Department of Health and Human Services

DEPARTMENTAL APPEALS BOARD

Civil Remedies Division

Lincoln Manor,
(CCN: 14-6064),

Petitioner,

v.

Centers for Medicare & Medicaid Services.

Docket No. C-17-485

Decision No. CR4903

Date: August 2, 2017

DECISION

I enter summary judgment in favor of the Centers for Medicare & Medicaid Services (CMS) and against Petitioner, Lincoln Manor, a skilled nursing facility. I sustain the imposition of civil money penalties against Petitioner of $10,091 for each day of a period that began on August 20, 2016, and that ran through September 19, 2016. I also sustain civil money penalties of $203 for each day of a period that began on September 20, 2016, and that ran through September 21, 2016. Finally, I sustain Petitioner's loss of a Nurse Competency Evaluation Program (NATCEP) for a two-year period beginning September 21, 2016.

I. Background

CMS determined to impose the remedies that I sustain based on findings of immediate jeopardy level and non-immediate jeopardy level noncompliance made at a survey of Petitioner's facility completed on September 21, 2016. CMS moved for summary judgment as to all of the deficiency findings and the remedies that it imposed. Petitioner

opposed CMS's motion insofar as it addresses the immediate jeopardy level findings of noncompliance.[1]

CMS filed 38 proposed exhibits in support of its motion for summary judgment that are identified as CMS Ex. 1-CMS Ex. 38. Petitioner objected to my receiving some of these exhibits into evidence. It filed 22 exhibits along with its opposition to the motion that are identified as P. Ex. 1-P. Ex. 22.

I do not address Petitioner's objections to CMS's exhibits nor do I rule as to the admissibility of either party's exhibits because it is unnecessary that I do so. I base my decision to grant summary judgment exclusively on the facts asserted by the parties that are not in dispute. In this decision I refer occasionally to the parties' exhibits but only to identify facts that are undisputed.

II. Issues, Findings of Fact, and Conclusions of Law

A. Issues

The issues are: whether Petitioner manifested immediate jeopardy level noncompliance with Medicare participation requirements beginning on August 20, 2016, and continuing through September 19, 2016; and whether CMS's remedy determinations are reasonable.

B. Findings of Fact and Conclusions of Law

In deciding this case I am mindful of the well-known criteria for entering summary judgment. I ground my decision only on material facts that are undisputed. I consider whether reasonable inferences favorable to Petitioner may be drawn from facts asserted by the parties.

CMS contends that during the August 20-September 19 period, Petitioner manifested immediate jeopardy level noncompliance with the following regulations:

- 42 C.F.R. § 483.10(b)(11), which requires a skilled nursing facility to immediately notify a resident's physician if the resident experiences a significant change in his or her physical, mental, or psychosocial status;

- 42 C.F.R. § 483.13(c), which provides in relevant part that a skilled nursing facility must develop and implement written policies and procedures that prohibit mistreatment, neglect, abuse of residents; and,

[1] Petitioner filed no opposition to CMS's findings of non-immediate jeopardy level deficiencies. I sustain CMS's findings in the absence of any opposition.

- 42 C.F.R. § 483.25, which requires a skilled nursing facility to provide each of its residents with the necessary care and services to attain or maintain the highest practicable physical, mental, and psychosocial well-being in accordance with that resident's comprehensive assessment and plan of care.

The undisputed material facts plainly establish that Petitioner manifested immediate jeopardy level noncompliance during the August 20-September 19 period. They amply support the remedies that CMS determined to impose. Indeed, I would sustain CMS's remedy determinations if Petitioner contravened just one of the above-cited regulations at the immediate jeopardy level of noncompliance. It is unnecessary that I find that Petitioner failed to comply with all of these regulations even though the undisputed facts strongly support my decision that Petitioner contravened all three regulations at the immediate jeopardy level of noncompliance.

CMS's noncompliance determinations all relate to the care Petitioner gave to a single resident, an individual who is identified as R-1. As of August 2016, the resident had been at Petitioner's facility for more than four years. She suffered a variety of ailments that included abnormal posture, age-related osteoporosis with fracture, unspecified hemiplegia (paralysis on one side of her body), muscle weakness, and a urinary tract infection. CMS Ex. 11 at 1, 31.

R-1 suffered from chronic pain for which she had received an implanted pain pump. The pain pump functioned by delivering prescribed amounts of pain-relieving medication via an internal catheter to a specific site in the resident's back. CMS Ex. 11 at 303. A surgeon implanted an original pump surgically in 2005. By June 2016 it had reached the end of its useful life. On June 27 of that year the resident received a new surgically implanted pump. *Id.* at 322.

Initially, the resident recovered well from the surgery. She resided at a hospital pain management center apparently until about August 1, 2016. *See* CMS Ex. 22 at 2-3. Her surgical wound had healed as of that date and did not require a dressing. *Id.*

However, there remained a potential for post-operative complications from the surgery. Petitioner's care plan in effect for R-1 after her return to Petitioner's facility acknowledged that. CMS Ex. 11 at 30. The care plan directed the facility staff to provide:

> treatment to surgical site per MD order and until healed . . . [and perform] weekly treatment documentation to include measurement of each area of skin breakdown's width, length, depth, type of tissue and exudate and any other notable changes or observations.

Id. This plan was in addition to the general plan of care for R-1, which required Petitioner's staff to monitor and document the location, size, and treatment of any skin injury and to report to the resident's physician any skin abnormalities, failures to heal, and signs and symptoms of infection. *Id.* at 17.

The resident's recovery from the surgery continued to be uneventful up until August 20, 2016. Facility records prior to that date showed that the resident's skin was intact and that she wore no dressings. CMS Ex. 11 at 65-66, 271.

However, the resident's medical condition changed significantly and dramatically beginning on August 20, 2016. On that date, a certified nursing assistant was preparing R-1 for bed when she noticed a small open wound at the site of the resident's pain pump incision. The assistant could see small piece of silvery metal, part of the resident's pain pump, inside the wound. CMS Ex. 22 at 46. The assistant notified a nurse who observed the wound and the visible metal part of the pain pump. *Id.* at 43; CMS Ex. 11 at 33. The nurse called the resident's treating physician's cell phone and left a message. It is unclear from Petitioner's records exactly what was the content of the message. In any event, the treating physician did not return the nurse's call and Petitioner's staff made no attempt to re-contact him. Petitioner's staff did not attempt to contact the surgeon who implanted the pump.

On August 20, 2016, the licensed practical nurse (LPN) placed a dressing on the wound. CMS Ex. 11 at 33; CMS Ex. 22 at 17. With the exception of that intervention there is nothing in Petitioner's records to show that Petitioner's staff provided any care for R-1's wound between August 20 and August 28, 2016. There is no record of an assessment of the wound, no documentation of orders or a care plan to treat the resident's abdominal wound, no observations of the wound, no record of treatment of the wound, and no evidence that Petitioner's staff consulted with either the resident's treating physician or the surgeon who implanted the pain pump during that period.

The only reference to the resident's wound in Petitioner's records relate to an overall skin assessment that a nurse performed on August 26, 2016.[2] CMS Ex. 11 at 271. The nurse noted the presence of a clean, dry, and intact dressing over the resident's abdominal wound, without signs of drainage. CMS Ex. 22 at 19. However, the nurse did not remove the dressing or inspect the underlying wound. Indeed, there is nothing in the record to show that Petitioner's staff changed the resident's dressing after August 20.

[2] Also, a Shower/Skin Notification Sheet dated August 25, 2016, indicates that R-1 was given a bed bath and notes only that there was a dressing for the pain pump on her abdomen. CMS Ex. 11 at 68.

The only reasonable inference that I can draw from the undisputed absence of any documentation of wound care is that staff did nothing regarding the resident's wound after placing a dressing on it on or before August 20, 2016.

Early on the morning of August 28, 2016, between 2:00 and 4:00, R-1 told a nursing assistant that she did not feel well. CMS Ex. 21 at 1. The resident appeared to be perspiring. *Id.*; CMS Ex. 24 at 3 - 4. As the assistant was providing care to the resident she noticed a brown stain on the front of R-1's hospital gown. CMS Ex. 21 at 1. She checked further and discovered the dressing over the resident's wound was saturated with fluid. *Id.* The nursing assistant reported her finding to another nursing assistant who also noticed that the resident was not looking well. One of the assistants informed the LPN that R-1 was not looking like herself but she did not apprise Petitioner's nursing staff of their findings with respect to the wound. CMS Ex. 22 at 44. Between 4:30 and 5:30 a.m. on August 28, a nurse provided care to the resident but did not notice the stain on the resident's gown and was unaware of the drainage from the resident's wound. CMS Ex. 22 at 38-39.

Nursing assistants transferred R-1 from her bed to a wheelchair at some time between 7 and 8:30 a.m. on the morning of August 28, so that she could be transported to breakfast. The resident had more difficulty standing than she normally displayed. She appeared to be groggy, her eyes were closed, and her urinary catheter was draining brownish urine. CMS Ex. 21 at 2; CMS Ex. 22 at 45. Her abdominal dressing continued to be saturated with fluid, which had soaked her gown. *Id.* Once again, the nursing assistants failed to notify a nurse of the resident's distress and the leaking wound. *Id.*

Nursing assistants transferred the resident back to bed at around 11:00 on the morning of August 28. They continued to notice fluid draining from the resident's wound onto her hospital gown and they changed the gown. However, the assistants did not notify a nurse of the resident's condition and nobody assessed the wound. CMS Ex. 21 at 2; CMS Ex. 24 at 3.

Nursing assistants continued to observe R-1 in bed. Assistants observed a brown stain on the resident's gown (the gown that had been supplied the resident at 11:00 that morning) and could detect an odor similar to that produced by an open sore. CMS Ex. 22 at 34-35. The resident's eyes were closed, she was not talking, and she had labored breathing. *Id.*

At some time after lunch on August 28, the nursing assistants finally informed a licensed practical nurse that R-1's pain pump incision was leaking drainage. CMS Ex. 22 at 24; CMS Ex. 11 at 32. In response the nurse removed the resident's dressing and found an open wound, approximately 2 ½ by 1 ½ inches in size, with the pain pump protruding about 1 ¼ inches from the wound. The nurse cleaned the wound with normal saline solution and left it open. CMS Ex. 22 at 25. At 12:46 p.m. the nurse notified the resident's family of her condition and immediately thereafter she called the resident's

physician. The physician ordered that the resident be transferred to a hospital emergency room and the nurse called an ambulance service. CMS Ex. 11 at 32.

On arrival at Petitioner's facility the ambulance technicians observed that an approximately 4 ½ inch round silver object was protruding from the resident's abdomen. CMS Ex. 11 at 291. A paramedic (nurse) found that the resident's abdominal wound was dry, indicating that the wound had opened days previously. CMS Ex. 22 at 28. He observed the wound to be about 6 inches long and about 1 ½ inches wide with the pain pump protruding about 3 inches. *Id.*

A surgeon removed the resident's pain pump on August 28. CMS Ex. 11 at 322. The surgeon noted that the resident's wound had opened along its suture line and that it had been that way for a number of days. *Id.* at 323. While in the hospital the resident's condition deteriorated and she expired on September 2, 2016, with the cause of death listed as "septic shock." *Id.* at 397-398, 426.

The undisputed facts of this case establish an appalling dereliction of duty to R-1 by Petitioner's staff. The staff was aware beginning on August 20, 2016, that the resident's surgical wound had opened, so much so that her pain pump was visible. However, the staff made no attempt to consult with the resident's treating physician between August 20 and August 28 except for a single call on the 20th that the physician did not return and that the staff did not follow up. Staff did not assess the resident's wound during the entire period between August 20 and 28. Staff did not even observe the wound during that period. Staff failed to develop a treatment plan for the wound and they provided no treatment aside from applying a dressing on August 20. On August 28, when the resident's condition deteriorated dramatically, the staff delayed consulting with the resident's physician for about nine hours, at least, from the time when a nursing assistant first noticed that drainage had soaked through wound dressing.

42 C.F.R. § 498.10(b)(11) requires facility staff to consult immediately with a resident's physician about a significant change in the resident's condition. The undisputed facts establish that Petitioner's staff failed utterly to comply with that requirement. The staff did not follow up on the unreturned call of August 20, and delayed consulting a physician for at least nine hours on August 28 when the resident deteriorated dramatically.

The regulation's requirement is plain and not subject to interpretation. A facility must immediately consult with a resident's physician whenever a resident experiences a significant change in condition. "Immediately" means just that. It does not mean leaving a phone message and failing to follow up when it isn't returned. Nor does it mean delaying calling the physician for hours after a resident's condition deteriorates dramatically. Furthermore, the regulation does not allow a facility to substitute "notification" for consultation. "Consult" means active communication and dialogue and not just leaving a message.

No reasonable clinician could argue that the resident's condition had not significantly changed on August 20, 2016. What had been a healed surgical incision opened on that date to the extent that it revealed the implanted pain pump inside the resident's abdomen. Any reasonable clinician would not only have found that development to be alarming, but would have called the resident's physician immediately. A reasonable clinician would not have left a message for the physician and failed to follow up when the physician didn't return the call. A reasonable clinician would have kept calling the physician until he or she achieved contact with the physician.

Furthermore, a reasonable clinician would have concluded immediately on August 28, 2016, that something was seriously amiss from the drainage from the resident's wound and her deteriorated physical state. The resident's condition necessitated immediate communication with a physician and not a call that was delayed for about nine hours.

Regulations define "neglect" as the failure by a facility to provide a resident with goods and services necessary to avoid physical harm, mental anguish, or mental illness. 42 C.F.R. § 488.301. Petitioner's staff neglected to provide necessary care to R-1 in contravention of the requirements of 42 C.F.R. § 483.13(c) because it failed to implement its anti-neglect policies in providing care to the resident. Petitioner had a policy requiring its staff to notify physicians of changes in resident's conditions. However, during the period beginning August 20 and running through August 28, 2016, Petitioner's staff violated that policy because they consistently failed to consult with R-1's physician about the changes in condition that the resident was sustaining. CMS Ex. 17 at 1; CMS Ex. 21 at 8; CMS Ex. 24 at 4. Moreover, Petitioner had skin and wound assessment policies that required its staff to evaluate residents with skin issues and wounds in order to assure that their needs were addressed. Petitioner's staff ignored these policies consistently during the August 20-28 period. The undisputed material facts are that beginning August 20 Petitioner's staff failed even to examine R-1's wound during the ensuing period.

The undisputed facts establish also that Petitioner's staff failed to provide the resident with necessary services, in substantial noncompliance with the requirements of 42 C.F.R. § 483.25. R-1's plan of care specifically directed Petitioner's staff to monitor, assess, and care for the site of the resident's surgery. Between August 20 and 28, 2016, the staff failed absolutely to perform these duties.

Each of these regulatory violations comprises immediate jeopardy level noncompliance. "Immediate jeopardy" is defined by 42 C.F.R. § 488.301 to mean noncompliance that causes or is likely to cause serious injury, harm, or death to a resident. On August 20, 2016, the discovery of an open wound extending into R-1's abdomen should have set off alarm bells among Petitioner's staff. That wound was a gateway for all sorts of possible complications, infection obviously being among them. And, yet, the staff did nothing to address that issue including failing to consult with the resident's physician. Petitioner's

staff's indifference to the resident's condition after August 20 compounded the dangers faced by R-1. By August 28, 2016, R-1 was in grave danger, with a massive, untreated open wound through which her pain pump protruded. The wound by that date had grown, due to the staff's failure to observe or treat it, to the extent that it provided literally a doorway into the resident's body, an entranceway that created the likelihood that the resident would suffer from a life-threatening infection.

The civil money penalties that CMS determined to impose are quite modest when measured against the severity of Petitioner's noncompliance. I have described the dereliction of duty to R-1 as appalling. That is, if anything, an understatement of the gravity of noncompliance in this case. For more than eight days Petitioner's staff did nothing to address the resident's open and expanding wound. They knew that the wound had opened but, in spite of that, they neither monitored, assessed, nor treated the wound, nor did they consult with the resident's physician. The direct consequence of that indifference was that the wound enlarged to become a gaping opening. The immediate jeopardy level civil money penalty amount that CMS determined to impose, $10,091 for each day of Petitioner's immediate jeopardy level noncompliance, is less than one-half of the regulatory maximum remedial amount. 42 C.F.R. § 488.438(a)(1)(i); *see* 45 C.F.R. § 102.3. Indeed, the undisputed material facts justify a much greater civil money penalty amount than that which CMS determined to impose.

I have considered Petitioner's arguments in opposition to CMS's motion and I find them to be without merit.

First, Petitioner argues that R-1 did not experience a significant change in her medical condition on August 20 or thereafter, and from that it contends that Petitioner's staff had no duty to consult with R-1's physician. Petitioner's Combined Pre-Hearing Brief and Response to CMS' Motion for Summary Judgment (Petitioner's brief) at 11. As purported support for this argument Petitioner asserts that the opening of the resident's surgical incision is not one of the examples of significant change listed in CMS's State Operations Manual (SOM). Thus, Petitioner contends that the resident did not experience a heart attack, a stroke, development of a Stage II pressure sore, recurrent periods of delirium, recurrent urinary tract infection, or onset of depression. *Id.*

But, these examples are just that – examples of what might constitute a significant change in a resident's condition – and not an inclusive list of all of the changes that demand consultation with a treating physician. By any measure the opening of R-1's surgical wound to the extent that the resident's pain pump was visible was a significant change. The whole point of the care plan adopted for the resident after her surgery was to protect the resident against such a development and to assure that her healing was complete. CMS Ex. 11 at 30. Staff should have reacted immediately and forcefully to evidence that the wound had reopened and it should have monitored the resident intensively thereafter in close consultation with the resident's physicians.

The changes exhibited by the resident on August 28 were not only significant but a warning of a grave deterioration in the resident's condition. On that date the resident was leaking fluid from her incision site, she displayed altered consciousness, she was weak, and she was clearly quite ill. Despite that, the staff delayed consulting with the resident's physician for at least nine hours, an unconscionable delay.

Petitioner argues also that its staff did attempt to notify R-1's physician on August 20, citing to the single unreturned call that staff placed on that date. As I have explained, attempted notification is not consultation. The regulation requires much more from a facility's staff than placing a call that is not answered. Not only should the staff have followed up on their August 20 call, but also they should have persistently attempted to consult with the resident's physician throughout the period from August 20 to 28, concerning the condition of the resident's wound. In fact, the staff not only failed to consult, but they failed even to monitor and assess the wound.

Petitioner asserts that CMS failed to adduce any facts showing that it had neglected to care for R-1. Petitioner's brief at 14. It argues, first, that it had policies in place designed to protect its residents against neglect. This argument is a red herring. CMS does not allege that Petitioner lacked policies but that it failed to *implement* those policies, especially policies relating to wound and skin care and to consultation with physicians about significant changes in a resident's condition.

Petitioner then asserts that CMS argues that the staff failed to comply with Petitioner's skin assessment policy based on a single failure to document the resident's dressing on August 22, 2016. This utterly mischaracterizes CMS's argument. The undisputed facts alleged by CMS establish that Petitioner's staff failed entirely to monitor the condition of the resident's wound after August 20, 2016. In another example of nit picking, Petitioner asserts that a nurse's failure to change the resident's dressing on August 26, 2016, was consistent with the resident's surgeon's orders not to disturb the dressing after the pain pump was implanted on June 28. This assertion ignores the fact that nearly two months had transpired since that initial order. It also mischaracterizes the physician's order, which related to the period immediately after the resident had undergone surgery. What may have been a perfectly reasonable order then had nothing to do with the facts that pertained months later.

Petitioner asserts that CMS failed to adduce facts showing that it did not provide necessary care to R-1 as is required by 42 C.F.R. § 483.25. It contends that CMS argues non-compliance based on a "strict liability" standard. Petitioner then asserts that "CMS does not identify a single aspect of R-1's care plan that was not followed" by Petitioner's staff. Petitioner's brief at 15.

This argument is unfathomable. CMS never asserts that it seeks to hold Petitioner strictly liable for some trivial instance of noncompliance. CMS alleges, and the undisputed facts establish, wholesale noncompliance by Petitioner's staff with regulatory requirements. The undisputed facts show that Petitioner's staff utterly disregarded R-1's care plan between August 20 and 28, 2016. The plan required the staff to monitor and assess the resident's surgical wound. The staff completely failed to do so and failed despite the knowledge that the wound had reopened.

Petitioner also seems to argue that findings of immediate jeopardy level noncompliance are unreasonable because there is at least a factual dispute as to whether its staff's care of R-1 caused the resident to suffer adverse consequences. It argues that R-1's deterioration and demise were the consequences of judgment errors made by the surgeon who implanted the pain pump in R-1 in June 2016, and by the apparent use of unapproved medication in the pump. Petitioner's brief at 6-10. It argues additionally that the infection that caused R-1's death developed while she was hospitalized beginning on August 28, 2016, and consequently cannot be attributed to the care that Petitioner's staff gave to the resident. *Id.*

I find these arguments and the facts that Petitioner offers in support of them to be irrelevant. The issue here is not whether Petitioner's care of the resident caused the resident to experience the infection that resulted in her death nor is it whether the surgeon's judgment errors contributed to or even were the original cause of the resident's wound reopening.

Petitioner had a duty of care, established by the regulations. It and its staff were obligated to carefully monitor, assess, and treat R-1's surgical wound. That duty existed irrespective of the prior care given to the resident. It existed without regard to the cause of the wound reopening. Petitioner cannot duck its responsibility by claiming that the reopening of R-1's wound was the consequence of someone else's judgment errors. It had a regulatory mandated duty to the resident no matter who had treated her previously and no matter what judgment errors that person may or may not have made.

Furthermore, it is irrelevant whether the infection that killed R-1 originated while she resided at Petitioner's facility or later, at the hospital. The undisputed facts are that Petitioner's staff, through wholesale neglect of the resident, allowed a massive wound to open in the resident's abdomen, a portal for infection. Whether a fatal infection actually developed at the facility or later, in the hospital, is irrelevant because the likelihood of serious injury, harm or death to R-1 existed due to that open wound and the negligence of Petitioner's staff.

Petitioner argues that CMS's determination to impose civil money penalties for each day of its noncompliance violates CMS's policies governing whether to impose daily versus per-instance civil money penalties. It contends that guidelines that CMS issues to state

survey agencies do not allow for daily penalties here, but only allow for a per-instance penalty. Petitioner's brief at 17. It also argues that the penalty amount, whether daily or per-instance, of $10,091, is unreasonably high because in comparable cases CMS imposed penalties in lesser amounts. Petitioner's brief at 17-19.

I do not have authority to consider Petitioner's argument that CMS ought to have imposed a per-instance penalty rather than penalties for each day of noncompliance. The penalties that CMS imposed here plainly are authorized by regulation. 42 C.F.R. § 488.438(a)(1)(i). The regulation also allows for imposition of a per-instance penalty in lieu of daily penalties. But, choosing which penalty to impose is a discretionary authority that the regulations vest in CMS. My authority is limited to deciding whether CMS's determination – whatever that may be – is authorized and reasonable. As I have explained, the penalty determinations made by CMS satisfy the regulatory standard.[3]

Nor do I have authority to make comparisons between the penalties that CMS determined to impose here and those that were sustained in other cases. The regulations direct me to make a decision as to reasonableness of penalty based on the facts that are unique to the case before me. 42 C.F.R. §§ 488.438(f)(1)-(4), 488.404 (incorporated by reference into 42 C.F.R. § 488.483(f)(3)). In this case the seriousness of Petitioner's noncompliance is more than sufficient support for the penalty amount that CMS determined to impose.

/s/
Steven T. Kessel
Administrative Law Judge

[3] Petitioner did not challenge the duration of its noncompliance. It offered no facts to prove that it remediated its noncompliance on a date earlier than that which was determined by CMS.