Department of Health and Human Services

DEPARTMENTAL APPEALS BOARD

Civil Remedies Division

In the Case of:	)	
	)	
Beverly Healthcare - Ingram, (CCN No.: 01-5189),	)	Date: May 10, 2007
	)	
Petitioner,	)	
	)	
- v. -	)	Docket No. C-06-356
	)	Decision No. CR1597
Centers for Medicare & Medicaid Services.	)	
	)	

DECISION

I sustain the determination of the Centers for Medicare & Medicaid Services (CMS) to impose civil money penalties against Petitioner, Beverly Healthcare - Ingram, in amounts of $200 per day, for a period that began on January 20, 2006 and which ended on March 9, 2006.

I. Background

Petitioner is a skilled nursing facility located in Pell City, Alabama. It participates in the Medicare program. Its participation in Medicare is governed by sections 1819 and 1866 of the Social Security Act and by federal regulations at 42 C.F.R. Parts 483 and 488.

Petitioner was surveyed for compliance with Medicare participation requirements in a survey that ended on January 20, 2006 (January survey). The surveyors found that Petitioner was not complying with several requirements. CMS concurred with the surveyors' findings to the extent that it determined that Petitioner was not complying with four participation requirements. It concluded that Petitioner was out of compliance for a period that began on January 20, 2006 and which ended on March 9, 2006. CMS determined to impose remedies against Petitioner consisting of civil money penalties of $200 per day for each day of Petitioner's noncompliance.

Petitioner requested a hearing and the case was assigned to me for a hearing and a decision. I scheduled a hearing to be held in Birmingham, Alabama on February 26, 2007. However, shortly prior to the hearing the parties informed me that they agreed that the case could be decided based on written submissions. Consequently, I established a briefing schedule for the parties. In addition to briefing the issues the parties offered proposed exhibits. CMS offered a total of 26 proposed exhibits (CMS Exs.) consisting of CMS Ex. 1 - CMS Ex. 26. Petitioner offered 41 proposed exhibits (P. Exs.) consisting of P. Ex. 1 - P. Ex. 41. The parties' exhibits include the written direct testimony of several witnesses. I receive all of the parties' exhibits into evidence.

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 during the January 20 - March 9, 2006 period; and

2. Civil money penalties of $200 per day are a reasonable remedy for whatever noncompliance that may have existed during the January 20 - March 9, 2006 period.

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 substantially with Medicare participation requirements during the January 20 - March 9, 2006 period.

As I discuss above, CMS determined, based on findings made by the surveyors at the January survey, that Petitioner failed to comply substantially with four distinct Medicare participation requirements. I sustain CMS's determinations as follows:

a. Petitioner failed to comply substantially with the requirements of 42 C.F.R. § 483.25(c).

The regulation that is at issue here governs the prevention and treatment of pressure sores. At subpart (1) the regulation provides that a resident who enters a facility does not develop pressure sores unless his or her clinical condition makes the development unavoidable. It imposes on a facility the duty to take all reasonable measures to ensure that a resident does not develop a pressure sore. The regulation is not a strict liability regulation but it presumes that pressure sores are avoidable. Where a resident develops a pressure sore the burden falls on the facility to explain why the sore was unavoidable.

CMS's case for noncompliance centers around the care that Petitioner gave to a resident who is identified as Resident # 9. This resident suffered a fracture of her right femur on or about December 7, 2005 and was hospitalized briefly for treatment. The fracture was treated at first with a temporary immobilizer. Some time shortly after sustaining the injury, and prior to the resident's discharge from the hospital, the temporary immobilizer was replaced with a custom-fit, long-leg, hinged, removable immobilizer. CMS Ex. 14, at 20; P. Ex. 6, at 3, 5, 6. The immobilizer was held together by velcro. The resident wore a cotton stocking under the device in order to protect her skin.

The physician who put the temporary immobilizer on the resident's leg ordered that the resident wear it at all times but noted that it could be removed for bathing only. CMS Ex. 14, at 17. The orthopedic physician who subsequently ordered the placement of a custom-fit immobilizer on the resident ordered that the device be worn at all times. *Id.* at 19.

The resident was assessed prior to her injury as being at high risk for the development of pressure sores. Petitioner's staff performed an additional assessment of the resident's pressure sore risk on December 9, 2005, immediately after the resident returned to the facility from the hospital. That assessment noted the fracture and listed as an intervention: "Daily skin inspection during care/bathing by the Beverly Care Specialist with a report to the nurse of any areas of skin breakdown or redness." CMS Ex. 14, at 16. The assessment also specifically referenced the resident's fracture and the resident's use of an immobilizer, stating as an intervention:

> Monitor skin under splint with bath[.] Notify nurse of any skin breakdown (Velcro Immobilizer).

Id.

Notwithstanding these instructions there is no dispute that the resident's immobilizer was not removed by Petitioner's staff at any time from December 9, 2005 until January 17, 2006. On that date the staff removed it so that the resident's family could wash the underlying stocking. The stocking had become soiled with feces and urine. It was then discovered that the resident had developed two Stage II pressure ulcers and a Stage I ulcer. CMS Ex. 4, at 6; CMS Ex. 14, at 5, 63 - 64.

The evidence that I have just summarized is strong support for a finding that Petitioner's staff failed to take necessary and reasonable steps to protect Resident # 9 against developing pressure sores. Petitioner's staff knew that the resident's age and general condition put her at a very high risk for developing pressure sores. The staff knew also that the risk was enhanced by virtue of the resident's fracture and her resulting immobility as well as by her need to wear an immobilizer to allow healing of her fractured leg. For that reason the staff planned to monitor the resident's skin under the immobilizer. I find it reasonable to infer from the resident's care plan that the staff envisioned bathing the resident from time to time and, in the course of doing that, removing the immobilizer and stocking and checking the condition of the resident's skin.

However, the staff failed to follow through on this plan. The staff never removed the immobilizer. They left the resident's skin essentially unattended for a period of a month and the resident developed three pressure sores. I make no finding that the sores which the resident developed were the direct consequence of the staff's failure to follow through on the resident's care plan. But, it is evident that Petitioner's staff failed to take the steps that were designed to protect the resident from developing sores. The staff's inaction was a prima facie violation of 42 C.F.R. § 483.25(c) because it constituted a failure to take necessary and reasonable measures – developed by the staff itself – to protect the resident against developing pressure sores.

I find Petitioner's explanations for the staff's failure to check the resident's skin condition not to be persuasive. Petitioner's primary argument is that the orthopedic physician who placed the custom-fit immobilizer on the resident's leg intended that the device *never* be removed by Petitioner's staff. Thus, according to Petitioner, the staff could not inspect the resident's skin under the immobilizer and would have no way of knowing whether the resident was developing pressure sores. As support for this argument Petitioner relies on the orthopedist's order and a March 27, 2006-letter by him, in which he stated that the resident was to wear the immobilizer at "all times" until her scheduled visit at an outpatient clinic on January 19, 2006. CMS Ex. 14, at 19; P. Ex. 33, at 1. Additionally, it relies on the testimony of its medical director, who averred that:

> When a physician has given an order for a brace not to be removed, even for bathing, nurses ordinarily should not try to remove or change the stocking under the brace in order to avoid moving the bone.

P. Ex. 41, at 2.

However, I do not read the physician's order as directing Petitioner's staff absolutely never to remove the immobilizer, "even for bathing." More to the point, neither did Petitioner's staff.

The immobilizer, which was closed by velcro, was designed to be removed from time to time. It is evident from the staff's assessment and plans for the resident that the staff contemplated periodic removal of the immobilizer and the underlying stocking in order to bathe the resident and check her skin for the possible development of pressure sores. CMS Ex. 14, at 16. That is exactly what the treatment plan for Resident # 9 stated.

Petitioner's plan for the resident would conflict explicitly with the orthopedist's order if, in fact, the order was that the immobilizer *never* be removed. Petitioner has not explained why its staff would write a treatment plan that would conflict with a physician's order. The explanation, however, is not obscure or complicated. The orthopedist's order meant only that the immobilizer should be left undisturbed at all times when Petitioner's staff was not providing care to the resident. It gave the staff leeway to remove the immobilizer on those occasions when direct attention – such as bathing and inspecting the skin – needed to be paid to the resident's leg.

In fact, the staff removed the immobilizer and stocking on January 17, 2006 – two days before the scheduled return visit to the orthopedist – so that the stocking could be cleaned. Obviously, the staff knew that doing so would not violate the orthopedist's order. Otherwise it would not have removed the immobilizer.

Petitioner relies also on the testimony of the staff nurse who was responsible for skin care. She asserted that, in a case such as that of Resident # 9, where the resident's leg is covered by an immobilizer, her technique for checking on a resident's skin condition is to:

> . . . look at the areas I can see, especially where the Resident's skin might touch or rub against the edge of the brace. In addition, I check pedal pulses to assure that there is adequate blood flow throughout the leg; monitor for drainage or foul odor; consider resident complaints of pain; and the like, to determine whether the skin may be compromised or require special protection. I used all of these techniques in the case of Resident #9 and did not find any potential problems.

P. Ex. 40, at 2.

However, what the nurse did with Resident # 9 expressly contradicted the staff's skin care plan for the resident. The plan for the resident was to monitor the resident's skin *under* the brace by checking it when the resident was bathed. CMS Ex. 14, at 16. Petitioner's staff clearly failed to do that and Petitioner offers no credible explanation of why it failed to do so.

Moreover, I am not satisfied that Petitioner's staff did even what its nurse claimed to have done for Resident # 9. The staff appeared not to have noticed that the stocking under the immobilizer had become contaminated with feces and urine because it was the resident's daughter who requested that the stocking be removed so that it could be cleaned. CMS Ex. 14, at 49. I find it hard to believe that the staff could have failed to notice the contamination if staff members were diligently checking the resident for foul odors. Also, the resident at times complained of pain in her right leg. *Id.* at 47. Although a complaint of pain was identified by Petitioner's nurse as something that the staff looked out for in assessing the condition of the resident's skin, it is apparent that Petitioner's staff did not react to the resident's complaints as signs of potential skin problems prior to January 17, 2006.

b. Petitioner failed to comply substantially with the requirements of 42 C.F.R. § 483.15(e)(1).

The relevant regulation requires a facility to provide its residents with reasonable accommodations of their individual needs and preferences except where a resident's or other residents' health and safety would be endangered. CMS alleges that Petitioner failed to comply with this requirement in that it failed, in several instances, to place call bells within residents' reach. CMS offered as proof the observations of the surveyors who conducted the January survey. CMS Exs. 13; 16; 17; 18. Their observations included the following findings:

- A resident identified as Resident # 7 complained to the surveyors that the staff frequently failed to put the call light bell with her reach. CMS Ex. 13, at 3, 5 - 6, 7 - 8.

- Resident # 22 suffered from left side paralysis. However, Petitioner's staff was observed to have placed the call bell on the left side of the resident's pillow, making it impossible for the resident to utilize the call bell. CMS Ex. 4, at 1; CMS Ex. 16, at 4.

- In the cases of several other residents Petitioner's staff were observed to have placed call bells in inconvenient positions or out of the residents' reach. CMS Ex. 18, at 25 - 26. Two residents were observed to be looking for call bells but were unable to find them due to the locations in which Petitioner's staff placed them. *Id.* at 25; CMS Ex. 17, at 4.

The evidence offered by CMS is strong prima facie proof that Petitioner failed to accommodate the needs of several of its residents. The obvious purpose of a call bell is to enable a resident to summon staff for assistance. Placing the bell in an inaccessible position renders the bell useless to the resident.

Petitioner's defense to these allegations is to argue that they offer no prima facie proof of a potential for more than minimal harm to residents.[1] According to Petitioner, there is no evidence that any resident complained that a call bell was not answered or, that residents were unkempt or poorly cared for. I find that this argument begs the question. The issue is not whether failure to provide residents with access to call bells caused the residents to suffer adverse consequences. Rather, it is whether failure to provide the residents with access to call bells put these residents, potentially, at risk for harm. The answer to that question is evident. The whole point of having call bells in a nursing facility is to give the residents, many of whom are severely handicapped, a way of quickly bringing problems and needs to the staff's attention. These problems obviously can include problems that are health or even life-affecting. Not giving residents access to call bells defeats the purpose of having the bells.

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[1] Petitioner suggests, with respect to this deficiency and with respect to those others that are based on surveyors' observations, that it has no way of knowing whether the surveyors' observations were accurate. But, Petitioner did not challenge these observations and offered no affirmative proof to show that they were inaccurate.

c. Petitioner failed to comply substantially with the requirements of 42 C.F.R. § 483.25(a)(3).

The regulation at issue here requires a facility to ensure that a resident who is unable to carry out the activities of daily living receives the necessary services to maintain good nutrition, grooming, and personal and oral hygiene. CMS alleges that Petitioner failed to comply with the requirements of this regulation because, in several instances, it failed to provide residents with incontinence care in a manner least likely to lead to skin breakdown. CMS offered evidence with respect to four residents, identified as Resident #s 5, 7, 20, and 23. CMS Exs. 12; 13; 15; 17. Each of these residents was identified by Petitioner's staff as needing extensive or total care with respect to their activities of daily living. These residents had continence problems. CMS offered evidence about Petitioner's care of these residents, consisting of surveyors' observations of the care that the staff provided to them:

- The staff failed to dry the legs and lower back of Resident # 5, after providing continence care to the resident. CMS Ex. 4, at 4; CMS Ex. 12, at 5 - 6. The staff was also observed putting a dry sheet over a visibly wet mattress. CMS Ex. 12, at 5.

- The staff failed to clean the pubic and genital areas of Resident # 7, a paraplegic individual, after an episode of incontinence. CMS Ex. 4, at 4; CMS Ex. 26, at 2.

- The staff applied a clean incontinence brief to Resident # 20, a demented individual, after an episode of incontinence, without first completely washing and drying the resident's skin. CMS Ex. 4, at 5; CMS Ex. 15, at 8, 9 - 10.

- The staff failed to dry the skin of Resident # 23 before applying a moisture barrier to the skin. CMS Ex. 4, at 3; CMS Ex. 17, at 4.

Petitioner's only response to these allegations is to assert that there was no evidence cited by the surveyors to the effect that residents remained wet or unattended for unreasonably long periods of time. I find that not to be a defense. The issue, as stated by CMS, is whether these residents received necessary services to maintain hygiene. Extended periods of wetness or lengthy periods of lack of attention are not an element of CMS's case against Petitioner. Failure to provide continence care, as described in CMS's prima facie evidence, is clear proof of a failure by Petitioner's staff to satisfy the regulatory standard. The potential for harm here is clear. Residents who do not receive appropriate

continence care are, at a minimum, at risk for chafing and skin irritation. Other problems, such as infections, are foreseeable. Petitioner has not denied that such failures of care, as described by the surveyors, occurred nor has it offered any affirmative proof to challenge the surveyors' observations.

d. Petitioner failed to comply substantially with the requirements of 42 C.F.R. § 483.65(b)(3).

The regulation at issue here requires facility staff members to wash their hands after each direct resident contact for which hand washing is indicated by accepted professional practice. The evident purpose of this regulation is to prevent the spread of disease or infection in a facility. The surveyors who conducted the January survey observed that Petitioner's staff failed to wash their hands or change gloves after providing incontinence care to Resident #s 5, 7, 20, and 23. CMS Ex. 12, at 6; CMS Ex. 13, at 6; CMS Ex. 15, at 6; CMS Ex. 17, at 4; CMS Ex. 26, at 3 - 4.

Petitioner argues that these incidents, which it characterizes as "isolated," fail to demonstrate the potential for more than minimal harm to residents in the absence of any evidence of residents remaining wet, complaining, or of proof that infections were spreading as a consequence of poor staff hygiene. I find this argument to be without merit. Petitioner seems to be saying that a deficiency cannot exist unless CMS provides evidence of a causal relationship between poor hygiene and the actual spread of infection at Petitioner's facility or other adverse consequences. But, actual harm is not a necessary element of CMS's case. The issue here is whether the failure by the staff to wash their hands after providing incontinence care posed the potential for more than minimal harm to residents. I find such potential to be obvious. As CMS asserts, citing the Centers for Disease Control:

> Handwashing is the single most important procedure for preventing nosocomial infections.

CMS Ex. 21, at 7.

2. Civil money penalties of $200 per day for each day of the January 20 - March 9, 2006-period are reasonable.

Petitioner did not offer argument or evidence concerning the duration of its noncompliance. It did not assert, for example that, if any deficiency was present at its facility as of January 20, 2006 it corrected that deficiency prior to March 9. Consequently, I find that CMS's determination as to the duration of Petitioner's noncompliance is administratively final.

The remaining issue is whether civil money penalties of $200 for each day of the noncompliance period are reasonable. I find that they are.

The penalties that CMS determined to impose against Petitioner fall within the range of civil money penalties that are reserved to remedy deficiencies that do not put residents of a facility in a state of immediate jeopardy. The range for such penalties is between $50 and $3,000 per day. 42 C.F.R. § 488.438(a)(1)(ii). I note at the beginning of this discussion that the penalties that CMS determined to impose are extremely modest, falling at the bottom end of the non-immediate jeopardy range and, comprising less than seven percent of the maximum permissible non-immediate jeopardy penalty amount.

Regulations establish criteria for evaluating penalty amounts. The criteria include: the seriousness of the noncompliance; the facility's noncompliance history; the facility's culpability; and, the facility's 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)). Here, neither CMS nor Petitioner presented evidence or argument relating to any of the regulatory criteria other than the seriousness of Petitioner's noncompliance.

I conclude that Petitioner's noncompliance was relatively serious. The potential for harm resulting from the deficiencies that I discuss above was palpable. The potential harm included the risk that Petitioner's failure to look after its residents' skin condition might lead to the development of pressure sores by residents. It also included the probability that residents in distress would be unable to communicate their needs. It included the risk that incontinent residents might develop skin problems. And, finally, it included the heightened possibility that infections might be spread by Petitioner's staff.

Those risks were evident. Any one of the deficiencies that I have found that Petitioner manifested was, in and of itself, of sufficient gravity to justify the very modest penalties that CMS determined to impose. Collectively these deficiencies were more than sufficient to justify the penalties of $200 per day.

Petitioner argues that CMS failed to prove that residents were actually harmed by its noncompliance and, for that reason, it asserts that civil money penalties should not be imposed against it. It argues that the surveyors originally found deficiencies other than those that were the basis for CMS's final remedy determination and that these deficiencies were ultimately deleted. It contends that I should not sustain penalties against it because the aggregate level of noncompliance, minus the deleted deficiencies, is lower than that which was originally determined. Also, Petitioner argues that CMS did not prove prima facie that the failure to provide planned skin care for Resident # 9 actually harmed the resident, as alleged, and it argues that it should benefit from this asserted failure of proof.

I find these arguments to be unpersuasive. My conclusion that civil money penalties of $200 per day are reasonable is not based on findings that residents were harmed by Petitioner's noncompliance. In this case it is the *potential for harm* that justifies the penalty amounts. I make no findings here that Petitioner's noncompliance actually harmed residents because it is unnecessary that I do so in order to conclude that the penalty amount is reasonable.

Moreover, the fact that there may have, at one time, been more serious findings of noncompliance than those that are the basis for my decision is irrelevant. Implicit in Petitioner's arguments is the assumption that my review of penalty determinations is some type of appellate review in which I measure the reasonableness of the penalties against the evidence that CMS had before it at the time it made its determinations. Petitioner's logic evidently is that I am obligated to reduce a penalty amount where I find fewer, or less serious, deficiencies than those upon which CMS originally based its remedy determination. That is incorrect. I conduct a *de novo* review of the evidence relating to penalty amount. Here, my decision that penalties of $200 per day are reasonable is based solely on the evidence before me and without regard to how CMS might have reviewed the same or different evidence.

/s/

Steven T. Kessel
Administrative Law Judge