Department of Health and Human Services

DEPARTMENTAL APPEALS BOARD

Civil Remedies Division

Legacy Health and Rehabilitation Center
(CCN: 04-5267),

Petitioner,

v.

Centers for Medicare and Medicaid Services.

Docket No. C-10-613

Decision No. CR2513

Date: March 14, 2012

DECISION

Contrary to the findings and conclusions of a complaint survey of Petitioner's facility completed on January 22, 2010, there was no deficiency under 42 C.F.R. § 483.25[1] (Tag F309) that posed more than minimal harm to any resident and Petitioner remained in substantial compliance with program participation requirements. No enforcement remedy is authorized or reasonable.

I. Background

Petitioner is located in Fort Smith, Arkansas, and participates in Medicare as a skilled nursing facility (SNF) and the state Medicaid program as a nursing facility (NF). On January 22, 2010, Petitioner was subject to a complaint survey by the Arkansas Department of Human Services, Office of Long Term Care (state agency). The state agency concluded that Petitioner was not in substantial compliance with program

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

participation requirements. The Centers for Medicare and Medicaid Services (CMS) notified Petitioner by letter dated February 8, 2010, that it was imposing the following enforcement remedies: termination of Petitioner's provider agreement if Petitioner did not achieve substantial compliance with program participation requirements before April 22, 2010; a per instance civil money penalty (PICMP) of $5,000 for an alleged violation of 42 C.F.R. § 483.25 (Tag F309); a denial of payment for new admissions (DPNA) effective February 23, 2010, if Petitioner did not achieve substantial compliance before that date; and withdrawal of any prior approval to conduct a Nurse Aide Training and Competency Evaluation Program (NATCEP). CMS advised Petitioner by letter dated March 25, 2010, that Petitioner had returned to substantial compliance and, as a result, the termination remedy and DPNA were rescinded. Joint Stipulation of Undisputed Facts (Jt. Stip.); CMS Exhibit (Ex.) 3, at 1-3; CMS Post-Hearing Brief (CMS Br.) at 2.

Petitioner requested a hearing before an administrative law judge (ALJ) on April 8, 2010. The case was assigned to Judge Alfonso Montano on April 14, 2010. The case was reassigned to me on July 27, 2010, upon Judge Montano's departure from the Departmental Appeals Board (the Board). On January 25 through 26, 2011, a hearing was convened in Fort Smith, Arkansas, and a transcript (Tr.) of the proceedings was prepared. CMS offered CMS Exs. 1 through 10 that were admitted as evidence. Petitioner offered Petitioner's exhibits (P. Exs.) 1 through 20 that were admitted as evidence. Tr. at 33-36. CMS called the following witness: Surveyor Eva Applegate, RN. Petitioner called the following witnesses: Kristi Kizer, LPN; Trish Lewis, LPN; Marie Henson, LPN; Heather Popa, LPN; Cassie White, RN, Petitioner's Director of Nursing (DON) during the survey; and Phillip K. Bobo, MD. The parties filed post-hearing briefs and post-hearing reply briefs.[2]

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[2] In its post-hearing brief, CMS cites to an article, K.K. Burkhard, S. Metcalf, E. Surnas, et al, *Exchange Transfusion and Multidose Activated Charcoal Following Vancomycin Overdose*, 30 Clin Toxicol 285-94 (1992), to rebut the testimony of DON White (Tr. at 504-05). CMS Br. at 9 n.3. Petitioner objects to my consideration of the information included in the CMS brief on grounds that it was not properly offered as evidence by CMS. P. Reply at 9. The article is evidence which is clearly offered in rebuttal of witness testimony. CMS did not move to reopen its case in chief or to present a rebuttal case. CMS did not submit copies of the article properly marked as a post-hearing exhibit or move for leave to do so. Petitioner's objection is sustained and the article that CMS cited is not considered for any purpose. Petitioner also objected to CMS's reliance upon other extra-record evidence cited in the CMS post-hearing brief (CMS Br. at 5 n. 1 and 10 n. 4) and Petitioner's objection is sustained on the same grounds.

II. Discussion

A. Issues

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 of a SNF in Medicare are found at section 1819 of the Social Security Act (Act) and at 42 C.F.R. Part 483. Section 1819(h)(2) of the Act authorizes the Secretary of Health and Human Services (Secretary) 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.[3] The Act requires that the Secretary terminate the Medicare participation of any SNF that does not return to substantial compliance with participation requirements within six months of being found not to be in substantial compliance. Act § 1819(h)(2)(C). The Act also requires that the Secretary deny payment of Medicare benefits for any beneficiary admitted to a SNF, if the SNF fails to return to substantial compliance with program participation requirements within three months of being found not to be in substantial compliance – commonly referred to as the mandatory or statutory denial of payments for new admissions (DPNA). Act § 1819(h)(2)(D). The Act grants the Secretary discretionary authority to terminate a noncompliant SNF's participation in Medicare, even if there has been less than 180 days of noncompliance. The Act also grants the Secretary authority to impose other enforcement remedies, including a discretionary DPNA, CMPs, 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. §

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[3] Participation of a NF in Medicaid is governed by section 1919 of the Act. Section 1919(h)(2) of the Act gives enforcement authority to the states to ensure that NFs comply with the participation requirements established by sections 1919(b), (c), and (d) of the Act.

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. Noncompliance refers to any deficiency that causes a facility not to be in substantial compliance. 42 C.F.R. § 488.301. State survey agencies survey facilities that participate in Medicare on behalf of CMS to determine whether the facilities are complying with federal participation requirements. 42 C.F.R. §§ 488.10-.28, 488.300-.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 a CMP, $3,050 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). "*Immediate 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." 42 C.F.R. § 488.301 (emphasis in original). The lower range of CMPs, $50 per day to $3,000 per day, is reserved for deficiencies that do not pose 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). A CMP of $1,000 to $10,000 for each instance of noncompliance is also authorized. 42 C.F.R. § 488.438(a)(2).

Petitioner was notified in this case that it was ineligible to conduct a NATCEP for two years. Petitioner did not have a NATCEP at the time of the survey. Tr. at 43-44. Pursuant to sections 1819(b)(5) and 1919(b)(5) of the Act, SNFs and NFs may only use nurse aides who have completed a training and competency evaluation program. Pursuant to sections 1819(f)(2) and 1919(f)(2) of the Act, the Secretary was tasked to develop requirements for approval of NATCEPs and the process for review of those programs. 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 that the Secretary established and a process for reviewing and reapproving those programs using criteria the Secretary set. 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 SNF or NF that has been: (1) 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) assessed a CMP of not less than $5,000; or (3) 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 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. *The Residence at Salem Woods*, DAB No. 2052 (2006); *Cal Turner Extended Care*, DAB No. 2030 (2006); *Beechwood Sanitarium*, DAB No. 1906 (2004); *Emerald Oaks*, DAB No. 1800, at 11 (2001); *Anesthesiologists Affiliated*, DAB CR65 (1990), *aff'd*, 941 F.2d 678 (8th Cir. 1991). A facility has a right to appeal a "certification of noncompliance leading to an enforcement remedy." 42 C.F.R. § 488.408(g)(1); 42 C.F.R. §§ 488.330(e), 498.3. However, the choice of remedies and 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 determined by CMS, if a successful challenge would affect the range of the CMP that may be imposed or impact the facility's authority to conduct a NATCEP. 42 C.F.R. § 498.3(b)(14), (d)(10)(i). The CMS determination as to the level of noncompliance, including the finding of immediate jeopardy, "must be upheld unless it is clearly erroneous." 42 C.F.R. § 498.60(c)(2); *Woodstock Care Ctr.*, DAB No. 1726, at 9, 38 (2000), *aff'd*, 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). ALJ Review of a CMP 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 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. *Batavia Nursing & Convalescent Inn*, DAB No. 1911 (2004); *Batavia Nursing & Convalescent Ctr.*, DAB No. 1904 (2004), *aff'd, Batavia Nursing & Convalescent Ctr. v. Thompson*, 129 F. App'x 181 (6th Cir. 2005); *Emerald Oaks*, DAB No. 1800; *Cross Creek Health Care Ctr.*, DAB No. 1665 (1998); *Hillman Rehab. Ctr.*, DAB No. 1611 (1997), *aff'd, Hillman Rehab. Ctr. v. United States*, No. 98-3789 (GEB), 1999 WL 34813783 (D.N.J. May 13, 1999).

C. Findings of Fact, Conclusions of Law, and Analysis

My conclusions of law are set forth in bold text followed by my findings of fact and analysis. I have carefully considered all the evidence and the arguments of both parties, though not all may be specifically discussed in this decision. In this decision, I discuss the credible evidence given the greatest weight in my decision-making.[4] The fact that evidence is not specifically discussed should not be considered sufficient to rebut the presumption that I considered all the evidence and assigned such weight or probative value to the credible evidence that I determined appropriate within my discretion as an ALJ. There is no requirement for me to discuss the weight given every piece of evidence considered in this case, nor would it be consistent with notions of judicial economy to do so.

CMS alleges based upon the complaint survey completed on January 22, 2010, that Petitioner was not in substantial compliance with program participation requirements on January 22, 2010, due to a violation of 42 C.F.R. § 483.25 (Tag F309) at a scope and severity of H, which represents a pattern of actual harm. Petitioner disputes the conclusion that it was noncompliant.

1. There was no violation of 42 C.F.R. § 483.25 (Tag F309) that posed a risk for more than minimal harm to any resident.

2. Contrary to the allegations of the survey that ended on January 22, 2010, Petitioner remained in substantial compliance with program participation requirements.

3. There is no basis for the imposition of an enforcement remedy.

The surveyors allege in the Statement of Deficiencies (SOD) for the survey completed on January 22, 2010, that Petitioner violated 42 C.F.R. § 483.25 and that the violation resulted in actual harm to Resident 2. The surveyors allege as the basis for the violation that:

> Petitioner failed to ensure that laboratory work was done with reports being sent to the infectious disease control doctor as ordered; and

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[4] "Credible evidence" is evidence that is worthy of belief. *Black's Law Dictionary* 596 (18th ed. 2004). The "weight of evidence" is the persuasiveness of some evidence compared to other evidence. *Id*. at 1625.

> Petitioner failed to ensure that appointments with medical specialists for evaluation and treatment of a pressure sore were kept.

The surveyors allege that Petitioner's failures resulted in actual harm of Resident 2, who required a below the knee amputation of his right leg. The surveyors also alleged that Petitioner's failures had the potential to affect other residents who had pressure sores. CMS Ex. 1, at 1-2; P. Ex. 1, at 1-2.

I conclude that Petitioner failed to strictly comply with physician orders. However, because Petitioner's failure to strictly comply with physician orders did not pose a risk for more than minimal harm, there was no noncompliance. Accordingly, Petitioner remained in substantial compliance and there is no basis for the imposition of an enforcement remedy.

a. Stipulated and Otherwise Undisputed Facts

Resident 2 was admitted to Petitioner's facility on December 11, 2009, on being discharged from Sparks Regional Medical Center (Sparks). Resident 2 had been in Sparks since October 2009, due to osteomyelitis (bone infection) of the right heel and infected ulcers on his right heel and sacrum, among other problems. A partial calcanectomy (removal of the heel bone (Tr. at 133)) of the right heel was performed at Sparks to remove infected bone. The calcanectomy was necessary as the resident and his family refused to permit a right below the knee amputation as recommended by the resident's physicians. CMS Ex. 5, at 16, 53, 79, 95.

The parties stipulated that on October 28, 2009, Resident 2 was seen by a podiatrist who noted that the ulcer on the resident's right heal had become progressively worse during the past six months. The parties stipulated that both a wound care physician and an orthopedic surgeon recommended that the resident's right foot be amputated before his admission to Petitioner. The parties stipulated that when Resident 2 was admitted to Petitioner on December 11, 2009, he suffered from acute osteomyelitis of the sacrum, an infected decubitus ulcer, diabetes mellitus, and he had a history of cerebrovascular accident with residual effects. The parties stipulated that when Resident 2 was admitted to Petitioner, the wound on his right foot was 12.6 centimeters long by 3 centimeters wide. On December 21, 2009, the wound was 11 centimeters long by 2.6 centimeters wide with no exudates or odor. On December 30, 2009, the wound measurements were unchanged. On January 5, 2010, the wound on the right foot was 10 centimeters long by 4 centimeters wide with no exudate or odor. The parties stipulated that the wound was noted to have a dark brown colored eschar and a minimal amount of clear yellow drainage on January 6, 2010. On January 11, 2010, the wound on the right foot measured 9.7 centimeters long by 3.8 centimeters wide with no exudate or odor. Jt. Stip. ¶¶ 5, 6, 7, 9, 10, 11, 12, 13, 14.

The parties stipulated that when Resident 2 was admitted to Petitioner on December 11, 2009, he had orders from the infectious disease physician, Raed Khairy, for weekly laboratory blood draws with the results to be sent to Dr. Khairy and the resident's primary care physician by facsimile. There was also an order for the resident to follow-up with the primary care physician in one week and to schedule appointments with Dr. Khairy and the podiatrist, Dr. Kenneth Seiter. Jt. Stip. ¶ 8. The parties stipulated that Resident 2 had an appointment to be seen by Dr. Khairy on December 30, 2009. Dr. Khairy's office staff advised Petitioner's staff on December 29, 2009, that Dr. Khairy had not received laboratory results for the resident. Petitioner sent the laboratory results to Dr. Khairy by facsimile on December 29, 2009. Jt. Stip. ¶ 15. Resident 2 was seen by his podiatrist on December 30, 2009 and new orders were issued by the physician related to cleaning and dressing the surgical wound. Jt. Stip. ¶ 16. On January 14, 2010, Resident 2's primary care physician, Phil Agent, discussed a right below the knee amputation for Resident 2 with the wound therapy physician and podiatrist. Dr. Agent recommended the procedure to the resident and family who agreed to the amputation. Jt. Stip. ¶ 17.

Petitioner does not disputed that it did not order laboratory testing December 14, 2009, the first Monday after Resident 2's admission, but waited to begin ordering testing until December 21, 2009. P. Reply at 10.

b. CMS Evidence

At the close of the CMS case-in-chief, Petitioner requested a judgment that CMS had failed to make a prima facie showing of noncompliance, specifically that CMS failed to show that any deficiency posed a risk for more than minimal harm. Tr. at 231-32. Therefore, it is necessary to consider whether the evidence presented by CMS satisfies its burden to make a prima facie showing of a violation of a participation requirement that posed a risk for more than minimal harm.

The clinical records for Resident 2 presented by CMS as CMS Ex. 5 were, I infer, obtained by Surveyor Eva Applegate during the survey. The evidence shows that Resident 2 was 51 years old when he was admitted to Petitioner on December 11, 2009. A family member was his responsible party. Resident 2 was assessed as having memory problems; his cognitive skills for daily decision-making were moderately impaired; he rarely or never could make himself understood but he sometimes understood others; and his ability to communicate had deteriorated.[5] He was assessed shortly after admission as

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[5] The evidence shows that Resident 2 was a Native American and Cherokee was his primary language. The evidence is conflicting as to the degree to which he communicated in English. CMS Ex. 5, at 46-47, 51-53, 96.

being totally dependent upon staff for most activities of daily living, except eating, and he required limited assistance from one person for that activity. He could not get out of bed unassisted and required someone to push him in a wheelchair. He was incontinent of bowel and had an indwelling urinary catheter. His diseases and impairments included diabetes mellitus, hypertension, a history of cerebrovascular accident and traumatic brain injury with residual aphasia and limitation in range of motion on one side of his body; he had an antibiotic resistant infection, osteomyelitis, and an open wound on his foot that was assessed as a surgical wound and he was also assessed as having an infection of the foot. He had a feeding tube through which he received nutrition and hydration. He was noted to receive medication by intravenous (IV) line. CMS Ex. 5, at 9-23.

A nurse note at 9:23 p.m. on December 11, 2009, shows that Resident 2 arrived from the hospital at 8:00 p.m. The resident was on isolation as an infection precaution. He had a wound on his right heel with an intact dressing. He had a history of osteomyelitis in the right heel. He also had an open wound on his coccyx with an intact dressing. CMS Ex. 5, at 53. A nurse note on December 15, 2009, records that on December 14 a body audit was done. The wound nurse visualized the right heel and described a healing surgical wound with 12 sutures with a dark brown scab covering the wound. The wound nurse also recorded healing abrasions on the second, third, and fourth toes of the right foot. CMS Ex. 5, at 52. On December 16, 18, and 23, 2009, the wound nurse recorded that the right heel wound was responding well to treatment, the wound bed was clean and moist with a scant amount of clear yellow drainage, no odor, and the surrounding skin was pink and blanched when touched. CMS Ex. 5, at 49, 52-53. On December 23, 2009, the wound nurse characterized the abrasion on the toes of the right foot as being "healed off." CMS Ex. 5, at 49. The next wound nurse entry on December 30, 2009 sets forth Dr. Kenneth Seiter's new order from an appointment on that day. CMS Ex. 5, at 46. A note dated January 6, 2010, indicates that the resident was treated on January 5, and the right heel wound was responding well, it was clean and moist with a minimal amount of clear yellow fluid drainage with no odor and surrounding tissue that was pink and blanched when touched. CMS Ex. 5, at 44. The wound nurse entry on January 8, 2010, states that the wound on the right heel continued to respond well to treatment; the wound bed continued to remain clean and moist with dark brown eschar, no drainage or odor was detected, and no signs or symptoms of infection. CMS Ex. 5, at 42. The wound nurse note dated January 11, 2010, states that the right heel wound continued to respond well to treatment; the wound bed continued to present a dark brown moist eschar with scant clear yellow fluid drainage with no odor; surrounding tissue flakey and blanching with touch; and the second, third, fourth, and fifth toes on the right foot were again noted to be abraded but healing well with current treatment. CMS Ex. 5, at 41-42. The wound nurse examined the resident following his return from his blood transfusion on January 13 and her note shows the wound continued to respond well, with a dark brown eschar, no drainage or odor, and the surrounding skin remained pink and blanched when touched. CMS Ex. 5, at 40.

A restorative nurse note on January 11, 2010, at 7:37 p.m. indicates that Dr. Agent had visited the resident and issued new orders including a blood transfusion at Sparks due to anemia. A note dated January 12, 2010, shows the transfusion was scheduled for January 13, at 7:00 a.m. CMS Ex. 5, at 41. A charge nurse note dated January 13, 2010, at 3:19 p.m. shows that the resident had been returned to the facility. CMS Ex. 5, at 40. A restorative nurse note at 7:15 p.m. on January 14, 2010, indicates that Dr. Agent spoke with the resident's family and they agreed to the right below the knee amputation. CMS Ex. 5, at 40. Dr. Agent's note dated January 14, 2010, indicates that he discussed the need for the amputation with both the resident and family and they were agreeable. His note indicates the resident was to see Dr. Seiter to discuss the right heel and the probable amputation. CMS Ex. 5, at 77. Notes from the wound nurse dated January 15 state that she did a body audit after the resident returned from his appointment with Dr. Jason Seiter. She noted that the second, third, forth, and fifth toes on the right foot had healing abrasions and the wound on the right heel had a clean and dry dressing. The wound nurse note at 1:36 p.m. on January 15, 2010, shows that the resident was being transported to Sparks for the amputation. CMS Ex. 5, at 40.

The clinical records for Resident 2 include physicians' orders dated December 11, 2009, related to the resident's discharge from Sparks to Petitioner. Orders of Dr. Hodge, dated December 11, 2009 at 5:30 p.m., include the following: medications per medication record; low air loss mattress; tube feeding of full strength Glucerna; follow Dr. Kenneth Seiter's specific orders of care of the right lower extremity; note infectious disease orders for weekly laboratory work; and schedule for follow-up appointments with no indication of when the follow-up appointments should be scheduled. CMS Ex. 5, at 79.

The orders from the infectious disease physician, Dr. Khairy, dated December 11, 2009, at 10:00 a.m. required: PICC line (peripherally inserted central catheter) per nursing home policy; continue the antibiotic ceftriaxone, two grams by IV every 24 hours until December 29, 2009; continue the antibiotic vancomycin, 750 milligrams by IV every 24 hours until December 29, 2009; continue the antibiotic levofloxacin, 750 milligrams by the residents feeding tube every 24 hours until December 19, 2009; laboratory testing every Monday to include a complete blood count with differential (CBCD), comprehensive metabolic panel, and a vancomycin trough; the laboratory reports related to the testing were to be sent to Dr. Khairy and Resident 2's primary care physician;[6] follow-up visit with the primary care physician within one week; follow-up with Dr.

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[6] Resident 2's primary care physician was Wendell Ross from his release from Sparks until January 1, 2010, when Dr. Ross retired. Thereafter Dr. Phillip Agent was the resident's primary care physician beginning January 5, 2010. Tr. at 212; CMS Ex. 5, at 44.

Seiter as scheduled; and follow-up with Dr. Khairy on December 30, 2009.[7] CMS Ex. 5, at 89, 107; Tr. at 70-71.

Dr. Kenneth Seiter's orders dated December 11, 2009, specified that: the dressing on the right foot was to be kept clean, dry, and intact, and the dressing was not to be removed; if the dressing became wet it was to be removed, the incision was to be cleaned with a saline soaked gauze pad, a sterile pad was to placed over the incision and a sterile dressing was to be applied; the resident was to wear pressure relieving boots to prevent tissue breakdown; the resident was to have a follow-up appointment at the podiatrist's practice in ten days. CMS Ex. 5, at 81, 106; Tr. at 66-68.

A charge nurse note dated December 11, 2009 at 10:58 p.m. states that Resident 2 had an appointment with Dr. Kenneth Seiter at 9:45 a.m. on December 21, 2010; that a follow-up appointment with the primary care physician should occur in one week; and an appointment should be made with Dr. Khairy for December 30, 2009. CMS Ex. 5, at 53. Nurse notes from December 21, 2009, do not show that Resident 2 had an appointment with Dr. Seiter. CMS Ex. 5, at 50. There is also no dispute that Resident 2 did not attend an appointment with Dr. Kenneth Seiter on December 21, 2009.

A charge nurse note on December 22, 2009, shows that Dr. Ross, the primary care physician, ordered that the resident's PICC line be replaced. Dr. Ross also ordered that the vancomycin be administered through the feeding tube and the rocephin (ceftriazone) by intramuscular injection. On December 23 Resident 2's PICC line was replaced at Sparks. CMS Ex. 5, at 49. A nurse note on December 28, 2009, shows that laboratory reports were sent to the primary care physician, Dr. Ross, and he ordered bactrim, a sulfa antibiotic, twice per day for 14 days. CMS Ex. 5, at 47. A nurse note on December 30, 2009, shows that Resident 2 left the facility at 7:30 a.m. for appointments with Dr. Khairy and Dr. Seiter. The note shows that on returning from Dr. Khairy the resident had orders to continue vancomycin, 750 milligrams by IV every 24 hours and ceftriazone, 2 grams by IV every 24 hours, and his PICC line was to be cared for in accordance with facility policy. Dr. Khairy's orders also required the same laboratory testing he previously ordered every Monday; follow-up appointments with infectious disease and podiatry in one week, and a follow-up evaluation with Dr. Ross for anemia. The note shows that both Dr. Ross and the family were notified of the new orders. Dr. Seiter also issued new orders related to the dressing of the right heel wound. CMS Ex. 5, at 46. A charge nurse note dated December 31, 2009, shows that the resident continued on the antibiotics vancomycin, rocephin (ceftriazone), and bactrim. CMS Ex. 5, at 46.

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[7] The physician wrote "11/30" but there is no dispute that he intended December 30, 2009. Tr. at 96.

Charge nurse notes on January 6, 2010, do not reflect a missed appointment with Dr. Khairy or Dr. Seiter. But a note at 2:03 p.m. on January 6 states that orders were received to continue current treatment and laboratory testing and that a follow-up appointment was set with Dr. Khairy for January 13, 2010 at 11:10 a.m. and with Dr. Seiter at 2 p.m. on that day. CMS Ex. 5, at 43-44. There is no dispute that Resident 2 did not make the appointments with either physician on January 13 due to his blood transfusion.

Based upon the stipulated facts and facts gleaned from the documents produced by CMS, and considering the testimony of Surveyor Applegate regarding her findings,[8] I find the following facts have been shown by CMS regarding the bases for the alleged deficiency.

(i) Petitioner failed to ensure that all physician-ordered laboratory testing was done.

On December 11, 2009, Dr. Khairy ordered laboratory testing of Resident 2's blood every Monday, specifically a CBCD, comprehensive metabolic panel, and a vancomycin trough. The following table reflects the dates for Mondays falling between the resident's admission on December 11, 2009 and January 15, 2009, when he was admitted to Sparks for the amputation. Petitioner concedes that no blood was drawn for testing on Monday, December 14, 2009, and that no testing was done that week. P. Reply at 10; Tr. 466-73. The table shows that for the remaining four weeks: blood draws were not done on three Mondays; all ordered testing was accomplished during three weeks, but not on Monday; and no CBCD and comprehensive metabolic panel were done the week of December 28, 2009.

Mondays	**Blood Drawn Monday**	**Actual Date of Blood Draw**	**Tests Performed**[9]	**CMS Ex. 5, at**
12/14/2009	No		None	
12/21/2009	No	12/23/2009	CBCD, CMP, VT	26, 27
12/28/2009	Yes		VT	29, 47
1/4/2010	No	1/5 & 6/2010	CBCD, CMP, VT	2, 31, 32-35, 44-45
1/11/2010	No	1/12 & 14/2010	CBCD, CMP, VT	36-39

[8] Resident 2's amputation occurred on January 18, 2010 (CMS Ex. 5 at 84) and the survey occurred on January 22, 2010. Therefore, Surveyor Applegate made no direct observations of Resident 2's right leg below the knee.

[9] The following abbreviations are used for the table: vancomycin trough (VT), complete blood count with differential (CBCD), and comprehensive metabolic panel (CMP).

(ii) Petitioner failed to ensure that all laboratory reports were delivered to physicians as ordered.

There is no dispute that laboratory test results were sent to Resident 2's primary care physician, initially Dr. Ross and then Dr. Agent. There is no dispute that some laboratory reports were sent to Dr. Khairy when his office requested the reports. Petitioner asserts that all reports requested by Dr. Khairy were sent to him, but CMS denies the assertion. CMS Br. at 11-12; P. Br. 18; P. Reply at 10-11. The evidence shows that not all laboratory reports for testing were sent to Dr. Khairy as not all the tests were done. It is not necessary to determine exactly how many or which reports were not sent to Dr. Khairy.

(iii) Petitioner failed to ensure that Resident 2 attended all physician appointments as ordered.

The CMS evidence shows that no appointment was scheduled for Resident 2 to see Dr. Seiter on December 21, 2009. Resident 2 saw both Dr. Seiter and Dr. Khairy on December 30, 2009. Resident 2 missed his appointment with Dr. Khairy on January 6, 2010. Resident 2 did not go to appointments with Dr. Khairy and Dr. Seiter on January 13, 2010, as he was at Sparks receiving a blood transfusion. Resident 2 did attend an appointment with Dr. Jason Seiter, Dr. Kenneth Seiter's partner, on January 15, 2010. CMS Ex. 5, at 95-99.

(iv) The CMS evidence does not show that Resident 2 suffered any harm due to the missed physician appointments or the delayed or missed laboratory draws and testing.

Wound nurse notes and records indicate that the Resident 2's right heel wound was stable or showed slight improvement between his admission to Petitioner on December 11, 2009 and his transfer to Sparks on January 15, 2010. The wound nurse characterized the right heel wound as having a dark brown eschar, sometimes characterized as being moist; with brown or yellow drainage on most observations; with no odor; and pink surrounding tissue that blanched when pressed. CMS Ex. 5, at 40-42, 44, 46, 49, 52-53, 62-76. Dr. Jason Seiter's notes from his examination of Resident 2 are not inconsistent with the wound care nurse's observations. Dr. Jason Seiter characterized the heel surgical wound as having "dead black tissue" with "purulent and serosanguineous drainage." CMS Ex. 5, at 96. Dr. Seiter's observation that there was drainage or discharge from the wound is not particularly helpful as he does not describe the color or appearance of the fluid. The wound nurse on most occasions described discharge of yellow or brown fluid drainage from the wound. Dr. Seiter did not describe seeing pus and he did not indicate in his note that there was an odor. Dr. Seiter's note that he observed the wound had dead black tissue, which he also characterized as gangrene, is also consistent with the wound nurse's observations that the wound had an eschar. The State Operations Manual (SOM) app.

PP, Tag F314 advises surveyors that eschar is thick, leathery, frequently black or brown dead or devitalized tissue that has lost its usual physical properties and biological activity. CMS Ex. 5, at 95, 97-98. Therefore, Dr. Seiter's report supports no inference that the condition of the resident's wound had deteriorated. While Dr. Seiter complained that it was difficult to treat Resident 2 given the missed appointments and laboratory reports, among other things, he did not point to any resulting deterioration in the resident's condition.[10] Clearly, Dr. Seiter's report dated January 15, 2010, which is labeled "Final Report," was drafted for the purpose of justifying termination of the treating relationship between the Dr. Seiters and Resident 2 and further justification for the amputation.

c. Analysis Related to the CMS Prima Facie Showing of Noncompliance

Failure to follow physician orders is not acceptable! However, failure to follow physician orders is not per se a basis for the imposition of an enforcement remedy. In the context of 42 C.F.R. § 483.25 (Tag F309), noncompliance exists and an enforcement remedy is authorized under 42 C.F.R. § 488.402(b), only if the failure to follow physician orders:

> (1) deprives a resident of a care or services necessary to attain or maintain the highest practicable physical, mental, and psychosocial well-being, in accordance with the comprehensive assessment and plan of care; and
>
> (2) poses a risk for more than minimal harm.

These are the elements of the CMS prima facie case.

The Departmental Appeals Board (Board) has been consistent in its view that CMS has the burden of coming forward with evidence to establish a prima facie case that Petitioner was not in substantial compliance with federal participation requirements to justify the

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[10] Dr. Jason Seiter's treatment note mentions that he noted wounds on the toes of the right foot, which he characterized as ulcers. CMS Ex. 5, at 96. The evidence shows that Resident 2 had abrasions on the toes of his right foot upon transfer to Petitioner on December 11, 2009 (CMS Ex. 5, at 52) that healed by December 23, 2009 (CMS Ex. 5, at 49). On January 11, 2010, the wound nurse also noted that the second, third, fourth, and fifth toes on the right foot were again abraded but healing well with current treatment. CMS Ex. 5, at 41-42. The source of the abrasions or ulcers on the toes of the right foot is not reflected by the evidence. However, the toe wounds are not cited as a basis for any noncompliance and no further analysis regarding those wounds is necessary or appropriate.

imposition of an enforcement remedy. The Board has stated that CMS must come forward with "evidence related to disputed findings that is sufficient (together with any undisputed findings and relevant legal authority) to establish a prima facie case of noncompliance with a regulatory requirement." *Evergreene Nursing Care Ctr.*, DAB No. 2069, at 7 (2007); *Batavia Nursing and Convalescent Ctr.*, DAB No 1904. Only when CMS makes a prima facie showing of noncompliance, is the facility burdened to show, by a preponderance of the evidence on the record as a whole, that it was in substantial compliance or had an affirmative defense. *Evergreene Nursing Care Ctr.*, DAB No. 2069, at 4.

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 generally 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). In *Hillman Rehabilitation Ctr.*, the Board described the elements of the CMS prima facie case in general terms as follows:

> HCFA [now known as CMS] must identify the legal criteria to which it seeks to hold a provider. Moreover, to the extent that a provider challenges HCFA's findings, HCFA must come forward with evidence of the basis for its determination, including the factual findings on which HCFA is relying and, if HCFA has determined that a condition of participation was not met, HCFA's evaluation that the deficiencies found meet the regulatory standard for a condition-level deficiency.

DAB No. 1611, at 8. Thus, CMS has the initial burden of coming forward with sufficient evidence to show that its decision to impose an enforcement remedy is legally sufficient under the statute and regulations. To make a prima facie case that its decision was legally sufficient, CMS must: (1) identify the statute, regulation or other legal criteria to which it seeks to hold the provider; (2) come forward with evidence upon which it relies for its factual conclusions that are disputed by the Petitioner; and (3) show how the deficiencies it found amount to noncompliance that warrants an enforcement remedy, i.e., that there was a risk for more than minimal harm due to the regulatory violation.

In *Evergreene Nursing Care Ctr.*, the Board explained its "well-established framework for allocating the burden of proof on the issue of whether a SNF is out of substantial compliance" as follows:

> CMS has the burden of coming forward with evidence related to disputed findings that is sufficient (together with any undisputed findings and relevant legal authority) to establish a prima facie case of noncompliance with a regulatory

> requirement. If CMS makes this prima facie showing, then the SNF must carry its ultimate burden of persuasion by showing, by a preponderance of the evidence, on the record as a whole, that it was in substantial compliance during the relevant period.
>
> CMS makes a prima facie showing of noncompliance if the evidence CMS relies on is sufficient to support a decision in its favor absent an effective rebuttal. A facility can overcome CMS's prima facie case either by rebutting the evidence upon which that case rests, or by proving facts that affirmatively show substantial compliance. "An effective rebuttal of CMS's prima facie case would mean that at the close of the evidence the provider had shown that the facts on which its case depended (that is, for which it had the burden of proof) were supported by a preponderance of the evidence."

DAB No. 2069, at 7-8 (citations omitted).

The regulation gives Petitioner notice of the criteria or elements it must meet to comply with the program participation requirement established by the regulation. 5 U.S.C. §§ 551(4), 552(a)(1). Therefore, in order to make a prima facie showing of noncompliance, CMS must show that Petitioner violated the regulation by not complying with one or more of the criteria or elements of the regulation, which is a deficiency. CMS must also show that the deficiency amounted to "noncompliance," i.e., that Petitioner was not in substantial compliance because the deficiency posed a risk for more than minimal harm. The Board's prior decisions are consistent with this construction. Whether CMS makes a prima facie showing is determined by review of the credible evidence CMS presents to establish each element necessary to show that a facility is not in substantial compliance. To establish a prima facie case of noncompliance, the required basis for imposition of an enforcement remedy, CMS must show that the participation requirement was violated and that one or more residents suffered or were exposed to a risk for more than minimal harm. *See Jennifer Matthew Nursing & Rehab. Ctr.,* DAB No. 2192, at 20 n.12 (2008).

The facts in this case show that there were physician orders for laboratory work and follow-up appointments with physicians. The facts show that Petitioner failed to ensure compliance with the orders. I conclude, absent evidence to support a contrary conclusion, that the physician orders were for care or services necessary for the resident to attain or maintain the highest practicable physical, mental, and psychosocial well-being, in accordance with the resident's comprehensive assessment and plan of care. I further conclude that Petitioner's failure to ensure compliance with the orders deprived the resident of necessary care and services and amounted to a violation of 42 C.F.R. § 483.25. I conclude however, that CMS has failed to show that the regulatory violation

prevented Resident 2 from attaining and maintaining his highest practicable state or posed a risk for any other harm. The evidence also fails to show that any other residents were at risk for harm.

Surveyor Applegate opined in the SOD that Resident 2 suffered actual harm due to the deficiency. CMS Ex. 1, at 1. However, the foundation for Surveyor Applegate's opinion that the missed or delayed laboratory work and missed or delayed physician visits caused deterioration of the resident's foot or other harm is not in the record. She testified that she did not know whether there may have been a different result if all the laboratory reports had been done on time and no appointments had been missed. She opined that Petitioner's failings prevented the physicians from altering their treatment. But, she cited no evidence to show that any physician altered treatment or might have altered treatment based upon the presence or absence of any laboratory result or any of the missed appointments. Tr. at 159. Thus, Surveyor Applegate's opinion is based on nothing more than mere speculation. Surveyor Applegate admitted on cross-examination that there was evidence that the heel wound actually showed signs of some improvement between the resident's admission to Petitioner on December 11, 2009 and his transfer to the hospital on January 15, 2010. Tr. at 166. She admitted on cross-examination that Dr. Khairy did not direct that he see Resident 2 prior to December 30, 2009; he did see the resident on that date; he had all the laboratory reports done to the date; and he issued new orders that did not change treatment. Tr. at 169-70. Surveyor Applegate faulted Petitioner for not arranging for Resident 2 to see Dr. Seiter on December 21, 2009. But she pointed to no evidence that the failure of the resident to attend an appointment with Dr. Kenneth Seiter on December 21, 2009, had any impact upon the resident's condition or that there was a risk for harm to Resident 2 or any other resident. Tr. at 208-09.

CMS relies upon the report of Dr. Jason Seiter as evidence that the resident experienced harm. CMS Br. at 15; CMS Reply at 4. CMS's reliance is misplaced. CMS asserts that because Dr. Jason Seiter characterized the "resident's wound as gangrenous" the wound was actually worse than evaluated by Petitioner's staff. Dr. Jason Seiter was not Resident 2's regular podiatrist and there is no evidence that he had ever seen the resident previously or that he had reviewed the resident's records. The fact that he was Dr. Kenneth Seiter's partner does not support an inference that Dr. Jason Seiter was familiar with the resident's wound or its appearance prior to his observation on January 15, 2010. Dr. Jason Seiter does not purport to compare the status of the wound on January 15, 2010 with the status of the wound when it was last observed by Dr. Kenneth Seiter on December 30, 2009, or when Resident 2 was released from Sparks on December 11, 2009. Furthermore, as already noted, Dr. Jason Seiter's description of the wound is little different from that of the wound nurse. Dr. Seiter's characterization of the wound having dead black tissue is consistent with both eschar and gangrene. CMS did not call Dr. Jason Seiter as a witness so it is not established whether he considered gangrene to be different than eschar, which is by CMS's own definition, dead black or brown tissue.

I conclude that CMS has failed to show that Resident 2 suffered any harm or that any other resident was at risk for harm due to Petitioner's violation of 42 C.F.R. § 483.25. CMS must show a risk for more than minimal harm due to a statutory or regulatory violation in order to have a basis for and authority to impose an enforcement remedy. CMS has failed to make a prima facie showing of noncompliance. Accordingly, there is no basis for the imposition of an enforcement remedy.

d. Petitioner's Evidence

If one concluded that CMS satisfied its burden to make a prima facie showing, triggering Petitioner's burden to rebut the CMS case, Petitioner has satisfied its burden. Petitioner presented evidence that was also presented by CMS. The cumulative evidence is not discussed again here as it does not alter the findings of fact already set forth. I discuss the evidence Petitioner presented that rebuts the CMS evidence that there was a risk for more than minimal harm.

Petitioner presented additional medical evidence not presented by CMS and I infer not evaluated by Surveyor Applegate when she made her findings and conclusions in the SOD. On October 27, 2009, Dr. Haraway, Resident 2's wound care therapy physician, writes that following examination of the resident he noted the presence of a large eschar on the resident's right heel with a foul-smelling odor coming from the area. P. Ex. 13, at 3. Dr. Haraway also noted that following debridement of the area, there was no purulent material but there was necrotic, dark tissue under the eschar. P. Ex. 13, at 4. On October 28, 2009, Dr. Kenneth Seiter noted that the resident's right heel ulceration did probe to the bone; that there was malodor from the heel area; and that there was extensive destruction, tissue necrosis, and damage to underlying muscle tendon, and bone, as well as the supporting structures within the area. P. Ex. 14, at 2-3. Dr. Kenneth Seiter's notes indicate that he believed that any attempt to salvage the lower right leg would fail and that Resident 2 would be better off if the leg was amputated before his infection progressed and killed him. P. Ex. 14, at 4. In a discharge summary dated December 11, 2009, Dr. Trevor Hodge provided an overview of the resident's medical problems, the treatment he received while at Sparks, listed consultations the resident had received, and what care was recommended for follow-up. In the summary Dr. Hodge noted that "orthopedic surgery" recommended that the resident have an amputation, and that the family refused. P. Ex. 12, at 1-2.

Following the December 30, 2009 office visit with Resident 2, Dr. Kenneth Seiter again wrote that Resident 2 would best be served by an amputation but the family resisted despite his warning that a right below the knee amputation would be required to avoid sepsis. P. Ex. 14, at 9. Dr. Seiter also noted on December 30, that he had discussed the resident's status with Dr. Khairy, and that they were "both in agreement that the patient requires a below-knee amputation of the lower right extremity as his debilitated state inhibits him from successful wound closure." P. Ex. 14, at 9.

In a note dated January 14, 2010, Dr. Agent, the resident's primary care physician, notes that he discussed with Dr. Haraway Resident 2's care and that the resident was to see Dr. Seiter to discuss a right heel debridement and "probable amputation." Dr. Agent notes that he talked with the resident and his family regarding the below the knee amputation and they consented to it. P. Ex. 16, at 4.

Petitioner called Phillip K. Bobo, MD, a consultant to North Port Health Services, the owner of Petitioner. Tr. at 520; P. Ex. 20, at 4-5. Dr. Bobo testified that he reviewed Resident 2's medical records from the facility, the medical records from Sparks, and notes from the resident's treating physicians. Tr. at 528-29. Dr. Bobo testified that in reviewing the hospital records he noted that black eschar was identified, which is gangrene. Tr. at 546, 570. Dr. Bobo's statement is supported by Dr. Buie's January 15, 2010 notation that Resident 2 had been treated for gangrene earlier in the year. P. Ex. 18, at 1. Dr. Bobo opined that amputation was inevitable and that Petitioner's staff did an excellent job maintaining Resident 2 as well as they did. Tr. at 529. He testified that the resident's primary care physician was actually in charge of the resident's care so long as Resident 2 was in a nursing home. Tr. at 531. He testified that the primary care physician was the physician that needed to see the laboratory reports to coordinate care and he did. He testified that only the primary care physician has authority to change orders anyway. Tr. at 533-34. Dr. Bobo explained that because Resident 2 was in a nursing home the infectious disease physician would make recommendations to the resident's primary care physician, Dr. Agent. Tr. at 555- 61. Dr. Bobo testified that the clinical records show that Resident 2's primary care physician had been looking at the resident's wound and was knowledgeable about the resident's condition. Tr. at 556. Dr. Bobo further testified that the method and manner of medical care provided to Resident 2 was consistent with the type of care for his medical condition. He opined that given the number of specialists involved with Resident 2, "he had excellent care," noting that every specialty was covered with an infectious disease physician, an orthopedic surgeon, podiatrists, and the primary care physician all involved in the residents care. Tr. at 530. Dr. Bobo testified that he reviewed Dr. Kenneth Seiter's notes and it was clear from those notes that Dr. Seiter expected no improvement and believed that amputation was necessary. Tr. at 541-42. He testified that he reviewed the laboratory reports in issue and concluded that there was no negative impact to Resident 2 and no impairment of the delivery of care and services by the physicians due to the availability or unavailability of the specific reports to any of the physicians. Tr. at 552-53. He opined that the missed appointments with Dr. Seiter and Dr. Khairy had no negative impact. He testified that he was not sure why the resident needed to be taken to Dr. Khairy's office at all and it may have been better had the resident not been required to leave Petitioner's facility for appointments. Tr. at 556-57, 568-69. I have no reason to discount the credibility of Dr. Bobo; he articulated bases for his opinions; and I conclude that his opinions are sufficiently weighty to rebut the opinion of Surveyor Applegate that the resident suffered harm.

Petitioner's Director of Nursing (DON), Cassie White, also testified, consistent with the clinical records in evidence, that Resident 2 had drainage from the day of admission and the presence of drainage did not reflect a change of condition. Tr. at 602. This testimony is unrebutted.

e. Further Analysis Related to Rebuttal of the CMS Prima Facie Case

If CMS makes a prima facie showing of noncompliance the prior Board decisions already discussed, impose the burden upon Petitioner to rebut the prima facie showing or to prove an affirmative defense. I conclude based upon all the evidence that, if CMS is found to have made a prima facie showing of noncompliance, Petitioner has rebutted that showing. The clinical records in evidence and the opinions of Dr. Bobo and DON White show that it was more likely than not that Resident 2 suffered no harm due to Petitioner's failure to ensure that Resident 2 attended all ordered physician appointments and to ensure that all laboratory reports were done and delivered to the infectious disease physician.

4. No enforcement remedy is authorized or reasonable in this case.

I have concluded that Petitioner remained in substantial compliance. Therefore, no enforcement remedy is authorized or reasonable. 42 C.F.R. § 488.402(b). Further, Petitioner was not ineligible to conduct a NATCEP for two years from the end of the survey.

III. Conclusion

For the foregoing reasons, I conclude that Petitioner remained in substantial compliance and no enforcement remedy is reasonable.

/s/
Keith W. Sickendick
Administrative Law Judge