Department of Health and Human Services

DEPARTMENTAL APPEALS BOARD

Civil Remedies Division

Grace Nursing Home
(CCN: 19-5258),

Petitioner

v.

Centers for Medicare and Medicaid Services.

Docket No. C-09-623

Decision No. CR2250

Date: September 24, 2010

DECISION

Petitioner, Grace Nursing Home (Petitioner), challenges the decision of the Centers for Medicare and Medicaid Services (CMS) that it was not in substantial compliance with program participation requirements and CMS's imposition of remedies, including a per instance civil money penalty (PICMP) totaling $10,000 and loss of Petitioner's ability to operate a nurse aide training and competency evaluation program (NATCEP). For the reasons discussed below, I affirm CMS's determination and the imposed remedies.

I. Background

On May 1, 2009, the Louisiana Department of Health and Hospitals (state survey agency) completed an annual survey at Petitioner's Clinton, Louisiana facility. CMS notified Petitioner by letter dated June 11, 2009 that Petitioner was determined not to be in substantial compliance with certain federal requirements governing participation in the Medicare and Medicaid programs for long term care facilities. CMS (Exhibit) Ex. 1, at 1-2. Specifically, CMS advised that it agreed with the findings of the state survey agency that Petitioner was not in substantial compliance with the requirements of F-309, 42

C.F.R. § 483.25 (2008) and F-490, 42 C.F.R. § 483.75 (2008) and that these particular deficiencies constituted immediate jeopardy to the health and safety of the residents at Petitioner's facility. *Id.* Petitioner was also cited for several other deficiencies at the non-immediate jeopardy level. *Id.* CMS stated that it was imposing several enforcement remedies including the termination of Petitioner's Medicare provider agreement, a PICMP in the amount of $10,000 for the violation of F-309, 42 C.F.R. § 483.25, denial of payment for all new Medicare and Medicaid admissions (DPNA), and the loss of approval of Petitioner's NATCEP. *Id*. By letter dated July 9, 2009, CMS advised Petitioner that it had achieved substantial compliance with the requirements for Medicare participation and certain enforcement remedies had been rescinded. CMS Ex. 1, at 4-5. However, the imposed PICMP and the loss of the NATCEP remained in effect. Petitioner requested a hearing by letter dated July 29, 2009.

I held the hearing in New Orleans, Louisiana from January 11-12, 2010. At the hearing, I admitted CMS Exs. 1-16 and Petitioner's Exhibits (P. Exs.) 1-24. A transcript of the hearing was prepared (Tr.). The parties also submitted prehearing briefs (CMS or P. Prehearing Br.) CMS submitted a post-hearing brief (CMS Br.), and Petitioner submitted a closing argument brief (P. Br.) and a response to CMS's closing argument (P. Rep. Br.).

II. Issues

1. Whether Petitioner was out of substantial compliance with Medicare participation requirements.

2. Whether CMS's determination as to the immediate jeopardy level of noncompliance was clearly erroneous.

3. Whether the enforcement remedies imposed by CMS are reasonable.

III. Applicable Law

The statutory and regulatory requirements for Medicare participation by a long-term care facility are found at sections 1819 (skilled nursing facility or SNF) and 1919 (nursing facility or NF) of the Social Security Act (Act), and at 42 C.F.R. Part 483. Section 1819(h)(2) of the Act vests the Secretary of the Department of Health and Human Services (Secretary) with authority to impose enforcement remedies against a SNF for failure to comply substantially with federal participation requirements established by sections 1819(b), (c), and (d) of the Act (section 1919(h)(2) of the Act gives similar enforcement authority to the states). Included among these remedies are: termination of a noncompliant facility's participation in Medicare; imposition of a DPNA; CMPs; and appointment of temporary management. Act § 1819(h)(2)(B). The Secretary has

delegated authority to CMS and the states 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 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, including imposition of CMPs. 42 C.F.R. § 488.406. CMS may impose a CMP for each day a facility is not in substantial compliance, or for each instance of noncompliance. The regulation provides 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, from $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). CMS is authorized to impose a PICMP from $1,000 to $10,000, whether or not an immediate jeopardy situation is identified. 42 C.F.R. § 488.438(a)(2).

The Act and regulations make a hearing before an ALJ available to a long-term care facility against which CMS has determined to impose an enforcement remedy. Act § 1128(A)(c)(2); Act § 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*, 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 Pavilion*, DAB No. 2030 (2006); *Residence at Salem Woods*, DAB No. 2052 (2006). A facility has a right to appeal a "certification of noncompliance leading to an enforcement remedy." *See* 42 C.F.R. § 488.408(g)(1); *see also* 42 C.F.R. §§ 488.330(e), 498.3. However, CMS's choice of remedies, 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 that CMS finds, if a successful challenge would affect the range of the CMP that CMS could impose or impact the facility's authority to conduct a NATCEP. 42 C.F.R. §§ 498.3(b)(14), 498.3(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 Ctr. v. Thompson*, 363 F.3d 583 (6th Cir. 2003). The Departmental

Appeals Board (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. 1750 (2000). ALJ review of a CMP is subject to 42 C.F.R. § 488.438(e).

IV. Burden of Proof

As an evidentiary matter, CMS must set forth a *prima facie* case that a facility is not in substantial compliance with Medicare participation requirements. Petitioner then has the burden of coming forward with evidence sufficient to establish the elements of any affirmative argument or defense, and bears the ultimate burden of persuasion. To prevail, Petitioner must prove, by a preponderance of the evidence that it was in substantial compliance with relevant statutory and regulatory provisions. *See Hillman Rehab. Center*, DAB No. 1611 (1997), *aff'd*, No. 98-3789, 1999 WL 34813783 (D.N.J. May 13, 1999); *Cross Creek Health Care Center,* DAB No. 1665 (1998); *Emerald Oaks,* DAB No. 1800; *Batavia Nursing & Convalescent Center,* DAB No. 1904 (2004), *aff'd, Batavia Nursing & Convalescent Center v. Thompson*, 129 F. Appendix 181 (6th Cir. 2005); *Batavia Nursing & Convalescent Inn,* DAB No. 1911 (2004).

V. Findings of Facts, Conclusions of Law, and Discussion

I make findings of fact and conclusions of law to support my decision in this case. I set forth each finding below, in italics, as a separate heading. I discuss each finding in detail. I do not, however, make a finding on every deficiency cited in the statements of deficiencies. I discuss only those examples I find to be necessary to support the noncompliance and the remedy imposed. *See Community Skilled Nursing Center*, DAB No. 1987 (2005); *Batavia Nursing and Convalescent Inn*, DAB No. 1911 (2004); *Beechwood Sanitarium*, DAB No. 1824, at 19-22 (2002).

1. Petitioner was out of compliance with the participation requirement at 42 C.F.R. § 483.25 (F Tag 309) as of the survey completed on May 1, 2009.

This regulation requires that each resident of a facility must receive, and the facility must provide, the necessary care and services to attain or maintain a resident's highest practicable physical, mental, and psychosocial well-being, in accordance with the resident's comprehensive assessment and plan of care. The State surveyor found that Petitioner did not meet this requirement based on clinical record review, review of the Petitioner's policy and procedure manual, and interviews with Petitioner's staff. Specifically, the surveyor found that Petitioner failed to ensure that ordered PT (Prothrombin Time)/ INR (International Normalized Ratio) testing was performed on a

resident on anticoagulant therapy with ordered PT/INR laboratory studies on specific days of the week. I sustain the deficiency citation, as I explain below.

This case involves the care that Petitioner provided during the week of September 15, 2008 to September 19, 2008. The State Surveyor, Sandra Mizell, R.N. (Surveyor Mizell) cited Petitioner for a violation of F-309, 42 C.F.R. § 483.25 "Quality of Care," based on Petitioner's failure to ensure that PT/INR testing was performed on the days ordered for one particular resident at Petitioner's facility, Resident 1. CMS contends that Surveyor Mizell reviewed the facility's policy on orders for anticoagulants and determined that the facility violated its own policy, which required orders for anticoagulants be prescribed only with proper clinical and laboratory monitoring. CMS Br. at 6-8.

The May 1, 2009 statement of deficiencies asserts that Petitioner was out of compliance with 42 C.F.R. § 483.25 at the level of immediate jeopardy[1] and recites that Petitioner:

> "placed one of fourteen residents receiving Coumadin therapy (R1) in immediate jeopardy when the ordered PT/INR studies were not drawn for one week on Monday, Wednesday, and Friday. When the PT/INR was drawn on the following Monday, the resident had critical lab values and Coumadin Toxicity. The facility failed to:
> a) ensure residents on Coumadin therapy did not develop Coumadin Toxicity.
> b) have a system in place to ensure PT/INR laboratory studies were obtained as ordered.

[1] Scope and severity levels are used by CMS and a state when selecting remedies. The scope and severity level is designated by an alpha character, A through L, selected by CMS or the state agency from the scope and severity matrix published in section 7400E of the State Operations Manual (SOM). *See* 42 C.F.R. § 488.408. 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. 42 C.F.R. § 488.301. 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. The matrix, which is based on 42 C.F.R. § 488.408, specifies which remedies are required and optional at each level based upon the frequency of the deficiency, i.e., whether a deficiency is isolated, part of a pattern, or widespread. *Id.* The immediate jeopardy level deficiencies under review here were found to be at a level J, which indicates that they are isolated.

c) follow, revise, and update the Care Plan related to anticoagulant therapy for the resident.

CMS Ex. 2, at 16-17.

Petitioner's Care of Resident 1

Resident 1 was admitted to Petitioner's facility on September 10, 2008 with diagnoses that included atrial fibrillation, respiratory insufficiency, congestive heart failure, chronic obstructive pulmonary disease, lung edema, septicemia, coronary atherosclerotic vascular disease, hypertension, and cardiomegaly. CMS Ex. 2, at 18. Resident 1 was prescribed anticoagulant (blood thinning) medication including a daily dose of Coumadin. CMS Ex. 7, at 5-7; Tr. at 45. The admitting physician ordered that PT/INR lab studies be performed every Monday, Wednesday, and Friday to monitor Resident 1's Coumadin therapy. Tr. at 45, 51. When Resident 1 was admitted, she was on Coumadin therapy at 8 milligrams a day, a fairly large dose. Tr. at 50.

On September 22, 2008 PT/INR testing was performed on Resident 1. Resident 1's Protime (PT) level was 47.5, which is very high and far above the normal range of 11 to 13.5. Tr. at 55-56. Ten days previously, on the date of Resident 1's last recorded PT/INR test, her level had been recorded as 12.3, within the normal range. Tr. at 55. Resident 1's INR level was recorded as 15.1 on September 22, 2008, also far above the normal range of .7 to 1.2. Tr. at 55-56. Resident 1 had recorded an INR level of 1.0 ten days before, shortly after being admitted to Petitioner's facility. Tr. at 56. On September 22, 2008, Resident 1 was determined to have critical PT/INR levels and was immediately sent to the hospital emergency room for treatment and evaluation. CMS Ex. 7, at 11, 39; Tr. at 55. Resident 1 was treated in the hospital for approximately a week, from September 22, 2008 to September 29, 2008. Tr. at 57. While in the hospital, Resident 1's primary diagnosis was Coumadin toxicity. CMS Ex. 7, at 1, 4 ; Tr. at 57.

At hearing, Surveyor Mizell testified that Coumadin therapy flow sheets were generally used by the facility to record PT/INR testing results. Tr. at 55. Petitioner's flow sheets regarding Resident 1 indicated that the last PT/INR test was performed on September 12, 2008 and testing was not performed again until September 22, 2008. CMS Ex. 7, at 8-9; Tr. at 55. Surveyor Mizell also reviewed the nurses' notes between September 12, 2008 and September 22, 2008 and could find no documentation as to why no blood work was completed on Monday, Wednesday or Friday during the week of September 15, 2008. Tr. at 53. Petitioner now asserts that Resident 1 refused venipunctures for blood work for PT/INR lab studies during the timeframe in question, however Surveyor Mizell found no written record of any refusal in Resident 1's medical records. Tr. at 173.

Surveyor Mizell also testified that she conducted an interview on April 30, 2009 with the MDS nurse that wrote the assessments when new residents came into the facility. During

that interview, the nurse admitted that Resident 1 did not have a specific care plan for anticoagulation therapy that included monitoring side effects and symptoms. Tr. at 58-60. In addition, Surveyor Mizell testified that during the interview the MDS nurse confirmed that no PT/INR testing was completed on Resident 1 during the week of September 15, 2008. Tr. at 60. Moreover, during an interview with the Director of Nursing (DON), the DON confirmed that there were no testing results of Resident 1's PT/INR levels recorded during the week of September 15, 2008. Tr. at 60. The DON also confirmed that when the PT/INR levels were analyzed after a week, the results were abnormal and Resident 1 was sent to the hospital for drug toxicity. Tr. at 59-61. Surveyor Mizell testified that Coumadin toxicity is very serious and occurs when a resident's blood becomes too thin, resulting in the resident's becoming vulnerable to life-endangering bleeding. Tr. at 46. Based upon her review of the records and interviews with Petitioner's staff, Surveyor Mizell concluded that Petitioner failed adequately to ensure that residents on anticoagulant therapy did not develop Coumadin toxicity. Tr. at 61, 68-72.

CMS Presented a *Prima Facie* Case That Petitioner Was Not In Substantial Compliance

Petitioner's policy required that the lab values of residents on anticoagulants be properly monitored. CMS Ex. 9; Tr. at 47-49. Resident 1 was on 8 milligrams a day of Coumadin, a fairly large dose, when admitted to Petitioner's facility. Tr. at 50. Surveyor Mizell testified that she reviewed the nurse's notes to ascertain if there was a reason why the PT/INR tests were not performed as ordered for such a large dose, however, the nurse's notes provided no explanation for the lack of PT/INR testing for the period from September 12, 2008 until September 22, 2008. Tr. at 52-54; CMS Ex. 7 at 8-9.

Surveyor Mizell concluded that Petitioner's failure to adhere to its own policy posed immediate jeopardy to Resident 1's health and safety, and resulted in Resident 1's being hospitalized because of those critical lab values and Coumadin toxicity. Tr. at 61, 70. Petitioner's own policy may be relied upon as "evidence of the standard of care the facility expects its staff to provide" and evidence of the professional standards of care. *Life Care at Hilton Head*, DAB CR1908 (2009) (citing *The Laurels at Forest Glen*, DAB No. 2182 (2008)). The testimony of Surveyor Mizell, including her interviews with Petitioner's staff and review of the nurses' notes, is *prima facie* evidence of Petitioner's noncompliance with F-309, 42 C.F.R. § 483.25.

Additionally, CMS presented a witness, Captain Daniel McElroy, R.N., a Nurse Consultant responsible for nursing home regulatory enforcement, to testify that Petitioner was not in substantial compliance with F-309, 42 C.F.R. § 483.25. Tr. at 156-57. Captain McElroy testified that Resident 1 was at high risk for side effects and that the standard of care required close monitoring for patients on a high dose of anticoagulant

medication. Tr. at 159. Captain McElroy also testified regarding the lack of documentation PT/INR testing and consults with Resident 1's physician regarding the inability to perform the physician's orders. Tr. at 159, 173, 178. Captain McElroy stated that based upon his review of the events, Resident 1 was placed in immediate jeopardy and at risk for serious injury or death from potential blood clots, stroke, or severe bleeding because Petitioner did not monitor Resident 1's level of Coumadin. Tr. at 159, 186.

Thus, CMS has met its burden of presenting a *prima facie* case that Petitioner was not in substantial compliance with F-309, 42 C.F.R. § 483.25. CMS presented evidence of Petitioner's failure to ensure the physician ordered PT/INR tests were performed every Monday, Wednesday and Friday to monitor Resident 1's dosing of Coumadin and failure to comply with its own policy which required that orders for anticoagulants be prescribed only with proper clinical and laboratory monitoring. "The failure to perform basic nursing monitoring and assessment and to provide the resident with continuous support are egregious failures to comply with professionally recognized standards of nursing care and the requirement of 42 C.F.R. § 483.25. Those failures are enough, by themselves, to establish noncompliance." *Emerald Park Health Care Center*., DAB CR1462 (2006).

Petitioner Has Not Proven By A Preponderance of the Evidence That it Was in Substantial Compliance

Petitioner has failed to meet its burden of proving by a preponderance of the evidence that it provided the necessary care and services to Resident 1. Petitioner did not demonstrate that it was in substantial compliance with Medicare and Medicaid participation requirements, specifically 42 C.F.R. § 483.25. Petitioner's witnesses, Keisha McMillan, Melissa Redditt, Kaley Hill, Dr. Richard Rathbone did not adequately address Petitioner's failure to perform PT/INR testing for Resident 1 as ordered during the week of September 15, 2008 or sufficiently explain why the nurses' notes and other documentation lacked explanation as to why PT/INR laboratory monitoring was not performed.

Petitioner contends that the staff attempted to obtain Resident 1's PT/INR levels during the week of September 15, 2008, however, Resident 1 refused to allow staff to draw her blood. P. Br. at 15-16. Petitioner also contends that Resident 1's treating physician, Dr. Rathbone, was notified of Resident 1's refusals and instructed staff members to continue to attempt to obtain the ordered PT/INR tests. P. Br. at 18; P Rep. Br. at 5-6. However, Petitioner did not provide a consistent explanation as to why the nurses' notes contain no reference to the fact that Resident 1 refused the ordered PT/INR draws or why the nurses' notes failed to document that the physician was notified that the ordered PT/INR tests were not being performed. Tr. at 279-80, 303-04. Also, although Petitioner attempts to argue that the PT/INR testing every Monday, Wednesday, and Friday was unnecessary during this timeframe and was not ordered by Dr. Rathbone, Petitioner seemingly

contradicts this by also arguing that it did attempt to follow the transferring physicians orders and Dr. Rathbone ordered the nurses to "keep trying" when he learned the PT/INR testing could not be completed on the days previously ordered. P. Br. at 18-19; P. Rep. Br. at 5-6. Dr. Rathbone specifically testified that he was informed of Resident 1's refusal to participate in PT/INR checks on September 15, 2008, September 17, 2008, and September 19, 2008 and instructed staff from the facility to keep attempting to obtain blood work. Tr. at 169-170. However, Dr. Rathbone did not adequately explain why he allowed for Resident 1's PT/INR tests to not be performed as previously ordered or why there is absolutely no documentation of Resident 1's purported refusals of treatment during the week of September 15, 2008 and staff communication regarding the purported refusals. When asked why Petitioner did not document that these critical tests were not being performed, Dr. Rathbone stated that "it could be that they were busy documenting the entire last week". Tr. at 390. Furthermore, Surveyor Mizell testified that the staff did not volunteer information that Resident 1 was refusing treatment in her interviews with them. Tr. at 136.

It is clear that a facility cannot adequately monitor Coumadin levels without testing a resident's PT/INR levels. *Saturn Nursing and Rehab Center.*, DAB CR1826 (2008). As CMS points out, if a refusal of treatment had occurred, Petitioner should have recorded the refusal, recorded the reasons for the refusal, and recorded that the facility conveyed to the resident the consequences of such a refusal. CMS Br. at 7, f.n. 4; Tr. at 173. Finally, if Resident 1 had truly refused treatment during the relevant period, Petitioner should have had a system in place to deal appropriately with such a refusal. Petitioner has not shown by a preponderance of the evidence that it had implemented a system to approach and address correctly Resident 1's refusal of physician-ordered PT/INR monitoring.

Petitioner also contends that its staff was operating under an increased burden as a result of the influx of new residents and other exceptional circumstances created as a result of Hurricanes Ike and Gustav. Petitioner essentially argues that the lack of documentation of Petitioner's system at this time was reasonable. For example, Melissa Redditt, the Director of Nurses (DON) at Petitioner's facility testified that during this time period the system became "skewed" due to moving residents and nurses have to spend a great deal of time providing care and reassurance to residents. Tr. at 320-21. Kaley Hill, a registered nurse at Petitioner's facility also testified that additional demands were placed on staff during this period and patient care became difficult under such extraordinary conditions. Tr. at 351-54. Also, Keisha McMillan, the licensed practical nurse (LPN) who provided care to Resident 1 during the week of September 15, 2008 testified regarding the difficulties in caring for residents during this period and stated that she was spending much more time providing direct patient care and had less time available for documenting. Tr. at 296. She stated that Petitioner's records lack essential documentation because "we were focusing on care at the time." Tr. at 304.

Petitioner also asserts that compliance with certain regulations was temporarily waived when the Secretary of HHS declared a public health emergency as a result of Hurricanes Ike and Gustave. P. Br. at 24-31. However, CMS presented testimony the quality of care requirements of 42 C.F.R. Part 483 had not been waived during the survey period in question. Tr. at 170. CMS contends that the waivers applicable during the relevant time period were intended to be administrative in nature and designed to facilitate access to care and to allow for reimbursement to a facility in times of emergency. CMS Br. at 19. CMS argues that the waiver cannot be used as a rationale for a facility to provide substandard care to residents, especially those residents on powerful medications which require proper clinical and laboratory monitoring. Tr. at 191-92, 215. The CMS Regional Office previously articulated which specific regulations were of critical importance to the care of residents during an emergency and the regulation at issue was not determined to be waivable. Tr. at 170. Captain McElroy testified that although the emergency situation regarding the hurricane would have been considered by CMS in its enforcement decision, it would not have affected the ultimate determination as to whether Petitioner was found to be noncompliant at the immediate jeopardy level. Captain McElroy stated that "[t]here's a certain level of care that people need. And we're talking in this case basic safety in giving a very dangerous drug for very dangerous conditions. . . And this one . . . rises to a level that whatever the situation was at the time that that's not sufficient to say it's okay." Tr. at 202-03.

The Waiver or Modification of Requirements under Section 1135 of the Social Security Act states that the Secretary waives or modifies "requirements of Title XI of the Act, and regulations thereunder, insofar as they relate to Titles XVIII, XIX, or XXI of the Act, but in each case, only to the extent necessary, as determined by the Centers for Medicare & Medicaid Services, to ensure that sufficient health care items and services are available to meet the needs of individuals enrolled in the Medicare . . . programs . . ." P. Ex 8, at 1. In this case, CMS determined that its regulations, specifically the quality of care requirements of 42 C.F.R. § 483.25 would not be waived under the circumstances. CMS was vested with the authority to make this decision, and I will not disturb CMS's determination.

Essentially, Petitioner contends that the fact that no ordered PT/INR testing was performed on Resident 1 during the week of September 15, 2008 was reasonable under the circumstances. However, the circumstances alone do not excuse Petitioner's failure to comply with the basic requirements of 42 C.F.R. § 483.25 to provide quality care. I have taken into account the extraordinary circumstances at Petitioner's facility during this period and I recognize that Petitioner was attempting to deal with a difficult situation. Nothing in this decision should be understood to trivialize or to minimize the challenges — implicit and explicit — in the effects of two hurricanes and an influx of new residents at Petitioner's facility, and nothing in this decision should be understood to marginalize or to undervalue the remarkable efforts extended by all of Petitioner's staff and management in meeting those challenges. However, though Petitioner was quite

obviously operating under suboptimal conditions, these facts alone do not excuse Petitioner's failure to comply with federal regulations which require that necessary care and services remain available to meet the needs of residents.

I find that Petitioner was not in substantial compliance with F-309, as this regulation has been interpreted to require a facility to provide its residents with care that meets professionally recognized standards of care. *Royal Manor*, DAB No. 1990 (2005). CMS has provided strong evidence that Petitioner was not providing Resident 1 with care consistent with regulatory standards and Petitioner has not presented adequate evidence to prove it was in substantial compliance with program requirements. Thus, I conclude that Petitioner did not provide the care and services necessary to allow Resident 1 the highest practicable physical well-being in accordance with federal requirements.

2. Petitioner does not have a right to challenge F-490, 42 C.F.R. § 483.75, because CMS did not impose a remedy against Petitioner as a result of F-490.

The hearing rights of a long-term care facility are established by federal regulations at 42 Part 498. A provider dissatisfied with CMS's initial determination is entitled to further review, but administrative actions that are not initial determinations are not subject to appeal. 42 C.F.R. § 498.3(d). The regulations specify which actions are "initial determinations" and sets forth examples of actions that are not. A finding of noncompliance that results in the imposition of a remedy specified in 42 C.F.R. § 488.406 is an initial determination for which a facility may request an administrative law judge (ALJ) hearing. 42 C.F.R. § 498.3(b)(13). No right to a hearing exists pursuant to 42 § 498.3(b)(13), unless CMS actually imposes one of the specified remedies. *Lutheran Home – Caledonia*, DAB No. 1753 (2000). The remedy, not the citation of a deficiency, triggers the right to a hearing. *Schowalter Villa*, DAB No. 1688 (1999); *Arcadia Acres, Inc.*, DAB No. 1607 (1997).

It is clear that the finding of noncompliance with F-490, 42 C.F.R. § 483.75 did not result in the imposition of a remedy specified in 42 C.F.R. § 488.406. The PICMP imposed related specifically to F-309. CMS Ex. 1, at 2. Also, Act § 1819(f)(2)(B) and § 1919(f)(2)(B) prohibit an NATCEP to be offered by any facility which was assessed a CMP of not less than $5,000 within the previous two years. Thus, because CMS did not impose a remedy relating to this deficiency, Petitioner has no right to a hearing to challenge Tag F-490.

3. CMS's immediate jeopardy finding is not clearly erroneous.

Immediate jeopardy is defined as a situation in which a facility'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. CMS's determination as

to the level of noncompliance must be upheld unless it is clearly erroneous. 42 C.F.R. § 498.60(c). Under the clearly erroneous standard, CMS's immediate jeopardy finding is presumed to be correct, and the facility has a heavy burden to overturn it. *Stone County Nursing & Rehabilitation Center*, DAB No. 2276, at 17; *Edgemont Healthcare*, DAB No. 2202, at 20 (2008); *Daughters of Miriam Center*, DAB No. 2067, at 7 (2007).

Petitioner placed Resident 1 in immediate jeopardy when it failed to perform physician ordered PT/INR tests for a 10 day period, resulting in the resident being hospitalized for critical lab values and Coumadin toxicity. Resident 1 experienced dangerous levels of Coumadin and the INR level fluctuated from 1.0 to 15.1 in tests taken in September of 2008. Tag F-329 details that an INR level above 9.0 is considered immediate jeopardy. Tr. at 184.

Immediate jeopardy has been found when the Petitioner did not act reasonably to ensure that the resident received necessary are and services as required by 42 C.F.R. § 483.25, as in this case when the physician's orders were not properly followed. *Sunnyview Nursing Home & Apartments*, DAB CR 1745 (2008). Petitioner's failure to perform physician ordered PT/INR testing placed Resident 1 at risk of serious injury, harm, impairment or death as Resident 1 could have developed a blood clot, suffered a stroke, or developed uncontrollable bleeding. Tr. at 159, 175. Although Petitioner argues that Resident 1 was not at risk of serious injury or death during the period from September 15, 2008 to September 19, 2008 because she exhibited no other side effects, signs, or symptoms of bleeding and bruising which would indicate any clinical complications were present, the fact remains that Petitioner's failure to monitor Resident 1's dosing of Coumadin resulted in an abnormally high lab reading and in Resident 1's being hospitalized for Coumadin toxicity for a week.

CMS's determination is thus, in this instance, not clearly erroneous. Because I have concluded that CMS's determination was not clearly erroneous, I do not address CMS's argument that Petitioner may not challenge CMS's immediate jeopardy determination given CMS's imposition of a PICMP.

4. The remedies imposed are reasonable.

CMS imposed remedies consisting of a PICMP in the amount of $10,000 for F-309 and the loss of Petitioner's NATCEP. I find Petitioner noncompliant at a level of immediate jeopardy. A PICMP of $3050 to $10,000 per day is authorized for each day of immediate jeopardy level noncompliance. 42 C.F.R. § 488.438(a)(1)(i). Deciding on a penalty amount within this range must be based on evidence relating to factors which include: the seriousness of a facility's noncompliance; its noncompliance history; and its financial condition. 42 C.F.R. §§ 488.438(f)(1)-(4); 488.404 (incorporated by reference into 42 C.F.R. § 488.438(f)(3)). I find the single PICMP in the amount of $10,000 imposed by

CMS to be supported by evidence establishing the seriousness of Petitioner's noncompliance. In addition, CMS could have cited Petitioner for a per-day CMP for the entire week of September 15, 2008, or the entire period until the survey was conducted in May of 2009, due to the apparent ongoing nature of the immediate jeopardy. Tr. at 184-185, 192. Instead, CMS chose to impose a PICMP of $10,000.

Also, because Petitioner was not in substantial compliance with program requirements, and CMS assessed a penalty within the range authorized, I have other no authority to review CMS's choice of remedies. 42 C.F.R. § 498.3(b)(13); *see also* 488.408(g)(2). Finally, it is clear that Sections 1819(f)(2)(B) and 1919(f)(2)(B) prohibit approval of NATCEP where a facility has been subject to has been assessed a CMP of not less than $5000. Thus, I conclude that all the remedies imposed by CMS in this case were reasonable.

V. Conclusion

Because I have found Petitioner to have been out of substantial compliance with participation requirements, and at a level of immediate jeopardy, I sustain the remedies imposed by CMS, including the PICMP totaling $10,000 and the loss of NATCEP.

/s/
Richard J. Smith
Administrative Law Judge