Department of Health and Human Services

DEPARTMENTAL APPEALS BOARD

Civil Remedies Division

Life Care Center of Elizabethton,
(CCN: 44-5302),

Petitioner,

v.

Centers for Medicare & Medicaid Services.

Docket No. C-08-45

Decision No. CR2201

Date: August 05, 2010

DECISION

I find that Life Care Center of Elizabethton (Petitioner) failed to comply substantially with 42 C.F.R. § 483.25 and 42 C.F.R. § 483.25(m) and that the noncompliance constituted immediate jeopardy to Petitioner's residents. I also find that the Centers for Medicare & Medicaid Services' (CMS) determination of immediate jeopardy with respect to its findings of verbal abuse pursuant to 42 C.F.R. §483.13(b) is clearly erroneous. CMS further failed to sustain its burden of proving that Petitioner failed to substantially comply with 42 C.F.R. § 483.75. I sustain CMS's imposition of a civil money penalty at a level commensurate with finding immediate jeopardy but at the reduced amount of $3050 per day, effective March 26 through August 14, 2007.

I. Background

Petitioner participates in the Medicare program. Its participation in Medicare is governed by sections 1819 and 1866 of the Social Security Act (Act) and by its implementing regulations at 42 C.F.R. Parts 483 and 488. Its right to a hearing in this case is governed by regulations at 42 C.F.R. Part 498.

On August 15, 2007, the Tennessee State Survey Agency (Survey Agency) conducted a complaint and standard survey at Petitioner's facility and found numerous deficiencies with the Medicare participation requirements. Petitioner Exhibit (P. Ex.) 1 (Statement of Deficiencies). The surveyors concluded that with respect to four of the deficiencies cited, Petitioner's noncompliance was so egregious so as to constitute immediate jeopardy to the residents. The term "immediate jeopardy" is defined at 42 C.F.R. § 488.301 as noncompliance that has caused or is likely to cause serious injury, harm, impairment, or death to a resident.

On August 22, 2007, CMS notified Petitioner that as a result of the surveyors' findings of deficiencies, it was imposing a civil money penalty (CMP) in the amount of $4550 per day for 142 days, effective March 26, 2007 through August 14, 2007; and a CMP in the amount of $100 per day effective August 15, 2007 until Petitioner was found in substantial compliance.[1] The Survey Agency later determined that Petitioner achieved substantial compliance as of August 22, 2007.[2]

This case was assigned to me for hearing and decision. I conducted a hearing on November 5, 6, and 7, 2008; the parties received a transcript (Tr.) of the proceedings. CMS offered and I admitted CMS Exhibits (CMS Exs.) 1 – 40. Tr. at 5. Petitioner offered and I admitted Petitioner Exhibits (P. Exs.) 1- 52. Tr. at 6, 374. The parties submitted posthearing briefs and reply briefs.[3]

---

[1] CMS also indicated it would impose a Denial of Payment for New Admissions and termination of the provider agreement but those remedies were rescinded.

[2] Petitioner only appealed the four deficiencies cited at the immediate jeopardy level- Tags F223 (Abuse), F490 (Administration), F309 (Quality of Care) and F333 (Significant medication errors). Petitioner, however, was cited for seven other deficiencies at scope and severity levels of D and G (patient suffered actual harm when staff failed to follow plan of care and transferred the patient without the required mechanical lift; patient fractured her femur). Petitioner also does not dispute the $100 per-day CMP from August 15 through August 22, 2007 and that CMP is sustained. P. Posthearing Brief at 3.

[3] CMS counsel initially did not submit a reply brief. However, after reviewing the posthearing submissions, I found that CMS's failure to submit a reply brief left the record incomplete with respect to certain critical arguments. My review also found that CMS counsel made certain factual errors with respect to the duration of the CMP at the immediate jeopardy level which needed to be reconciled. I therefore issued an order directing CMS counsel to submit a posthearing reply brief and to address in that brief issues and arguments I specifically identified which Petitioner had raised and to which CMS had not responded. June 8, 2009 Order Directing CMS to respond.

II. Applicable Law

The regulatory requirements for long-term care facilities that participate in the Medicare and Medicaid programs are set forth at 42 C.F.R. Part 483. Facility compliance with the participation requirements is determined through a survey and certification process. Sections 1819 and 1919 of the Social Security Act; 42 C.F.R. Parts 483, 488, and 498. This process is performed on behalf of the Secretary and CMS by state survey agencies. Under Part 488, CMS may impose a CMP against a facility that is not complying substantially with participation requirements. 42 C.F.R. §§ 488.406, 488.408, 488.430. The penalty may start accruing as early as the date that the facility was first out of compliance and runs until the date substantial compliance is achieved or the provider agreement is terminated.

"Deficiency" is defined as a facility's "failure to meet a participation requirement specified in the Act" or in 42 C.F.R. Part 483. 42 C.F.R. § 488.301. The term "substantial compliance" means "a level of compliance with the requirements of participation such that any identified deficiencies pose no greater risk to resident health or safety than the potential for causing minimal harm." *Id*. "Noncompliance" means "any deficiency that causes a facility to not be in substantial compliance." *Id*. "Immediate jeopardy" is defined as "a situation in which the provider's noncompliance . . . has caused, or is likely to cause, serious injury, harm, impairment, or death to a resident." *Id.*

The regulations specify that a CMP that is imposed against a facility on a per day basis will fall into one of two broad ranges of penalties. 42 C.F.R. §§ 488.408, 488.438. The upper range of CMP, 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)(i), (d)(2). The lower range of CMP, from $50 per day to $3000 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). There is only a single range of $1000 to $10,000 for a per-instance CMP that applies whether or not immediate jeopardy is present. 42 C.F.R. §§ 488.408(d)(1)(iv), 488.438(a)(2).

The Act and regulations make a hearing before an ALJ available to a long-term care facility against which CMS has determined to impose a CMP. Act § 1128A(c)(2); 42 C.F.R. §§ 488.408(g), 498.3(b)(13). The hearing before an ALJ is a *de novo* proceeding. *Anesthesiologists Affiliated, et. al*, DAB CR65 (1990), *aff'd*, 941 F.2d 678 (8th Cir. 1991); *Emerald Oaks*, DAB No. 1800, at 13 (2001); *Beechwood Sanitarium*, DAB No. 1906 (2004); *Cal Turner Extended Care Pavilion*, DAB No. 2030 (2006); *The Residence at Salem Woods*, DAB No. 2052 (2006). A facility has a right to appeal a "certification of noncompliance leading to an enforcement remedy." 42 C.F.R. § 488.408(g)(1); *see also*,

42 C.F.R. §§ 488.330(e), 498.3. However, the choice of remedies by CMS or the factors CMS considered when choosing remedies are not subject to review. 42 C.F.R. § 488.408(g)(2). A facility may only challenge the scope and severity level of noncompliance found by CMS if a successful challenge would affect the amount of the CMP that could be collected by CMS or impact upon the facility's nurse aide training program. 42 C.F.R. §§ 498.3(b)(14), (d)(10)(i),(ii). CMS's determination as to the level of noncompliance "must be upheld unless it is clearly erroneous." 42 C.F.R. § 498.60(c)(2). This includes CMS's findings of immediate jeopardy. *Woodstock Care Ctr.*, DAB No. 1726, at 9, 39 (2000), *aff'd*, *Woodstock Care Ctr. v. U.S. Dept. of Health and Human Servs.*, 363 F.3d 583 (6th Cir. 2003). The Departmental Appeals Board (the Board) has long held that the net effect of the regulations is that a provider has no right to challenge the scope and severity level assigned to a noncompliance finding, except in the situation where that finding was the basis for an immediate jeopardy determination.[4] *See*, *e.g.*, *Ridge Terrace*, DAB No. 1834 (2002); *Koester Pavilion*, DAB No. 1750 (2000). Review of a CMP by an ALJ is governed by 42 C.F.R. § 488.438(e).

III. Issues, findings of fact and conclusions of law

A. Issues

The issues in this case are whether:

1. Petitioner failed to comply substantially with Medicare participation requirements;

2. CMS's determination of immediate jeopardy level of noncompliance is clearly erroneous; and

3. CMS's remedy determinations are reasonable.

B. Findings of fact and conclusions of law

I make findings of fact and conclusions of law (Findings) to support my decision in this case.[5] I set forth each Finding below as a separate heading.

---

[4] Such a challenge is only applicable where CMS has imposed a per day CMP within the upper range; there is no such challenge available if a per instance CMP is imposed.

[5] I have reviewed the entire record, including all the exhibits and testimony. As I am not bound by the rules of evidence, I may admit evidence or testimony and determine later upon a review of the record as a whole, what weight, if any, I should accord that evidence or testimony. To the extent that any contention, evidence, or testimony is not explicitly

(continued…)

1. Petitioner was in substantial compliance with the requirements of 42 C.F.R. § 483.13(b) (Tag F223).

CMS determined that Petitioner was not in substantial compliance with Tag F223 which requires pursuant to 42 C.F.R. § 483.13(b), that a resident has the right to be free from verbal, sexual, physical, and mental abuse. The State Operations Manual (SOM) (CMS Pub. 100-7), Appendix PP, entitled, Interpretive Guidelines for Long-Term Care Facilities, restates the regulatory definition of "Abuse" as "the willful infliction of injury, unreasonable confinement, intimidation, or punishment with resulting physical harm, pain or mental anguish." 42 CFR § 488.301. It further provides –

> "Verbal abuse" is defined as the use of oral, written or gestured language that willfully includes disparaging and derogatory terms to residents or their families, or within their hearing distance, regardless of their age, ability to comprehend, or disability. Examples of verbal abuse include, but are not limited to: threats of harm; saying things to frighten a resident, such as telling a resident that he/she will never be able to see his/her family again.

SOM, Appendix PP (Tag F223). The surveyor determined that Petitioner was not in compliance with this requirement because it failed to ensure that Resident #1 was free from verbal abuse.

Resident #1 was an elderly woman with diagnoses including depressive disorder, anxiety and dementia with behavior disorder. The surveyor noted that her Minimum Data Set dated May 16, 2007 indicated that she had short and long term memory problems; she had moderately impaired cognitive skills; she was resistive to care; and she was totally dependent on staff for transfers, dressing, eating, hygiene and bathing needs. CMS Ex. 1, at 2. She also was hard of hearing. Tr. at 19. The staff told her physician that Resident #1 continued to yell out, often repeating the same thing, in a loud voice, such as "I'm wet, take this off me." P. Ex. 17, at 14. Because of an increase in her agitation and anxiety, the physician's nurse practitioner ordered a psychiatric consult on May 24, 2007. *Id*. The report of the consult on May 25, 2007, found Resident #1 to be disheveled and disorganized. P. Ex. 17, at 16. Her speech was loud; she was paranoid; and she would not take her medications by mouth. ***Id.*** As a result of the consult, the psychiatrist recommended that her psychiatric medications be administered by means other than orally and that if she was severely agitated, that certain medication be given. ***Id.***

---

[5] (…continued)

addressed or mentioned, it is not because I have not considered the contentions. Rather, it is because I find that the contentions were not supported by the weight of the evidence or by credible evidence or testimony.

I have reviewed the documentary evidence and the testimony of the witnesses. The overwhelming evidence establishes that there was no basis for the surveyor's finding of abuse. This started as a classic she said/she said situation. There was never any evidence that CNA 1 willfully "cursed" at the resident. Moreover, my review of the evidence shows that CNA 2 was far from credible. Moreover, the evidence suggests that Surveyor Moody was less than objective in her review of this matter. She failed to take into account Resident #1's increased agitation and propensity for yelling loudly; she disregarded the clear inconsistencies in CNA 2's retelling of events and additional allegations raised first and only to Surveyor Moody during her survey some months later (CMS Ex. 26, at 8-9; P. Ex. 9, at 2-3;) and she disregarded completely any exculpatory evidence related to CNA 1 (she even disregarded her own interviews with other staff that indicated that they had never heard CNA 1 use inappropriate language with residents or act roughly with patients).[6] P. Ex. 9, at 8; CMS Ex. 26, at 7, 27, 28, 29; Tr. at 21-23. While Surveyor Moody may have disagreed, Petitioner's corrective action with respect to CNA 1 was an appropriate response to the findings of its investigation. Tr. at 183; Tr., at 40-41, 84-85. The facility followed their procedures by immediately suspending the CNA involved, reassigning her to the day shift so that she could be monitored and assessed, and providing her with in-service training on abuse and the facility policy, but Surveyor Moody did not find this adequate. She simply did not agree with the finding of the investigative report—that the allegation of verbal abuse was unsubstantiated—and she was not going to be satisfied until CNA 1 was terminated.[7] I find that there was no

---

[6] Contrary to Surveyor Moody, I find CNA 1's statements credible. She consistently stated that she did not believe she cursed, but, if she did, it was never directed at the resident. Her frustration, if any, was related to how long it was taking CNA 2 to return with the soap given Resident #1's dislike for the shower and her agitation. CNA 1 repeatedly and forthrightly stated that she did not think she cursed at all and that she would never in any event curse at a resident. The facility investigation took that distinction into account together with all the other evidence. Surveyor Moody completely ignored that distinction and any other exculpatory evidence and concluded that the use of any inappropriate language, even if not directed at a resident or willfully intended for a resident, should be considered verbal abuse.

[7] Surveyor Moody interviewed the facility's administrative staff during the survey. However, some of that staff were not in those positions or even at the facility at the time of the incident. Tr. at 74-76. I must agree with Petitioner that the fact that the new administration was not aware in August 2007 of certain documents in a investigative report made on May 29, 2007 that found an incident unsubstantiated is not critical and any inference made by Surveyor Moody that it was, is simply improper. Tr. at 75-76. Moreover, I do find the record supports Petitioner's belief that Surveyor Moody would not abate the finding of immediate jeopardy unless CNA 1 was removed from the facility. P. Br. at 9, n.9 citing Tr. at 187, 215-16; 265-66; P. Exs. 15 and 16.

verbal abuse towards Resident #1. The evidence related to the incident shows that there was never any willful or intended infliction of injury by the use of disparaging language directed at Resident #1 by CNA 1.

The following facts appear to be undisputed. On May 26, 2007, CNA 1 was in the shower room with Resident #1 when she discovered there was no soap in any of the dispensers or the cupboard. CMS Ex. 25, at 3. CNA 1 called to another associate, CNA 2, to get some. CMS Ex. 25, at 3. CNA 2 walked down the hall to get the body wash and said she was gone several minutes. CMS Ex. 26, at 8; P. Ex. 9, at 6. Resident #1 hated the shower and yells a lot. CMS Ex. 26, at 8. CNA 2 claimed that upon returning with the soap, she overheard from outside the shower room, CNA 1 allegedly yelling and cursing at Resident #1. *Id.*; Tr. at 20, 37. CNA 2 claimed upon returning to the shower room she told CNA 1 to turn the hot water down and then CNA 2 left the shower room. CMS Ex. 26, at 8. There appears little dispute that the alleged incident occurred sometime between 2:15 pm and 2:30 pm. Tr. at 79. However, CNA 2 did not report the alleged incident until some 6 hours later. Tr. at 80. The Charge Nurse to whom CNA 2 reported the alleged incident immediately notified the Weekend Supervising Nurse. She in turn contacted the Director of Nursing at her home. The Supervising Nurse then interviewed CNA 1, took her statement, took the statement from CNA 2, removed CNA 1 from the situation and sent her home for a 3-day suspension without pay pending investigation of the incident. All of this occurred within minutes of the Supervising Nurse receiving the report of the alleged incident. CMS Ex. 22; CMS Ex. 25, at 3-4; P. Ex. 9, at 6-8; and Tr. at 80. There is no dispute that the alleged incident was timely reported to the state as required. Tr. at 64. There is no dispute that a complete investigation was performed and the allegation of abuse was determined to be unsubstantiated on May 29, 2007. There is no dispute that the facility took corrective action, issuing a "1st written warning" to CNA 1, telling her that she is expected to follow the policies and procedures of the facility with respect to Resident Rights, reassigning her to the day shift starting May 30, 2007 where there were more supervisors available to monitor her and to reorient her; and providing in-service training. CMS Ex. 22; P. Ex. 10, at 1-4. There is no dispute that there were no further allegations or complaints against CNA 1. At least, not until some two months later, when the state sent Surveyor Moody to investigate the complaint and CNA 2 told Ms. Moody an embellished story with some additional allegations of physical abuse that had never been previously reported. Tr. at 76.

Why Surveyor Moody chose to accept these new allegations by CNA 2 and elevate the importance of these statements to the exclusion of all the other evidence is incredible. Frankly, even a cursory review of the evidentiary record before Ms. Moody would raise considerable doubts about the credibility of CNA 2. For example, the record shows that CNA 2 did not report the alleged incident of verbal abuse on May 26, 2007 for some 6 hours after the alleged incident occurred; she never explained any reason for the delay. Second, CNA 2's first statement to the surveyor on July 31, 2007 indicated that even

though she allegedly heard CNA 1 say, "shut the hell up" to the resident, after she entered the shower room and gave CNA 1 the soap, she left. CMS Ex. 26, at 8. If she was concerned about CNA 1's behavior, why did she leave the shower room? Furthermore, why did she wait 6 hours to report the incident? During that same interview on July 31, 2007, some two months after the alleged incident, CNA 2 claims, for the first time, that she also saw CNA 1 slap Resident #1 and slap another resident. CNA 2 told the surveyor that she reported this, but she could not remember to whom, that she did not tell anyone else, and that could not remember specifically when the incident or reporting occurred. CMS Ex. 26, at 8-9. On August 2, 2007, CNA 2 filled out a Witness Statement form alleging this new unreported incident of physical abuse by CNA 1. P. Ex. 9. She indicated that incident occurred in May 2007 but did not indicate the specific date yet she alleged that the alleged abuse occurred at around 6 p.m. Rather than questioning the veracity of this new allegation by CNA 2 (considering she had never said anything about it before and there is no documentation of any incidents of this nature), Surveyor Moody determined to accept this statement and found that any lack of documentation or corroboration of the statement was because the unknown and unnamed nurse to whom CNA 2 claimed she first reported the incident failed to document it! Tr. at 28-33. This flies in the face of all the other evidence in the record.

In contrast, I find that the statements of CNA 1 and the findings of Petitioner's investigative report to be entirely credible. The accused CNA denied that she cursed at the resident. She indicated that Resident #1 was yelling. CMS Ex. 22, at 3; P. Ex. 9, at 6. CNA 2 also indicated that Resident was yelling and yelling loudly prior to her leaving the shower room. CMS Ex. 26, at 8. CNA 1 stated that it took several minutes for CNA 2 to come back with the soap and Resident #1 continued to yell to get her out of the shower and to put her back to bed. CNA 1 said that she had to repeatedly try to make the resident understand that that someone was getting the soap. CNA 1 said her response was loud because Resident #1 was hard of hearing and she was also yelling. She denied, however, that she cursed at or yelled at the resident. CMS Ex. 25, at 3; CMS Ex. 22, at 3. CNA 1 has repeatedly stated that she never cursed at the resident, nor did she believe that she cursed at all. Later, in her interview with the surveyor she reiterated that she did not believe that she cursed at the resident. If any curse words were spoken, the context was in the nature of where was CNA 2 with the soap and why was it taking so long. CMS Ex. 26, at 20. She explicitly told the surveyor that she would never say anything like "shut the hell up!" as CNA 2 contended she said. *Id.*

Thus, I conclude that Petitioner was in compliance with Tag F223 and that CMS's determination of immediate jeopardy with respect to this Tag was clearly erroneous.

2. Petitioner failed to comply substantially with the requirements of 42 C.F.R. § 483.25(m)(2) (Tag F333).

This deficiency finding centers on Petitioner's administration of the medication, Coumadin, to its residents. The surveyors reviewed the medical records for a sample of the residents in the facility. Out of the sample of six residents (from a total of 24 residents prescribed Coumadin), the surveyors found that Petitioner failed to ensure that Residents #22 and #25 were free from significant medication errors with respect to the blood thinner, Coumadin. The surveyors further determined that the scope and severity of Petitioner's failure to ensure that residents were free from significant medication error with respect to Coumadin constituted immediate jeopardy.

Resident #22 and Resident #25

I review the evidence related to the administration of the anticoagulant drug, Coumadin, to Resident #22 and Resident #25 to determine if Petitioner rebuts CMS's determination of a significant medication error for these residents.

At the time of the survey, Resident #22 was a 70-year old male, admitted to the facility with multiple medical conditions including anxiety and depression, atrial fibrillation and chronic airway obstruction. P. Ex. 18. Resident #22 received Coumadin daily as prescribed to him by his physician, Dr. Clark, who is also Petitioner's medical director. P. Ex. 24, at 4; P. Ex. 25; P. Ex. 26. CMS determined, based on a review of Resident #22's medical records for March 2007, that Petitioner failed to give the resident the appropriate dosage on March 12, March 16, and March 19, 2007, (Resident #22 was supposed to receive 7.5 mg and instead received 5 mg) and then gave the resident a double dose (12.5 mg.) of Coumadin on March 26, 2007. P. Ex. 27, at 13. A PT/INR test was taken on March 28, 2007 which revealed critically high values (91.7/8.7). P. Ex. 31, at 6. As a result of his critically high levels, the physician's nurse practitioner made an acute visit to evaluate Resident #22 for any symptoms from the elevated PT/INR; his levels indicated that he was at severe risk for bleeding out. She ordered a hold on his Coumadin until his PT/INR levels were substantially reduced and ordered 10 mg. of Vitamin K immediately as an antidote. P. Ex. 20, at 5; P. Ex. 25, at 5.[8]

[8] I am disturbed that the Nurse's Notes make absolutely no mention of Resident #22's critically high PT/INR levels or whether anyone contacted the resident's family with respect to these lab values. P. Ex. 29, at 5. An incident report indicates that the family was notified two days after the incident when they were visiting the facility. P. Ex. 32, at 5.

At the time of the survey, Resident #25 was an 81-year old female, admitted to the facility with numerous medical conditions, including fractures of her leg and knee, hypertension, and atrial fibrillation. P. Ex. 34. Resident #25's care plan for the period relevant to the surveyor's findings indicates that the resident is at risk for bleeding tendencies related to taking Coumadin and instructs the facility staff to give Resident #25 her Coumadin as ordered. P. Ex. 40, at 3. The surveyor noted that on July 27, 2007, Resident #25's physician changed the order for Coumadin to 7.5 mg on Monday, Wednesday and Friday and 5 mg on Tuesday, Thursday, Saturday and Sunday. P. Ex. 1, at 30; P. Ex. 42, at 22. Upon reviewing Resident #25's medical records, specifically the Medication Administration Record (MAR) for the period of July 27, 2007 through July 31, 2007, the surveyor found that Resident #25 was given 7.5 mg five days in a row, rather than the alternating dose. P. Ex. 43, at 35. That same MAR suggests that Resident #25 also may have been given both a 7.5 mg dose of Coumadin and a 5 mg dose on July 31, 2007 (there are staff initials for each dose under July 31, 2007 on the MAR). *Id*. Moreover, Petitioner's own exhibits include an Incident Report that Petitioner filed indicating that Resident #25 received a double dose of Coumadin on July 31, 2007. P. Ex. 50. There is also a facility incident report which notes that Resident #25 was given the wrong dosage of Coumadin (at the higher dosage) on two days. P. Ex. 48. These incident reports were not done contemporaneously with the incidents, however. The evidence shows that the Incident Reports were done on or about August 15 and 16, 2007, after the surveyor brought these errors to the attention of the facility. P. Ex. 1, at 30; P. Ex. 48 and 50 [indicates signatures dated from August 15, 16, and September 4, 2007]; *see also* P. Exs. 49 and 51, Corrective Action Forms indicating that the staff who administered the medication were re-educated on August 28 and August 29, 2007, consistent with my finding that the facility did not take any action or even have any knowledge of the medication errors until the surveyor brought it to the facility's attention.[9]

[9] There is a similar incident report for Resident #22. While Petitioner claims the mistaken administration of the double dose of Coumadin was reported at the time of the incident, the document itself indicates that staff members did not sign off on the report until August 16, 2007 and September 4, 2007. Moreover the report indicates it was entered into Incident Data Archive (IDA) on August 16, 2007. P. Ex. 32, at 2. Also, there is no indication the facility was aware at the time of the incident that a double dose was given. I do not find credible Mr. Parris's suggestion that he was first contacted about this incident on or about the date of its occurrence. The evidence suggests that the incident occurred on March 26, 2007, but that the facility was not aware of the double dose until the survey. They were aware on March 28, 2007 of Resident #22's very elevated PT/INR which was reported to the physician, but not necessarily that the elevated PT/INR was due to an erroneous double dose of Coumadin.

The regulatory requirements for long-term care facilities that participate in the Medicare program are set forth at 42 C.F.R. Part 483. Among the requirements, 42 C.F.R. § 483.25(m)(2) provides that "[t]he facility must ensure that– . . . Residents are free of any significant medication errors."

Petitioner does not dispute that errors were made in the administration of Coumadin to Resident #22 and Resident #25. Petitioner contends that the errors either individually or collectively were not "significant" pursuant to the regulation. P. Br. at 2, 10; P. Reply at 7; Tr. at 95. Petitioner further contends that neither resident suffered any actual harm as a result of the errors which it contends is an important factor in considering whether a medication error is significant. P. Br. at 26.

I disagree. The issue of what is considered a "significant" medication error has been discussed previously in other ALJ decisions as well as by the Board. The Board, in *Franklin Care Ctr*, DAB No. 1900 (2003), affirmed the ALJ's finding of a significant medication error despite Petitioner's contentions that there was no pattern of medication errors at the facility because the medication "accidents" were isolated and there was no evidence that it acted improperly or imprudently. The Board stated that the ALJ did not need to find specifically that Petitioner engaged in improper acts or failed to act prudently or that there was a pattern of medication errors at the facility in order to conclude that Petitioner failed to substantially comply with 42 C.F.R. § 483.25(m)(2).

The Board has held that the compliance issue under section 483.25(m)(2) "turns solely on whether [Petitioner] made a medication error or errors that were 'significant'." *Franklin Care Ctr*, DAB No. 1900 at 8; see also *Ocean Springs Nursing Ctr*, DAB No. 2212 (2008). "To 'ensure that residents are free of any significant medication errors' as required by section 483.25(m)(2), a facility must administer the 'right dose' of the 'right medication' by the 'right route' to the 'right patient' at the 'right time'. . . This is not reasonably considered 'an obviously difficult task' since . . . this task does not typically involve any factors outside the facility's control." *Franklin Care Ctr.*, at 11.

As the Board pointed out, "the preamble to the final regulation makes clear that a facility's compliance with section 483.25(m)(2) turns solely on whether it made a medication error . . . that [was] 'significant' and that a single medication error can be 'significant'." *Id.* at 6. The preamble states in pertinent part:

> Since medication errors vary in their significance (e.g., from significant errors such as a double dose of a potent cardiac drug like digoxin to a small error in the dose of an antacid like milk of magnesia), we have based sanctions on two different criteria. First, if a facility has a significant medication error, then it is sanctioned. This policy satisfies consumers, who maintain that

> a five percent tolerance in medication errors is too lenient and that one medication error could be disastrous for a resident. Second, a facility is sanctioned if it has an error rate of five percent or greater. This satisfies providers who maintain that there must be some tolerance of errors because all systems have some errors. . . .
>
> A significant medication error is judged by a surveyor, using factors which have been described in interpretive guidelines since May 1984. The three factors are: (1) Drug category. Did the error involve a drug that could result in serious consequences for the resident (2) Resident condition. Was the resident compromised in such a way that he or she could not easily recover from the error (3) Frequency of error. Is there any evidence that the error occurred more than once[.] Using these criteria, an example of a significant medication error might be as follows: A resident received twice the correct dose of digoxin, a potentially toxic drug. The resident already had a slow pulse rate, which the drug would further lower. The error occurred three times last week.

56 Fed. Reg. 48,826, at 48,853 (Sept. 26, 1991). These criteria are reflected in CMS's interpretive guidelines for section 483.25(m)(2). State Operations Manual (SOM), App. PP (tag F333).[10] The guidelines describe the factors relevant in determining whether an error is "significant" as follows:

> **"Resident Condition"–**The resident's condition is an important factor to take into consideration. For example, a fluid pill erroneously administered to a dehydrated patient may have serious consequences, but if administered to a resident with a normal fluid balance may not. If the resident's condition requires rigid control, a single missed or wrong dose can be highly significant.
>
> **"Drug Category"–**If the drug is from a category that usually requires the patient to be titrated to a specific blood level, a single medication error could alter that level and precipitate a reoccurrence of symptoms or toxicity. This is especially important with a drug that has a Narrow Therapeutic Index (NTI)(i.e., a drug in which the therapeutic dose is very close to

[10] http://cms.gov/manuals/Downloads/som107ap_pp_guidelines_ltcf.pdf.

> the toxic dose). Examples of drugs with NTI are as follows: Anticonvulsant: phenytoin (Dilantin) . . . Anticoagulants: warfarin (Coumadin) . . . .
>
> **"Frequency of Error"**-If an error is occurring with any frequency, there is more reason to classify the error as significant. For example, if a resident's drug was omitted several times . . . , classifying that error as significant would be in order. This conclusion should be considered in concert with the resident's condition and the drug category.

Thus, a medication error involving residents can be considered a "significant" medication error based on the drug category alone regardless of whether the error was widespread or whether the resident suffered actual harm. *See Franklin Care Ctr*, DAB No. 1900. Coumadin falls within this drug category. Therefore, I need not find that the resident suffered actual harm as a result of the medication error in order to determine that the medication error was significant. *See Parkway Manor Health Center*, DAB CR1146 (2004).

Coumadin (warfarin) is an anticoagulant medicine used to lower the chance of blood clots forming in the body and causing stroke, heart attack or other serious conditions. *See* www.coumadin.com/patient_guide.aspx. It is often used in treating patients who have been diagnosed with atrial fibrillation or other diseases in which the propensity for blood clotting is increased. *Id.* There are major risks associated with the use of Coumadin. Coumadin can cause serious and life-threatening bleeding problems and the risk of bleeding increases with the intensity of therapy. *Id.* Therefore, it is necessary to test a patient's blood clotting time through a test known as international normalized ratio (INR) and Prothrombin Time (PT), otherwise referred to as INR/PT.[11] Generally, an INR of 1.0

---

[11] *See* www.coumadin.com (Warfarin sodium can cause major or fatal bleeding. Bleeding is more likely to occur during the starting period and with a higher dose (resulting in a higher International Normalized Ration (INR)). Risk factors for bleeding include high intensity of anticoagulation (INR>4.0), age ≥65, highly variable INRs, history of gastrointestinal bleeding, hypertension, cerebrovascular disease, serious heart disease, anemia, malignancy, trauma, renal insufficiency, concomitant drugs (see **PRECAUTIONS**), and long duration of warfarin therapy. Regular monitoring of INR should be performed on all treated patients. Those at high risk of bleeding may benefit from more frequent INR monitoring, careful dose adjustment to desired INR, and a shorter duration of therapy. Patients should be instructed about prevention measures to minimize risk of bleeding and to report immediately to physicians signs and symptoms of bleeding (see **PRECAUTIONS: Information for Patients**). . . Acceptable intervals for

(…continued)

is considered to show normal blood clotting time and increases above 1.0 show an enhanced risk for bleeding. An INR of between 2.0 and 3.0 is considered to be an acceptable risk for bleeding in a patient who is receiving Coumadin when measured against the benefits that the patient may obtain from Coumadin therapy. The risk of bleeding while on Coumadin is increased if certain factors are present such as the patient is 65 years of age or older, the patient has highly variable INRs, or the patient is taking other medications (prescription, nonprescription, or herbal supplements) or eats certain foods that may interact with Coumadin. *Id.*

Next, both Resident #22 and Resident #25 conditions required increased attention to the administration of Coumadin to make sure they were given the correct dosage on the correct days as prescribed. Both residents were over 65 years of age, had variable PT/INRs and were on other medications which could interact with the Coumadin. All three of these factors required that Coumadin was correctly given so as to properly determine the correct therapeutic dosage of the medication. *See also* Tr. at 345, 350, and 365. When Petitioner failed to give the dosages prescribed, besides putting the residents at risk for harm, it made it difficult to discern whether the residents were responding appropriately to the dosage of the medication—was it the patient's norm to have a variable INR or was the INR variable because of the incorrect dosages of Coumadin? That is why administering the correct dosage on the correct day and monitoring the blood clotting time by administration of a PT/INR test at regular intervals is necessary. Of considerable concern to me in this case is the fact that neither the facility nor the residents' doctor was even aware of the medication errors until the surveyor brought them to their attention. Under the circumstances here, the likelihood of the risk of harm from the patient receiving too much of the drug, with the increased risk for life threatening bleeding problems, or the risk of harm from receiving too little of the drug, with the risk for blood clots forming, was great.

CMS met its burden of establishing a prima facie case of noncompliance that Petitioner failed to ensure that Residents #22 and #25 were free from significant medication errors which Petitioner failed to rebut. I find that the preponderance of the evidence supports CMS's determination; Petitioner's failures to administer Coumadin as prescribed to Residents #22 and 25 constituted a significant medication error. Therefore, I find that Petitioner was not in substantial compliance with Tag F333.

---

[11] (…continued)

PT/INR determinations are normally within the range of 1 to 4 weeks after a stable dosage has been determined.)

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

This regulation requires a facility to provide each of its residents with the necessary care and services in order for that resident to attain or maintain the highest practicable physical, mental, and psychosocial well-being, in accordance the resident's comprehensive assessment and plan of care. CMS alleges that Petitioner failed to satisfy the requirements of this regulation in providing care to two of six residents sampled, Resident #22 and Resident #25, who were receiving the anti-coagulant medication, Coumadin. The survey found that facility failed to follow the physician's order regarding the administration of Coumadin for two of six residents reviewed. The survey also found that the facility's failure to administer the drug as ordered placed Residents #22 and 25 in immediate jeopardy.

Petitioner did not really present any independent arguments with respect to this deficiency finding. It contended only that it was not appropriate to bootstrap a violation of the quality of care requirement under the same facts as the violation with respect to the significant medication errors. P. Br. at 27.

Clearly, this regulation requires the facility to accord each resident a certain standard of care. Petitioner does not dispute that the regulation requires a facility to attain and maintain a resident's highest practicable level of well being in accordance with the resident's plan of care. There is also no dispute that both Residents #22 and #25 had plans of care which indicated that they were being prescribed a blood-thinning medication (Coumadin) that put them at an increased risk for bleeding. Their plans of care provided for a specified approach to the problem; they were to be given their medications as ordered, monitored for bleeding, and have their blood drawn [labs] for PT/INRs as ordered. P. Exs. 24, at 4 and 40, at 3. Petitioner does not dispute that Residents #22 and #25 were not given the blood-thinning medication as ordered by the physician and as set forth in the care plans. CMS made a prima facie case with respect to a violation of the requirement at 42 C.F.R. § 483.25; Petitioner would have me overlook the clear deficiency contending that it is merely a "catchall 'quality of care' requirement." The facility must provide each resident the necessary care and services to attain or maintain the highest practicable physical, metal and psychosocial well-being in accordance with the comprehensive assessment and plan of care.[12] Moreover, Petitioner

---

[12] In *The Laurels at Forest Glenn*, DAB CR1681, at 14-15, n.15 (2007); *aff'd* DAB No. 2182 (2008), an ALJ commented on Petitioner's dismissal of the "quality of care" regulation as a "catchall." The ALJ found that "[w]hile a facility that fails to comply with the quality of care requirements often has deficiencies under other regulations, that hardly negates the significance of quality of care findings. Indeed, while compliance with all Medicare long term care requirements is important, the quality of care regulation

(continued…)

is bound to comply with each of these regulatory requirements in order to be in substantial compliance with Medicare requirements. Petitioner fails to address that the residents' plans of care clearly addressed the administration of Coumadin as being important for the individuals' well-being and the necessity that it be administered as ordered by the physician. The evidence supports the finding that Petitioner failed to follow the residents' care plans and Petitioner clearly failed to rebut CMS's prima facie case.

Thus, I sustain CMS's finding that Petitioner was not in substantial compliance with 42 C.F.R. § 483.25 (Tag F309) because Petitioner failed to administer the Coumadin to Residents #22 and 25 in accordance with the provisions of their care plans.

4. CMS failed to sustain its burden of establishing a primae facie case that Petitioner failed to comply substantially with the requirements of 42 C.F.R. § 483.75 (Tag F490).

This regulation requires a facility to be administered in a manner that enables it to use its resources effectively and efficiently to attain or maintain the highest practicable physical, mental, and psychosocial well-being of each resident. The surveyors determined that Petitioner was not in substantial compliance with this requirement and that the scope and severity of its noncompliance put its residents in immediate jeopardy. Specifically, they determined that the facility failed to be administered in a manner to ensure: 1) Freedom from abusive treatment; 2) effective implementation of the facility's abuse policy to ensure the safety of the residents; 3) supervision to ensure physician's orders are implemented accurately; and 4) accurate administration of medication and the prevention of significant medication errors. CMS Ex. 1, at 46. Petitioner argues that there is no basis to cite an administration deficiency on the present facts, much less citing the deficiency at the immediate jeopardy level.[13] Petitioner contends that its noncompliance with other requirements is not in itself sufficient to establish a deficiency under the administration requirement. I disagree. The Board has held that a finding on noncompliance with respect to 42 C.F.R. § 483.75 may be derived from findings of noncompliance with other participation requirements. *Life Care Center of Tullahoma*,

---

[12] (…continued)

is particularly important because it encompasses the purpose of skilled nursing care. Medicare pays for placement in skilled nursing facilities in order for residents to receive the quality of care described in the regulation."

DAB No. 2304, at 45 (2010), citing *Stone County Nursing and Rehab. Ctr*, DAB No. 2276, at 15-16 (2009) (citing cases).

Petitioner also argues that if I do not set aside this deficiency finding on the merits, I should treat this deficiency as abandoned by CMS because CMS did not address it in its brief. Petitioner argues that CMS offered no evidence to show a nexus between Petitioner's noncompliance and the manner in which it is administered. Petition is correct that CMS did not address this specific deficiency in its brief despite the fact that Petitioner has addressed this issue in its brief on the merits. This is an example of the lack of attention by CMS to this matter. CMS has not attempted to prove its primae facie case or address the arguments advanced by Petitioner in its post hearing brief. Based on CMS's complete failure to addresses the issue, I find that CMS has not met its burden of establishing a primae facie case that Petitioner was not in substantial compliance with the requirements of 42 C.F.R. § 483.75.

5. The evidence supports CMS's immediate jeopardy determinations with respect to the noncompliance under Tags F309 and F333.

I next consider whether CMS's immediate jeopardy findings with respect to the Petitioner's noncompliance with the requirements of 42 C.F.R. §§ 483.25(m)(2) and 483.25 are "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 an immediate jeopardy finding ─ must be upheld unless it is "clearly erroneous." 42 C.F.R. § 498.60(c). Under that standard, Petitioner has a heavy burden to overturn the immediate jeopardy determination. *Edgemont Healthcare*, DAB No. 2202, at 20 (2008) (citing cases). The existence of actual harm is not a prerequisite for a finding of immediate jeopardy. *Stone County Nursing & Rehab. Ctr.*, DAB No. 2276, at 19 (2009).

Essentially, Petitioner's only argument against the findings of immediate jeopardy with respect to Tags F309 and F333 is that none of the residents suffered any actual harm as a consequence. P. Br. at 26 and 28-29. This is not exactly true. The evidence shows that Resident #22 received a double dose of Coumadin and shortly thereafter his PT/INR indicated he was at critical levels requiring the administration of Vitamin K to assist in counteracting the effects of the blood thinner. Moreover, as the analysis above clearly shows, the administration of Coumadin requires constant and meticulous administration to ensure that the patient is receiving the correct therapeutic dose without putting the patient at risk for bleeding out or for forming a blood clot. The lack of administration of the medication, let alone the proper dosage of the medication, would make it nearly impossible for the physician to correctly determine whether the dosage prescribed was the correct therapeutic dose for that patient. That was particularly critical with respect to Residents #22 and 25 who were considered to have certain factors which could result in

variable PT/INRs and required even closer vigilance. There is also no evidence that the facility was even aware of the errors with respect to Resident #22 and Resident #25 until the survey discovered the particular errors. I therefore conclude that Petitioner failed to carry its burden of showing clear error in CMS's findings of immediate jeopardy.

6. The amount of the CMP imposed by CMS for Petitioner's period of immediate jeopardy is not reasonable; a $3050 per-day CMP for the period of March 26 through August 14, 2007 is reasonable.

If CMS finds noncompliance at the level of immediate jeopardy, the regulations authorize it to impose a per-day CMP in the range of $3,050 to $10,000 per day. 42 C.F.R. § 488.438(a)(1)(i). Here CMS imposed a $4550 per-day CMP for Petitioner's immediate jeopardy noncompliance for the period of March 26 through August 14, 2007. Thus, the total amount of the penalty for this period was $646,100 ($4,550 multiplied by 142 days).

The applicable regulations provide that CMS may impose a CMP for the number of days a facility is not in substantial compliance with one or more participation requirements. 42 C.F.R. § 488.430. Here, Petitioner complains about the duration of the penalty imposed but I find that the duration of the penalty is in direct correlation with days that Petitioner was not in substantial compliance with participation requirements and the noncompliance constituted immediate jeopardy. The period of noncompliance at the immediate jeopardy level appropriately began on March 26, 2007 when Petitioner gave Resident #22 a double dose of Coumadin. The noncompliance at this level continued unabated until August 15, 2007, when Petitioner submitted a multi-step corrective action plan with respect to the administration of Coumadin, which was implemented and the state verified that the plan removed the immediate jeopardy situation. P. Ex. 1, at 42. Therefore, I conclude that CMS was authorized to impose a per-day CMP of between $3,050 and $10,000 for this period.

I now look at whether the per-day CMP chosen by CMS from that range is reasonable. In deciding whether the CMP is reasonable, I may consider only those factors specified in the regulations. 42 C.F.R. § 488.438(e), (f). Those factors are: the facility's history of noncompliance; the facility's financial condition; the factors specified in 42 C.F.R. § 488.404 (e.g., the severity and scope of the noncompliance); and the facility's degree of culpability, which includes neglect, indifference or disregard for resident care, comfort and safety. 42. C.F.R. § 488.438(f). I make a *de novo* review of the reasonableness of the CMP based on the facts found in the record.

First, neither party presented any evidence with respect to the facility's history of noncompliance or the facility's financial condition. Therefore the only factors for which I have any information are the severity and scope of the noncompliance and the facility's culpability. As to the scope and severity of the deficiencies, I note that CMS originally based its determination in large part on its determination that Petitioner did not protect a

resident from verbal abuse. CMS also based its immediate jeopardy finding under the administration tag in part based on the determination of verbal abuse. I however determined that Petitioner was in substantial compliance with this requirement. I therefore conclude that a corresponding reduction in the amount of the CMP is warranted to account for this. I therefore find that consideration of the relevant regulatory factors, warrants and supports a per-day CMP in the amount of $3,050 for the period of March 26 through August 14, 2007.

IV. Conclusion

Based upon my review of all of the evidence and testimony presented in this case I find that Petitioner failed to comply substantially with 42 C.F.R. § 483.25 and 42 C.F.R. § 483.25(m) and that the noncompliance constituted immediate jeopardy to Petitioner's residents. I also find that Petitioner was in substantial compliance with the requirements of 42 C.F.R. § 483.13(b) and that CMS's determination of immediate jeopardy with respect to its findings of verbal abuse pursuant to 42 C.F.R. § 483.13(b) is clearly erroneous. CMS also failed to sustain its burden of establishing a primae facie case that Petitioner failed to substantially comply with 42 C.F.R. § 483.75. I sustain CMS's imposition of a civil money penalty at a level commensurate with finding immediate jeopardy but at the reduced amount of $3050 per day, effective March 26 through August 14, 2007.

/s/
Alfonso J. Montaño
Administrative Law Judge