Department of Health and Human Services

DEPARTMENTAL APPEALS BOARD

Civil Remedies Division

In the Case of:	)	
	)	
Embassy Health Care Center, (CCN: 14-5316)	)	Date: July 24, 2009
	)	
Petitioner,	)	
	)	
- v. -	)	Docket No. C-08-505
	)	Decision No. CR1980
Centers for Medicare & Medicaid Services.	)	
	)	

DECISION

I sustain the determination of the Centers for Medicare & Medicaid Services (CMS) to impose remedies against Petitioner or facility, Embassy Health Care Center. The remedies that I sustain include civil money penalties in daily amounts of $200 for each day of a period that began on March 17, 2008 and ran through June 8, 2008, (84 days) for a total civil money penalty of $16,800.

I. Background

Petitioner, located in Wilmington, Illinois, is authorized to participate in Medicare as a skilled nursing facility (SNF) and in the Medicaid program as a nursing facility (NF). Petitioner was subject to surveys by the Illinois Department of Public Health and Human Services (state agency). On March 17, 2008, a complaint investigation was completed at Petitioner's facility by the state agency to determine if the facility was in compliance with Federal requirements for nursing homes participating in the Medicare and Medicaid programs. The survey found that the facility was not in substantial compliance at a severity level that involved actual harm, but did not amount to immediate jeopardy. The deficiency was cited as: F314 – scope and severity: G – 483.25(c) – pressure ulcers. On April 1, 2008, the state agency conducted another complaint investigation at Petitioner's facility, which found that Petitioner was still not in substantial compliance with participation requirements. The deficiency was cited as: F323 – scope and severity: G –

483.25(h) – accidents and supervision. CMS conducted additional surveys on May 16 and May 28, 2008, respectively in which additional deficiency findings were made at F253 and F406.[1]

As a result of the survey findings, CMS determined to impose remedies including directed in-service training effective May 1, 2008, a mandatory three-month denial of payment for new admissions effective June 17, 2008, and a civil money penalty of $200 per day beginning March 17, 2008.

Petitioner timely requested a hearing before an administrative law judge (ALJ), and the case was assigned to me for hearing and decision.

By agreement dated October 23, 2008, the parties stipulated that the scope of the hearing would be limited to evidence related to the F314 and F323 tags, and that all other deficiency findings would be considered uncontested.

I conducted an in-person hearing in Chicago, Illinois, on December 8 and 9, 2008. CMS offered exhibits (CMS Exs.) 1 through 11, which were admitted. Petitioner offered exhibits (P. Exs.) 8 through 31, which I admitted into evidence. Petitioner withdrew P. Exs. 1 through 7. CMS elicited testimony from Arletha Henson-Walker, state agency surveyor; and Mary Durand, state agency surveyor. Petitioner elicited testimony from Frank Brazier, a maintenance supervisor employed by Petitioner; Kelly Bates, director of social services, Deerbrook Care Centre, Joliet, Illinois; Sue Bessette, administrator employed by Petitioner; Joshua Ryan Schott, certified nurse's assistant employed by Petitioner at the time of the March survey. On December 16, 2008, Petitioner arranged for the deposition of Daniel M. Jurak, M.D., a physician at Petitioner's facility, and was subject to examination by Petitioner and CMS. A transcript of Dr. Jurak's testimony was prepared and received into evidence as P. Ex. 34.

Each party submitted a post hearing brief (CMS Brief and P. Brief, respectively) and a reply brief (CMS Reply and P. Reply, respectively) and each party received a copy of the hearing transcript (Tr.)

In the interest of judicial economy I do not address, and therefore make no findings or conclusions regarding, the alleged violation of F323, 42 C.F.R. § 483.25(h) from the April 1, 2008 survey. The violation discussed hereafter provides a sufficient basis for the enforcement remedies proposed by CMS that I approve. *See Beechwood Sanitarium*,

[1] These matters were docketed under C-08-505 and C-08-749 and consolidated under C-08-505.

DAB No. 1824, at 22 (2002). I do not consider the deficiencies not specifically addressed as any part of the basis for the imposition of an enforcement remedy.

II. Issues, applicable law, findings of fact and conclusions of law

A. Issues

The issues in this case are:

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

2. Whether the remedies imposed are reasonable.

B. Applicable Law and Regulations

Petitioner is considered a long-term care facility under the Social Security Act (Act) and regulations promulgated by the Secretary of Health and Human Services (Secretary). The statutory requirements for participation by a long-term care facility are found at sections 1819 and 1919 of the Act, and at 42 C.F.R. Part 483. Sections 1819 and 1919 of the Act vest the Secretary with authority to impose civil money penalties (CMPs) and other remedies against a long-term care facility for failure to comply substantially with participation requirements.

Pursuant to the Act, the Secretary has delegated to CMS the authority to impose various remedies against a long-term care facility that is not complying substantially with federal participation requirements. Facilities which participate in Medicare may be surveyed on behalf of CMS by State survey agencies in order to ascertain whether the facilities are complying with participation requirements. 42 C.F.R. §§ 488.10-488.28; 42 C.F.R. §§ 488.300-488.335. Under Part 488, CMS may impose a per instance or per day CMP against a long-term care facility when a State survey agency ascertains that the facility is not complying substantially with participation requirements. 42 C.F.R. §§ 488.406, 488.408, 488.430. The regulations in 42 C.F.R. Part 488 also give CMS a number of other remedies that can be imposed if a facility is not in compliance with Medicare requirements.

Pursuant to 42 C.F.R. Part 488, CMS may terminate a long-term care facility's provider agreement when a survey agency concludes that the facility is not complying substantially with federal participation requirements. CMS may also impose a number of alternative enforcement remedies in lieu of or in addition to termination. 42 C.F.R.

§§ 488.406; 488.408; 488.430. In addition to termination and the alternative remedies CMS is authorized to impose, pursuant to section 1819(h)(2)(D) of the Act and 42 C.F.R. § 488.417(b), CMS must impose the "mandatory" or "statutory" DPNA. Section 1819(h)(2)(D) requires the Secretary to deny Medicare payments for all new admissions to a SNF, beginning 3 months after the date on which such facility is determined not to be in substantial compliance with program participation requirements. The Secretary has codified this requirement at 42 C.F.R. § 488.417(b).

The regulations specify that a CMP imposed against a facility can be either a per day CMP for each day the facility is not in substantial compliance or a per instance CMP for each instance that a facility is not in substantial compliance. 42 C.F.R. § 488.430(a).

The regulations specify that a CMP that is imposed against a facility on a per day basis will fall into one of two broad ranges of penalties. 42 C.F.R. §§ 488.408, 488.438. The upper range of CMP, of from $3050 per day to $10,000 per day, is reserved for deficiencies that constitute immediate jeopardy to a facility's residents, and in some circumstances, for repeated deficiencies. 42 C.F.R. §§ 488.438(a)(1)(i), (d)(2). The lower range of CMP, from $50 per day to $3000 per day, is reserved for deficiencies that do not constitute immediate jeopardy, but either cause actual harm to residents, or cause no actual harm, but have the potential for causing more than minimal harm. 42 C.F.R. § 488.438(a)(1)(ii). There is only a single range of $1000 to $10,000 for a per instance CMP, which applies whether or not immediate jeopardy is present. 42 C.F.R. §§ 488.408(d)(1)(iv); 488.438(a)(2).

The regulations define the term "substantial compliance" to mean "a level of compliance with the requirements of participation such that any identified deficiencies pose no greater risk to resident health or safety than the potential for causing minimal harm." 42 C.F.R. § 488.301. Non-compliance that is immediate jeopardy is defined as "a situation in which the provider's noncompliance with one or more requirements of participation has caused, or is likely to cause, serious injury, harm, impairment, or death to a resident." *Id.* The Act and regulations make a hearing before an administrative law judge (ALJ) available to a long-term care facility against whom CMS has determined to impose a CMP. Act, section 1128A(c)(2); 42 C.F.R. §§ 488.408(g); 498.3(b)(13). The hearing before an ALJ is a de novo proceeding. *Anesthesiologists Affiliated, et al*, DAB CR65 (1990), *aff'd*, 941 F2d. 678 (8th Cir. 1991).

A facility has a right to appeal a "certification of noncompliance leading to an enforcement remedy." 42 C.F.R. § 488.408(g)(1); *see also* 42 C.F.R. §§ 488.330(e) and 498.3. However, the choice of remedies by CMS or the factors CMS considered when choosing remedies are not subject to review. 42 C.F.R. § 488.408(g)(2). A facility may

only challenge the scope and severity level of noncompliance found by CMS if a successful challenge would affect the amount of the CMP that could be collected by CMS or impact upon the facility's nurse aide training program. 42 C.F.R. §§ 498.3(b)(14) and (d)(10)(I). CMS's determination as to the level of noncompliance "must be upheld unless it is clearly erroneous." 42 C.F.R. § 498.60(c)(2). This includes CMS's finding of immediate jeopardy. *Woodstock Care Center*, DAB No. 1726, at 9, 38 (2000), *aff'd, Woodstock Care Center v. U.S. Dept. of Health & Human Services*, 363 F.3d 583 (6th Cir. 2003). The Departmental Appeals Board (the Board or DAB) has long held that the net effect of the regulations is that a provider has no right to challenge the scope and severity level assigned to a noncompliance finding, except in the situation where that finding was the basis for an immediate jeopardy determination. *See, e.g.*, *Ridge Terrace*, DAB No. 1834 (2002); *Koester Pavilion*, DAB No. 1750 (2000). Review of a CMP by an ALJ is governed by 42 C.F.R. § 488.438(e).

In a CMP case, CMS must make a prima facie case that the facility has failed to comply substantially with participation requirements. To prevail, a long-term care facility must overcome CMS's showing by a preponderance of the evidence. *Hillman Rehabilitation Center*, DAB No. 1611 (1997); *aff'd, Hillman Rehabilitation Center v. U. S. Dept. of Health & Human Services*, No. 98-3789 (GEB) (D.N.J. May 13, 1999).

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

I make two findings of fact and conclusions of law to support this decision. I set them forth below as separate headings in bold type, and then discuss each in detail.

1. Petitioner failed to comply substantially with the requirement in 42 C.F.R. § 483.25(c) (F314) that it protect its residents against the development of pressure sores.

The regulation at issue here mandates that a resident who enters a skilled nursing facility without pressure sores will not develop a pressure sore or sores unless the resident's clinical condition demonstrates that the development of a pressure sore was unavoidable. 42 C.F.R. § 483.25(c)(1). Additionally, it requires a facility to provide necessary treatment and services to any resident having pressure sores, to promote healing, prevent infection, and prevent new sores from developing. 42 C.F.R. § 483.25(c)(2).

CMS alleges in its March 17, 2008 statement of deficiency (SOD) that Petitioner failed to protect Resident 3 against the development of pressure sores. Specifically, CMS alleges that Petitioner: (1) failed to accurately assess pressure sores of Resident 3 upon her re-

admission to the facility; (2) failed to treat pressures sores as ordered by Resident 3's physician; and (3) failed to take the necessary steps to prevent Resident 3 from developing stage III and stage IV pressure sores.

At the time of the survey, Resident 3 was a 95-year old woman with multiple ailments including a history of cerebrovascular accident, osteoporosis, anemia, renal insufficiency, and urinary tract infection. P. Ex. 8, at 3-5; CMS Ex. 6, at 83.

Resident 3 was originally admitted to Petitioner's facility in 2003, and upon readmittance from a local hospital in November of 2007, she had a decubitus ulcer on her coccyx and left heel. Resident 3 also had a cast on her right leg due to surgery as a result of osteoporosis. P. Ex. 34, at 9. CMS points out that facility records indicate that Resident 3 had no skin breakdown, but noted areas of blistering and reddening. CMS contends that Petitioner's notation was inaccurate because the blistered area should have been assessed as a stage II pressure sore, and that this inaccuracy was caused by a failure of Petitioner to assess Resident 3 adequately for pressure sores. CMS Br. 4-5.

The record shows that Resident 3's physician ordered treatment for these ulcers. The orders required a daily dry dressing, a cleansing of the coccyx wound with normal saline solution, as well as an application of DuoDerm every three days as needed until healed. P. Ex. 16; P. Ex. 34, at 12-13; CMS Ex. 6, at 95.

However, surveyors found that Petitioner's staff failed to administer treatment as required and ordered. CMS Ex.1, at 4-7. Specifically, on at least three occasions in November (15, 17, and 18) Petitioner failed to change Resident 3's dry dressing on her heel as required by her physician's orders. CMS Ex. 6, at 158. Similarly, Petitioner's staff failed to cleanse Resident 3's pressure sore with normal saline solution and every three days DuoDerm as required and ordered. Instead, Petitioner's treatment records show that facility staff failed to follow the physician's explicit orders, allowing four days to elapse between November 13 and 17, and six days to elapse between November 17 and 23, before administering treatment as directed. CMS Ex. 6, at 158. On February 25, 2008, Resident 3 died. CMS Ex. 6, at 20-24. A preliminary coroner's report indicated that Resident 3 had stage III and stage IV pressure sores. CMS Ex. 6, at 22; Tr. 66-67. CMS has established a *prima facie* violation of 42 C.F.R. § 483.25(c).

Petitioner does not dispute the surveyor's findings. However, Petitioner maintains that the development of Resident 3's pressure sores were unavoidable; that the pressure sores'

worsening was due to her extremely poor health; and that Resident 3's decline was inevitable. P. Br. 2-3. Petitioner further explains its argument as follows:

> [The] presence of pressure sores is largely explained by the fact that [Resident 3's] body could not metabolize the food that it was taking in. Moreover, [Resident 3] had poor circulation because of the fact that she had no palpable pulses in her feet. The combination of poor nutrition, lack of mobility, and poor circulation positively made it very easy for [Resident 3] to develop pressure sores.

P. Br. 2.

Petitioner insists that it implemented a rigorous plan of care accompanied with interventions in order to promote Resident 3's healing, prevent infection, and prevent new sores from occurring. These interventions included: (1) providing Resident 3 with a pressure-relieving mattress; (2) placing a cushion in Resident 3's wheelchair; (3) assuring that Resident 3's skin was clean and dry at all times; (4) encouraging Resident 3 to eat all her food, consume fluids, and take vitamin supplements; (5) performing daily skin care checks; and (6) applying topical antibiotic ointments. CMS Ex. 6, at 158; P. Ex. 34, at 18-19; Tr. 138-139.

Petitioner's arguments are unavailing and I find that Petitioner failed to carry out physician orders for the treatment of existing pressure sores which the physician deemed important to promote healing and fight infection as required pursuant to 42 C.F.R. § 483.25(c)(2). I find that Petitioner suffered actual harm.

The record shows that Petitioner simply failed to adhere to Resident 3's doctor's orders. Petitioner did not change the dry dressing every day on Resident 3's right heel as required by her doctor's orders, and Petitioner did not cleanse Resident 3's coccyx with normal saline and DuoDerm every three days as her doctor's orders had required. I note that Petitioner on at least one occasion in its medical records and brief referred to the sore on Resident 3's heel upon admittance in November 2007 as a "scab" or "blister." P. Br. 3. CMS has maintained from the beginning that Petitioner's characterization of the sore was inaccurate and that it should have been coded as a stage II pressure sore or ulcer. CMS Br. 4. Despite Petitioner's description of Resident 3's sore, Petitioner does not dispute and the record is clear that Resident 3 arrived at Petitioner's facility in November of 2007 with sores on her heel and coccyx. P. Ex. 34, at 9-10; P. Br. 2. Thus, since Resident 3 arrived at Petitioner's facility with pressure sores, the regulations at 42 C.F.R. § 483.25(c)(2) require Petitioner to provide the necessary treatment and services to promote healing, prevent infection, and prevent new sores from developing.

The application of this regulation is well-established by decisions of various appellate panels of the Board. *Koester Pavilion*, DAB No. 1750 (2000); *Cross Creek Health Care Center*, DAB No. 1665 (1998). With respect to prevention and treatment of pressure sores, the Board has concluded that a facility bears a duty to "go beyond merely what seems reasonable to, instead, always furnish what is necessary to prevent new sores unless clinically unavoidable, and to treat existing ones as needed." *Koester Pavilion*, DAB No. 1750, at 32.

Petitioner admits that on at least three days in November 2007 it failed to change Resident 3's dry dressing on her heel and on at least two occasions allowed four or more days to elapse before cleansing Resident 3's coccyx with normal saline and DuoDerm. P. Reply 2-5. However, Petitioner argues essentially that it substantially complied with Resident 3's doctors orders and that, "CMS has attempted to label [Petitioner] has (sic) a violator due to its failure to document and follow every physician order to a "T"." P. Reply 4. Petitioner further argues that its case is similar to *Koester Pavilion*, and that the facts here are much more favorable to its legal position. In *Koester Pavilion,* the facility properly prescribed footwear that was specifically designed to prevent pressure sores in high risk situations. The Health Care Financing Administration (HCFA) — now CMS — argued that the design of the boot caused the development of the pressure sore and therefore the facility did not properly care for the patient's pressure sores. The ALJ disagreed with HCFA, finding that despite the use of the boot, the sore was clinically unavoidable as a result of the disease process.

I agree with Petitioner that the regulations do not require a facility to be perfect in its execution when providing care to its residents. However, a facility is obligated to provide the necessary quality and quantity of care and services in order to meet a resident's needs. *Kelsey Memorial Hospital*, DAB CR583 (1999). In a sickly, immobile, 95 year-old woman such as Resident 3, pressure sores may develop very quickly. A pressure sore may greatly diminish a resident's quality of life and may even be lethal. Petitioner's failure to follow her doctor's explicit orders to provide the necessary dressing changes and cleansing of Resident 3's pressure sores on several occasions, as scheduled and required by those orders, falls below the quality of care that the regulations require.

Moreover, Petitioner's reliance on *Koester Pavilion* to support its position is misguided. In *Koester Pavilion* the ALJ did in fact rule in favor of the facility, finding that the resident's sores were clinically unavoidable. However, in *Koester Pavilion*, the ALJ specifically found that the facility took *all appropriate measures* to treat the resident's pressure sores, and despite these efforts pressure sores developed. Such was not the case here, where Petitioner did not administer treatment as required and ordered, and thus failed to deliver necessary treatment and services to promote healing, prevent infection, and prevent new sores from developing. 42 C.F.R. § 483.25(c)(2).

Petitioner points out that Resident 3's treating physician, Dr. Daniel Jurak agreed with Petitioner's assessment that because of her poor health, Resident 3's pressure sores worsened and that her decline was inevitable. Eventually, because of Petitioner's deteriorating physical condition, Dr. Jurak concluded that:

> [Resident 3] did not improve and there did become a point where the treatments seemed to be causing her more discomfort with trying to turn her and give her dressing changes and those kinds of things, to the point where, you know, I think the guardian eventually said that she just wanted her to be continued on the comfort measures, and then we discussed about hospice coming in to see her . . . .

P. Ex. 34, at 20.

Petitioner's argument is unpersuasive and Dr. Jurak's testimony does not change my conclusion. The regulations impose an identical duty of care on a facility with respect to every resident regardless of physical condition. *See Clermont Nursing and Convalescent Center*, DAB No. 1923 (2004). They require a facility to assume that no pressure sore is inevitable or unavoidable. A facility must do its best to assure that a resident does not develop a pressure sore or that an existing pressure sore does not worsen. Inevitability is not a defense as Petitioner urges here, where a facility has failed to discharge its regulatory obligations by failing to follow a doctor's orders concerning the treatment of that doctor's patient. Inevitability may be a defense where a facility takes all reasonable measures to protect a resident, and the resident's sores develop or worsen despite those measures. I have no reason to doubt Dr. Juraks's sincerity when he testified that he believed that Resident 3 was not likely to be helped much by the measures he ordered, and that she was physically very compromised, *but the fact is that the treatment orders he gave were not followed*, and neither he nor anyone else available to give credible testimony in this case can say what might have happened, or not happened, if those orders had been followed. Furthermore, as Resident 3's treating physician, if Dr. Jurak believed that the dress changes and cleansing of Resident 3's pressure sores were causing her more harm and pain than benefit, he could have simply changed his orders. He did not, and the facility did not enjoy the option simply to ignore a physician's treatment order.

Remaining Tags

The parties stipulated that the scope of the hearing would be limited to evidence related to the F314 and F323 tags, and that all other deficiency findings would be considered uncontested. Because I have sustained CMS's deficiency finding F314, 42 C.F.R.

§ 483.25(c), I will not discuss the remaining F323 deficiency tag. It is not necessary that I make a finding concerning this additional alleged deficiency inasmuch as its presence or absence will add nothing to my decision in this case. The applicable regulations authorize imposition of a CMP if a provider is found to be out of substantial compliance with even a single program requirement. 42 C.F.R. §§ 488.406, 488.408, 488.430.

Additionally, I have the discretion to exercise judicial economy and not discuss every alleged deficiency. *Beechwood Sanitarium*, DAB No. 1824, at 22 (2002); *Western Care Management*, DAB CR1020 (2003).

2. The amount of the CMP imposed by CMS is reasonable.

In determining the amount of the CMP, the following factors specified at 42 C.F.R. § 488.438(f) must be considered: (1) the facility's history of non-compliance, including repeated deficiencies; (2) the facility's financial condition; (3) the seriousness of the deficiencies as set forth at 42 C.F.R. § 488.404; and (4) the facility's degree of culpability.

The lower range of CMP, from $50 per day to $3000 per day, is reserved for deficiencies that do not constitute immediate jeopardy, but either cause actual harm to residents, or cause no actual harm, but have the potential for causing more than minimal harm. 42 C.F.R. § 488.438(a)(1)(ii).

CMS seeks to impose a CMP of $200 a day from March 17, 2008 through June 8, 2008, for a total civil money penalty of $16,800.

Petitioner denied the existence of deficiencies at F314 and F323, but did not argue that substantial compliance was achieved at any earlier date than alleged by CMS. However, Petitioner argues with respect to the deficiency at F314, that its failure to follow Resident 3's physician orders was an isolated incident; that its failure did not amount to actual harm; and that the $200 per day CMP was excessive. P. Reply 9-10.

I disagree. The deficiency determination at F314 easily supports a $200 per day CMP imposition. The record shows that Petitioner failed to follow treatment orders as required and that Resident 3 developed stage III and stage IV pressure sores while at Petitioner's facility, thus a determination that she suffered actual harm is warranted. There was no

compelling evidence presented that persuaded me that Petitioner was not culpable, nor were there facts that indicated that its culpability is in any way diminished which would warrant the reduction of the CMP amount in this case. The $200 per day CMP is reasonable since it is in the lower range of penalties for deficiencies that do not constitute

immediate jeopardy but involved actual harm or caused no harm but have the potential for more than minimal harm.

Neither party has contended that the penalty amount should be affected by Petitioner's compliance history or financial condition. There is no evidence showing that Petitioner has a history of noncompliance other than during this survey cycle. Petitioner has not provided any evidence to show that its financial condition precludes it from paying the proposed CMP totaling $16,800.

III. Conclusion

For the foregoing reasons, I conclude that there is a basis for the imposition of a CMP. I further find that a CMP of $200 per day for 84 days from March 17, 2008 through June 8, 2008, for a total CMP of $16,800, is reasonable.

/s/
Richard J. Smith
Administrative Law Judge