

Department of Health and Human Services

DEPARTMENTAL APPEALS BOARD

Civil Remedies Division

In the Case of:)	
)	
Columbus Nursing & Rehabilitation)	
Center, (CCN: 52-5445),)	Date: September 29, 2008
)	
Petitioner,)	
)	
- v. -)	Docket No. C-07-138
)	Decision No. CR1849
Centers for Medicare & Medicaid)	
Services.)	

DECISION

I sustain the determination of the Centers for Medicare & Medicaid Services (CMS) to impose per instance Civil Money Penalties (CMPs) against Petitioner, Columbus Nursing & Rehabilitation Center, for failure to comply substantially with federal requirements governing participation of long term care facilities in Medicare and state Medicaid programs. The two per instance CMPs, of \$4150 each, are reasonable, and Petitioner's loss of its nurse aide training and competency evaluation program (NATCEP) is required by law.

I. Background

This case came before me pursuant to a request for hearing filed by Petitioner on December 8, 2006, in accordance with section 1128A(c)(2) of the Social Security Act (Act) and 42 C.F.R. §§ 488.408(g) and 498.40.¹

CMS informed Petitioner that, based on a survey completed on October 4, 2006, it was imposing selected remedies due to Petitioner's failure to be in substantial compliance with the applicable federal requirements for nursing home participants.

¹ Petitioner submitted another hearing request, dated February 8, 2007, to challenge the results of a revisit survey completed on November 21, 2006, which was docketed as No. C-07-252. I consolidated the two cases into Docket No. C-07-138 on March 1, 2007. Consolidation Order, March 1, 2007.

CMS imposed the following remedies:

- Termination of the provider agreement, effective April 4, 2007.
- Denial of Payment for New Admissions, effective November 1, 2006.
- Two per instance CMPs of \$4150 for violations of participation requirements at 42 C.F.R. §§ 483.13(c) and 483.13(c)(1)(ii)-(iii), (c)(2)-(4) (F Tags 225 and 226²) at a scope and severity level of J (immediate jeopardy).
- Loss of Petitioner's NATCEP for two years from October 4, 2006.

A revisit survey found Petitioner back in substantial compliance as of October 27, 2006. At this time the only issues remaining are the two per instance CMPs and Petitioner's loss of NATCEP.

I held a hearing in this case on May 20 and 21, 2008, in Madison, Wisconsin. Testifying were two surveyors employed by the Wisconsin Department of Health and Family Services, Division of Disability and Elder Services (State Agency); Kathleen Healy, R.N. (Surveyor Healy), and Ann Angell, R.N. (Surveyor Angell); Nichele "Shelly" Sharkey Vander Galien, a licensed social worker employed by Petitioner at the relevant time (Ms. Sharkey Vander Galien); Deana Westby, R.N., Petitioner's Director of Nursing at the

² A "Tag" designation refers to the part of the State Operations Manual (SOM), Appendix PP, "Survey Protocol for Long-Term Care Facilities," "Guidance to Surveyors," that pertains to the specific regulatory provisions allegedly violated. The cited deficiencies are set forth in the statement of deficiencies (SOD), also called a Form 2567, prepared by surveyors (such as the SOD in this case found at CMS Exhibit (Ex.) 1). Each deficiency includes a scope and severity level. A scope and severity level is designated by an alpha character, A through L, selected by CMS or a state agency from the scope and severity matrix published in the SOM at section 7400E. A scope and severity level of A, B, or C indicates a deficiency that presents no actual harm, but has the potential for minimal harm. Facilities with deficiencies of a level no greater than C remain in substantial compliance. A scope and severity level of D, E, or F indicates a deficiency that presents no actual harm, but has the potential for more than minimal harm that does not amount to immediate jeopardy. A scope and severity level of G, H, or I indicates a deficiency that involves actual harm that does not amount to immediate jeopardy. Scope and severity levels J, K, and L are deficiencies that constitute immediate jeopardy to resident health or safety. Letters A, D, G, and J indicate an isolated occurrence; letters B, E, H, and K indicate a pattern of occurrences; and letters C, F, I, and L indicate widespread occurrences. The matrix, which is based on 42 C.F.R. § 488.408, specifies which remedies are required and optional at each level based on the frequency of the deficiency.

relevant time (DON Westby); and Thomas Zwicker, a licensed nursing home administrator and Petitioner's Administrator at the relevant time (Administrator Zwicker). I admitted into evidence CMS Exs. 1-12 and 15-37 and Petitioner's Exs. 1-7, 11-12, and 14-16. Transcript (Tr.) at 3-4. Both parties submitted briefs (CMS and P. Br.) and reply briefs (CMS and P. Reply).³

Based on the testimony at hearing, the documentary evidence, the written arguments of the parties, and the applicable law and regulations, I find that Petitioner was not in substantial compliance with Medicare participation requirements and that the remedies imposed are reasonable.

II. Applicable Law and Regulations

Petitioner is considered a long-term care facility under the Act and regulations promulgated by the Secretary of Health and Human Services (Secretary). The statutory requirements for participation by a long-term care facility are found at sections 1819 and 1919 of the Act, and at Title 42 C.F.R. Part 483.

Sections 1819 and 1919 of the Act invest the Secretary with authority to impose CMPs and other remedies against a long-term care facility for failure to comply substantially with participation requirements.

Pursuant to the Act, the Secretary has delegated to CMS and the states the authority to impose remedies against a long-term care facility that is not complying substantially with federal participation requirements. 42 C.F.R. Part 483 provides that facilities which

³ With its posthearing reply brief CMS submitted the declaration of Shari Busse and attachments including: a December 16, 2004 CMS clarification of nursing home reporting requirements; a March 23, 2005 clarification of nursing home reporting requirements; an October 26, 2005 State of Wisconsin update regarding nursing home reporting requirements; and an October 14, 2005 CMS summary of changes, Transmittal 12. Petitioner objected to their admission, asserting that Ms. Busse had never been listed as a potential witness nor was she unavailable to testify and, at hearing, CMS did not request the record be held open and indicated it had no further evidence. Petitioner rebuts CMS's argument that Petitioner's posthearing brief first laid out as an issue whether Wisconsin law required reporting allegations of abuse by non-caregivers by asserting that CMS was required to show Petitioner failed to report allegations of abuse as required by state law and that CMS can hardly claim surprise. Moreover, Petitioner asserts that waiting until the reply brief to submit the declaration was extremely prejudicial and untimely. I am not admitting Ms. Busse's declaration, as CMS had ample time prior to hearing to introduce the declaration. However, while I do not admit as exhibits the 18 pages of attachments submitted, since they are public documents promulgated by CMS or the state agency, I may take judicial notice of them.

participate in Medicare may be surveyed on behalf of CMS by state survey agencies in order to ascertain whether the facilities are complying substantially with participation requirements. 42 C.F.R. §§ 488.10-488.28. The regulations contain special survey conditions for long-term care facilities. 42 C.F.R. §§ 488.300-488.335. Under Part 488, a State or CMS may impose a CMP against a long term care facility where a state survey agency ascertains that the facility is not complying substantially with participation requirements. 42 C.F.R. §§ 488.406, 488.408, 488.430. The CMP may start accruing as early as the date that the facility was first out of substantial compliance until the date substantial compliance is achieved or the provider agreement is terminated.

If a CMP is imposed on a per day basis, the regulations specify that the CMP will fall into one of two broad ranges of penalties. 42 C.F.R. §§ 488.408, 488.438. The upper range of CMPs, of from \$3050 per day to \$10,000 per day, is reserved for deficiencies that constitute immediate jeopardy to a facility's residents, and in some circumstances, for repeated deficiencies. 42 C.F.R. §§ 488.438(a)(1), (d)(2). The lower range of CMPs, of from \$50 per day to \$3,000 per day, is reserved for deficiencies that do not constitute immediate jeopardy, but either cause actual harm to residents, or cause no actual harm, but have the potential for causing more than minimal harm. 42 C.F.R. § 488.438(a)(1)(ii). If a CMP is imposed on a per instance basis, the range of penalty is \$1000 to \$10,000 per instance. 42 C.F.R. § 488.438(a)(2).

The regulations define the term “substantial compliance” to mean:

[A] level of compliance with the requirements of participation such that any identified deficiencies pose no greater risk to resident health or safety than the potential for causing minimal harm.

42 C.F.R. § 488.301. “Immediate jeopardy” is defined to mean:

[A] situation in which the provider’s noncompliance with one or more requirements of participation has caused, or is likely to cause, serious injury, harm, impairment, or death to a resident.

Id. In determining the amount of the CMP, the following factors, specified at 42 C.F.R. § 488.438(f), must be considered:

1. The facility’s history of noncompliance, including repeated deficiencies;
2. The facility’s financial condition;
3. The seriousness of the deficiencies as set forth at 42 C.F.R. § 488.404;
4. The facility’s degree of culpability.

In a CMP case, CMS must make a *prima facie* case that the facility has failed to comply substantially with participation requirements. To prevail, a long term care facility must overcome CMS's showing by a preponderance of the evidence. *Woodland Village Nursing Center*, DAB No. 2172 (2008); *Batavia Nursing and Convalescent Center*, DAB No. 1904 (2004), *aff'd Batavia Nursing and Convalescent Ctr. v. Thompson*, 129 Fed. Appx. 181 (6th Cir. 2005); *Hillman Rehabilitation Center*, DAB No. 1611 (1997), *aff'd Hillman Rehabilitation Center v. U.S. Dept. of Health and Human Services*, No. 98-3789 (D.N.J. May 13, 1999).

The Act and regulations make a hearing before an administrative law judge (ALJ) available to a long term facility against whom CMS has determined to impose a CMP. Act, section 1128A(c)(2), 42 C.F.R. §§ 488.408(g), 498.3(b)(12), (13). The hearing before an ALJ is a *de novo* proceeding. *Anesthesiologists Affiliated, et al*, DAB, CR65 (1990), *aff'd* 941 F2d. 678 (8th Cir. 1991).

III. Issues

A. Whether Petitioner was in substantial compliance with participation requirements and, if not;

B. Whether the remedies imposed by CMS are reasonable.

IV. Findings of Fact, Conclusions of Law, and Discussion

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

A. Petitioner was out of substantial compliance with the participation requirement at 42 C.F.R. § 483.13(c)(2)-(4) (F Tag 225).

The participation requirements in question are found at 42 C.F.R. § 483.13, resident behavior and facility practices, staff treatment of residents, and states that:

(2) The facility must ensure that all alleged violations involving mistreatment, neglect, or abuse, including injuries of unknown source, and misappropriation of resident property are reported immediately to the administrator of the facility and to other officials in accordance with State law through established procedures (including to the State survey and certification agency).

(3) The facility must have evidence that all alleged violations are thoroughly investigated, and must prevent further potential abuse while the investigation is in progress.

(4) The results of all investigations must be reported to the administrator or his designated representative and to other officials in accordance with State law (including to the State survey and certification agency) within 5 working days of the incident, and if the alleged violation is verified appropriate corrective action must be taken.⁴

The Statement of Deficiencies (SOD) in question, dated October 4, 2006, asserted that,

Based on observation, record review and interview, the facility did not ensure that all alleged violations of mistreatment and abuse, including injuries of unknown origin, were thoroughly investigated and reported to the appropriate officials (including the State survey and certification agency) in accordance with State law through established procedures for . . . Resident . . . 1 . . . reviewed for potential abuse. The facility did not ensure that all residents were protected from further potential abuse while an investigation was in progress.

CMS Ex. 1, at 2.

Resident 1, a 69-year-old woman (CMS Ex. 15, at 1), had dementia, severely impaired cognition, severe muscle contractures in her arms and legs, presented a flat expression, could not communicate, and was totally dependent on Petitioner's staff for all activities of daily living. CMS Ex. 1, at 4; CMS Ex. 11, at 11; CMS Ex. 12, at 1; Tr. at 20-21. She was incapable of defending herself against a physical attack or reporting such an attack to staff or others. Tr. at 21.

CMS asserts that prior to the noon lunch at Petitioner's facility on August 20, 2006, Resident 1 was given incontinence care (peri-care) by two certified nursing assistants (CNAs), Janelle Cashmore and Sherry Hull (CNA Cashmore and CNA Hull). CMS Ex. 12, at 26-28; Tr. at 25. During this care, no injury or bleeding was observed in Resident 1's vaginal area. CMS Ex. 12, at 26-28. Resident 1's husband, as was his usual practice, arrived at lunch time, fed his wife lunch in her bedroom, and departed her bedroom at about 1:30 p.m. CMS Ex. 12, at 11; CMS Ex. 10, at 4; Tr. at 25-26, 88-89. At or before 2:00 p.m. that afternoon, CNAs Cashmore and Hull returned and began to provide

⁴ Petitioner would have me read this section of the regulations as solely restricted to abuse of residents by staff and not to potential abuse by other residents, family members, or persons not employed by the nursing home. I do not take such a narrow view. While 42 C.F.R. § 483.13(c)(1)(i) refers particularly to abuse by staff, the introductory sentence is not so restrictive and refers to abuse in more general terms. *Mountain View Manor*, DAB CR1076; *aff'd Mountain View Manor*, DAB No. 1913 (2004). Further, with regard to sections (c)(2)-(4) of 483.13(c), that section cannot be read as restricted to abuse of residents by staff where the injuries are of "unknown source."

incontinence care for Resident 1. Tr. at 22, 88-89; CMS Ex. 12, at 11.⁵ Upon removing her diaper, the CNAs observed blood in her diaper and vaginal area. Tr. at 22; CMS Ex. 12, at 26. They summoned Carol Wehland, R.N. (RN Wehland), the nurse on duty, who found a two centimeter (2/3 inch) long laceration on Resident 1's right inner labia, just outside the vagina, and who then cleaned the area. Tr. at 22, 25; CMS Ex. 12, at 11. RN Wehland reported a large amount of blood, some of which was still oozing from the wound, and noted that Resident 1 was agitated and made crying noises. Tr. at 24, 27; CMS Ex. 11, at 6; CMS Ex. 12, at 11. RN Wehland stated to the surveyor that she thought Resident 1's husband "did it." Tr. at 27; CMS Ex. 11, at 6. CMS Br. at 4.⁶

⁵ Surveyor Angell's surveyor notes include notes regarding an interview she had with CNA Hull on August 19, 2006. Surveyor Angell wrote, "Came in Early Janelle got up & fine then she had lunch in room [with husband] 1:30 Janelle take off bloody." At hearing, Surveyor Angell stated that CNA Hull told her that Resident 1's husband left at about 1:30. She came in to do some care and lay her down about 2:00 p.m. and discovered the bleeding. The nurse told her to write a statement and, other than the social worker lifting the restrictions, she hadn't talked to anyone about the incident. Surveyor Angell also said that CNA Hull felt the husband should be restricted. On cross-examination, Petitioner's counsel queried Surveyor Angell about how she knew that it was 2:00 p.m. when CNA Hull came in to care for Resident 1 after lunch, as the time was not in Surveyor Angell's notes. Surveyor Angell was not able to answer. Tr. at 97-100. In its reply brief, Petitioner cites this as a material difference between her surveyor notes and her testimony and argues that this casts doubts upon all of her testimony. P. Br. at 12. Petitioner also asserts that it differs from the statement contained in the SOD, where results of the interview are reflected as, "I put her to bed around 2:00 PM and seen a lot of blood in her brief. I got the nurse and seen about a 2 cm cut. (Resident 1's) husband had been there that day and left at 1:30 pm he feeds her lunch in her room. That day we had to write up a statement and then the next time was when the social worker told us he didn't need restrictions anymore. No one has talked to me about the incident before. I feel he should be supervised when he is here." CMS Ex. 1, at 17. I disagree that a material inconsistency exists. I do not find Surveyor Angell's notes, testimony, and the SOD to be inconsistent. Details may be left out of surveyor notes and, when writing the draft of a SOD, details left out of surveyor notes may be included. Tr. at 109. Petitioner had the opportunity at hearing to rebut the specific allegations set forth in the SOD.

⁶ At the time of the incident, Resident 1 had a roommate. The roommate had short and long term memory deficits, impaired decision making skills, and a legal guardian. Tr. at 89-90. Petitioner argues that CMS should have produced the minimum data set (MDS) on which it relied regarding the roommate's condition. However, to rebut the surveyor's recitation of facts found in the MDS, Petitioner, who had a copy of the MDS, could have introduced the MDS to refute the surveyor's statements regarding the roommate's condition. As Petitioner has not done so, I accept the statement of the surveyor.

(continued...)

Petitioner does not dispute the essential facts of this incident. P. Br. at 1-4.

Neither CNA Cashmore, CNA Hull, nor RN Wehland testified. The only contemporary documentary evidence regarding Petitioner's investigation of this incident was that provided to the surveyors by the facility and consisted of documents contained in a file kept by Ms. Sharkey Vander Galien after the incident, which is in the record as CMS Ex. 12. The only contemporaneous documentary evidence regarding the initial injury is reflected in the nurse's notes dated August 20, 2006, and the statements of CNAs Cashmore and Hull.⁷ The nurse's notes, prepared by RN Wehland at 2:00 p.m. on that date, state,

Large am[ou]nt of bright red bleeding noted [with] depends change and peri care. Resident incontinent of bowel and bladder. Stool soft. 2 cm laceration noted [right] upper inner labia. Bleeding from area. Resident appears agitated [with] exam. Husband noted to have been visiting at 1330 [1:30 p.m.].⁸

⁶(...continued)

Moreover, although Petitioner asserts that the roommate was a reliable witness and stated to RN Wehland and DON Westby that she observed nothing unusual during the husband's visit (Tr. at 128-29; CMS Ex. 22, at 3), no contemporary documentary evidence recording her statements was provided by Petitioner (DON Westby's note regarding the episode occurring after the survey (CMS Ex. 22, at 3)), despite the assertion of DON Westby that notes of her interview were written down, nor did a mention of the conversations appear in Ms. Sharkey Vander Galien's notes summarizing her investigation. CMS Ex. 12. While the roommate's memory deficits do not automatically disqualify her as a reliable witness, Petitioner has not submitted any contemporary documentary statement made by the roommate, nor presented any convincing medical evidence, that the roommate was a reliable witness. P. Reply at 8-9. In the absence of such evidence, I find unconvincing the testimony of Petitioner's witnesses regarding the roommate's assertion that nothing unusual occurred during the relevant time.

⁷ Petitioner asserts that staff in a position to provide direct relevant information, and the primary initial suspect, were questioned about their knowledge of the incident. P. Reply at 4. Petitioner did not submit any written evidence of those interviews, despite asserting that they were done. This despite Administrator Zwicker's testimony that he generally takes notes (Tr. at 153) and Ms. Sharkey Vander Galien's statement that she normally would retain written records of interviews and statements concerning case investigations. Tr. at 116.

⁸ Petitioner asserts that the cares were done "right after" Resident 1's husband left. P. Br. at 5. However, as the only contemporaneous evidence shows Resident 1's husband left her room about 1:30 p.m., and that documentation in the nurse's notes shows the

(continued...)

Nurse Wehland made the resident's physician and the DON aware of this "injury of unknown origin." CMS Ex. 12, at 11. CNAs Cashmore and Hull were the only facility employees to prepare written incident investigation witness interview forms regarding this injury of unknown origin. CNA Cashmore wrote,

When washing [resident] up before breakfast I noticed no sore or blood around her vaginal cavity. I also did not notice any laceration or blood when [changing] her depends before lunch.

Id. at 27. CNA Hull wrote,

At about 12:00 pm Janelle & I got [Resident 1] up from her bed. We noticed no sore of any kind to her bottom.

Id. at 28.

Following the incident, the documentary evidence regarding Petitioner's investigation is reflected in the information kept by Ms. Sharkey Vander Galien, which documents were provided to the surveyors. Notes written by Ms. Sharkey Vander Galien on August 21, 2006, state that the

Res[ident] is not to be in her room [with] husband until abuse investigation is complete. Res[ident] & husband will visit during the day in the lobby per Social Services.

Id. at 12.⁹ On August 23, 2006, Ms. Sharkey Vander Galien noted in social service progress notes that

Writer looked through past medical charts on [Resident 1] today.¹⁰ I received an

⁸(...continued)

discovery of the laceration at 2:00 p.m., the window of opportunity for someone to have been in Resident 1's room appears to be something less than a half hour but not right after the husband left.

⁹ DON Westby testified that she gave this order. Tr. at 137-38.

¹⁰ Ms. Sharkey Vander Galien stated in social service progress notes that she looked through charts in the "med" room to track Resident 1's husband's past behaviors. She found that on

4-25-04 - "Husband to be pulling sling up from under Res[ident]. Husband denies
(continued...)

incident report regarding heavy bleeding and laceration on Resident's labia. Resident was immediately protected by addressing this concern to her husband and requesting that all visits take place in common areas. Husband was not happy, but has been cooperative. This writer continued looking for more information - finally going through past charts in the med records room. Husband's [behaviors] have been ongoing since Resident was first brought to CNNRC in 2001. I noted a few past incidences that stuck out in . . . the medical records. This writer also took into consideration the Resident's current medical issue - a UTI. Looking at the nurses notes a catheter could have perhaps caused a laceration in the Resident's vagina - but this is uncertain. This writer spoke with Brenda Welsh-McClain, SW'r from Columbia H.S. regarding this issue. She expressed that she feels [Resident 1's husband] should be only visiting with [Resident 1] in common areas. Brenda said there has been way too many suspicious incidences with [Resident 1's husband] and his wife in the past 5 years here. [Resident 1's husband] expressed to writer that he feels we are constantly targeting him. This writer expressed that I went into this investigation with an open mind - but after looking through the Resident records it is clear that there are inappropriate behaviors occurring. And because the Resident cannot make competent decisions, then I am here to be her strongest advocate and protect her rights. [Resident 1's husband] disagreed that I was protecting her and I gave him that right to his opinion. From the information I collected and from this current incident I believe [Resident 1] would be the safest if she and her husband only visited in common areas.¹¹

¹⁰(...continued)

doing this he stated it was tucked behind her. Husband also took a picture of her in that state.

7-18-04 - CNA witnessed resident was sleeping in chair in dining room. Res[ident]'s husband wanted to check O2 and pushed back head & pulled cannula out of nose hard enough to pull & fold both ears over. - Husband being monitored.

10-3-04 - CNAs reported seeing resident's husband feeding her. She wouldn't eat so he threw her fork in her potatoes and called her a bitch.

3-7-04 - Res[ident]'s] husband was seen sitting in car watching through windows.

¹¹ The facility considered whether a catheterization done on Resident 1 nine days before the incident could have caused the injury. However, Surveyor Healy spoke to Dr. Mitchell on September 19, 2006, and he indicated that such an injury being the cause of Resident 1's laceration was "very unlikely," and RN Wehland stated the laceration was a new, not an old, wound. Tr. at 27; CMS Ex. 11, at 3, 6. Petitioner has not presented

(continued...)

Id. at 30-31.

Social service progress notes written by Ms. Sharkey Vander Galien reflect that also on August 23, 2006, she noted that

Resident's Quarterly Care Conference was held today. Husband was invited but did not attend. Res[ident] is a no code with husband being guardian. I am meeting [with] husband today to discuss the investigation. I am advising husband that he is unable to be in [resident's] room alone with her. They are to have visits in common areas. This decision was made after I spoke [with] county social worker about his behaviors. She was under the impression that he was still not suppose[d] to be in her room [with] her. Will follow up [with] husband today.

Id. at 19.

On August 23, 2006, Resident 1's physician, Tom Mitchell, M.D. (Dr. Mitchell), wrote in his progress notes,

Note: Vaginal bleeding 2° to 2 cm laceration [right] upper inner labia documented by RN @ 1400, 8/20/06. I spoke with DON today who informs me this may have been a complication of straight-cathing in order to obtain a urine sample to evaluate for UTI. However, an abuse investigation is underway, and until completed, spouse has been restricted to visits in lobby only. Under the circumstances, I agree that this is an appropriate action to take.

Id. at 20.

On August 24, 2006, Ms. Sharkey Vander Galien wrote

Writer spoke [with] Tom - Administrator on 8/23/06 regarding the recent issue with [Resident's husband]. Tom agreed to take over the situation and handle it when he comes to a conclusion. Will continue to consult [with] Tom regarding the issue. Until further notice - [husband] is not to be in [resident's] room. They are to visit in common areas.

Id. at 19.

¹¹(...continued)
evidence that it ever concluded that such an injury was the likely cause of the laceration.

Ms. Sharkey Vander Galien noted in nurse's notes on August 24, 2006, that the

Res[ident] and husband are to continue [with] visits in common areas only until further notice. If he has questions he can consult the Social Worker or Administrator.

Id. at 13.

On August 28, 2006, Ms. Sharkey Vander Galien wrote

Tom, Administrator notified writer that [husband] is allowed to enter Resident's room again without supervision . . . not even grounds to say whether or not he was the cause of the last incident. Will monitor closely.

Id. at 19.

And, on August 28, 2006, Ms. Sharkey Vander Galien wrote in the nurse's notes,

Res[ident] & husband ARE allowed to visit in Res[ident's] room again via Tom & Shelly.

Id. at 13-14.

The state agency became aware of the incident after a complaint was called in to the agency on September 5, 2006. Tr. at 103. DON Westby testified that Resident 1's husband called in the complaint because he was being restricted in his visits with his wife. Tr. at 140.

Following the September 19, 2006 exit conference, Administrator Zwicker wrote on September 20, 2006, to the state agency;

I was notified of the incident of unknown origin on August 20, 2006 at 17:20 by Carol Wehland, RN indicating that an investigation was to commence per the instruction of Deana Westby, RN, DON, to which I offered my approval. An investigation was immediately commenced.

On August 21, 2006 I was apprised of the on-going investigation by Ms. Westby and notified that the areas of concern related to a 2 cm cut near [Resident 1's] vaginal area. During a requested conversation by [Resident 1's husband] he assured me that he was innocent and I informed him that I could not comment pending the investigation.

On August 24, 2006 I had further discussion and deliberation with Ms. Shelly Sharkey, LSW and requested that she look back in the medical record to [Resident 1] to assure me that there was no evidence of abuse related to [Resident 1's husband's] behavior. I also requested that a legal review be accomplished related to legal guardianship and protective placement.

On August 25, 2006 I again met with Ms. Sharkey related to this investigation and was informed of the following: (1) there is no evidence in the chart review that [Resident 1's husband] was ever found guilty of physical or sexual abuse, (2) the legal review provides that [Resident 1's husband] is in fact the legal guardian for [Resident 1], (3) that protective placement was granted and updated . . . on 07/07/06. (4) On 3/04/03 the care center sought legal protection for [Resident 1] and were denied by the Columbus Police and Columbia Circuit Court stating, "There is no way to determine domestic violence for lack of evidence."

Following the review, I met with Ms. Sharkey to note "Shelly, on what evidence do I continue the action of restricting a husband and wife from privacy and intimacy." I interviewed [Resident 1's husband] shortly following this and informed him of my decision.

Admittedly, [Resident 1's husband] is an individual of difficult temperament and demeanor. As he states, "I am uneducated and ruff around the edges, but I love my wife.

Post decision updates: (1) There is no further evidence of abuse related to [Resident 1] at this time and date, (2) Last evening a physical inspection of [Resident 1] revealed no unusual physical outcomes nor behavioral changes.

CMS Ex. 22, at 1-2.

During the hearing, Administrator Zwicker testified that he based his decision to end the restrictions on Resident 1's husband due to

[a] lack of any sort of evidence, the fact that Deana Westby, our DON, had had an interview with the roommate, who, although I did not interview this individual myself, I was informed by Deanan and, I believe, by Shelly, because typically the three of us would be talking about the investigative process, but I was informed that this woman was of sound mind and that she had her mental faculties, that she was in the room during the alleged incident.

Tr. at 150. Administrator Zwicker also testified that he believed it was more likely than not that no sexual or other abuse had occurred and that he believed she had a catheter that could have caused an abrasion. Tr. at 150-51. On cross-examination, Administrator

Zwicker admitted that he was not aware that the roommate's MDS assessment recorded that she had limited short and long-term memory or that the catheterization took place nine days before the injury. Administrator Zwicker only spoke to Resident 1's husband. And, Administrator Zwicker testified that it is Petitioner's policy to retain the written records of any interviews or investigations conducted for potential abuse or other issues. Tr. at 152-53.

CMS asserts Petitioner's investigation was inadequate and that it did not take proper measures to protect Resident 1. It also asserts that Petitioner's written policy concerning investigation and reporting of an allegation of misconduct or an injury of unknown source was not followed.¹²

1. Petitioner conducted an inadequate investigation.

CMS asserted that Petitioner did not conduct a thorough investigation for several reasons. First, Petitioner did not preserve evidence of the suspected sexual assault or seek assistance from an outside agency, such as Wisconsin's Sexual Assault Nurse Examiner (SANE) program, experienced in the area of sexual abuse investigation. Second, Petitioner did not conduct and document thorough interviews with staff regarding Resident 1's activities or unusual occurrences at the facility that may have been noted. And, after Surveyor Healy asked for all written records of interviews or statements connected with the investigation, the only written statements were those of CNAs Cashmore and Hull.¹³ CMS asserts that another CNA, Amber Bussian, who was on duty around the time of the incident was not interviewed. Tr. at 87-88; CMS Ex. 10, at 4. CMS asserts RN Wehland's only statements occurred in the context of limited nursing

¹² That policy, in pertinent part, required that Petitioner: take immediate steps to assure residents were protected from subsequent incidents; immediately conduct a thorough investigation; report the incident (if reportable) to the state agency within 24 hours; if non-reportable, document the decision making process and attach to the investigation documentation; compose a written statement detailing the alleged incident; notify other agencies if there were grounds to believe a crime had been committed; complete forms for investigation of injury of unknown origin; collect relevant physical evidence; and send reports to the state agency following completion of the internal investigation. CMS Ex. 26; P. Ex. 1, at 2-3; P. Ex. 16, at 1-2.

¹³ DON Westby stated in writing on September 20, 2006, that all staff working the 24 hours prior to or during the shift where the incident took place were interviewed, but Petitioner could not locate any written records of those interviews. CMS Ex. 22, at 3. DON Westby also testified that she did not write a summary report but that Administrator Zwicker and Ms. Sharkey Vander Galien "had the report together." No such report was found in Ms. Sharkey Vander Galien's records. CMS Ex. 12, at 19, 30-31. Administrator Zwicker testified that no comprehensive report was prepared. Tr. at 156.

notes and the incident report. And, RN Wehland was apparently never asked whether she observed anyone other than Resident 1's husband enter her room (although Petitioner notes that RN Wehland had just come on shift). Tr. at 26, 28; CMS Ex. 11, at 6-8. Due to the lack of interviews, CMS says it was impossible for Petitioner to determine whether any male staffers or strangers were seen in Resident 1's room, and notes that there were male caregivers at the facility. Tr. at 50.

Petitioner responded that a SANE investigation would have been an emotionally traumatic experience for Resident 1, given that her agitation following the incident appeared to be related to the examination by the RN. P. Reply at 3. Petitioner states that there is no requirement that a facility have a written report of an abuse investigation, only that it have evidence that alleged violations are thoroughly investigated. Petitioner asserts that documentation contained in CMS Ex. 12 constitutes evidence of a thorough investigation, as it includes interview notes and a summary report - specifically, the doctor's documentation of an examination; Ms. Wehland's notes describing her observations and what was reported to her; a completed incident report; completed witness interview forms; the decision tree used to determine that the incident was not reportable; and Ms. Sharkey Vander Galien's notes. CMS Ex. 12. Moreover, alluding to the decision in *Claudette Box Nursing Facility*, DAB CR1161, at 6 (2004), Petitioner asserts that an investigation is not made inadequate simply because in the view of CMS the facility ought to have taken certain steps to investigate the abuse.

Petitioner asserts that there is no legal authority which would require Petitioner to preserve evidence of a potential sexual assault in this instance by sending clothing and other evidence for DNA analysis, and that CMS has cited no legal authority to require it. Petitioner refers to the decision in *Amboy Care Center*, DAB CR1411, at 6 (2006) and asserts that each facility can determine for itself what procedures to follow in pursuing an investigation, as long as they are thorough. Petitioner argues that it interviewed staff members on duty at the time of R1's injury who were likely to have knowledge of how it occurred. Petitioner asserts that CMS's argument is that it failed to conduct and document interviews with all staff on duty in the facility regarding Resident 1's activities and ask about any possible unusual occurrences - but, Petitioner asserts that a facility is not required to interview every staff member on duty during an incident or to document all interviews in writing, citing *Westview Manor*, DAB CR1308 (2005) (a facility might reasonably limit staff interviews to those expected to have knowledge of an incident) and *Claudette Box* (no requirement that a signed interview statement be obtained from each member of the staff who is interviewed and the regulation does not require a facility to obtain written statements or even to interview them). And, Petitioner refers to the testimony of DON Westby that RN Wehland talked to the CNAs that were working and that no-one saw or heard anything and that the resident's roommate did not hear anything. Tr. at 128-29.

As noted by CMS, during its investigation Petitioner considered three possible causes of the laceration to Resident 1's vaginal area; the resident's husband, a catheterization of the resident's bladder, and an inadvertent injury during incontinence care. An injury with a catheter appears to have been unlikely given that the catheterization occurred substantially before the injury. And, an injury during cares does not appear from the documentary evidence to have occurred as it was never reported and both CNAs indicated that Resident 1 did not have the laceration during cares before lunch. Thus, Petitioner's argument that an injury during cares was a more likely scenario than abuse (P. Brief at 31) is not borne out by the record before me. Petitioner did not seriously consider whether a member of Petitioner's staff could have intentionally caused the injury, given the less than one half hour time frame in which the injury could have occurred. P. Ex. 16, at 3; Tr. at 155. Perhaps Petitioner should have given more consideration to that possibility.

Where Petitioner is deficient under this tag, however, is in its failure to adequately, thoroughly, or reasonably pursue an investigation of the resident's husband. The injury of unknown source in this case was evidence of possible sexual abuse. Both RN Wehland and Ms. Sharkey Vander Galien were extremely suspicious of Resident 1's husband. Sexual abuse is a criminal matter. Yet, Administrator Zwicker does not appear to have considered calling in outside help, such as the state agency or the police, to bring in individuals experienced in investigating sexual abuse. And, Administrator Zwicker appears to have made this decision without fully informing himself of the facts of the situation. He ended the investigation not knowing that Resident 1's roommate might not have been a reliable witness or realizing that the catheterization he relied upon as a possible source of the injury had occurred nine days before the incident.

2. Petitioner did not take proper measures to protect Resident 1.

The regulations require that a facility must "prevent further potential abuse while the investigation is in progress." 42 C.F.R. § 438.13(c)(3).

Petitioner asserts that Resident 1 was adequately protected from any potential abuse during its investigation. Petitioner asserts that if abuse occurred here the only person in a position to have done it was Resident 1's husband. And, Petitioner believes that Resident 1 only needed to be protected during the pendency of the investigation. I disagree.

At the start of Petitioner's investigation, when Petitioner suspected that Resident 1's husband might have sexually abused her, the husband was limited to visiting with her in public areas. The limitation lasted eight days, during the time the investigation continued. Petitioner argues that the regulations only require it to protect a resident during an investigation. And, Petitioner asserts that Resident 1's husband was not allowed unrestricted visits until Administrator Zwicker determined there was insufficient evidence

to conclude abuse had occurred (and that, because of Resident 1's contractures, an inadvertent injury during cares was a more likely scenario). P. Br. at 31.

Petitioner also asserts that the regulations require personal privacy between a resident and a family member and that in this case the husband was Resident 1's guardian and was objecting to the restrictive visits. P. Br. at 34. Petitioner states that it did everything within its legal power to protect Resident 1 while its investigation was proceeding. P. Reply at 17.

Petitioner properly acted to protect Resident 1 during the initial investigatory period by limiting the husband's access to her. However, Petitioner's failure to adequately and thoroughly investigate the incident meant that Petitioner should not have dropped those restrictions. I agree with CMS that while the relevant language of 42 C.F.R. § 483.13(c)(3) requires that a facility "must prevent further potential abuse while the investigation is in progress," it does not state that a facility is free to cease such protection merely because a facility terminates an investigation that is not adequate or thorough. CMS Reply at 19-20. I also agree with CMS that Petitioner's argument that the husband could not be barred because a resident has a right to private visits with her family is faulty. The rights are those of the resident, not her husband. Due to her inability to communicate, defend herself, or report an attack to staff or others, it was up to the facility to protect her from such danger. Moreover, as Resident 1's husband was her guardian, it is even more problematic that Petitioner did not call in the help of the state agency or police to investigate the incident before letting the husband have unrestricted access to her or to make decisions for her.

3. Petitioner did not report the incident to the state agency.

The regulations require that a facility ensure that all alleged violations involving injuries of unknown source "are reported immediately to the administrator of the facility and to other officials in accordance with State law through established procedures (including to the State survey and certification agency).

Petitioner argues that it was not required to report this incident to the state agency because it ruled out potential abuse by a caregiver within 24 hours. Petitioner relied on a "decision tree" distributed by the state agency to decide it had no obligation to report. P. Ex. 4, at 1; P. Ex. 16, at 3. And, Petitioner asserts that relevant law in Wisconsin only requires reporting when the allegation of abuse is by a caregiver, not a family member.

Deficiencies covered by 42 C.F.R. § 483.13(c) are not restricted to staff abuse, but include abuse of residents where the perpetrator is someone else, including a family member. Although I have not admitted the declaration of Ms. Busse (see footnote 3), the decision tree relied on by Petitioner was superseded by CMS and state agency notices in calendar year 2005. Specifically, on March 23, 2005, the state agency clarified that

nursing homes must ensure that all violations involving, among other things, injuries of unknown source must be reported within 24 hours to both the facility administrator and the state agency through the Department of Health and Family Services, Bureau of Quality Assurance. Letter referring to DDES-BQA-05-004 dated March 23, 2005 from Jan Eakins, Chief, Provider Regulation and Quality Improvement Section.

B. Petitioner was not in substantial compliance with the participation requirement at 42 C.F.R. § 483.13(c) (F Tag 226).

The regulation in question states that the facility must develop and implement written policies and procedures that prohibit mistreatment, neglect, and abuse of residents and misappropriation of resident property.

CMS asserts that Petitioner failed to implement its own policy (found at CMS Ex. 26) which required Petitioner to, among other things: immediately take steps to ensure that its residents were protected from subsequent incidents; immediately conduct a thorough investigation; report the incident to the state agency within 24 hours; if non-reportable, document the decision making process and attach it to the investigation documentation; compose a written statement detailing the alleged incident; notify other agencies, such as law enforcement, if there were reasonable grounds to believe a crime had been committed; complete a form for investigation of an injury of unknown origin; collect relevant physical evidence upon completion of the internal investigation; and send the required reports to the state agency.

Specifically, CMS asserted that Petitioner failed to assure that Resident 1 was protected from her husband, as the steps taken to protect her were removed a mere eight days after they were instituted with no definitive resolution concerning the cause of the suspicious injury; Petitioner failed to conduct a thorough investigation; Petitioner did not report the incident and, even if non-reportable, did not document the decision making process and there was no written decision; Petitioner did not notify law enforcement in the face of grounds to believe the husband might have sexually assaulted Resident 1; Petitioner failed to collect physical evidence, such as the diaper or other clothing and did not preserve the scene; and Petitioner did not send required reports to the state agency.

Petitioner agrees that the issue here is not that it did not have the required procedures, but that it did not implement them. P. Br. at 34. Petitioner asserts that it was in compliance, but, even if it was not, an isolated incident of a failure to comply with its policies does not establish a prima facie case of a failure to implement such policies.

I agree with CMS that the regulation does not state that more than one incident must be cited to find the facility out of compliance. Here Petitioner did not conduct a thorough investigation, ended the protection it instituted for Resident 1 with no definitive conclusion to the investigation, did not involve law enforcement where a possibility of

sexual abuse existed, and did not report the incident. Petitioner's failure to follow its procedures in these circumstances evidences a systemic failure to understand how to implement its procedures in the face of what could have been an incidence of sexual abuse.

C. CMS's finding of immediate jeopardy is not clearly erroneous.

Under the regulations, a determination concerning the seriousness of a facility's noncompliance is appealable to an ALJ only if a successful challenge would affect either the range of CMP amounts CMS could impose for the noncompliance or a finding of substandard quality of care that has resulted in the loss of a facility's NATCEP. 42 C.F.R. § 498.3(b)(14). Here, CMS has imposed two per instance CMPs. Because per instance CMPs are imposed within a single dollar range of \$1000 to \$10,000 a decision with respect to the validity of CMS's immediate jeopardy determination would have no effect on the range of CMP amounts that CMS may impose. Based only on the imposition of per instance CMPs, I would not address whether or not CMS's finding of noncompliance was clearly erroneous.

However, because CMS asserted in its Notice letter to Petitioner that its NATCEP was lost because Petitioner was subject to a partial extended survey (and not because the CMP imposed was greater than \$5000), I will briefly discuss this finding (although I note that because I have sustained a total CMP of over \$5000 Petitioner is subject to loss of its NATCEP based on that criteria as well).

CMS's finding of immediate jeopardy in this instance is not clearly erroneous. Given that the injury in question was a laceration that was suggestive of sexual abuse, and that I have found that Petitioner conducted an inadequate investigation and did not take proper measures to protect Resident 1, I cannot find that Resident 1 was not at risk for further harm, including sexual abuse, at the hands of her husband who was allowed unrestricted access to her - and Petitioner, who has the burden, has not proved that the finding was clearly erroneous. Further, Petitioner knew or should have known that if it failed to immediately report the incident, properly investigate the incident, and protect the resident, she would be exposed to the likelihood of further injury. And, as Petitioner failed to adequately investigate, other residents were equally exposed.

D. The remedies imposed by CMS are reasonable.

Petitioner argues that the immediate jeopardy was declared for only one day and notes that CMS has conceded that the allegation of noncompliance in both Tags "deals with the same incident and facts . . ." CMS Br. at 21. Thus, Petitioner argues that having imposed the two \$4150 per instance CMPs is imposing close to the maximum permissible daily CMP for a situation of immediate jeopardy. Thus, if I sustain CMS's prima facie case,

any CMP should more reasonably be assessed at or near the minimum per instance CMP of \$1000.

In deciding whether the CMPs imposed are reasonable I must consider the factors enunciated in 42 C.F.R. § 488.438(f), which include; the facility's history of noncompliance, including repeated deficiencies; the facility's financial condition; the factors specified in 42 C.F.R. § 488.404 which include the seriousness of the deficiency, the relationship of one deficiency to other deficiencies, and the facility's prior history of noncompliance; and, the facility's degree of culpability.

Petitioner has a history of noncompliance with participation requirements (CMS Ex. 34); Petitioner has not asserted that it does not have the assets to pay the CMP; the deficiency is serious in that it involves a case of possible sexual abuse which was not thoroughly investigated nor reported. Each of the CMPs is in the lower half of the range of per instance CMP. Based on this I find the CMP to be reasonable.

As noted above, Petitioner's loss of NATCEP is required by law.

V. Conclusion

I conclude that CMS correctly determined that Petitioner was not complying with federal requirements governing participation of long-term care facilities in Medicare and state Medicaid programs. The two per instance CMPs, of \$4150 each, are reasonable, and Petitioner's loss of NATCEP is required by law.

/s/

José A. Anglada
Administrative Law Judge