies and procedures, as well as accepted professional standards.

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[3] Dr. Lesesne is a physician Board-certified in geriatric medicine and internal medicine. He is an assistant professor in the Division of Geriatric Medicine and Gerontology at Emory University School of Medicine. CMS Ex. 26.

1. Facility staff allowed R3 to suck on oral swabs, in contravention of the instructions from the swab manufacturer, the facility's own policies and procedures, and acceptable standards of care.

R3 was without teeth. Her care plan required that her mouth be cleaned several times a day. CMS Ex. 4, at 1. To clean her mouth, staff used a brand of disposable oral swabs called toothettes. A toothette consists of a small star-shaped sponge affixed to a small (3.5 inch) stick resembling a lollipop stick. CMS Ex. 25; CMS Ex. 27, at 4 (Lesesne Decl. ¶ 8); CMS Ex. 28, at 4 (Bridges Decl. ¶ 8); P. Ex. 18.

Toothettes were a problem for R3. She liked to suck on them. P. Ex. 1, at 2 (Leazer Decl. ¶ 4); CMS Ex. 4, at 16; CMS Ex. 28, at 10, 11 (Bridges Decl.). But sucking on toothettes was dangerous for R3. She risked ingesting all or part of the toothette, and she risked aspirating liquid from the toothette into her lungs. CMS Ex. 28, at 7 (Bridges Decl. ¶ 11).

In a nursing note dated March 21, 2006, licensed practical nurse (LPN) Carolyn Morton writes that R3 "likes to have a toothette (wet) to keep in her mouth like a sucker." CMS Ex. 4, at 16. I agree with Dr. Lesesne that this note "should have raised very serious safety concerns in the minds of the facility staff caring for the resident" and that the facility's failure to identify and act on the risk represents a significant departure from the standard of care. CMS Ex. 27, at 4, 5 (Lesesne Decl. ¶¶ 8, 9). The facility should have conducted an immediate assessment as to whether sucking on toothettes placed the resident at risk. CMS Ex. 27, at 4-5 (Lesesne Decl. ¶¶ 8, 9).

Yet, the facility did not evaluate whether the behavior was safe; it undertook no investigation into that behavior, and took no action in response to the nurses note. CMS Ex. 28, at 7 (Bridges Decl. ¶ 11).

LPN Morton serves as charge nurse on the second shift, having responsibility for the overall care of the residents. P. Ex. 2, at 1 (Morton Decl. ¶ 1). In her declaration she admits writing the March 21 nurses note, but she claims that her intention was "to record historical information I learned from R3's responsible party, Debbie Leazer, and from observing [R3] when I provided dental care to her using a toothette." P. Ex. 2, at 1 (Morton Decl. ¶ 2). She denied that the note meant that the staff gave R3 toothettes to suck on. P. Ex. 2, at 2 (Morton Decl. ¶ 2).

In fact, although the facility's witnesses have disputed the prevalence of the practice, all agree that staff – notably LPN Morton – *did* give R3 toothettes to suck on. By her own admission:

> On two occasions I allowed [R3] to retain a toothette in her mouth while I performed her G-tube care. This was because [R3] was very combative during her G-tube care. On more than one occasion, I have been struck by [R3] while attempting to perform her G-tube care. I observed that having a toothette in her mouth calmed [R3] . . . while I performed her G-tube care, watching her closely. The sole purpose of leaving the toothette in [R3's] mouth on those two occasions was to allow me to safely perform her G-tube care and the entire incident lasted only several minutes. On both occasions, I then retrieved the toothette, checked to make sure it was fully intact, and then disposed of it.

P. Ex. 2, at 2-3 (Morton Decl. ¶ 6). LPN Morton seems oblivious to the risks inherent to her actions. She goes on to opine that allowing R3 to suck on a toothette was "in my opinion, reasonable given that performing the G-tube care was very difficult, and allowing the resident to retain a toothette in her mouth, from her just-completed oral care, calmed her long enough for me to safely complete the G-tube care which was critical since it was her only source of nutrition and hydration." P. Ex. 2, at 4 (Morton Decl. ¶ 9).

LPN Morton also admitted that when she reported to the nurse coming on duty, she "made her aware that this did calm her down because we were having a hard time trying to do care on her with her G tube." Tr. 79. So at least one other nurse was aware of LPN Morton's practice, although LPN Morton did not know whether that nurse also used a toothette to calm the resident. Tr. 79.

LPN Morton explained that R3's granddaughter recommended using the toothettes to calm R3 when she became combative. Tr. 76-77. LPN Morton did not inform the facility's director of nursing (DON) or the facility administrator that R3's granddaughter had suggested allowing R3 to suck on toothettes, apparently because she did not see the practice as risky. Tr. 77.

> [T]he granddaughter said they used that at home to calm her, so that's what I used, and she – and she readily took it. So that made me know that she had had it before.

Tr. 80.[4]

LPN Morton's testimony presents several problems for the facility. First, the practice of allowing R3 to suck on the oral swabs was simply dangerous. As Dr. Lesesne observes, it was not safe to allow R3 to suck on the oral swabs for any period of time, whether or not she was supervised.

Second, R3 was not care-planned for her combative behavior during G-tube care. If, in fact, staff were unable to provide necessary care safely, that behavior should have been identified, assessed, and addressed in her care plan. Staff are not supposed to come up with *ad hoc* solutions, particularly where those solutions present their own risks.

Third, compelling evidence establishes that LPN Morton allowed the practice more often than she admits, and that multiple staff members knew it. Surveyor Bridges testified that, in addition to her own observation (CMS Ex. 28, at 10 n.7), three certified nurse aides (CNAs), Courtney Hoey, Winnie Crow, and Sandra Brown, told her that they had seen R3 sucking on toothettes unsupervised. Each also told Surveyor Bridges that she had reported her observations to LPN Morton, the charge nurse. CMS Ex. 28, at 11 (Bridges Decl. ¶ 16); P. Ex. 12 (Crow Decl. ¶ 1); Tr. 45. In testimony before this tribunal, the CNAs essentially confirmed the surveyor report.

CNA Crow could not remember exactly when she made the observation, but she testified that she entered R3's room, and found R3 alone with a toothette in her mouth. LPN Morton was out in the hallway, passing meds. She told LPN Morton that R3 had the toothette in her mouth, and LPN Morton "said yes she knew that and she was right outside the door." LPN Morton later removed the toothette. Tr. 46-47. CNA Crow did not document the incident.[5]

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[4] In this regard, her testimony directly contradicts the granddaughter's declaration. The granddaughter testified that she told home care staff not to leave R3 alone with toothettes and reprimanded them for doing so. P. Ex. 1, at 2-3. I find this unlikely. Although LPN Morton was generally not a very credible witness, this part of her testimony rang true, and was supported by statements from other staff. CMS Ex. 22, at 15 (Certified Nurse Assistant (CNA) observed family providing toothettes to R3).

[5] As discussed, *infra*, the facility's written policy required that *all* incidents be reported, documented, and investigated, no matter how minor. CMS Ex. 10, at 1-2.

CNA Brown initially testified that she observed R3 with a toothette in her mouth "on one occasion," which she reported to LPN Morton. P. Ex. 13 (Brown Decl. ¶ 1). However, under cross-examination, she admitted that she had in fact *twice* observed R3 alone in her room with a toothette in her mouth, although she had reported it only once. Tr. 52.

> I walked into the room and I saw her with one in her mouth. And I was taken aback. But I thought it was an isolated incident and I thought maybe someone was in a hurry . . . I took it away from her. And then when . . . it happened again, I was like, well, I've got to say something, you know, this is not okay.

Tr. 53. She reported the second observation to LPN Morton, who was then at the far end of the hall, passing out medications. Tr. 54. She did not document the incident. LPN Morton essentially confirms CNA Brown's version, although she claims that she was "only a few feet away," having stepped out to retrieve an item from the medication cart. "I told her I was keeping an eye on the resident." P. Ex. 2, at 3 (Morton Decl. ¶ 7).

CNA Hoey also testified that she observed R3 with a toothette in her mouth. P. Ex. 11, at 1 (Hoey Decl. ¶ 1). She subsequently explained that she was passing nourishments, and went into R3's room to wash her hands and give nourishment to R3's roommate. R3 had a toothette in her hand "like a sucker." She had been sucking on it, "back and forth," in and out of her mouth.

> So I went immediately to the nurse and told her that she had this toothette. And [LPN Morton] told me that she knew about it and that she was keeping an eye on her.

Tr. 66-67. LPN Morton was in the hall with her med cart, passing out medicine. Tr. 67 No one prepared an incident report or otherwise documented CNA Hoey's observation.[6]

LPN Morton has been less than forthright on this issue. In contrast to the admission in her declaration, she told Surveyor Bridges that no one had reported seeing a resident alone sucking on a toothette. CMS Ex. 28, at 11 n.10 (Bridges Decl.). In her written declaration, aside from the CNA Brown admission, she said that she did "not recall" staff

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[6] Because they did not document and because they had no recollection of when they made these observations, I find unpersuasive the CNAs' unsupported claims that all of these events occurred prior to June 1. *See* discussion *infra*.

telling her that they observed R3 alone or unsupervised with a toothette in her mouth. P. Ex. 2, at 3 (Morton Decl. ¶ 7); *see also* CMS Ex. 22, at 10 (LPN Morton admits that "one time," while giving R3 her meds, she left a toothette in her mouth, but she denied ever leaving the room.).

According to Dr. Lesesne,

> An LPN presented with reports by CNAs who observed the resident sucking on toothettes should certainly have been able to understand the need to immediately evaluate the safety risk to the resident and adopt measures that would address that risk.

CMS Ex. 27, at 7 (Lesesne Decl. ¶ 13). But LPN Morton was dismissive, if not outright hostile, to the suggestion that her actions put the resident at risk. Based on her March 21 note, her admissions, and the CNA testimony, I am convinced that she did not recognize the safety risk posed by allowing R3 to suck on toothettes, and that she repeatedly allowed the unsafe practice.

I find it also likely that staff knew that R3's family provided R3 with toothettes to suck on, but they did not report or otherwise prevent the practice. In addition to LPN Morton's testimony, a second staff member belatedly described them doing so. On August 8, 2006, CNA Cristy Ballard told the facility's administrator, Linda Miller, that R3's great-granddaughter visited most of the day for the first week or two following R3's admission. CNA Ballard saw R3's great-granddaughter soaking toothettes in water and giving them to R3, saying that R3 was thirsty. CNA Ballard also said that she had seen R3 with a toothette in her mouth, "gumming it" while the granddaughter was visiting. CMS Ex. 22, at 15. Again, none of these incidents were documented.

The facility's administration was apparently unaware that R3 was given the toothettes. DON Becky Taylor, testified that, until June 19, 2006, neither LPN Morton nor anyone else told her that R3 liked to suck on toothettes. Tr. 172. Administrator Miller conceded that, until sometime after June 12, she was not aware that R3 had been given toothettes to suck on during her care. Tr. 99.

Curiously, considering that these toothettes proved so problematic for the facility, the facility's mouth care policies do not mention them in its list of equipment and supplies. The listed procedures instruct staff to "hold the tongue in place with a tongue depressor," and call for use of an unspecified "applicator" and "prepared swab or a water soluble lubricant." CMS Ex. 9. In this regard the facility procedures seem at odds with the swab manufacturer's instructions which direct staff 1) to use a bite block when performing oral

care on patients who cannot comprehend commands, and 2) to ensure that the foam is intact following its use. CMS Ex. 25, at 2.[7] But staff apparently did not follow either the manufacturer's instructions or the facility procedures. Surveyor Bridges testified that she observed staff providing oral care to R3; no one used a bite block, and the resident appeared to be sucking on the toothette. CMS Ex. 28, at 10 n.7 (Bridges Decl.). No staff member has claimed to use a bite block when providing oral care to R3 or any other resident.[8]

At least one staff member, as well as R3's family members, allowed R3 to engage in behavior that posed a significant risk to her. Multiple other staff were aware of it, but no one mentioned it to the facility's administration, and nothing was done about it. The safety of the behavior was not assessed, and no actions were taken to protect the resident, in contravention of acceptable standards of care. The facility was therefore not complying with the requirement that it provide necessary care and services to allow the resident to attain or maintain the highest practicable physical, mental, and psychosocial well-being. Specifically, it did not ensure that her environment was free from accident hazards, nor was it providing her adequate supervision to prevent accidents. In fact, staff were putting her in harm's way. The facility was therefore not in substantial compliance with 42 C.F.R. § 483.25.

Allowing a resident to engage in risky behavior also constitutes neglect, and the facility lacked adequate written procedures to prevent it, as required by 42 C.F.R. § 488.301. Moreover, as the following discussions address, when the facility was faced with evidence of the unsafe practice, it neither documented, investigated, nor adequately intervened to protect the resident.

2. In contravention of accepted professional standards as well as its own policies and procedures, the facility did not adequately document or investigate the appearance of plastic in R3's stool on June 1, 2006.

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[7] A bite block is a small device, usually made of plastic, inserted between the upper teeth and jaw, which prevents the patient from biting down. CMS Ex. 28, at 4 (Bridges Decl. ¶ 8).

[8] Facility staff subsequently identified eight residents as at risk because they bit down on or sucked toothettes during oral care. Tr. 139-140.

June 1 incident. In a nursing note dated June 1, 2006, LPN Linda Goode reports that, at midnight, she found a large amount of hard stool in R3's rectum. She administered a Ducolax suppository (which is a laxative), and, later that morning (5:30 a.m.), she broke up and removed the stool. CMS Ex. 4, at 20. As discussed below, LPN Goode's note deliberately omitted the critical fact that R3's stool contained a piece of plastic.

In a July 22, 2006 incident report, written during the time of the survey, LPN Goode writes: "Large hard ball noted [at] rectal door. Broke it up by pressing sides of rectum. BM along [with] plastic expelled. CMS Ex. 5, at 6; CMS Ex. 22, at 8. LPN Goode also told Surveyor Patricia A. Bridges, R.N., that, four hours after administering a suppository to R3, she was able to reach into the resident's rectum with her finger and remove the stool, which contained the plastic. CMS Ex. 28, at 7.

On July 20, 2006 (also during the time of the survey), DON Taylor prepared a report on the incident. She writes: "No injury reported! 3rd shift nurse reported to this RN that she found a piece of plastic . . . in the stool of the diaper of resident."[9] CMS Ex. 5, at 1-2.

A June 5, 2006 update to R3's plan of care confirms the episode of R3's ingesting a foreign object: "Nursing found plastic in her stool." To prevent her from putting objects in her mouth, staff are to "keep all inappropriate objects out of her reach." CMS Ex. 4, at 50.

Notwithstanding the written and oral statements of the sole witness to the incident (LPN Goode), Petitioner now insists that this record contains no credible evidence that R3 ingested and expelled the plastic. Petitioner did not call LPN Goode as a witness to explain or refute her written and oral statements.[10] Instead, Petitioner relies on the conclusions of DON Taylor, who was charged with investigating the incident (Tr. 103,

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[9] The preposition "with" was crossed out and "in" substituted.

[10] Petitioner suggests that, in order to make its case, CMS should have produced LPN Goode as its witness. I disagree. CMS can reasonably rely on the facility's own documents to make its *prima facie* case. *See Hillman Rehabilitation Center*, DAB No. 1611 (1997), *aff'd Hillman Rehabilitation Center v. HHS*, No. 98-3789 (GEB), slip op. at 25 (D.N.J. May 13, 1999). If Petitioner's strategy is to impeach its own records, it must come forward with persuasive evidence, which might include the testimony of the employee who generated the purportedly erroneous document. *But see* 42 C.F.R. § 483.75(l) (the facility must maintain records that are complete and accurate).

169). But, as the absence of timely investigative reports or contemporaneous statements attest, that "investigation" was woefully inadequate. Nor has DON Taylor credibly explained her actions and conclusions. In this regard, her testimony was so confusing and riddled with inconsistencies as to be wholly unreliable.

LPN Goode was apparently sufficiently concerned about finding the plastic that she called DON Taylor at home at a very early hour to report it. P. Ex. 3, at 1 (Taylor Decl. ¶ 3).[11] DON Taylor obviously did not appreciate the disturbance: "She shouldn't have woke me up . . . to ask me all these questions when I wasn't alert enough. . . ." Tr. 167. According to DON Taylor:

> Ms. Goode had initially suggested that [R3] had expelled the plastic in her stool and therefore this is what was reflected in the resident's care plan. However, when I discussed the situation with Ms. Goode, she stated that this was merely an assumption on her part. Ms. Goode agreed that the plastic did not resemble anything in [R3's] room and that, in fact, there was no evidence that the resident ate the plastic. I concluded that the plastic was not necessarily "in" the resident's stool, but was perhaps in her diaper and became mixed with the resident's stool.

P. Ex. 3, at 2-3 (Taylor Decl. ¶ 8). *See also* Tr. 154 (Per DON Taylor, during the early morning telephone conversation, LPN Goode indicated that this "was merely an assumption on her part.");[12] *but see* CMS Ex. 5, at 2 (where DON Taylor writes that plastic was found "in" the stool).

But DON Taylor's explanation is inconsistent with the statement found in R3's updated care plan – that "nursing found plastic in her stool." DON Taylor's effort to explain away that language casts additional doubt on her credibility. She says that the care plan update reflected LPN Goode's initial unwarranted assumption that R3 expelled the plastic in her

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[11] In an IDR (informal dispute resolution) statement, DON Taylor says that LPN Goode placed the call at 5:30 a.m. CMS Ex. 22, at 22.

[12] In an apparent inconsistency, however, when CMS counsel asked about LPN Goode's saying that "it might have just been her assumption," DON Taylor denied that LPN Goode had said that, and recounted a slightly different conversation: "No. She asked me – she asked me if I thought the resident could have eaten it, and I said 'Oh, no. She's a G tube feeder.'" Tr. 161.

stool. But the care plan was not altered until *after* DON Taylor completed her investigation and purportedly concluded that the plastic was "introduced externally into R3's diaper." P. Ex. 3, at 3 (Taylor Decl. ¶ 9); Tr. 156. Why would the care plan reflect information that the facility has deemed erroneous?

Based on the facility's own documentation, I find it probable that R3 ingested the plastic. But I need not decide that question in order to find that the facility's response to the June 1 incident put it out of compliance with the neglect and quality of care requirements, as well as the requirement that the facility maintain complete and accurate records. First, LPN Goode wrote an incomplete and inaccurate nurses note. Second, neither LPN Goode nor DON Taylor generated any incident report until the time of the survey, even though the facility's policy on investigating and reporting unanticipated occurrences requires that all incidents be reported to the department supervisor and that a report form be completed, "regardless of how minor an Unanticipated Occurrence may be." CMS Ex. 10, at 1-2. The charge nurse and/or department director or supervisor "must initiate an immediate investigation of the occurrence." CMS Ex. 10, at 2; *see also* CMS Ex. 11 (Administration policy); CMS Ex. 12 (Nursing Services).

Documenting the June 1 incident. Unquestionably, LPN Goode should have accurately documented her observations in both the nursing notes and in a separate incident report. 42 C.F.R. § 483.75(l)(1). Such documentation helps ensure that details are preserved for purposes of conducting an investigation as well as using the information for quality assurance and quality improvement activities, tracking trends and outcomes, and educational efforts. For this reason, acceptable standards of practice and the facility's own written policy require that a report form be completed "regardless of how minor an unanticipated occurrence may be." CMS Ex. 10, at 1-2. But, by her own admission, when LPN Goode asked if she should document the incident, DON Taylor told her to "wait for me at the facility until I arrived so we could discuss the issue and I could personally examine the plastic." P. Ex. 3, at 1 (Taylor Decl. ¶ 3).

Ultimately, LPN Goode wrote a misleading nurses note, omitting the critical fact that she had found the plastic. She completed no incident report form at all until the time of the survey. In fact, the amendment to R3's care plan, which was written four days later, represents the facility's only arguably contemporaneous documentation of the incident. Neither the facility's incident log, nor the "24-hour report," nor its June 1 "stand-up report" mentions any plastic.[13] CMS Ex. 28, at 7 (Bridges Decl. ¶ 12).

[13] The "24-hour report" is a report nurses use to pass on to the next shift important information about a resident's behavior or condition. The "stand-up report" is a report

In her declaration, DON Taylor defends LPN Goode's failure to document finding the plastic:

> After my investigation . . . I concluded that there was no evidence that [R3] ingested and expelled the plastic. Instead, I was unable to determine where the plastic came from, but concluded that it was most likely introduced into the diaper of [R3] externally, and was perhaps mixed in with the bed sheets or a washcloth from the linen cart used to clean [R3]. As such, *I did not believe, and do not believe today, that this constituted an "incident" which required documentation other than the nurses' note originally entered by Ms. Goode.*

P. Ex. 3, at 3 (Taylor Decl. ¶ 9) (Emphasis added).[14] At the hearing, however, DON Taylor repeatedly agreed that LPN Goode *should have documented* her observations at the time. Tr. 167.

> Q: Shouldn't she have documented it?
>
> A: Yes, she should have.
>
> Q: Did you call her on that?
>
> A: Yes, I did.
>
> Q: Was there any late entry made to reflect the fact that she missed documenting that on the day of the incident?
>
> A: I don't remember if she came back and wrote a late entry or not.

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that documents the daily meeting between the facility administrator and the department heads to discuss important developments and facility needs. CMS Ex. 28, at 7 n.3 (Bridges Decl.).

[14] Of course, even if the plastic had been introduced externally – which I find highly unlikely in view of LPN Goode's eyewitness account – that finding should have been documented at the time it occurred.

JUDGE HUGHES: If she did, I don't think it is in the record.

Q. BY MS. KEE: Isn't that a routine practice though? Late entries for events that happened earlier.

A: Yes. But I did ask her to write a late entry, but she didn't.

JUDGE HUGHES: Ms. Taylor, in your declaration, though, you say "Ms. Goode asked me if she should document the findings." This is Petitioner's Exhibit Three, page one. It's in the third paragraph.

WITNESS: Yes, it is. But I didn't tell her not to. All I did was tell her to wait for me.

JUDGE HUGHES: But shouldn't she have documented it right away?

WITNESS: Yes, she should have. But I didn't tell her not to. I told her to wait for me.

* * * *

JUDGE HUGHES: That is the first step in the investigation would be for her to write down, objectively, what she saw without asking you or your telling her what she saw. She should write down what she saw and that would be a piece of information for you to use in your investigation.

WITNESS: Exactly. But she didn't do it.

Tr. 164-166.

But then, when reminded of her written testimony, DON Taylor reversed herself and said that she found sufficient LPN Goode's original nurses note, which did not even mention a piece of plastic.

Q: And that entry does not mention anything about plastic found in either the diaper –

A: No, it does not.

Q: Okay. But you thought that was sufficient?

A: At the time, yes.

JUDGE HUGHES: Well, as you sit here today?

A: I still believe it, Your Honor. I still do.

Tr. 170-171.

DON Taylor's investigation. When DON Taylor arrived at the facility on the morning of June 1, LPN Goode was not there, apparently having disregarded her superior's instructions to wait. DON Taylor claims that she "immediately examined the plastic. . . and conducted a thorough investigation." P. Ex. 3, at 1 (Taylor Decl. ¶ 4).

DON Taylor apparently searched R3's room and asked staff if they recognized the plastic. No one recognized it, and she could not find anything that resembled it. She then concluded that R3 could not have ingested it, and that was the end of the investigation. She took no written statements from staff. She wrote no reports. She did not even advise, much less consult, R3's treating physician. In fact, R3's physician and the facility's medical director, Dr. Tom Long, M.D., testified that he only learned of the incident a couple of weeks later, after a second incident, when staff found toothettes in R3's bowel movement. Tr. 188, 190-191; CMS Ex. 4, at 22-23.[15]

DON Taylor justified her conclusions by claiming that

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[15] R3's ingesting of foreign objects was cause for concern, and her physician should certainly have been informed of the incident. *See* CMS Ex. 10, at 1 (Facility policy states: "The charge nurse should . . . notify the medical director or the victim's personal or attending physician, and inform the physician of the occurrence."). Because he was not even informed, Dr. Long obviously did not examine R3 to insure that she had suffered no harm. That she did not appear injured did not relieve DON Taylor of the responsibility to consult with her physician. As Dr. Long acknowledged, "[p]eople can sometimes suffer harm and not know it." Tr. 194. When, for example, 11 days later toothettes were found in R3's stool, staff reported the incident to a physician who ordered staff to turn off her G-tube and monitor bowel sounds. CMS Ex. 22, at 25.

> I had no witness tell me that they saw her eat the plastic. So I had no proof that there was – there was a possibility that she could eat it. . . . There is a possibility that the plastic could have gotten into a diaper through the sheets.

Tr. 158. DON Taylor then (somewhat inconsistently) denied claiming that the only way to be sure R3 ate the plastic would have been someone seeing her do it. "No that's not what I'm saying. I'm saying that I didn't have any proof that she ate it." Tr. 159.

No reliable evidence supports DON Taylor's opinion that R3 could not have swallowed the plastic. In his direct testimony, Dr. Long stated, "It is my professional opinion that [R3] could not have swallowed this substance given its size, shape and texture." P. Ex. 4, at 7 (Long. Decl. ¶ 14). But, when asked to explain this opinion, he replied, "I'm not sure I could." Tr. 186. He said that he based his opinions on the information provided by the facility. He did not see or examine the plastic. Tr. 187-188. Petitioner's expert witness, Dennis R. Sinar, M.D., a Board-certified gastroenterologist, expressed no opinion as to R3's capacity to ingest the plastic. *See* P. Ex. 9 (Sinar Decl.). CMS's expert, Dr. Lesesne, on the other hand, opined that she could and did ingest the plastic:

> To the extent that staff may have believed that [R3's] swallowing problems limited her ability to ingest substances the June 1, 2006 incident would have alerted them to the fact that this was not the case.

CMS Ex. 27, at 6 (Lesesne Decl. ¶ 10).

With respect to the size, shape and texture of the plastic, we have only DON Taylor's unreliable description. Although she testified that she showed it to the facility's MDS (minimum data set) Coordinator and to the Assistant Director of Nurses, the record contains no statements from those employees. P. Ex. 3, at 2 (Taylor Decl. ¶ 7). Since no one generated a contemporaneous report of the incident, there is obviously no contemporaneous description. The reports eventually generated by DON Taylor and LPN Goode omit any description of the plastic. And the plastic was disposed of, although no one seems to know who disposed of it or why. Tr. 126.

Nor am I even convinced that DON Taylor remembers what the plastic looked like, or, if she remembers, that she has accurately described it. She described it as a "flimsy" piece of clear plastic, 5 or 6 inches long. Tr. 151-152. In her direct testimony, she described it as perfectly smooth. P. Ex. 3, at 2 (Taylor Decl. ¶ 5). Under cross-examination, she denied that ("I didn't say it was perfectly smooth.") until reminded of her direct testimony ("I guess I did. I'm sorry. I forgot."). Tr. 152.

Administrative response. Notwithstanding the obvious inadequacies of DON Taylor's investigation, the facility's administration appears to have accepted uncritically her conclusions. The facility's administrator, Linda Miller, did not talk to LPN Goode until July 22, when LPN Goode finally filled out an incident report. Tr. 125. Administrator Miller did not see the plastic. Tr. 125. She did not know who disposed of the it or when it was disposed of. Tr. 126.

Nevertheless, in her written declaration, Administrator Miller testified that "there was no evidence [R3] ingested the plastic at Centerclair and expelled it in her stool, but that it was likely introduced into her diaper externally." P. Ex. 5, at 2 (Miller Decl. ¶ 4). This testimony is especially perplexing because Administrator Miller had obviously reviewed and signed LPN Goode's written statement that "BM along [with] plastic expelled" from R3's rectum. CMS Ex. 5, at 6. Administrator Miller was unwilling or unable to explain her declaration, in light of the eye-witness report to the contrary:

> JUDGE HUGHES: She unambiguously said. I mean, there's [no] question about the meaning of this, right? Am I right?
>
> WITNESS: Well, her statement "There is BM along with plastic expelled."
>
> JUDGE HUGHES: And you rejected that?
>
> WITNESS: I don't know how to answer that.

Tr. 94.

When Administrator Miller had a second opportunity to reconcile LPN Goode's written statement with her conclusion that the plastic was never ingested, she said:

> WITNESS: Well, it says "BM along with plastic expelled." What I understood from the director of nursing was that there was a plastic film in the diaper. I wasn't there. You know, I – I don't – I don't know for a fact. The nurse said that BM and plastic was expelled.

Tr. 103. Inasmuch as she had two opportunities to explain herself, but could not, I did not find credible her subsequent agreement with the suggestion by Petitioner's counsel that "you felt that during the survey, the surveyor wanted to see a report that reflected what had occurred and had been reported by Ms. Good[e] on June 1st, is that a fair statement?"

Tr. 103. Moreover, if LPN Goode were documenting an erroneous finding, under any reasonable standard of practice, her report should have reflected that she was in error.

Nor could Administrator Miller explain why LPN Goode had not provided a written statement at the time of the incident, except to suggest that the occurrence was "very unusual." Tr. 104, 122. In this regard, Administrator Miller seemed unfamiliar with her facility's reporting policy. She testified that "if we have a potential or actual event that results in harm that occurs on our premises then we complete the report for purposes of continuous quality improvement." Tr. 122. But the written policy requires reporting "regardless of how minor" the occurrence, even if no actual harm has resulted. CMS Ex. 10, at 1-2.

Thus, compelling evidence establishes that, on June 1, 2006, LPN Goode found plastic in R3's stool. Appropriately, she immediately reported it to the facility's DON, and the facility changed R3's care plan, adding instructions that inappropriate objects be kept out of R3's reach. The facility alerted staff to the changes via R3's "closet sheet"[16] and by adding the instruction to a previously scheduled in-service training, held June 1. P. Ex. 5, at 2-3 (Miller Decl. ¶ 6); Tr. 96.

On the other hand, CMS raises some legitimate questions about the effectiveness of that training. First, the documentation of the in-service does not reflect any discussion of preventing the ingestion of foreign objects. CMS Ex. 19, at 8. Second, based on the number of speakers and the topics covered during a short training period, little time would have remained for discussing the hazards of leaving ingestable objects within resident reach. Third, no staff member who testified could remember much about the training (Tr. 55-57, 60, 71), which suggests that it was not very memorable. Finally, the training did not include any mention of the appropriate use of toothettes during oral care, and no reliable evidence suggests that staff made any connection between keeping inappropriate objects out of R3's reach and allowing R3 to suck on toothettes. *See*, discussion *supra*; Tr. 100 (training did not mention the appropriate use of toothettes during oral care).

Moreover, LPN Goode – with what must have been the DON's tacit approval, if not direct instruction – wrote an incomplete and inaccurate nurses note. Neither nurse completed an incident report, even though professional standards of practice and the facility's written policies required that they do so. And DON Taylor then conducted an

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[16] The closet sheet is a document taped to the inside of the resident's closet door that communicates to staff clinical and care instructions. P. Ex. 5, at 2 (Miller Decl. ¶ 5).

inadequate investigation which the facility nevertheless accepted uncritically.

These actions put the facility out of substantial compliance with requirements 1) that it maintain complete and accurate clinical records (42 C.F.R. § 483.75(l)(1)); 2) that it provide necessary care and services necessary to allow R3 to maintain the highest practicable physical, mental and psychosocial well-being (42 C.F.R. § 483.25); and 3) that it implement policies and procedures that prohibit resident neglect (42 C.F.R. § 483.13(c)).

3. In contravention of accepted professional standards and its own policies and procedures, the facility did not adequately document or investigate the appearance of toothette tips in R3's stool on June 12, 2006.

June 12 incident. In a note dated June 12, 2006, at 2:40 a.m., LPN Roni Hefner describes R3's abdominal distention, and absence of bowel sounds.[17] She checked the rectal vault, and observed a large amount of gas and liquid stool expelled, along with a large hard stool containing four soft toothette tips. CMS Ex. 4, at 21; CMS Ex. 5, at 7-8; CMS Ex. 22, at 24-26.

In this instance Petitioner concedes that R3 must have ingested the toothette tips found in her stool. Nevertheless, citing the opinion of its expert, Dr. Dennis R. Sinar, Petitioner argues that she likely ingested them months earlier, while she was still living at her granddaughter's house. Dr. Sinar opined that, although "impossible to determine the exact amount of time the sponges would be retained in [R3's] digestive system," it would have taken "a minimum of four weeks to pass through her system," and as long as "an indeterminate period of time." P. Ex. 9, at 3 (Sinar Decl. ¶ 10); Tr. 9.

I find it far more likely than not that R3 ingested both the plastic and the toothettes while at the facility. She had been there for more than thirteen weeks (March 10 to June 12), so even accepting Dr. Sinar's assertion, she could have ingested them while there. We also know that staff and visitors acted in ways that made it possible – even likely – for her to ingest the sponge tips while in the facility. Further, although well-credentialed,[18] Dr.

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[17] Absence of bowel sounds suggests that the intestines may not be functioning properly, and (along with abdominal distention) may be a symptom of blockage. CMS Ex. 28, at 10 n.8 (Bridges Decl.).

[18] Dr. Sinar is a Board-certified gastroenterologist and professor of medicine at East Carolina University School of Medicine. P. Ex. 9, at 1 (Sinar Decl. ¶¶ 1-3).

Sinar admitted that no research supports his position. He based it solely on "clinical experience." Tr. 10, 31, 35, 42. And at least some of R3's conditions that he said would have caused the delay (staples in her colon, history of chronic fecal impaction) were not well-supported. P. Ex. 9, at 3 (Sinar Decl. ¶¶ 11, 12); Tr. 10-11, 16, 19, 22, 40; CMS Ex. 4, at 50 *et seq*., 60, 74. Further, he testified that the digital checking and repositioning that occurred June 12 would have stimulated her bowels and caused the toothettes to be expelled. P. Ex. 9, at 2 (Sinar Decl. ¶ 7); Tr. 42. But he did not explain why the digital checking and repositioning that occurred on June 1 would not have caused the toothettes to be expelled at that time.

In any event, whether these particular toothettes were ingested at the facility is not the dispositive question. The real deficiency here was that, with staff's assistance (if not active encouragement), R3 engaged in a dangerous behavior. Then, when confronted for a second time with evidence that it had a serious problem, the facility's response was wholly inadequate.

Investigation. The facility's response to the June 12 incident was an improvement over its June 1 response in two respects: 1) staff did not write a deceptive nurses note; and 2) staff notified a physician of the incident.

Nevertheless, the facility's subsequent investigation was completely inadequate. Penny Hill, the Assistant Director of Medicine, was apparently charged with investigating the incident. Tr. 169-170. What she did is a mystery, since the record contains no documentation of any investigation. She took no written statements; she wrote no report.[19]

According to Administrator Miller, following the discovery, CNAs again searched R3's room and, at some unidentified point, "the entire care team" discussed the incident and decided that the facility's response to the June 1 incident adequately resolved any problems. P. Ex. 5, at 5 (Miller Decl. ¶¶ 12, 13). No documentation memorializes this discussion or conclusion. *See also* Tr. 129 (After finding the toothettes in R3's stool on June 12, the facility took no additional steps.). Late in July, the administration finally interviewed staff about their use of toothettes, but, as late as July 26, 2006, staff had not provided the facility's continuous quality improvement committee information or eyewitness accounts of the toothette incident. CMS Ex. 8, at 5; *see* CMS Ex. 5, at 10-13.

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[19] Petitioner concedes that someone should have completed an unanticipated occurrence report for this incident. P. Cl. Br. at 18.

I do not consider this an adequate response. In Dr. Lesesne's view, and I agree, this fell below the standard of care. The discovery should have raised the concern that staff were not consistently keeping inappropriate objects out of R3's reach, and unquestionably suggested that staff continued to use the toothettes improperly. The facility should have conducted an immediate investigation, which includes interviewing staff who cared for R3 about how they implemented her care plan and their use of toothettes. CMS Ex. 27, at 6 (Lesesne Decl. ¶ 11).

Plainly, based on this response and staff's admitted use of the toothettes, facility staff did not appreciate the risk of injury posed by dysphagia, the need to use precautions in caring for residents with NPO status, and the need to respond promptly to information indicating that the resident was engaging in unsafe behavior likely to result in serious injury to herself and other facility residents with impaired swallowing abilities. *See* CMS Ex. 27, at 8 (Lesesne Decl. ¶ 13). As a result, the facility was not in substantial compliance with the program requirements cited.

B. CMS's determination that the facility's deficiencies posed immediate jeopardy was not clearly erroneous.

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. 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), citing *Florence Park Care Center*, DAB No. 1931, at 27-28 (2004) (citing *Koester Pavilion*, DAB No. 1750 (2000)).

Here, R3 was not supposed to take anything by mouth. Allowing her to suck on toothettes put her in grave danger of ingesting them or aspirating the liquid from them into her lungs. CMS Ex. 28, at 7 (Bridges Decl. ¶ 11). CMS's determination was therefore not clearly erroneous.

C. The duration of the noncompliance and the immediate jeopardy is consistent with statutory and regulatory requirements.

Petitioner also complains that, notwithstanding the administration's nearly complete ignorance of the problem, it nevertheless corrected its deficiencies as early as June 1, 2006, when it mentioned, during an in-service training, that staff should keep inappropriate objects out of R3's reach. I have already discussed the inadequacies of that training.

Moreover, 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. 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 19-20 (2002). A facility's return to substantial compliance usually must be established through a resurvey. *Cross Creek Care Center*, DAB No. 1665 (1998).

Here, Petitioner provides no reliable evidence that it achieved substantial compliance prior to August 18. I am not persuaded that, after the June 1 training, staff halted its misuse of toothettes. Petitioner's only evidence in this regard were the testimonies of the CNAs who observed R3 alone with a toothette. But not one of them could remember when she made her observation. No one documented her observation. Certainly nothing in LPN Morton's testimony suggests that she halted the practice as a result of any in-service training. The facility then compounded its deficiencies when it generated a misleading nurses note on June 1, and when it failed to investigate adequately either incident, in contravention of acceptable standards of practice and its own policies and procedures. Indeed, the facility's administration was not even fully aware of its problems until the time of the survey. Unless the facility investigates fully and identifies the cause of the deficiency, it has little hope of meaningful correction. *See Century Care of Crystal Coast*, DAB No. 2076, at 21 (2007) (Where no one among the facility's administration was even aware of an incident, "the facility lost an opportunity to analyze and correct the problems. . . .").

IV. Conclusion

For all of the reasons discussed above, I find that Petitioner was not in substantial compliance with program participation requirements from June 1 through August 18, 2006. I find that from June 1 through July 31, 2006, its deficiencies posed immediate jeopardy to resident health and safety.

/s/
Carolyn Cozad Hughes
Administrative Law Judge