Department of Health and Human Services

DEPARTMENTAL APPEALS BOARD

Civil Remedies Division

In the Case of:	)	
	)	Date: August 5, 2008
Saturn Nursing and Rehab Center, (CCN: 34-5489),	)	
	)	Docket No. C-06-468
Petitioner,	)	Decision No. CR1826
- v. -	)	
Centers for Medicare & Medicaid Service.	)	

DECISION

Petitioner, Saturn Nursing and Rehab Center, violated 42 C.F.R. § 483.25(l)(1)(iii)[1] with regard to two residents during the period March 7 through 14, 2006. The determination that the violation posed immediate jeopardy for Petitioner's residents during the period of March 7 through 14, 2006 is not clearly erroneous. A civil money penalty (CMP) of $3050 per day for eight days, a total CMP of $24,400, is reasonable. Petitioner's authority to conduct a Nurse Aide Training and Compentency Evaluation Program (NATCEP) was required to be withdrawn for the two year period March 16, 2006 through March 15, 2008.

I. Background

Petitioner, located in Charlotte, North Carolina, is certified to participate in the Medicare program as a skilled nursing facility (SNF) and the North Carolina Medicaid program as a nursing facility (NF). Petitioner was subject to an annual survey by the North Carolina State Survey Agency (the state agency), which began on March 14 and concluded on March 16, 2006, the results of which are reported in a statement of deficiencies (SOD) dated March 16, 2006. Joint Stipulations of Fact (Jt. Stip.); Petitioner Exhibit (P. Ex.) 1.

[1] References are to the Code of Federal Regulations (C.F.R.) effective at the time of the survey unless otherwise indicated.

The Centers for Medicare and Medicaid Services (CMS) notified Petitioner by letter dated March 30, 2006, that the survey concluded on March 16, 2006, found Petitioner was not in substantial compliance with program participation requirements and that CMS was imposing remedies, including a CMP of $3050 per day effective March 7, 2006 through March 14, 2006 and $50 per day thereafter until substantial compliance was achieved; a denial of payments for new admissions (DPNA) effective June 16, 2006 until substantial compliance was achieved; and termination of Petitioner's provider agreement effective September 16, 2006, unless substantial compliance was achieved prior to that date. CMS Exhibit (CMS Ex.) 7, at 2-3; P. Ex. 2. CMS advised Petitioner by letter dated May 4, 2006, that an April 19, 2006 revisit survey concluded that Petitioner returned to substantial compliance on April 10, 2006, and the DPNA and termination remedies were rescinded. CMS Ex. 7, at 5; P. Ex. 3. The $50 per day CMP also ceased accruing as of April 9, 2006 due to Petitioner's return to substantial compliance on April 10, 2006.

Petitioner requested a hearing by an administrative law judge (ALJ) by letter dated May 19, 2006. Petitioner requested a hearing only as to the alleged violation of 42 C.F.R. § 483.25(l)(1)(iii), the finding of substandard quality of care and immediate jeopardy related to that violation, and the CMP of $3050 per day for the period of March 7 through 14, 2006, which was imposed based upon that violation.[2] The case was assigned to me for hearing and decision on May 30, 2006. I convened a hearing in Charlotte, North Carolina on November 8, 2006. CMS offered and I admitted CMS Exs. 1 through 22. Transcript (Tr.) 16. Petitioner offered and I admitted P. Exs. 1 through 33. Tr. 17. CMS called as witnesses Amy Barnes, Registered Nurse (R.N.) and Linda Felts, both surveyors. Petitioner called as witnesses, Ted Clontz, M.D., Petitioner's current Medical Director, and Angela Conrade, Petitioner's Administrator. The parties submitted post-hearing briefs; Petitioner filed a post-hearing reply brief, but CMS elected not to file a reply brief.

II. Discussion

A. Findings of Fact

The following findings of fact are based upon the exhibits admitted, the parties' stipulations of fact, and the testimony received at hearing. Citations to exhibit numbers related to each finding of fact may be found in the analysis section of this decision if not indicated here.

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[2] Petitioner specifies that it did not request review as to the violations of 42 C.F.R. §§ 483.20(k)(3)(i) (Tag F281, scope and severity (s/s) D); 483.20(k)(3)(ii) (Tag F282, s/s D); 483.25(g)(2) (Tag F322, s/s D); 483.25(m)(2) (Tag F333, s/s D); and 483.35(h)(2) (Tag F371, s/s F). Request for Hearing at 2, n. 1.

1. Resident 10 had an order to receive Coumadin daily. CMS Ex. 10, at 10, 11; P. Ex. 11, at 3; P. Ex. 12, at 1.

2. Resident 10's order dated March 3, 2006, required that he have blood drawn for laboratory testing on March 7, 2006, for Prothrombin Time (PT) and International Normalized Ratio (INR). CMS Ex. 10, at 11; P. Ex. 12, at 1.

3. Resident 17 also had a physician's order for Coumadin. P. Ex. 26, at 2; P. Ex. 27, at 1.

4. A physician's order for Resident 17 dated February 28, 2006, required a laboratory draw for PT/INR recheck in one week, which would have been March 7, 2006. P. Ex. 27, at 1.

5. Blood draws from both Resident 10 and 17 occurred on March 7, 2006.

6. The laboratory completed the PT and INR testing for the March 7, 2006 samples from Resident 10 and 17, but the results were not reported back to Petitioner the next day as they should have been.

7. During the survey on March 15, 2006, the surveyors discovered that there were no laboratory reports for PT/INR for Resident 10 and 17 from a blood draw on March 7, 2008, and that they reported the problem to Petitioner's Director of Nursing (DON) and the laboratory results were obtained. Tr. 99; CMS Ex. 5, at 11; P. Ex. 14, at 3; P. Ex. 31, at 2; CMS Post-Hearing Brief (CMS Brief) at 3-4; Petitioner's Post-Hearing Brief (P. Brief) at 9; Petitioner's Reply Brief (P. Reply) at 6.

8. There is no dispute that the untimely delivery of the reports to Petitioner was the fault of the laboratory. P. Ex. 33.

9. When the laboratory reports were received they showed that the laboratory reported high results for both Residents 10 and 17. P. Ex. 14, at 3; P. Ex. 31, at 2.

10. Residents 10 and 17 suffered no harm due to delayed receipt of the laboratory reports for PT/INR. Tr. 50, 68, 97-99.

11. Coumadin is a type of blood thinner used to decrease the risk of blood clots that may develop in the body. Tr. 37.

12. If the Coumadin dose is too low, the blood is not adequately thinned and the patient is not protected from risks posed by blood clots, but if the dose of Coumadin is too high, the patient is at risk for spontaneous hemorrhages or other bleeding and bruising that may result from even minimal trauma. Tr. 38-39, 52.

13. Regular monitoring of Coumadin levels is a standard of care. Tr. 51.

14. Long-term Coumadin therapy was appropriate for both Residents 10 and 17 (Tr. 38) and the laboratory testing ordered for PT/INR on March 7, 2006 was necessary because their dose of Coumadin was being adjusted (Tr. 50-51).

15. Petitioner's staff did not notice that no laboratory results for PT/INR testing for Residents 10 and 17 were received by March 8, 2006.

16. Petitioner failed to monitor the laboratory results from the samples drawn on March 7, 2006, and failed to report the results to the treating physicians so that the physicians could make decisions regarding adjusting the Coumadin dose for each resident.

17. Residents 10 and 17 were at risk for serious harm or death because their Coumadin levels were not monitored.

B. Conclusions of Law

1. Petitioner's request for hearing was timely and I have jurisdiction.

2. CMS made a prima facie showing of a violation of 42 C.F.R. § 483.25(l)(1)(iii) (Tag F329) (unnecessary drugs).

3. Petitioner failed to rebut CMS's prima facie showing of a violation of 42 C.F.R. § 483.25(l)(1)(iii) (Tag F329) either by showing by a preponderance of the evidence that the facility was in substantial compliance or that Petitioner had an affirmative defense.

4. CMS's finding of immediate jeopardy was not clearly erroneous.

5. A CMP of $3050 per day for the period March 7 through 14, 2006, a total CMP of $24,400, is reasonable.

C. 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.

D. Applicable Law

Petitioner is a long-term care facility participating in the federal Medicare program as a SNF and in the state Medicaid program as a NF. The statutory and regulatory requirements for participation by a long-term care facility are found at sections 1819 and 1919 of the Social Security Act (Act) and at 42 C.F.R. Part 483. Sections 1819 and 1919 of the Act vest the Secretary of the Department of Health and Human Services with authority to impose civil money penalties against a long-term care facility for failure to comply substantially with federal participation requirements.

Pursuant to the Act, the Secretary has delegated to CMS and the states the authority to impose remedies against a long-term care facility that is not complying substantially with federal participation requirements. "*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 the Secretary through his regulations at 42 C.F.R. Part 483. 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. Pursuant to 42 C.F.R. Part 488, CMS may impose a per instance or per day CMP against a long-term care facility when a state survey agency concludes that the facility is not complying substantially with federal participation requirements. 42 C.F.R. §§ 488.406; 488.408; 488.430. The regulations also give CMS a number of other enforcement remedies that may be imposed if a facility is not in 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 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). The upper range of CMP, 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). 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 Act and regulations make a hearing before an ALJ available to a long-term care facility against which CMS has determined to impose an enforcement remedy. Act, section 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 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 upon the facility's Nurse Aid Training and Competency Evaluation Program (NATCEP). 42 C.F.R. §§ 498.3(b)(14) and (d)(10)(i). 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 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 governed by 42 C.F.R. § 488.438(e).

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) that 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.

When a penalty is proposed and appealed, CMS must make a *prima facie* case that the facility has failed to comply substantially with federal participation requirements. "*Prima facie*" means that the evidence is "(s)ufficient to establish a fact or raise a presumption unless disproved or rebutted." *Black's Law Dictionary* 1228 (8th ed. 2004). *See also Hillman Rehabilitation Center*, DAB No. 1611, at 8 (1997), *aff'd Hillman Rehabilitation Center v. U.S. Dept. of Health and Human Services*, No. 98-3789 (GEB) (D.N.J. May 13, 1999). To prevail, a long-term care facility must overcome CMS's showing by a preponderance of the evidence. *Evergreene Nursing Care Center*, DAB No. 2069, at 7-8 (2007); *Emerald Oaks*, DAB No. 1800 (2001); *Cross Creek Health Care Center*, DAB No. 1665 (1998); *Hillman Rehabilitation Center*, DAB No. 1611.

E. Analysis

1. Petitioner violated 42 C.F.R. § 483.25(l)(1)(iii) (Tag F329[3]) for the period of March 7 through March 14, which posed immediate jeopardy to resident health and safety.

Petitioner is obligated by its participation in Medicare, to provide and ensure 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 under 42 C.F.R. § 483.25, must ensure that a resident's drug regimen is free of unnecessary drugs, which includes any drug used without adequate monitoring. 42 C.F.R. § 483.25(l)(1)(iii).

The surveyors concluded based upon staff interviews and records review that Petitioner failed to monitor ordered laboratory studies for Coumadin levels for Residents 10 and 17, with immediate jeopardy arising on March 7, 2006 and being abated on March 16, 2006. CMS Ex. 5, at 9; P. Ex. 1, at 9.

Resident 10 had an order to receive Coumadin daily. CMS Ex. 10, at 10, 11; P. Ex. 11, at 3; P. Ex. 12, at 1. Coumadin is a type of blood thinner used to decrease the risk of blood clots that may develop in the body. Tr. 37. Resident 10's order dated March 3, 2006, required that she have blood drawn for laboratory testing on March 7, 2006, for PT/INR. CMS Ex. 10, at 11; P. Ex. 12, at 1. Resident 17 also had a physician's order for Coumadin. P. Ex. 26, at 2; P. Ex. 27, at 1. A physician's order for Resident 17, dated February 28, 2006, required a laboratory draw for PT/INR recheck in one week, which would be March 7, 2006. P. Ex. 27, at 1.

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[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 if interpreted clearly 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, he may seek to enforce the provisions of the Act or regulations as interpreted by the SOM.

The parties agree that blood draws from both Residents 10 and 17 occurred on March 7, 2006. The parties also agree that the laboratory completed the PT and INR testing, but the results were not reported back to Petitioner the next day as they should have been. There is also no dispute that the surveyors discovered that there were no laboratory reports for PT/INR for Residents 10 and 17 from a blood draw on March 7, 2006, and that they reported the problem to Petitioner's DON and the laboratory results were obtained. Tr. 99; P. Ex. 14, at 3; P. Ex. 31, at 2; CMS Brief at 3-4; P. Brief at 9; P. Reply at 6. There is no dispute that the untimely delivery of the reports to Petitioner was the fault of the laboratory. P. Ex. 33. There is no question that, when the laboratory reports were received they showed that the laboratory reported high results for both Residents 10 and 17. P. Ex. 14, at 3; P. Ex. 31, at 2.

Surveyor Amy Barnes, R.N. testified that the surveyors did not find that there was harm to any resident due to the missing laboratory results. She testified that the surveyors declared immediate jeopardy based upon the likelihood of harm or injury due to Petitioner's failure to monitor Coumadin levels. Tr. 68. Surveyor Linda Felts testified that Resident 17 had a history of gastrointestinal bleed and too much Coumadin put her at risk for bleeding. Tr. 89. On cross-examination she stated that the immediate jeopardy determination was based upon the survey team's conclusion that there was a risk for serious injury or harm or death. Although she agreed that there was no harm to a resident, she noted that Resident 17's history of gastrointestinal bleed placed her at risk for serious harm due to an unmonitored Coumadin level. Tr. 97-99. CMS argues that while there may have been no actual harm to Residents 10 and 17, the administration of Coumadin to any resident without the laboratory results for blood testing posed the potential for serious harm. Dr. Ted Clontz, Petitioner's Medical Director, testified that it is always important to review laboratory values when administering Coumadin. Tr. 37. He testified that if the Coumadin dose is too low and the blood is not adequately thinned the patient is not protected from risks posed by blood clots. If the dose of Coumadin is too high the patient is at risk for spontaneous hemorrhages or other bleeding and bruising that may result from even minimal trauma. Tr. 38-39, 52. In his opinion, there was no question that long-term Coumadin therapy was appropriate for both Residents 10 and 17. Tr. 38. He testified that INR is the indicator that he relied upon and that when it was in the range of 4 or 4.4 he knew an adjustment in Coumadin level was necessary. He was not concerned about the risk of bleeding until the INR level was in the range of 6. Tr. 45. He did not consider either Resident 10 or 17 to be in the danger-zone based upon the PT/INR results from March 7, 2006. Tr. 44-45; P. Ex. 24. He was aware of no harm to either Resident 10 or 17 resulting from the missed laboratory report on March 7, 2006. Tr. 50. On cross-examination Dr. Clontz testified he was not the Medical Director for the

facility at the time of the survey. However, he reviewed the charts for Residents 10 and 17. He noted that the Coumadin dose for the residents was being adjusted and orders for laboratory tests for monitoring were appropriately ordered due to the adjustments. Tr. 50-51. According to Dr. Clontz, regular monitoring of Coumadin levels is a standard of care. Tr. 51.

The evidence shows that the physicians for Residents 10 and 17 ordered laboratory testing for PT/INR to be done on March 7, 2006. Although the testing was done, the results were not reported to the facility and Petitioner's staff failed to recognize that no results were received. Thus, the facility failed to monitor the laboratory results reflecting the Coumadin level and failed to report the results to the treating physicians so that the physicians could make decisions regarding adjusting the Coumadin dose for each resident. Petitioner does not deny, and in fact, Petitioner's Medical Director agreed that the orders for laboratory testing were reasonable and necessary and consistent with standard of practice. I have no difficulty concluding that Residents 10 and 17 were thus deprived of a necessary care or service and did not receive the quality of care required. Further, based upon the testimony of the surveyors and Petitioner's Medical Director, I conclude that there was a risk for more than minimal harm for both residents even though neither suffered harm due to the missed laboratory reports. Furthermore, the evidence is consistent with a conclusion that both residents were at risk for serious harm or death because their Coumadin level was not monitored.

Petitioner raises several defenses.

Petitioner argues that the deficiency is not appropriately charged under 42 C.F.R. § 483.25(l) but would be appropriately charged under the laboratory services regulation 42 C.F.R. § 483.75(j) or the medication error regulation 42 C.F.R. § 483.25(m). P. Brief at 2, 14-15; P. Reply at 4. Petitioner suggests that 42 C.F.R. § 483.25(l) primarily governs use of psychoactive medications based upon the discussion at SOM, App. PP, Tag F329. P. Brief at 14-15; P. Reply at 4. While Petitioner is correct that the bulk of the discussion of Tag F329 in the SOM relates to psychoactive medications, Petitioner points to no authority for the proposition that the application of 42 C.F.R. § 483.25(l) is limited to psychoactive medications. The regulation includes two subsections: subsection (1) is entitled "General" and subsection (2) is entitled "Antipsychotic Drugs." Subsection (1) which is cited by the surveyors and CMS in this case defines an unnecessary drug as "any drug" when used without adequate monitoring. 42 C.F.R. § 483.25(l)(1)(iii). Thus, the plain language of the subsection shows that its application is to any drug and not just psychoactive drugs. The charge made by the surveyors is that Petitioner failed to monitor the use of Coumadin because laboratory results were not received by Petitioner and Petitioner's staff failed to notice. CMS Ex. 5, at 9. The surveyors and Petitioner's Medical Director agreed in testimony that it is standard of practice to monitor Coumadin

use by laboratory testing for PT/INR. I conclude that the charge Petitioner failed to monitor Coumadin use is appropriately alleged as a violation of 42 C.F.R. § 483.25(l)(1). I need not determine whether Petitioner's failure might also be charged as violation of other regulations as Petitioner suggests.

Petitioner argues that it was the laboratory's fault that the results were not received; that the regular charge nurse was absent due to illness at the time the laboratory reports should have been received; the Administrator was absent due to surgery when walking rounds should have been done; and that Petitioner had an effective system in place but the surveyors came before the system had time to catch that laboratory results were missing. P. Brief at 2, 5, 8-12, 17; P. Reply at 4-8. None of these arguments excuse Petitioner's failure in this case.

CMS does not dispute that the laboratory failed to deliver reports to Petitioner for testing the March 7, 2006 blood samples of Residents 10 and 17. However, the focus in this matter is not upon the conduct of the laboratory. Rather, the surveyors appropriately focused upon whether Petitioner was doing appropriate monitoring of Coumadin use for Residents 10 and 17. Monitoring for Coumadin use requires PT/INR testing, not just observing the residents as Petitioner suggests in argument. P. Brief at 11-12. PT/INR testing was ordered for both residents. Petitioner did not receive reports after blood was drawn and submitted for testing. Petitioner did not identify that it did not receive reports. Because Petitioner did not receive reports, it could not adequately monitor Coumadin levels for the two residents and because Petitioner could not report results of testing to the treating physicians, Petitioner's error prevented the treating physicians from assessing whether the Coumadin dose in use was necessary. Although the laboratory may have been at fault for not delivering test results to Petitioner, Petitioner was at fault for not identifying that results were not received thus preventing it from doing required monitoring of Coumadin levels.

There is also no dispute by CMS that Petitioner did have a system for monitoring receipt of laboratory results for PT/INR. Both Surveyor Felts and Petitioner's Administrator Conrade testified that Petitioner had a system for the ensuring the return of laboratory reports. The system involved using a PT/INR flow sheet and the medication administration record (MAR). Surveyor Felts testified that the system Petitioner adopted was commonly used in long-term care facilities. Tr. 92. The problem for Petitioner is that the system failed in this case. Petitioner argues that the failure of its system was attributable in part to the absence of the regular charge nurse from March 7 to March 9, 2006, and Administrator Conrade was absent for surgery and periodic walking rounds were not done during the period from March 7 to 17, 2006. P. Brief at 10. I do not find this an acceptable defense. Petitioner is responsible to deliver quality care, including necessary care and services, whether or not some member of its staff is absent. If, as

Petitioner asserts, its system failed due to the absence of two individuals, the system is clearly defective as the system must work all the time, not just when all staff are present and attending to their duties.

Petitioner argues that there were backup systems that should have identified that laboratory reports had not been received. Petitioner argues that both Residents 10 and 17 are required to receive weekly physician visits. However, Petitioner acknowledges that the treating physicians did not mention following their visits that any laboratory results were missing (P. Brief at 11), demonstrating that they did not provide an effective backup. Petitioner also argues that monthly pharmacist reviews are required and that, had not the survey occurred first, the pharmacist would have caught the oversight. P. Brief at 11. There is no question that pharmacist reviews are required and that one did not occur before the surveyors discovered that the laboratory reports were missing. Petitioner, however, has not shown that a pharmacist review that would occur from a few days to 30 days after the results were due is a reasonable and effective means for monitoring Coumadin level laboratory reports or would serve to prevent harm to the residents if levels were too high or low at the time of testing. The blood samples were drawn on March 7 and results for other samples were reported to Petitioner on either March 7 or March 8. P. Ex. 7. The survey began on March 14, seven days later. The witnesses were consistent in their testimony that a laboratory test result indicating a dangerous level of Coumadin requires immediate action. Tr. 51-52, 66. Petitioner's Medical Director, Dr. Clontz, testified that Coumadin levels are generally monitored once every six or seven days. Tr. 51. Given that Petitioner's backup systems had not caught the error in this case within seven days, it is apparent that those backup systems would not be effective to prevent serious harm from a dangerous level of Coumadin.

Petitioner also argues that, even if it was deficient, there was no harm and no immediate jeopardy. P. Brief at 18-20; P. Reply at 8-12. As I have already noted, there is no allegation that either Resident 10 or 17 suffered actual harm. Rather the surveyors testified that they cited immediate jeopardy due to the risk for serious harm or death that failure to monitor Coumadin posed. Dr. Clontz also testified that a Coumadin level that was too high or low posed the risk for serious harm either by blood clots or spontaneous hemorrhage. CMS's determination as to the level of a facility's noncompliance, which includes its immediate jeopardy finding, must be upheld unless it is "clearly erroneous." 42 C.F.R. § 498.60(c). The Board has observed repeatedly that the "clearly erroneous" standard imposes on facilities a "heavy burden" to show no immediate jeopardy, and has sustained determinations of immediate jeopardy where CMS presented evidence "from which '[o]ne could reasonably conclude' that immediate jeopardy exists." *Barbourville Nursing Home*, DAB No. 1962, at 11 (2005); *Florence Park Care Center*, DAB No. 1931, at 27-28 (citing *Koester Pavilion*, DAB No. 1750 (2000)). Immediate jeopardy exists if the facility's noncompliance has caused or is likely to cause "serious injury,

harm, impairment, or death to a resident." 42 C.F.R. § 488.301. I conclude that the finding of immediate jeopardy was not clearly erroneous in this case based upon the testimony of the surveyors and Dr. Clontz regarding the potential for harm.

The evidence shows that the blood draws occurred on March 7, 2006. The laboratory reports related to the March 7 samples were not received until March 15, 2006 when the surveyors identified they were missing and Petitioner requested the results from the laboratory. P. Ex. 14, at 3; P. Ex. 31, at 2. Thus, the period of immediate jeopardy alleged by CMS, March 7 through 14, is consistent with and supported by the evidence.[4] Indeed, the surveyors and CMS credit Petitioner with having abated the immediate jeopardy immediately upon discovery of the deficiency. Petitioner argues that imposing a large CMP has no remedial purpose. P. Brief at 20; P. Reply at 12. Contrary to Petitioner's assertions, the CMP serves a remedial purpose of encouraging Petitioner to take reasonable steps to ensure that its delivery of necessary care and services does not fail simply because a charge nurse and the Administrator are absent for a few days.

I conclude that during the eight-day period from March 7 through 14, 2006, Petitioner was in violation of 42 C.F.R. § 483.25(l)(1)(iii) with respect to its residents on Coumadin therapy. The regulatory violation posed immediate jeopardy. Accordingly, Petitioner was not in substantial compliance with program participation requirements. Petitioner did not demonstrate by a preponderance of the evidence that it was in substantial compliance or that it had an affirmative defense.

2. The burden of persuasion is not an issue in this case.

Petitioner argues that it is inappropriate to impose upon Petitioner the burden of persuasion by a preponderance of the evidence. Request for Hearing at 4-5; P. Prehearing Brief at 15. The evidence in this case is not in equipoise and the allocation of the burden of persuasion does not control the disposition of this case.

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[4] The surveyors found that immediate jeopardy was abated on March 16, 2006. CMS Ex. 5, at 9. CMS advised Petitioner by its March 30, 2006 notice that it proposed imposing a $3050 daily CMP for March 7 through March 14, 2006 rather than through March 15, 2006 as proposed by the state. I find it unnecessary to resolve the inconsistency because I resolve it in Petitioner's favor. The CMP of $3050 from March 7 through March 14, 2006, proposed by CMS is consistent with a determination by CMS that immediate jeopardy was actually abated on March 15, 2006 rather than March 16, 2006 as alleged by the surveyors. I so find.

3. A per day CMP of $3050 for eight days from March 7 through March 14, 2006 is reasonable in this case.

I have concluded that the CMS finding of immediate jeopardy was not clearly erroneous and it will not be disturbed. The CMP of $3050 per day is the lowest per day CMP authorized for a deficiency that poses immediate jeopardy. 42 C.F.R. § 488.438(a)(1)(i). Accordingly, a CMP of $3050 per day is reasonable as a matter of law. Because I have concluded that the duration of the deficiency at the immediate jeopardy level was eight days, the total CMP of $24,400 is reasonable.

Petitioner argues that it is deprived of due process because CMS is not required to offer evidence that it considered the factors specified at 42 C.F.R. §§ 488.404 and 488.438(f). P. Prehearing Brief at 15. However, Petitioner cites no authority in support of this assertion. Further, my review of the reasonableness of the enforcement remedy is de novo and does not turn upon whether CMS properly considered regulatory factors when proposing remedies.

III. Conclusion

For the foregoing reasons I conclude that Petitioner violated 42 C.F.R. § 483.25(l)(1), with regard to two residents during the period March 7 through 14, 2006 and the violation posed immediate jeopardy. Therefore, Petitioner was not in substantial compliance. A CMP of $3050 per day from March 7 through 14, 2006, a total CMP of $24,400, is reasonable.

/s/
Keith W. Sickendick
Administrative Law Judge