Department of Health and Human Services

DEPARTMENTAL APPEALS BOARD

Civil Remedies Division

In the Case of:	)	
Maysville Nursing & Rehabilitation Facility (CCN: 18-5207),	)	Date: November 20, 2009
Petitioner,	)	Docket No. C-08-230
	)	Decision No. CR2032
v.	)	
Centers for Medicare & Medicaid Services.	)	

DECISION

Petitioner, Maysville Nursing & Rehabilitation Facility, was not in substantial compliance with program participation requirements from July 31, 2007 through November 22, 2007, due to violations of 42 C.F.R. §§ 483.25(l) (Tag F329); 483.60(c) (Tag F428); 483.15(a) (Tag F241); 483.25(d) (Tag F315); and 483.25(h) (Tag F323).[1] A civil money penalty (CMP) of $3050 per day from July 31, 2007 through November 1, 2007, and $250 per day from November 2 through November 22, 2007, a total CMP of $291,950; and a denial of payment for new admissions (DPNA) from November 17 through November 22, 2007, are reasonable enforcement remedies. The state agency was required to withdraw approval of Petitioner to conduct a nurse aide training and competency evaluation program (NATCEP) for a period of two years.

[1] References are to the version of the Code of Federal Regulations (C.F.R.) in effect at the time of the surveys, unless otherwise indicated.

I. Background

Petitioner, located in Maysville, Kentucky, is authorized to participate in the federal Medicare program as a skilled nursing facility (SNF) and in the Kentucky Medicaid program as a nursing facility (NF). A complaint investigation by the Kentucky State Agency (state agency) began at Petitioner's facility on October 30, 2007. On November 1, 2007, the facility was notified that state agency surveyors found deficiencies that posed immediate jeopardy to Petitioner's residents. The surveyors returned on November 6, 2007, to conduct a partial-extended survey. The complaint and partial-extended survey concluded on November 7, 2007, and found that Petitioner was not in substantial compliance with program participation requirements. A statement of deficiencies (SOD) was issued dated November 7, 2007. CMS Exhibit (CMS Ex.). 46. CMS notified Petitioner of the findings of substantial noncompliance and related remedies by letter dated November 15, 2007. Request for Hearing; Joint Stipulation (Jt. Stip.) 1(b).

CMS notified Petitioner by letter dated November 15, 2007, that CMS was imposing a CMP in the amount of $4550 per day effective July 31, 2007, and continuing until immediate jeopardy was removed or Petitioner's provider agreement was terminated; that a discretionary DPNA would be imposed effective November 17, 2007, if Petitioner did not return to substantial compliance before that date; and that Petitioner's provider agreement would be terminated on November 30, 2007, unless immediate jeopardy was removed by that date. CMS further advised Petitioner that its authority to conduct a NATCEP would be withdrawn by the state. Request for Hearing.

The state agency conducted a revisit survey on November 26 and 27, 2007, the results of which are recorded in a SOD dated November 27, 2007. CMS Ex. 53. The state agency determined that the immediate jeopardy was abated on November 2, 2007, but Petitioner was not found to have returned to substantial compliance. CMS notified Petitioner by letters dated December 3 and 4, 2007, that effective November 2, 2007, the CMP was lowered to $250 per day and that it would continue to accrue at that rate until Petitioner returned to substantial compliance or until further notice from CMS; that the discretionary DPNA effective November 17, 2007, would continue; and that Petitioner was subject to mandatory termination of its provider agreement on May 7, 2008. Request for Hearing; Jt. Stip. 1(b).

On December 13, 2007, Petitioner submitted a plan of correction alleging substantial compliance effective not later than November 23, 2007. CMS Ex. 53. A second revisit survey was conducted on January 4, 2008. The state agency notified Petitioner by letter dated February 15, 2008, that Petitioner's plan of correction was accepted and that Petitioner achieved compliance effective November 23, 2007. Petitioner's Exhibit (P. Ex.) 14. However, the state agency subsequently sent Petitioner a second letter dated March 13, 2008, in which the state agency advised Petitioner that, based on the January 4, 2008 revisit survey, Petitioner achieved compliance on January 4, 2008. P. Ex. 15. A letter from CMS dated March 13, 2008, advised Petitioner that, based on the January 4,

2008 revisit survey, Petitioner returned to substantial compliance on January 4, 2008; the discretionary DPNA continued from November 17, 2007 through January 3, 2008; and the termination action was rescinded. P. Ex. 16.

Petitioner requested a hearing by letter dated January 14, 2008. On January 28, 2008, the case was assigned to me for hearing and decision. I convened a hearing in Covington, Kentucky, on July 15 and 16, 2008, and a 251-page transcript (Tr.) was prepared. CMS Exs. 1 through 56 were admitted as evidence. Tr. 9. P. Exs. 1 through 16 were also admitted as evidence. Tr. 11. CMS elicited testimony from state agency surveyors: Jackie Aitkin, R.D.; Paula Foster, R.N.; Martina Burton, R.N.; and Dudley Ellis, R.Ph. Petitioner elicited testimony from its North Wing Charge Nurse Janet Bradford, R.N., and Administrator Anita Kennedy.

The parties submitted post-hearing briefs (CMS Brief and P. Brief, respectively) and Petitioner submitted a reply brief (P. Reply). CMS elected not to file a reply brief.

II. Discussion

A. Issues

The issues in this case are:

> Whether there is a basis for the imposition of an enforcement remedy; and,
>
> Whether the remedy imposed is reasonable.

B. Applicable Law

The statutory and regulatory requirements for participation by a long-term care facility are found at sections 1819 (SNF) and 1919 (NF) of the Act and at 42 C.F.R. Part 483. Section 1819(h)(2) of the Act vests the Secretary with authority to impose enforcement remedies against a SNF for failure to comply substantially with the federal participation requirements established by sections 1819(b), (c), and (d) of the Act.[2] Pursuant to 1819(h)(2)(C), the Secretary may continue Medicare payments to a SNF not longer than six months after the date the facility is first found not in compliance with participation

[2] Section 1919(h)(2) of the Act gives similar enforcement authority to the states to ensure that NFs comply with their participation requirements established by section 1919(b), (c), and (d) of the Act.

requirements. Pursuant to 1819(h)(2)(D), if a SNF does not return to compliance with participation requirements within three months, the Secretary must deny payments for all individuals admitted to the facility after that date – commonly referred to as the mandatory or statutory DPNA. In addition to the authority to terminate a noncompliant SNF's participation in Medicare, the Act grants the Secretary authority to impose other enforcement remedies, including a discretionary DPNA, civil money penalties, appointment of temporary management, and other remedies such as a directed plan of correction. Act § 1819(h)(2)(B).

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. "*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." 42 C.F.R. § 488.301 (emphasis in original). A deficiency is a violation of a participation requirement established by sections 1819(b), (c), and (d) of the Act or the Secretary's regulations at 42 C.F.R. Part 483, Subpart B. Facilities that participate in Medicare may be surveyed on behalf of CMS by state survey agencies in order to determine whether the facilities are complying with federal participation requirements. 42 C.F.R. §§ 488.10-488.28, 488.300-488.335. The regulations specify the enforcement remedies that CMS may impose if a facility is not in substantial compliance with Medicare requirements. 42 C.F.R. § 488.406.

The regulations specify that a CMP that is imposed against a facility on a per day basis will fall into one of two ranges of penalties. 42 C.F.R. §§ 488.408, 488.438. The upper range of CMP, $3050 per day to $10,000 per day, is reserved for deficiencies that pose 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). Pursuant to 42 C.F.R. § 488.301, "*(i)mmediate jeopardy* means 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." (Emphasis in original.) The lower range of CMP, $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).

In this case, the state agency was required to withdraw Petitioner's approval to conduct a NATCEP. Pursuant to sections 1819(b)(5) and 1919(b)(5) of the Act, SNFs and NFs may only use nurse aides who have taken a training and competency evaluation program. Sections 1819(e) and 1919(e) of the Act impose upon the states the requirement to specify what NATCEPs they will approve that meet the requirements established by the Secretary and a process for reviewing and reapproving those programs using criteria set by the Secretary. Pursuant to sections 1819(f)(2) and 1919(f)(2) the Secretary was tasked to develop requirements for approval of NATCEPs and the process for review of those programs. The Secretary promulgated regulations at 42 C.F.R. Part 483, subpart D.

Pursuant to 42 C.F.R. § 483.151(b)(2) and (e)(1) a state may not approve and must withdraw any prior approval of a NATCEP offered by a skilled nursing or nursing facility that: (1) has been subject to an extended or partial extended survey under sections 1819(g)(2)(B)(i) or 1919(g)(2)(B)(i) of the Act; (2) has been assessed a CMP of not less than $5000; or (3) has been subject to termination of its participation agreement, a DPNA, or the appointment of temporary management. Extended and partial extended surveys are triggered by a finding of "substandard quality of care" during a standard or abbreviated standard survey and involve evaluating additional participation requirements. "Substandard quality of care" is identified by the situation where surveyors identify one or more deficiencies related to participation requirements established by 42 C.F.R. § 483.13 (Resident Behavior and Facility Practices), § 483.15 (Quality of Life), or § 483.25 (Quality of Care) that are found to constitute either immediate jeopardy, a pattern of or widespread actual harm that does not amount to immediate jeopardy, or a widespread potential for more than minimal harm that does not amount to immediate jeopardy and there is no actual harm. 42 C.F.R. § 488.301.

The Act and regulations make a hearing before an administrative law judge (ALJ) available to a long-term care facility against which CMS has determined to impose an enforcement remedy. Act § 1128A(c)(2); 1866(h); 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 11 (2001); *Beechwood Sanitarium*, DAB No. 1906 (2004); *Cal Turner Extended Care*, 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) and 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 range of the CMP that could be imposed by CMS or impact the facility's authority to conduct a nurse aide training and competency evaluation program. 42 C.F.R. §§ 498.3(b)(14) and (d)(10)(i). The CMS determination as to the level of noncompliance "must be upheld unless it is clearly erroneous" (42 C.F.R. § 498.60(c)(2)), including the finding of immediate jeopardy. *Woodstock Care Center*, DAB No. 1726, at 9, 38 (2000), *aff'd, Woodstock Care Center v. Thompson*, 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. *See e.g., Ridge Terrace*, DAB No. 1834 (2002); *Koester Pavilion*, DAB No. 1750 (2000). Review of a CMP by an ALJ is subject to 42 C.F.R. § 488.438(e).

The standard of proof or quantum of evidence required is a preponderance of the evidence. CMS has the burden of coming forward with the evidence and making a prima facie showing of a basis for imposition of an enforcement remedy. Petitioner bears the

burden of persuasion to show by a preponderance of the evidence that it was in substantial compliance with participation requirements or any affirmative defense. *See Hillman Rehabilitation Center*, DAB No. 1611 (1997), *aff'd, Hillman Rehabilitation Ctr. v. United States Dep't of Health and Human Services, Health Care Fin. Admin.*, No. 98-3789 (GEB), slip op. at 25 (D.N.J. May 13, 1999); *Cross Creek Health Care Center*, DAB No. 1665 (1998); *Emerald Oaks*, DAB No. 1800; *Batavia Nursing and Convalescent Center*, DAB No. 1904 (2004), *aff'd, Batavia Nursing & Convalescent Ctr. v. Thompson*, 129 F. App'x. 181 (6th Cir. 2005); *Batavia Nursing and Convalescent Inn*, DAB No. 1911 (2004).

C. Analysis

My conclusions of law are set forth in bold text followed by my findings of fact and analysis.

The SOD dated November 7, 2007 (CMS Ex. 46), cited the following deficiencies: 42 C.F.R. § 483.15(a) (Tag F241) at a scope and severity level G[3]; 42 C.F.R. § 483.20(k)(3)(ii) (Tag F282) at a scope and severity level K; 42 C.F.R. § 483.25 (Tag F309) at a scope and severity level K; 42 C.F.R. § 483.25(d) (Tag F315) at a scope and severity level G; 42 C.F.R. § 483.25(h) (Tag F323) at a scope and severity level D; 42

[3] This is a "Tag" designation as used in the State Operations Manual (SOM, Appendix PP - Guidance to Surveyors for Long Term Care Facilities). The "Tag" refers to the specific regulatory provision allegedly violated and CMS's guidance to surveyors. Although the SOM does not have the force and effect of law, the provisions of the Act and regulations interpreted do have such force and effect. *State of Indiana by the Indiana Department of Public Welfare v. Sullivan*, 934 F.2d 853 (7th Cir. 1991); *Northwest Tissue Center v. Shalala*, 1 F.3d 522 (7th Cir. 1993). Thus, while the Secretary may not seek to enforce the provisions of the SOM, she may seek to enforce the provisions of the Act or regulations as interpreted by the SOM. The cited deficiency Tags are set forth in the SOD prepared by surveyors. Each deficiency indicates 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.

C.F.R. § 483.25(l) (Tag F329) at a scope and severity level K; 42 C.F.R. § 483.60(c) (Tag F428) at a scope and severity level J; 42 C.F.R. § 483.75 (Tag F490) at a scope and severity level K; and 42 C.F.R. § 483.75(o)(1) (Tag F520) at a scope and severity level K.

The SOD dated November 27, 2007 (CMS Ex. 53), reflects the results of the revisit survey concluded on that date. The SOD cites Petitioner with the same deficiencies cited by the SOD dated November 7, 2007. However, the revisit found that immediate jeopardy had been abated on November 2, 2007, and the scope and severity findings of some alleged deficiency citations were reduced as follows: Tags F282, F309, F329, F490, and F520 were reduced from scope and severity K to scope and severity E, and Tag F428 was reduced from scope and severity J to scope and severity D. CMS Ex. 53, at 2.

No SOD for the revisit survey completed on January 4, 2008 is in evidence, from which I infer that no deficiencies were cited during that survey.

Petitioner requested Informal Dispute Resolution (IDR) from the state agency related to the survey that concluded on November 7, 2007. The IDR was conducted on January 29, 2008. P. Ex. 3, at 1. During the hearing, CMS agreed that Petitioner was not notified that CMS rejected any of the IDR results and that CMS accepted the results. CMS Ex. 49; P. Ex. 3, at 1; Tr. 23-24. CMS agreed that as a result of IDR the example of Resident 1 was deleted from the deficiency cited under Tag F309 and the scope and severity of that deficiency citation was reduced from K to E. CMS also accepted the IDR result for Tag F282 that lowered the scope and severity from K to E. Petitioner advised me at hearing that the deficiencies cited under Tags F241 and F315 are not disputed, but Petitioner disputes that the residents involved suffered actual harm. Tr. 23-30, 170-72. Petitioner stated that the deficiency cited under Tag F323 is not disputed. Tr. 172.

The enforcement remedies at issue are a CMP of $4550 per day from July 31 through November 1, 2007, and $250 per day from November 2, 2007 through January 3, 2008; and a discretionary DPNA from November 17, 2007 through January 3, 2008. The state agency should also have withdrawn approval for Petitioner to conduct a NATCEP for two years, though I have no evidence it did so.

1. Petitioner violated 42 C.F.R. § 483.25(l) (Tag F329) and the violation posed immediate jeopardy.

2. Petitioner violated 42 C.F.R. § 483.60(c) (Tag F428) and the violation posed immediate jeopardy.

3. The finding of immediate jeopardy based upon the violations of 42 C.F.R. §§ 483.25(l) and 483.60(c) was not clearly erroneous.

The surveyors alleged in the SOD dated November 7, 2007, that Petitioner violated 42 C.F.R. § 483.20(k)(3)(ii) (Tag F282) because Petitioner failed to follow the care plan for five residents, Residents 1, 7, 11, 14, and 22, related to Coumadin therapy monitoring and laboratory testing as ordered by the residents' physicians. CMS Ex. 46, at 7. The surveyors alleged that Petitioner violated 42 C.F.R. § 483.25 (Tag F309) because Petitioner failed to have an effective system to ensure that five residents, Residents 1, 7, 11, 14, and 22, received laboratory monitoring for their Coumadin therapy. CMS Ex. 46, at 14. The surveyors alleged that Petitioner violated 42 C.F.R. § 483.25(l) (Tag F329) because Petitioner failed to have an effective system to ensure Residents 1, 7, 11, and 14, who were on Coumadin, received laboratory testing to ensure proper dosing of Coumadin at a therapeutic-level. CMS Ex. 46, at 40. The surveyors alleged that Petitioner violated 42 C.F.R. § 483.60(c) (Tag F428) because the monthly pharmacy review failed to identify that Resident 1 had no order for laboratory testing for Coumadin-level and when the laboratory did advise Petitioner that there was no laboratory order, Petitioner failed to act. CMS Ex. 46, at 48. CMS agreed at hearing that the alleged violation of 42 C.F.R. § 483.75 (Tag F490) was derivative of other alleged violations. Tr. 172. The surveyors allege under Tag F490, that Petitioner failed to provide adequate medication monitoring particularly related to Coumadin therapy; Petitioner failed to ensure residents with a decline in bowel and bladder function were reassessed, monitored, and reevaluated; and that Petitioner had a problem with staff responding to call-lights. CMS Ex. 46, at 52-54. The surveyors allege that Petitioner violated 42 C.F.R. § 483.75(o)(1) (Tag F520) because Petitioner did not have an effective Quality Assurance Committee (QAC), evidenced by the alleged failure of the QAC to address issues related to Coumadin laboratory monitoring, failure to evaluate incontinence as a possible factor in causing falls, and failure to identify and address a problem with call-lights. CMS Ex. 46, at 55-58.

The violations cited under Tags F282, F309, F329, and F428, are all related to an alleged failure to monitor Coumadin therapy and all were cited as posing immediate jeopardy to Petitioner's residents. The violations cited under Tags 490 and 520 were also cited as posing immediate jeopardy to the extent they related to Petitioner's failure to monitor Coumadin therapy. The IDR reduced the alleged scope and severity of Tags F282 and F309 from posing immediate jeopardy to posing more than minimal harm but with no actual harm. Having given careful consideration to all these alleged violations, I conclude that Petitioner violated 42 C.F.R. § 483.25(l) (Tag F329) and 42 C.F.R. § 483.60(c) (Tag F428); that these violations amply show the deficiency related to Coumadin therapy monitoring; that these violations show that immediate jeopardy was posed; and that these two violations were a sufficient basis for the imposition of the daily CMP at the low end of the range of CMPs reserved for deficiencies that are found to pose immediate jeopardy. Accordingly, I find and conclude that it is unnecessary to discuss and that it is in the interest of judicial economy not to discuss the violations cited under

Tags F282 and 309. I also find and conclude for purposes of this decision, that the examples of Residents 1 and 7 alleged under Tags F329 and F428, demonstrate the violations, and it is therefore not necessary to discuss the examples of the other residents cited under those deficiency citations. Finally, I find and conclude that it is not necessary to address the violations cited under Tags F490 and F520, as immediate jeopardy is justified based on other violations and there is an adequate basis for the proposed enforcement remedies without consideration of those deficiencies.

a. Facts

There is no dispute that Coumadin is an anticoagulant medication, often referred to as a blood thinner.[4] There is also no question that Coumadin dosage must be controlled by periodic determinations of Prothrombin Time (PT) and International Normalized Ratio (INR) (PT/INR). Failure to ensure that Coumadin is in a therapeutic range can lead to hemorrhage, necrosis (tissue and cell death), death or permanent disability. According to Petitioner's consulting pharmacist, routine PT/INR testing should be done monthly at a minimum, according to the Institute for Clinical Systems Improvement, Anticoagulation Therapy Supplement (2001). CMS Ex. 45, at 22.

Residents 1 and 7 were both prescribed Coumadin and the deficiencies were cited because the evidence reviewed by the surveyors did not show they received PT/INR testing every month.

(1) Resident 1

Resident 1 was readmitted to Petitioner's facility on May 8, 2007. His diagnoses included dementia, respiratory failure with tracheostomy, cerebellar hemorrhage, high blood pressure, coronary artery disease, deep-vein thrombosis (DVT), intraventricular hematoma, COPD (chronic obstructive pulmonary disease), alcoholism, diabetes, agitation, anxiety and pneumonia. Due to his history of DVT and cerebellar hemorrhage, he had orders for Coumadin at a dosage of 5 mg per day. CMS Ex. 45, at 30; P. Ex. 1, at 80-81; Tr. 175-76; Petitioner's Proposed Findings of Fact and Conclusions of Law, filed

[4] I advised the parties at hearing that I would take official notice of the Physician's Desk Reference (PDR) entry regarding Coumadin or its generic version, Warfarin. I also invited counsel to provide other source material with their post-hearing briefs that would provide a better understanding of Coumadin. Tr. 144, 240-41. Petitioner provided copies of pages from the PDR related to Coumadin as Attachment 1 to Petitioner's Reply Brief. CMS provided copies of web pages from "Drugs.com" related to anticoagulants as Attachment 1 to the CMS Post-Hearing Brief; and copies of web pages from PDRhealth.com, the lay-person version of the PDR, related to Coumadin as Attachment 2 to the CMS Brief.

with Petitioner's Reply Brief on October 15, 2008, Findings of Fact (P. Facts) 6. From May 8 to July 31, 2007, Resident 1 received laboratory testing for PT/INR and his Coumadin was adjusted. P. Facts 7; P. Ex. 1, at 78, 80-81, 150, 216, 218, 221-25; Tr. 40-41. The PT/INR results from July 31, 2007, were sent to the Resident 1's physician, and, on August 1, 2007, Nurses' Notes reflect that the physician called and advised there were no new orders "R/T [related to] lab.[5]" P. Ex. 1, at 150; P. Facts 8. Resident 1's PT/INR results from the July 31, 2007 laboratory report were PT 17.7 and INR 1.63 both of which were above the laboratory reference range but, Petitioner concedes, below therapeutic range for an individual with DVT. P. Ex. 1, at 215; CMS Ex. 30, at 2; Tr. 183-84; P. Fact 8. Surveyor Aitkin testified, and Petitioner does not disagree, that Resident 1's physician did not order and no PT/INR testing was done for Resident 1 between July 31 and October 10, 2007. Tr. 41-45; P. Fact 10, 11. On August 22 and September 19, 2007, Resident 1's physician visited but gave no new orders for PT/INR testing or for adjusting his Coumadin dosage. Tr. 185; P. Ex. 1, at 85-86; P. Fact 10. Resident 1 remained on Coumadin at 8.5 mg until his hospitalization on October 10, 2007, for a subdural hematoma. P. Fact 10, 12; P. Ex. 1, at 217; CMS Ex. 45, at 15.

The facility had developed a care plan for Resident 1 related to Coumadin therapy, which included monitoring for side effects by observing the resident for bleeding gums, the appearance of blood in his stool/urine or bruising. P. Ex. 1, at 12-13; P. Fact 9. Staff observed no adverse side-effects secondary to Coumadin therapy during August and September 2007. Tr. 190-91; P. Fact 9.

As required by the regulations, Resident 1's drug regimen was reviewed by Petitioner's pharmacist consultant in August and September 2007. During the August review, no irregularities were found in Resident 1's drug regimen. However, on September 28, 2007, the pharmacist consultant recommended PT/INR testing for Resident 1's Coumadin therapy. P. Ex. 1, at 226; CMS Ex. 45, at 20, 22; Tr. 186-87. The pharmacist consultant reported to Petitioner that:

> [Resident 1] is currently receiving warfarin 8.5mg qd. It is recommended to check the protime/INR monthly at a minimum. The last lab result for an INR was dated 7/31/07. Please follow up on these lab reports.

CMS Ex. 45, at 22. Petitioner acknowledges that it failed to follow-up. P. Br. at 4; P. Facts 11.

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[5] Rather than issue a standing order for monthly laboratory testing, Resident 1's physician ordered tests on what appears to have been an ad hoc basis. For example, on June 14, 2007, he ordered a recheck of PT/INR on July 9, 2007, but on July 24, 2007, he ordered a PT/INR in one week, the test that was done on July 31, 2007. CMS Ex. 45, at 9.

On October 10, 2007, Resident 1 was hospitalized with a right subdural hematoma. His PT/INR levels exceeded therapeutic ranges. Resident 1's discharge summary states that Coumadin was discontinued "for life because of his previous history of cerebellar hematoma and this is his second subdural." CMS Ex. 45, at 6; P. Facts 12.

(2) Resident 7

On August 10, 2007, Resident 7's physician ordered a PT/INR draw to be done in three days. CMS Ex. 43, at 11; P. Facts 13. Surveyor Aitkin testified that there is no evidence of record that this was done. Tr. 53-54. On August 16, 2007, the resident received a skin tear and was assessed by the charge nurse, RN Bradford. RN Bradford testified that she noticed that the tear was bleeding more than a normal skin tear. She called the physician to ask for an immediate PT/INR. The physician ordered the PT/INR. The results were high and the physician ordered Coumadin held until further notice and requested another PT/INR test in two days. CMS Ex. 43, at 4, 12; Tr. 212; P. Facts 13.

b. Analysis

Petitioner is obligated by its participation in Medicare to provide and ensure that each resident receives the "necessary care and services to attain or maintain the highest practicable physical, mental, and psychosocial well-being, in accordance with the comprehensive assessment and plan of care." 42 C.F.R. § 483.25. The facility, as part of its obligation to deliver quality care, must ensure that a resident's drug regimen is free of unnecessary drugs, which includes any drug used without adequate monitoring. Specifically, 42 C.F.R. § 483.25(l) requires that:

> (l) *Unnecessary drugs*-(1) *General.* Each resident's drug regimen must be free from unnecessary drugs. An unnecessary drug is any drug when used:
> (i) In excessive dose (including duplicate drug therapy); or
> (ii) For excessive duration; or
> (iii) Without adequate monitoring; or
> (iv) Without adequate indications for its use; or
> (v) In the presence of adverse consequences which indicate the dose should be reduced or discontinued; or
> (vi) Any combinations of the reasons above.

Residents 1 and 7 were both receiving Coumadin therapy. Unmonitored Coumadin use may result in serious injury or death. The evidence before me shows that periodic monitoring of PT/INR by laboratory testing is a standard of care for those receiving Coumadin therapy. According to Petitioner's consulting pharmacist, laboratory testing for PT/INR should be done monthly at a minimum, and I find that opinion credible. Petitioner does not dispute that Resident 1 did not receive a PT/INR test from July 31 to

October 10, 2007, more than 30 days. Petitioner also does not dispute that it failed to act upon the September 28, 2007 recommendation of its consulting pharmacist and immediately obtain an order for PT/INR testing for Resident 1. Petitioner does not dispute that Resident 7 did not receive a PT/INR test as prescribed by the resident's physician. I conclude that Residents 1 and 7 did not receive adequate monitoring of their Coumadin therapy because they did not receive necessary PT/INR testing either no less than monthly for Resident 1, or as prescribed by Resident 7's physician. Accordingly, CMS has made a prima facie showing of a violation of 42 C.F.R. § 483.25(l) (Tag F329).

The requirements established by 42 C.F.R. § 483.60(c) are that each resident's drug regimen be reviewed at least monthly by a licensed pharmacist, that any irregularities must be reported to the attending physician and director of nursing, and the reported irregularities must be acted upon.

In the case of Resident 1, it is undisputed that the pharmacist failed to identify the irregularity that Resident 1 had no order for a PT/INR within 30 days of his last PT/INR and no testing of PT/INR in nearly 30 days. It is also undisputed that the pharmacist did identify the irregularity that Resident 1 had no order for PT/INR testing and received no such testing in August and September 2007, but then Petitioner failed to act upon the consulting pharmacist's recommendation to obtain an order for testing. CMS Ex. 46, at 48. I conclude that each failure is a prima facie violation of 42 C.F.R. § 483.60(c) (Tag F428).

I further conclude that Petitioner's defenses are without merit.

Petitioner argues with respect to Resident 1 that staff followed the physician's decision not to order PT/INR laboratory testing. Petitioner asserts that CMS faults it for not insisting that Resident 1's physician take action to order additional laboratory tests. Petitioner asserts that the Kentucky Board of Nursing does not place a duty upon nurses to compel physicians to order tests, even if needed. Petitioner reasons that ordering laboratory tests and the monitoring of Coumadin and PT/INR levels is a physician's function, not a function of a nurse or the facility, except to the extent Petitioner care planned for Resident 1. Petitioner asserts it followed Resident 1's care plan, monitored for observable side-effects of excessive Coumadin dosing, and ensured monthly visits from the resident's attending physician, who was the one with the authority to issue orders for laboratory analysis, not Petitioner or its staff. Petitioner argues that it is not in a position to second-guess the physician's decisions with regard to laboratory testing for Coumadin. Petitioner argues that it does not have an obligation to ensure that physicians' services are delivered without error. The PDR states that monitoring for Coumadin effectiveness is a matter of unique physician involvement and physician judgment and nurses are not required to challenge judgments that physicians make that are uniquely within their skill and training. Petitioner's staff also saw no signs that Resident 1's Coumadin level was causing side-effects or that there was a need for more frequent laboratory testing. P. Br. at 11-18; P. Reply at 1-2; Petitioner's Proposed Findings of

Fact and Conclusions of Law, filed with Petitioner's Reply Brief on October 15, 2008, Conclusion of Law (P. Law) 3, 4. Petitioner asserts that the only possible period of immediate jeopardy would be following the facility's failure to follow through on the pharmacist consultant's recommendation with regard to Resident 1 after September 28, 2007. P. Reply at 2.

Petitioner admits that it was deficient by not following physician's orders with respect to PT/INR testing for Resident 7 and admits that due to staffing issues there were problems with laboratory monitoring during July and August. Petitioner argues that except in the cases of Residents 7, 11, and 14, it had a 99% accuracy in ordering laboratory tests. P. Brief at 10-11; P. Law 3. Petitioner further asserts that there was no immediate jeopardy. P. Reply at 1-2.

Petitioner is obligated by the regulation to ensure that each resident's drug regimen is free of unnecessary drugs, which includes any drug used without adequate monitoring. The standard of practice is to monitor Coumadin by laboratory testing for PT/INR monthly. The regulation squarely places the burden upon Petitioner to ensure there is adequate monitoring and Petitioner does not have the option of hiding behind either the physician's or consulting pharmacist's failure to act. I take no issue with Petitioner's assertion that nursing staff may not order laboratory tests or substitute its judgment for that of the physician. However, Petitioner does have the burden under the regulation to ensure that monitoring is done. When monitoring is not done, Petitioner has the burden to show that it took action to ensure the monitoring was done or that the clinical evidence reflects a reasonable explanation for why it was not. Furthermore, Petitioner has the burden to ensure that its records receive a competent pharmacist review, and Petitioner offers no explanation for why the consulting pharmacist missed the fact that there was no Coumadin monitoring between July 31 and September 28, 2007.

I further conclude that the finding of immediate jeopardy based upon the violations of 42 C.F.R. §§ 483.25(l) and 483.60(c) was not clearly erroneous. When Resident 1 was hospitalized on October 10, 2007, his INR was high. Resident 7's INR also tested high when he cut himself and the nurse observed excessive bleeding. There is no dispute that excessive Coumadin levels may lead to serious harm or death. I conclude Petitioner has not shown that serious harm or death was not likely due to its failure to monitor Coumadin therapy. I further conclude that Petitioner has failed to show clearly erroneous the determination that immediate jeopardy commenced on July 31, 2007 and continued until November 2, 2007, a date that is undisputed by Petitioner.

4. Petitioner concedes it violated 42 C.F.R. §§ 483.15(a) (Tag F241), 483.25(d) (Tag F315); and does not challenge the alleged violation of 42 C.F.R. § 483.25(h) (Tag F323).

5. Petitioner's violation of 42 C.F.R. §§ 483.15(a) (Tag F241) and 483.25(d) (Tag F315) resulted in actual harm to the resident involved.

6. Petitioner's violation of 42 C.F.R. § 483.25(h) (Tag F323) had the potential for causing more than minimal harm that was not immediate jeopardy and did not result in actual harm.

7. Petitioner has no right to ALJ review of the level of noncompliance, i.e. the scope and severity determination, except when a successful challenge would affect the range of CMP that can be imposed or the finding of substandard quality of care that resulted in loss of NATCEP authority. 42 C.F.R. § 498.3(b)(14), (b)(16), and (c)(10).

a. Facts

The surveyors allege that Petitioner violated 42 C.F.R. § 483.15(a) (Tag F241) because Residents 2, 5, and 17 had incontinent episodes while waiting for extended periods to be toileted by staff. The surveyors alleged actual psychosocial harm to Resident 5 based on the surveyors' observation that Resident 5 became tearful when discussing the incontinent episodes with surveyors. CMS Ex. 46, at 2; Tr. 110-11.

The surveyors allege that Petitioner violated 42 C.F.R. § 483.25(d) (Tag F315) because Petitioner failed to assess and provide appropriate treatment and services for five incontinent residents (Residents 1, 2, 5, 6, and 17) to achieve and maintain as much normal bladder function as possible. Actual harm was the decline in bladder function with failure to intervene to achieve more normal bladder function. CMS Ex. 46, at 25-26.

The surveyors allege that Petitioner violated 42 C.F.R. § 483.25(h), by failing to ensure that the resident environment remained as free of accident hazards as possible, because two residents fell while attempting to toilet themselves and Petitioner did not re-evaluate the residents' toileting plans and determine whether the toileting plans caused or contributed to the falls. Actual harm is not alleged as indicated by the assigned scope and severity level of D. CMS Ex. 46, at 35-36.

Petitioner does not dispute that it violated 42 C.F.R. §§ 483.15(a) (Tag F241), 483.25(d) (Tag F315), and 483.25(h) (Tag F323) as alleged. Tr. 172; P. Br. at 21-22; P. Law 7; Request for Hearing.

b. Analysis

Although Petitioner does not dispute the violations cited under Tags F241 and F315, Petitioner argues that CMS has not proved that those violations resulted in actual harm and a scope and severity of G is not justified. P. Br. at 21-22; P. Law 7; Request for Hearing.

Petitioner argues that the only evidence of psychosocial harm noted in the SOD is that Resident 5 cried when discussing the details of the deficiencies with the surveyors. Petitioner asserts that her crying was not an indication of psychosocial harm, but rather a

symptom of her condition relating to her CVA diagnosis, which made it difficult for her to express her feelings. Petitioner asserts that she frequently became emotional and weepy when she experienced difficulty in expressing herself or being understood and that her tearfulness is not a valid basis to establish that she experienced psychosocial harm as a result. Instead, it was simply her manner of communication. P. Br. at 22.

Petitioner's right to a hearing by an ALJ is not unlimited. The regulations, specifically 42 C.F.R. § 498.3(b)(14), (b)(16), and (c)(10), only grant Petitioner a right to ALJ review of the surveyors' scope and severity determination if such review might affect the range of CMP that may be imposed by CMS or affect a finding of substandard quality of care that resulted in the facility's loss of NATCEP authority. The violations cited under Tags F241 and F315 are not alleged to have posed immediate jeopardy and the range of CMPs available to CMS as an enforcement remedy for these violations is not affected, and would not be affected, if I decided favorably for Petitioner that the two violations did not cause actual harm. 42 C.F.R. § 488.438(a) (upper range of CMPs is for deficiencies that constitute immediate jeopardy and lower range for deficiencies that do not). Further, CMS found substandard quality of care only with regard to the deficiencies cited under Tags F309 and 329. Request for Hearing, CMS Notice Letter dated November 15, 2007, page 3; CMS Ex. 46, at 1-2; CMS Ex. 53, at 1-2. Thus, Petitioner has no right to ALJ review as to the determination that the violations of 42 C.F.R. §§ 483.15(a) (Tag F241), 483.25(d) (Tag F315), and 483.25(h) (Tag F323) caused actual harm to the residents. I further note that the state would be required to withdraw Petitioner's authority to conduct a NATCEP based upon the CMP exceeding $5000, even in the absence of a finding of substandard quality of care that triggered an extended survey.

However, even if I provided the review Petitioner requested, I would conclude that the evidence raised the inference of actual harm to Resident 5 and that Petitioner did not rebut the inference. Regarding the deficiency alleged under F315, there is no dispute that Resident 5 became tearful during an interview with surveyors when there was a discussion about her incontinent episodes; her assertion that she had to wait so long for a response to her call light that she urinated in her incontinent brief; and her statement that being incontinent made her feel awful. This undisputed evidence is sufficient to raise an inference that Resident 5 suffered embarrassment and possible shame, which is not rebutted by Petitioner's assertion that Resident 5 becomes tearful because she has difficulty expressing herself or being understood. The evidence does not show Resident 5 had difficulty expressing herself to the surveyors or being understood. Furthermore, it is within common experience that a cognizant adult would feel shame and or embarrassment at being incontinent. Whether shame or embarrassment rises to the level of psychosocial harm is a matter of professional judgment and Petitioner has not offered evidence to rebut the surveyors' professional opinion that Resident 5 suffered actual harm. Regarding the violation of 42 C.F.R. § 483.25(d) (Tag F315), Petitioner has not argued or offered evidence that the residents did not suffer actual harm in the form of decline in bladder function, at least with regard to continence.

8. Petitioner returned to substantial compliance with program participation requirements on November 23, 2007.

9. Alternative remedies, the DPNA and daily CMP, ended on November 22, 2007.

The regulations governing the duration of alternative remedies, including a daily CMP and a DPNA, are found at 42 C.F.R. §§ 488.454 and 488.440. Section 484.454(a) provides that "alternative remedies" continue to accrue until "[t]he facility has achieved substantial compliance, as determined by CMS or the State based upon a revisit or after an examination of credible written evidence that it can verify without an on-site visit." Section 488.454(e) states that an alternative remedy may terminate on a date prior to a revisit survey if the facility "can supply documentation acceptable to CMS or the State survey agency that it was in substantial compliance" on the earlier date and was capable of remaining in substantial compliance. Section 488.440(h)(1) of 42 C.F.R. states the same concept with reference to a CMP.

In this case both the testifying surveyors and facility representatives acknowledged that the facility established substantial compliance as of November 23, 2007. Tr. 89-97, 116, 234-35.

CMS argues that Petitioner did not come back into substantial compliance with participation requirements until January 4, 2008, the date of the revisit survey. However, there is no evidence that any deficiency was cited by the January 4, 2008 survey that would be the basis for finding Petitioner not in substantial compliance between November 23, 2007 and January 4, 2008. The surveyors specifically testified that Petitioner had completed its plan of correction not later than November 23, 2007, and they were of the opinion that Petitioner was in substantial compliance as of that date. CMS did not rebut the testimony of its surveyors or explain in its brief why I should not accept the testimony of its surveyors that Petitioner was in compliance as of November 23, 2007. Thus, I conclude Petitioner returned to substantial compliance on November 23, 2007, and the remedies in this case no longer had a basis and ended as of November 22, 2007.

10. The enforcement remedies proposed by CMS are not reasonable.

11. A CMP of $3050 per day for the period of immediate jeopardy from July 31, 2007 through November 1, 2007, and of $250 per day for the period November 2, 2007 through November 22, 2007, is reasonable.

CMS proposes the following enforcement remedies: a CMP of $4550 per day from July 31 through November 1, 2007; a $250 per day CMP from November 2, 2007 through January 3, 2008; and a discretionary DPNA from November 17, 2007 through January 3,

2008. I have concluded that Petitioner returned to substantial compliance with program participation requirements on November 23, 2007. Therefore, it is unreasonable for any of the proposed enforcement remedies to run beyond November 22, 2007.

A per day CMP of $4550 is not reasonable in this case. The factors I must consider in making my determination as to whether the proposed CMP amounts are reasonable are set out at 42 C.F.R. § 488.438(f) and include: (1) the facility's history of noncompliance, including repeated deficiencies; (2) the facility's financial condition; (3) the factors specified in 42 C.F.R. § 488.404 for determining the seriousness of deficiencies, the relationship of deficiencies, and history of noncompliance; and (4) the facility's degree of culpability, which includes but is not limited to neglect, indifference, or disregard for resident care, comfort or safety.

I conclude that the $4550 CMP CMS imposed for the period of immediate jeopardy is not reasonable and I am lowering the amount of the CMP to $3050 per day. The upper range of CMPs, from $3050 per day to $10,000 per day, is reserved for periods when substantial noncompliance with program participation requirements poses immediate jeopardy to facility residents. Immediate jeopardy existed at Petitioner's facility from July 31, 2007 through November 1, 2007, and a daily CMP in the upper range is appropriate for that period. The minimum authorized CMP is $3050. CMS proposed $4550 per day. CMS asserts that the CMP is reasonable and that Petitioner had a "casual attitude" toward residents receiving Coumadin. CMS Br. at 20. Petitioner asserts that it had an excellent compliance history of deficiency free surveys, that there is no evidence in the record of neglect or indifference towards residents that would enhance its culpability, and no evidence of a systemic breakdown with respect to its laboratory monitoring that warrants increased penalties. P. Br. at 23. CMS did not respond to Petitioner's assertions. CMS letter dated October 18, 2008, stating CMS determined not to submit a reply brief.

I have considered the regulatory factors. The evidence does not show a history of noncompliance. Petitioner has presented no evidence of an inability to pay. IDR lowered the scope and severity of two alleged deficiencies from immediate jeopardy to the potential for more than minimal harm that was not immediate jeopardy without actual harm. Although I did not specifically address the alleged deficiency under Tag F490, CMS agreed that the alleged violation was derivative of other alleged violations and I would not have treated that deficiency as the basis for a larger CMP in this case. I also elected not to specifically address the alleged deficiency under Tag F520, but that deficiency, even if founded, would have no effect on my determination of the reasonable remedy in this case; for while that alleged deficiency is not truly derivative, it cites Petitioner for not having an effective QAC based on the existence of the other alleged deficiencies.

The $250 per day CMP imposed for the period after immediate jeopardy was abated and before Petitioner returned to substantial compliance, is reasonable. The $250 per day CMP is at the lower end of the low range of CMPs and is consistent with Petitioner's degree of culpability and the seriousness of the deficiencies that remained uncorrected after immediate jeopardy was abated.

III. Conclusion

For the foregoing reasons, I conclude that Petitioner was not in substantial compliance with program participation requirements at a level of immediate jeopardy from July 31 through November 1, 2007, immediate jeopardy was abated on November 2, 2007, but Petitioner remained out of substantial compliance until November 23, 2007. Reasonable enforcement remedies are a CMP of $3050 per day for the period of immediate jeopardy; a CMP of $250 per day from November 2, 2007 through November 22, 2007; and a DPNA from November 17 through 22, 2007. The total CMP is $291,950 (94 days at $3050 and 21 days at $250). The state agency was required to withdraw Petitioner's authority to conduct a NATCEP for a period of two years effective November 7, 2007.

/s/
Keith W. Sickendick
Administrative Law Judge