Department of Health and Human Services

DEPARTMENTAL APPEALS BOARD

Civil Remedies Division

In the Case of:	)	
	)	
Edgemont Healthcare,	)	Date: February 25, 2008
(CCN: 18-5389),	)	
	)	
Petitioner,	)	
	)	
- v. -	)	Docket No. C-07-306
	)	Decision No. CR1741
Centers for Medicare &	)	
Medicaid Services.	)	
	)	

DECISION

I sustain the determination of the Centers for Medicare & Medicaid Services (CMS) to impose remedies against Petitioner, Edgemont Healthcare. The remedies that I sustain include civil money penalties in daily amounts of $4,050 for each day of a period that began on November 14, 2006 and ran through January 15, 2007. Additionally, I sustain civil money penalties against Petitioner in amounts of $250 for each day of a period that began on January 16, 2007 and which ran through February 1, 2007.

I. Background

Petitioner is a skilled nursing facility that is located in Cynthiana, Kentucky. It participates in the Medicare program. Its participation in Medicare is governed by sections 1819 and 1866 of the Social Security Act (Act) and by implementing regulations at 42 C.F.R. Parts 483 and 488.

Petitioner was surveyed for compliance with Medicare participation requirements on January 12, 2007 (January 12 survey). The surveyors and, subsequently CMS, found that Petitioner failed to comply with several participation requirements. Allegedly, its noncompliance with some of these requirements was so egregious as to pose immediate

jeopardy for residents of Petitioner's facility. "Immediate jeopardy" is defined in regulations to mean a facility's noncompliance with one or more participation requirements that has caused or is likely to cause serious injury, harm, impairment, or death to a resident. 42 C.F.R. § 488.301.

The surveyors and CMS determined that immediate jeopardy level noncompliance began on November 14, 2006. On January 30, 2007, the surveyors made a followup visit at which they determined that immediate jeopardy was abated on January 16, 2007. The surveyors and CMS subsequently determined that Petitioner attained full compliance with participation requirements effective February 2, 2007.

Based on these findings of noncompliance and duration, CMS determined to impose remedies against Petitioner consisting of the civil money penalties that I cite in the opening paragraph of this decision. Petitioner requested a hearing in order to challenge these remedy determinations and the case was assigned to me for a hearing and a decision.

I scheduled a hearing in Lexington, Kentucky. Shortly prior to the hearing the parties advised me that they had agreed that the case could be heard and decided without an in-person hearing and on the basis of their written exchanges. These exchanges included proposed exhibits which, among other things, contained the written direct testimony of the parties' witnesses. Based on the parties' representations, I cancelled the hearing and ordered the parties to submit final briefs. The parties then submitted briefs.

CMS's written exchange included proposed exhibits which it designated as CMS Ex. 1 - CMS Ex. 55. Petitioner's exchange included proposed exhibits which it designated as P. Ex. 1 - P. Ex. 45. Neither party filed objections to my receiving any of the proposed exhibits into evidence. Therefore, I receive into evidence all of the parties' exhibits.

II. Issues, findings of fact and conclusions of law

A. Issues

The issues in this case are whether:

1. Petitioner failed to comply with one or more Medicare participation requirements;

2. CMS's determination that Petitioner's noncompliance included instances of immediate jeopardy is clearly erroneous; and

3. CMS's remedy determinations are reasonable.

B. Findings of fact and conclusions of law

I make findings of fact and conclusions of law (Findings) to support my decision in this case. I set forth each Finding, below, as a separate heading. I discuss each Finding in detail.

1. Petitioner failed to comply with Medicare participation requirements.

CMS's allegations of noncompliance in this case focus on the care that Petitioner gave to two of its residents who are identified as Resident # 14 and Resident # 5 in the January 12 survey report.[1] The report alleges that, in providing care to these residents, Petitioner failed to comply with several distinct participation requirements. Five of these alleged episodes of noncompliance are argued to be at the immediate jeopardy level.

All of CMS's noncompliance allegations that I address in this decision emanate from the way in which Petitioner and its staff addressed residents' risk of developing pressure sores. I take notice that pressure sores have long been identified as a major problem confronting skilled nursing facilities. Residents who are elderly, who are very ill, debilitated, and often demented, are at high risk for developing pressure sores because of their lack of mobility and their deteriorated physical conditions. A pressure sore may greatly diminish a resident's quality of life and may even be lethal. Pressure sores may develop very quickly in a debilitated and immobile resident. Once a sore develops it may be extremely difficult to treat, and, in some cases, may lead to life threatening infection.

Regulations governing nursing facilities' participation in Medicare specifically address a facility's obligation to anticipate and treat pressure sores. A facility is required, based on its comprehensive assessment of a resident, to assure that: a resident who enters a facility without pressure sores does not develop one unless development of a sore is unavoidable; and that a resident having pressure sores receives necessary treatment and services to promote healing, prevent infection, and prevent new sores from developing. 42 C.F.R. § 483.25(c).

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[1] Specific allegations concerning the care that Petitioner gave to Resident # 5 are addressed in only one of the five alleged immediate jeopardy level deficiencies cited by CMS. That is Petitioner's alleged failure to comply with the requirements of 42 C.F.R. § 483.25(c). CMS makes additional allegations of non-immediate jeopardy level deficiencies that involve Petitioner's care of Resident # 5 and relating to Petitioner's alleged failure to comply with the requirements of 42 C.F.R. § 483.10(b)(11), and 42 C.F.R. § 483.20(b)(1).

There are also regulations that indirectly address a facility's duty to prevent and to treat pressure sores. For example, 42 C.F.R. § 483.20(k)(3)(i) requires that the care provided by a facility must satisfy professional standards of quality. Implicitly, this regulation requires a facility to assess a resident for the possibility of developing pressure sores and to provide that resident with appropriate care sufficient to prevent the development of avoidable sores.

A facility may not defend itself against evidence that it failed to do what was required to prevent and/or treat a pressure sore on ground that a resident would have developed a sore regardless of the efforts undertaken to protect that resident. The regulations impose the identical duty of care on a facility with respect to every resident. They require a facility to assume that *no* pressure sore is inevitable or unavoidable. A facility must do its utmost to assure that none of its residents develops a sore. Inevitability may be a defense in the circumstance where a facility takes all reasonable measures to protect a resident and the resident develops a sore in spite of those measures. But, it is *never* a defense where a facility has failed to discharge its regulatory obligations.

The essence of CMS's allegations about the care that Petitioner gave to Residents #s 14 and 5 is that Petitioner's staff failed to take all steps that were reasonable and necessary to protect these residents against developing pressure sores. These allegations are restated somewhat differently as they pertain to the various regulations with which Petitioner is alleged to be deficient. But, at bottom, CMS's case against Petitioner focuses on the preventive care that it believes to have been required and that Petitioner allegedly failed to provide to these residents.[2]

I sustain CMS's allegations as they pertain to two immediate jeopardy level deficiencies, Petitioner's failure to comply with the pressure sore prevention requirements of 42 C.F.R. § 483.25 and, Petitioner's failure to comply with quality of care requirements of 42 C.F.R. § 483.20(k)(3)(i). I find it unnecessary that I address Petitioner's other alleged deficiencies. The assertions of noncompliance relating to other alleged deficiencies all emanate from the allegations that Petitioner failed to protect residents against developing pressure sores that I address in this decision. Finding Petitioner to be noncompliant with a series of derivative deficiencies does not add anything significant to my conclusion that Petitioner failed, at an immediate jeopardy level of noncompliance, to provide reasonable and necessary care to its residents.

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[2] As I note above, at footnote 1, some of the immediate jeopardy deficiency allegations other than the specific allegation that Petitioner failed to comply with the pressure sore regulation, 42 C.F.R. § 483.25(c), relate only to the care that Petitioner gave to Resident # 14.

My analysis in this decision focuses first on the care that Petitioner gave to Resident # 14 because it is with this resident that Petitioner manifested its principal failure to comply with participation requirements. The evidence establishes conclusively that Petitioner and its staff failed to take measures in order to protect the resident against developing pressure sores when faced with a dilemma as to how to provide care that reconciled a physician's order with the resident's evident and enhanced risk of developing sores. As for Resident # 5, the evidence shows that Petitioner's staff failed to anticipate and to address a problem that could lead to the resident developing a pressure sore.

a. Petitioner failed to comply substantially with the requirement in 42 C.F.R. § 483.25(c) that it protect its residents against the development of pressure sores.

i. Petitioner failed to protect Resident # 14 against the development of pressure sores.

Resident # 14 was a long-term resident of Petitioner's facility. She had numerous debilitating physical problems including cancer, peripheral vascular disease, degenerative arthritis, chronic obstructive pulmonary disease, end stage congestive heart failure, and nutritional deficits as a consequence of failure to thrive. P. Ex. 40, at 2; CMS Ex. 28, at 63. The resident also had psychiatric problems. *Id.* In April 2006, the resident suffered a fracture to her right femur that required surgery and the placement of a rod in her right leg. In October 2006, she suffered a fall resulting in severe additional fractures in her leg. CMS Ex. 28, at 258; P. Ex 35, at 2. Petitioner's staff recognized that the resident's condition put her at a high risk for developing pressure sores and the staff expressed that concern in the resident's care plan. CMS Ex. 28, at 36. The staff was instructed to perform weekly skin assessments as well as to monitor the resident's skin condition during every nursing shift. *Id.*

The resident was hospitalized to treat the fractures that she suffered in October 2006. The hospital physician decided that her condition precluded surgery. He decided to treat her fractures by applying an immobilizer to her leg. An immobilizer is a device that serves the same function as a plaster cast. It holds a fractured extremity in position while healing takes place. The immobilizer is held in place by a set of velcro straps that can be loosened or opened. Thus, unlike a plaster cast an immobilizer may be removed temporarily.

Resident # 14 was discharged from the hospital to Petitioner's facility with the immobilizer attached to her leg. The transfer document from the hospital included the following physician's order :

"Knee immobilizer to . . . [right] knee at all times."

P. Ex. 32, at 5.[3]

The immobilizer was removed on November 6, 2006 for purposes of performing an x-ray of the resident's leg. At that time no skin breakdown was observed. Other than on that occasion, the immobilizer was not removed prior to November 14, 2006. With the exception of November 6, 2006, Petitioner's staff did not at any time check the condition of the skin under the immobilizer. The staff limited its skin checks of the resident's leg to looking at the skin that remained exposed and checking around the edges of the immobilizer. On November 14, 2006, an orthopedic physician removed the immobilizer while examining the resident's leg and discovered a Stage IV pressure sore over the resident's Achilles tendon and above her right ankle. I take notice that a Stage IV pressure sore is an extremely severe wound. In Resident # 14's case, the sore was so deep that it exposed underlying structures in the resident's leg.

CMS contends that Petitioner's staff should have removed the immobilizer periodically in order to check the condition of the resident's skin. Their failure to do so, according to CMS, led to the resident developing a Stage IV sore. CMS avers further that, if the staff perceived any conflict between their duty to check the resident's skin and the hospital physician's order concerning removal of the immobilizer, it was their duty to resolve that conflict so as to protect the resident.

CMS avers that the hospital transfer order did not preclude Petitioner's staff from removing the immobilizer periodically and checking the resident's skin. As support for its interpretation of the order, CMS notes that the physician who signed it stated in a January 16, 2007 letter in which he discussed the care that he provided to Resident # 14 that:

Clearly, the immobilizer could be removed for bathing and skin care.

CMS Ex. 28, at 23. CMS contends also that Petitioner's medical director, who had ordered that the resident's skin be assessed weekly for possible pressure sores, acknowledged that the immobilizer could be removed to check the resident's skin, citing a January 10, 2007 statement by him that: "the beauty of Velcro [is that] you can take it off to bathe or do skin assessments." CMS Ex. 9, at 13.

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[3] The order is undated. However, the resident was readmitted to Petitioner's facility from the hospital on November 3, 2006 so I find that the order concerning the immobilizer was written on or about that date. CMS Ex. 28, at 110.

CMS argues additionally that if the order was read by Petitioner's staff to preclude removal of the immobilizer under any circumstance that interpretation conflicted with the staff's assessment of the resident as being at high risk for developing pressure sores and with its own care plan that required the staff to perform skin assessments of the resident weekly. It argues that it was incumbent on Petitioner's staff to resolve that conflict if it interpreted the order as precluding skin checks.

Petitioner asserts that the order literally meant that the immobilizer should not be removed under any circumstance. As support for this argument it offers a declaration from the physician who applied the immobilizer in which he qualifies his January 16, 2007 letter by averring that his comments in that letter are general comments which do not represent the order that he gave concerning Resident # 14. P. Ex. 32, at 1. It also offers a declaration by its medical director who, in contrast to the statement he gave on January 10, 2007, asserts:

> I did not consider my order to conduct weekly skin assessments for Resident 14 which is facility protocol for all residents to be in conflict with a more specific order from the orthopedic physician to leave the immobilizer on at all times because the weekly skin assessment should be done to the remainder of the body.

P. Ex. 33, at 2.

Petitioner also contends that, in fact, there was no conflict between the asserted requirement that the immobilizer not be removed and its own determination that the resident's skin needed to be checked weekly. According to Petitioner, "between November 3 and November 14, 2006 it is obvious that the applicable intervention required staff to check ***around the edges*** instead of under the immobilizer." Petitioner's final brief at 15 (emphasis in original). Its argument, essentially, is that the staff reasonably concluded that the immobilizer should not be removed and determined that the best practice would be to check only under the edges of the immobilizer for possible skin breakdown. Thus, according to Petitioner's medical director:

> I do not think any obligation on the nursing staff arose to seek any clarification of these two orders, as they were both consistent with the other.

P. Ex. 33, at 2 - 3.

According to Petitioner, the determination by its staff that it could avoid conflict with the order concerning use of the immobilizer by checking only around the edges of the device was not only a reasonable reconciliation of the hospital physician's order and its own assessment and care plan for the resident but was, in fact, consistent with prevailing

standards of medical care. As support for this contention Petitioner offers the testimony of an expert orthopedic physician. P. Ex. 35. He asserts that, in the case of Resident # 14, the immobilizer was intended to remain in place and not be removed by Petitioner's staff, "as such removal could have aggravated the patient's pain and suffering and exposed the patient to an increased risk of serious complications, including further displacement of the bone fragments." *Id.*, at 2. He avers further that he would not have wanted Petitioner's staff to remove the immobilizer to assess the resident's skin underneath because of the possibility that the resident might experience complications. *Id.*, at 3.

I am not persuaded from the evidence offered by Petitioner that the physician who ordered the immobilizer for Resident # 14 envisioned an absolute prohibition against removing the device while the resident was at Petitioner's facility. That physician's recent attempt to explain away his previous assertion that the immobilizer could be removed for bathing and skin care is, on its face, not credible. And, indeed, the immobilizer was removed on one occasion between November 3 and November 14, 2006 – on November 6, 2006 – when the resident's leg was x-rayed. I find, therefore, that the physician's order that the immobilizer be left on the resident's leg at all times did not preclude the staff from removing it, if only momentarily, to check on the condition of the resident's skin.

But, Petitioner would not have been excused from its failure to do more for Resident # 14 even if the physician who applied the immobilizer had in fact ordered that the device not be removed under any circumstances. Petitioner's staff knew that Resident # 14 was at high risk for developing pressure sores even before she sustained the fracture for which she was prescribed the immobilizer. Moreover, it knew or should have known that, while the resident wore the immobilizer, she was at a greatly increased risk for development of pressure sores on the skin that was under the device. Indeed, Petitioner's own expert orthopedist concluded:

> I do not find it surprising that . . . [a pressure sore] would occur in . . . [the] area [under the immobilizer] *since the risk of such pressure from the use of an immobilizer is common, and I have seen such ulcers arise even where immobilizers are removed regularly for skin assessments.*

P. Ex. 35, at 3 (emphasis added). The heightened risks to Resident # 14 made it incumbent on Petitioner's staff to assess the resident's risk for pressure sores on the area beneath the immobilizer and to discuss with the resident's physicians the best way to address those risks. At the least, Petitioner's staff should have identified the increased risk to the resident and discussed it with the resident's treating physicians. It should have asked for advice as to what measures it could have taken in order to minimize the resident's risk of developing a sore.

It is possible that such assessment and consultation might have led to a conclusion that removing the immobilizer to check the resident's skin posed greater risks to the resident than leaving the immobilizer on at all times. And, it is also within the realm of reasonable possibility that the resident might have developed a pressure sore in spite of the staff's best efforts at protecting her.[4] But, those possibilities do not excuse Petitioner's staff from failing to anticipate the risks to the resident and failing to attempt to develop effective preventive measures. The staff's failure to take action to protect the resident – to assess and consult concerning the resident's condition – is not excused in this case by the possibility that her pressure sore was the inevitable result of the fractured leg and the use of an immobilizer to stabilize that leg.

The Act and implementing regulations do not envision that a nursing facility will serve as a passive residence for those beneficiaries whom it serves. The guiding spirit of the Act and regulations is that a facility's nursing staff play an active role in providing care to residents. Where there is an obvious likelihood – as there was here – that a physician's order might cause collateral problems for a resident it is the staff's duty to assess the increased risks, to consult about them, and to do its best to plan the resident's care accordingly. Resident # 14's circumstances mandated that Petitioner's staff do more than passively accept the possibility that she might develop a pressure sore under the immobilizer. The staff had a duty to ask questions, to assess, and to consult. It failed to exercise that duty with respect to Resident # 14.

Petitioner argues that the fact that the resident's skin was checked on November 6, 2006 when the immobilizer was removed so that the resident's leg could be x-rayed served as a "weekly" skin check of the resident. Thus, according to Petitioner, it literally complied with the care plan for Resident # 14 which called for weekly skin checks.

I am not persuaded that Petitioner fulfilled its duty to the resident by checking her skin on the 6th of November but not thereafter. The resident's risk of development of a severe pressure sore was such that even weekly checks of her skin may have been inadequate to fully protect her. P. Ex. 35, at 3. Petitioner's staff should have known that and should have factored that possibility into its investigation of how best to protect the resident. But, clearly, it failed to do so.

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[4] The parties argue whether Petitioner's care caused Resident # 14 to develop the sore on her leg. It is unnecessary that I decide whether the sore was caused by deficient care even as it is unnecessary that I decide whether the sore in this case was inevitable. What is at issue here is Petitioner's failure to take all necessary protective actions and not the end consequences of those failures. Similarly, I make no findings as to whether the pressure sore developed by Resident # 14 ultimately led to her death (she died about one month after the sore was first discovered).

ii. Petitioner failed to protect Resident # 5 against the development of pressure sores.

Resident # 5 was an individual who Petitioner's staff knew to be at extremely high risk for developing pressure sores. When he began his residence at Petitioner's facility in September 2006, the resident was afflicted with multiple pressure sores. P. Ex. 36, at 1; CMS Ex. 21, at 10. The staff assessed the resident to be at high risk for pressure sores on his admission to the facility and it was instructed that "any reddened area will be identified and treatment initiated." P. Ex. 2, at 8; CMS Ex. 21, at 31.

The resident's several medical problems included a diagnosis of sleep apnea. The treatment prescribed to the resident for that condition included his wearing a Continuous Positive Airway Pressure (C-PAP) mask. P. Ex. 36, at 2. The mask was affixed to the resident's head and face by means of adjustable straps. Petitioner's staff was aware that the mask's pressure against the resident's skin potentially could cause skin breakdown. Informational material provided to Petitioner by the supplier of the C-PAP mask warned against the possibility of skin irritation being caused by the mask or by its straps. CMS Ex. 9, at 16.

CMS's finding of noncompliance concerning the care Petitioner's staff gave to Resident # 5 is based on the foregoing information plus information obtained by surveyors during the January 12 survey. On January 8, 2007 a surveyor observed an area of redness and a scab on the bridge of Resident # 5's nose. CMS Ex. 9, at 14. On January 11 a surveyor interviewed the resident. He told the surveyor that the C-PAP mask was ill-fitting and that it had caused the sore on his nose. He stated further that the sore had been present for a week or two, that he had reported the sore to Petitioner's staff, that the staff was supposed to be obtaining a better fitting mask, but had not done so as of yet. *Id.*

A surveyor also interviewed one of the registered nurses on Petitioner's staff. The nurse told the surveyor that, on January 9, 2007 she had observed a sore on the resident's nose which, evidently, had been present for several days. However, she had not documented the sore nor had she reported it to the resident's physician or to Petitioner's wound nurse. CMS Ex. 9, at 15. The nurse averred that she had not been provided educational information or in-service training by Petitioner on the issue of how to care for a resident who wears a C-PAP mask. *Id.* Other members of Petitioner's staff, including a day shift nurse and Petitioner's respiratory therapists also stated during interviews that they had not been provided training concerning caring for a resident who wears a C-PAP mask. *Id.*, at 15 - 16.

The surveyors also interviewed the nurse responsible for preparing initial assessments of residents. She acknowledged that she had failed to assess Resident # 5 for the risk of pressure sore development associated with wearing a C-PAP mask. She acknowledged to the surveyors that failing to develop a care plan to address the possible risks was an oversight by Petitioner's staff. CMS Ex. 9, at 16 - 17.

The interviews are in some respect confirmed by Resident # 5's treatment record. There is nothing in the record prior to the January 12 survey identifying the wound on the resident's nose. Nor is there documentation showing that specific treatment was being provided for that injury. Finally, there is nothing in the record establishing that interventions were developed to prevent further problems resulting from the resident's use of the C-PAP mask. CMS Ex. 9, at 17.

The evidence offered by CMS is strong prima facie support for the conclusion that Petitioner and its staff failed to anticipate and to plan for, as well as react to, the problems that Resident # 5 faced as a consequence of wearing a C-PAP mask. It shows that Petitioner knew that the resident was at great risk for developing pressure sores. It shows also that Petitioner knew, or should have known, that a C-PAP mask can cause skin problems for the individual who wears it. But, notwithstanding that, the evidence offered by CMS shows that the resident was not specifically assessed for the possibility that his use of a C-PAP mask might cause skin problems. Nor were specific interventions designed to protect him against skin breakdown caused by his use of the mask. When problems became evident the staff failed to record them, assess them, and plan care specifically to address them.

Petitioner has not responded to evidence offered by CMS showing a failure by its staff to document the abrasion to the resident's nose, to specifically assess it, and to develop a care plan for dealing with it. Its primary argument in opposition to CMS's case appears to be that CMS has offered no evidence to prove that the injury suffered by Resident # 5 from wearing the C-PAP mask was avoidable. It asserts that: "[t]he fact that a small scabbed, non-open abrasion developed with respect to the utilization of a required piece of equipment does not support a conclusion of avoidability." Petitioner's final brief at 35.

Whether or not the injury suffered by Resident # 5 was avoidable is not a valid defense to evidence showing that Petitioner failed to assess the resident for possible problems related to using the C-PAP mask nor is it a defense to Petitioner's staff's failure to document the injury once it occurred or to assess it. As I discuss above, asserting that an injury is unavoidable is *never* a valid defense to evidence showing that a facility failed to take all reasonable measures to prevent the development of a pressure sore.

Petitioner also argues that, once the sore was identified, its staff took appropriate measures to treat it. Petitioner's final brief at 35. It is unnecessary that I decide whether Petitioner appropriately treated the sore once it was identified because the issue here is not whether it was ultimately treated appropriately but whether Petitioner's staff took all reasonable measures to prevent the injury from developing.

In an apparent response to CMS's evidence showing that Petitioner's staff received no specific training in protecting residents against problems that might result from the use of a C-PAP mask Petitioner contends that its staff was familiar with the risks associated with the use of C-PAP masks and was trained to monitor all potential sources for pressure in providing care for residents at high risk for skin breakdown. Petitioner's final brief at 19, citing P. Ex. 37, at 4 - 5; P. Ex. 38, at 5. However, the evidence cited by Petitioner avoids addressing CMS's specific allegations. What is at issue here is not whether the staff received training on skin issues generally. The issue is whether the staff was trained explicitly about using a device that posed a known hazard to a resident who was vulnerable to the development of pressure ulcers. Nothing offered by Petitioner rebuts evidence showing that the staff did not receive specific training in the risks of using a C-PAP mask.

Nor has Petitioner rebutted evidence showing that Petitioner failed to assess Resident # 5 specifically for the risks caused by his use of the mask. Petitioner argues that its staff assessed the resident generally for risks of pressure sores and that there was no need for it to specifically assess the resident for risks caused by use of the C-PAP mask. I disagree. The mask's distributor had issued a specific warning that the mask posed a hazard of skin abrasions to those who wore it. That put Petitioner and its staff on notice of a problem that transcended the general issue of the resident's vulnerability to skin problems. The staff should have identified the problem in the case of Resident # 5 and should have planned specifically for it.

b. Petitioner failed to comply substantially with the requirement of 42 C.F.R. § 483.20(k)(3)(i) that it provide care to its residents that met professional standards of quality.

CMS's assertion that Petitioner failed to comply with the professional standards of quality requirement rests largely on the facts that I have described above as they pertain to Resident # 14. CMS argues that professional standards of quality required Petitioner to be diligent in assessing the condition of the resident's skin. It avers that Petitioner's staff should have been especially alert to the likelihood that the resident would develop a pressure sore given her greatly debilitated state and the risks that were associated with her wearing an immoblizer. Yet, according to CMS, Petitioner did nothing to abate a situation that posed a grave danger to the resident.

I find CMS's argument to be persuasive when considered in light of the evidence that I discuss at Part 1a. of this Finding. Petitioner's own expert acknowledged the hazards posed to Resident # 14 as a consequence of her wearing the immobilizer. P. Ex. 35, at 3. The overwhelming evidence in this case is that Petitioner's staff reacted passively to those hazards.

As I discuss above, it is possible that nothing Petitioner's staff could have done would have ameliorated the risk to Resident # 14 that was caused by her overall condition and the use of the immobilizer. And, it is certainly possible that the resident's physicians, had they been consulted, would have concluded that the risk resulting to the resident from removing the immobilizer for frequent skin checks outweighed any benefit that might have resulted from more regular monitoring of her skin condition. But, those possibilities did not excuse Petitioner from at least considering whether more could be done to protect Resident # 14 nor from exploring all possible treatment approaches in order to find a way to better protect her. Its failure to do so was a violation of professional standards of quality incorporated into the regulations.

Petitioner argues that CMS failed to identify specifically the professionally recognized standard of quality that Petitioner allegedly contravened. I disagree. The standards of quality to which a facility is required to adhere by 42 C.F.R. § 483.20(k)(3)(i) may be standards that are recognized generally in the nursing profession and unstated in the governing regulations. But, they also include those standards stated explicitly in the regulations. Here, the applicable standard of quality is stated at 42 C.F.R. § 483.25(c). A facility must take all reasonable measures to protect a resident against developing a pressure sore.

Petitioner argues also that CMS's case against it "boils down to the allegation that the facility failed to follow Resident 14's physician's order for skin assessments by removing the resident's immobilizer." Petitioner's final brief at 22. As I discuss above, I conclude that the hospital physician's order that the immobilizer be left on at all times was not intended to be read literally by nursing personnel. The order gave the staff leeway to remove the immobilizer briefly to perform skin checks. But, if the order was meant to be applied literally that set up a conflict between what was ordered at the hospital and the staff's knowledge of and concerns for the resident. Petitioner's staff was under a duty to resolve that conflict.

Petitioner also relies heavily on physicians who now contend that checking around the edges of the immobilizer rather than removing the immobilizer to perform skin checks was adequate protection of the resident given the need to maintain stability in her fractured leg. Petitioner's final brief at 23 - 24. I do not take issue with these physicians' assessments of what was appropriate. But, I do take issue with the argument that the hospital physician's order was license for Petitioner's staff to react passively in the face

of the risks to Resident # 14 of which they were certainly aware. The staff's duty in this case was to raise questions as to whether they were providing adequate care to the resident by not checking under the immobilizer. They had an obligation to at least explore the possibility that checking around the edges of the immobilizer was inadequate care. Their passivity is made evident by the lack of any assessment in the resident's record prior to the January 12 survey showing that the staff conducted an inquiry into the risks posed to the resident or considered alternatives that might better protect her. At the least, the staff could have queried the residents' physicians about the care that had been prescribed.

2. Petitioner did not prove to be clearly erroneous CMS's determination that Petitioner's failure to comply with the requirements of 42 C.F.R. §§ 483.25(c) and 483.20(k)(3)(i) was so egregious as to comprise immediate jeopardy.

There is convincing evidence in this case that Petitioner's failure to take measures to protect Residents #s 5 and 14 from developing pressure sores and its failure to provide care that met professional standards of quality comprised immediate jeopardy for Petitioner's residents. As Petitioner's own expert notes, there was a very high risk that Resident # 14 would develop a pressure sore as a consequence of wearing an immobilizer. The entity that distributed the C-PAP mask worn by Resident # 5 warned that the mask could cause skin problems. Petitioner's staff was aware of these risks. Given that, their failure to act aggressively to take every reasonable measure to protect the residents put these residents at a very heightened probability of serious injury, harm, or death.

Petitioner offered no persuasive evidence to show that CMS's determination of immediate jeopardy was clearly erroneous. Petitioner has argued that the sores experienced by Residents #s 14 and 5 were inevitable but, as I discuss above, the possibility that sores were unavoidable gave Petitioner no excuse for failing to discharge its responsibilities. Petitioner also argues that there is no solid evidence that heightened vigilance on the part of its staff would actually have prevented Residents #s 14 and 5 from developing sores. Speculation from the vantage point of hindsight as to whether the sores would or would not have been prevented by increased vigilance is pointless. What is clear is that each of these residents were at a greatly increased risk for developing pressure sores and Petitioner's staff failed to address those risks.

3. Civil money penalties of $4,050 per day for each day of the period of immediate jeopardy are reasonable.

The period of immediate jeopardy determined by CMS in this case – and supported by the evidence – encompasses the period between November 14, 2006, the date when Resident # 14 was discovered to have developed a Stage IV sore under her immobilizer, and January 15, 2007, the last date prior to Petitioner's implementation of corrective actions to abate immediate jeopardy.

Petitioner argues that, if there was immediate jeopardy, it ended on November 14, 2006, the date when the pressure sore was discovered on Resident # 14's extremity. It reasons that the facility implemented appropriate care for this resident on that date thereby removing any risk that the resident would suffer additional harm. However, the immediate jeopardy in this case – while it certainly is evidenced by the deficiencies in care that Petitioner provided to Residents #s 5 and 14 – is not confined to the very limited circumstances in which Petitioner provided care to the two residents. The evidence shows that Petitioner's staff failed to recognize its obligations and to discharge them properly. That is a *general problem* of staff training, education and performance, evidenced to be sure by deficient conduct in caring for two residents, but not limited only to the care that these residents received. Petitioner eliminated the immediate jeopardy only when it implemented numerous corrective actions. These were not completed until January 16, 2007. CMS Ex. 10.

Regulations provide for civil money penalties within a range of between $3,050 and $10,000 per day as remedies for an immediate jeopardy level deficiency. 42 C.F.R. § 488.438(a)(1)(i). The regulations also provide criteria for deciding where within this range an immediate jeopardy level penalty amount should fall. 42 C.F.R. §§ 488.438(f)(1) - (4); 488.404 (incorporated by reference into 42 C.F.R. § 488.438(f)(3)). These criteria include: the seriousness of deficiencies; a facility's compliance history; its culpability; and its financial condition.

The daily civil money penalty amount of $4,050 that CMS determined to impose is relatively modest in that it is at the low end of the immediate jeopardy range. CMS asserts that the penalty amount reflects the seriousness of Petitioner's noncompliance and its culpability. It has offered no evidence concerning Petitioner's prior compliance history. Petitioner disputes CMS's assertions as to seriousness and culpability and argues, additionally, that its financial condition should merit a reduction in penalty amounts.

I find that the penalty amount of $4,050 per day is justified by the seriousness of Petitioner's noncompliance. As I discuss at the beginning of Finding 1, the problem of pressure sores is among the most pernicious that a nursing facility must deal with. And, the development of a pressure sore is, potentially, one of the most devastating events that can occur to a resident. In view of that there is an extremely heavy burden on a facility to assure that it leaves no stone unturned to protect its residents from developing pressure sores. Petitioner clearly failed to satisfy its obligations here. Petitioner and its staff were passive in the face of evidence that two of its residents were at greatly heightened risk for developing pressure sores. That passivity put these residents in jeopardy.

As concerns Petitioner's financial condition I conclude that it has not established that civil money penalties of $4,050 per day would jeopardize its ability to provide nursing care consistent with regulatory requirements.[5] Petitioner asserts that it is not part of a chain of nursing facilities, that it operated at a loss last year, and that the penalty amounts that CMS determined to impose against it would constitute an undue hardship. But, Petitioner has not offered hard evidence to support these contentions. Thus, although it has asserted that a daily penalty amount of $4,050 will adversely affect its ability to provide care it has not offered any detailed evidence of its actual financial condition.

Petitioner asserts that it qualifies for a hardship exemption from the Kentucky State Medicaid program's annual delay in Medicaid funding as is experienced by Medicaid certified facilities. Petitioner's final brief at 44. It argues that I should reduce the civil money penalty amount in light of the financial hardship acknowledged by the State of Kentucky. I find this contention to be unpersuasive because Petitioner has not provided me with evidence that explains how this asserted waiver came to be granted.

4. Civil money penalties of $250 for each day of the period beginning January 16 and ending February 1, 2007 are reasonable.

CMS determined that, although Petitioner had abated its immediate jeopardy level noncompliance by January 16, 2007, it remained noncompliant albeit at a reduced level until February 1, 2007. It determined to impose civil money penalties of $250 per day for each day of this period of non-immediate jeopardy level noncompliance.

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[5] The regulations grant me no authority to adjust a civil money penalty downward below the regulatory minimum level based on a facility's financial condition. The minimum daily civil money penalty amount that I may impose for Petitioner's immediate jeopardy level noncompliance is $3,050, irrespective of its financial condition. 42 C.F.R. § 488.438(a), (f); *see* 42 C.F.R. § 488.438(e). Nor do I have authority to adjust a total civil money penalty amount that accrues over a period of noncompliance so that the average daily penalty is below the regulatory minimum.

Before determining whether this penalty amount is reasonable I must resolve the threshold issue of whether Petitioner's noncompliance with participation requirements persisted after January 16. Petitioner submitted a detailed plan of correction addressing the immediate jeopardy level and other deficiencies that were identified at the January 12 survey. CMS Ex. 10. But, according to CMS, not all of the elements of Petitioner's corrective action plan were implemented as of January 16. CMS's final brief at 22.

A finding of noncompliance creates a presumption of continuing noncompliance until the noncompliant facility proves that it has met all requirements of participation. The burden rests entirely on a facility to prove that it attained compliance at a date earlier than is determined by CMS.

Petitioner has offered neither argument nor evidence – besides its assertion, which I have found to be without merit that it abated immediate jeopardy by November 14, 2006 – showing that it attained full compliance with participation requirements at a date prior to February 1, 2007. Consequently, I sustain CMS's determination as to the date when Petitioner attained full compliance with participation requirements.

The range of permissible civil money penalty amounts to remedy deficiencies that are not at the immediate jeopardy level is from $50 - $3,000 per day. 42 C.F.R. § 488.438(a)(1)(ii). The same regulatory criteria that apply to deciding where a penalty amount should fall within the non-immediate jeopardy range apply to determining reasonable immediate jeopardy amounts. 42 C.F.R. §§ 488.438(f)(1) - (4); 488.404 (incorporated by reference into 42 C.F.R. § 488.438(f)(3)). CMS contends that the penalty amounts of $250 per day are reasonable inasmuch as they are based on deficiencies that were quite serious when at the immediate jeopardy level and also because they are set at less than 10 percent of the maximum non-immediate jeopardy penalty amount.

I sustain CMS's determination to impose penalties of $250 per day. The penalty amount is actually extremely modest given the underlying noncompliance. Petitioner has offered neither evidence nor argument to show that this amount is unreasonable.

/s/
Steven T. Kessel
Administrative Law Judge