Department of Health and Human Services

DEPARTMENTAL APPEALS BOARD

Civil Remedies Division

In the Case of:	)	
	)	
Hallmark House Nursing Center,	)	
	)	Date: July 10, 2008
	)	
Petitioner,	)	
	)	
- v. -	)	Docket No. C-07-434
	)	Decision No. CR1814
CR1814		
Centers for Medicare & Medicaid Services.	)	
	)	
	)	

DECISION

I sustain the determination of the Centers for Medicare & Medicaid Services (CMS) to impose remedies against Petitioner, Hallmark House Nursing Center, consisting of: a civil money penalty of $5,000 for Petitioner's noncompliance with Medicare participation requirements on November 6, 2006; and civil money penalties of $200 for each day of Petitioner's noncompliance with Medicare participation requirements during a period that began on November 7, 2006 and which continued through January 30, 2007. The total civil money penalties that I sustain in this case are $22,000.

I. Background

Petitioner is a skilled nursing facility doing business in the State of Illinois. It participates in the Medicare program. Its participation is governed by sections 1819 and 1866 of the Social Security Act and by implementing regulations at 42 C.F.R. Parts 483 and 488. Additionally, Petitioner is required to comply with requirements governing its physical premises stated in the Life Safety Code. Its hearing rights in this case are governed by regulations at 42 C.F.R. Part 498.

CMS determined to impose remedies based on findings made at two surveys of Petitioner's facility. The first survey, completed on November 2, 2006 (November 2 survey), resulted in findings that Petitioner was not in compliance with sections of the Life Safety Code. The second survey, completed on November 9, 2006 (November 9 survey), resulted in determinations that Petitioner was not complying with Medicare participation requirements. The determinations of noncompliance made at the November 9 survey included a finding that Petitioner manifested an immediate jeopardy level deficiency on November 6, 2006. The term "immediate jeopardy" is defined by regulations to mean a situation in which a facility's noncompliance with Medicare participation requirements is so egregious as to have caused, or so likely to cause, serious injury, harm, impairment, or death to a resident. 42 C.F.R. § 488.301.

Petitioner requested a hearing and the case was assigned to me for a hearing and a decision. I scheduled an in-person hearing in Springfield, Illinois. Just prior to the hearing I learned that several of the witnesses would not be appearing in person but would testify by telephone. For that reason I determined that the entire hearing could be held by telephone and, I held a telephone hearing on April 15, 2008. At the hearing I received into evidence exhibits from CMS which I identified as CMS Ex. 1 - CMS Ex. 29 and exhibits from Petitioner which I identified as P. Ex. 1 - P. Ex. 16. Each party received a copy of the hearing transcript (Tr.), and filed a post-hearing brief.

II. Issues, findings of fact and conclusions of law

A. Issues

The issues in this case are:

1. Whether Petitioner failed to comply with Medicare participation requirements and Life Safety Code requirements during the period that ran from November 6, 2006 through January 30, 2007;

2. Whether Petitioner manifested an immediate jeopardy level deficiency on November 6, 2006; and

3. Whether 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.

The Life Safety Code noncompliance found at the November 2 survey comprised several distinct alleged compliance failures. CMS Ex. 3, at 1-23. At the November 9 survey it was found that Petitioner failed to comply with two Medicare participation requirements. CMS Ex. 6. In this decision I address a single Life Safety Code deficiency, which is stated at Tag K 038 of the November 2 survey report. This is a failure by Petitioner to maintain exit access so that exits are readily accessible at all times. I address a single finding of noncompliance made at the November 9 survey, an immediate jeopardy level failure by Petitioner to comply with the requirements of 42 C.F.R. § 483.25(m)(2). The regulation requires that a facility assure that residents are free from significant medication errors.

I do not address other deficiency findings because it is unnecessary that I do so in order to decide this case. The noncompliance that I discuss in this decision justifies the remedies that CMS determined to impose.

1. On November 6, 2006 Petitioner failed to comply with the requirements of 42 C.F.R. § 483.25(m)(2).

CMS bases its allegation of noncompliance on the following facts. A resident of Petitioner's facility, identified as Resident #1, was as of the November 9 survey 80 years old and suffered from a variety of medical conditions including dementia and diabetes. The resident had been prescribed insulin in order to manage her diabetes. Her prescribed insulin included both short and long acting forms of the medication.

On October 14, 2006, at 4:30 p.m., a nurse on Petitioner's staff administered a prescribed dose of short acting insulin, Novolin R, to Resident #1. CMS Ex. 10, at 62-63. This form of insulin begins to take effect about one-half hour after it is administered and attains maximum effectiveness between two and one-half and five hours after it is administered. CMS Ex. 26, at 4; Tr. 165-166.

At 8:30 p.m. on that same date – at about the time that the Novolin R was reaching its maximum effectiveness – the same nurse administered 100 units of Lantus insulin to Resident #1. Lantus is a long-acting insulin and can remain active in a person's system for up to 24 hours after it is administered. CMS Ex. 18, at 3; Tr. 19. It begins to operate almost immediately after it is administered and reaches peak performance about four hours after administration. Tr. 159.

The 100 units of Lantus insulin that the nurse administered to Resident #1 was ten times the amount that had been prescribed by the resident's physician. P. Ex. 6, at 1; Tr. 74-75. Petitioner's staff did not realize that the resident had received an overdose until about 6 hours after the Lantus had been administered to Resident #1. As of 2:30 a.m. on October 15, 2006 the resident was observed to be cold, diaphoretic, and clammy, with a blood

sugar level of 32. CMS Ex. 7, at 1, 8; CMS Ex. 10, at 23. Petitioner's staff administered glucose to the resident and received orders from the resident's physician to administer intramuscular glucogen to the resident and to send her to the hospital. *Id.* The resident was hospitalized until October 16, 2006. CMS Ex. 10, at 78. During the resident's hospital stay the Lantus continued to cause her to become hypoglycemic at times. CMS Ex. 10, at 74, 78; P. Ex. 1, at 2; Tr. 19-20.

An overdose of insulin of the amount received by Resident #1 can cause serious and even permanent brain damage and can be life threatening. Tr. 22. The overdose of Lantus received by Resident #1 caused her blood sugar level to plummet to a reading of 32. That is very close to being incompatible with life. *Id.*

These facts, which are well-supported by the record, are more than sufficient to establish that Petitioner failed to assure that its residents be free from significant medication errors. The administration of an overdose of Lantus insulin to Resident #1 of ten times the prescribed amount was a medication error that was not only significant but it was life threatening.

Petitioner does not deny that administering an overdose of Lantus insulin to Resident #1 was a medication error nor does it appear to deny that this error was significant. Petitioner's arguments concerning its compliance with the regulatory requirement appear to be limited to asserting that this error was simply an isolated error with reversible consequences. Petitioner's pre-hearing brief, at 9.[1] But, the fact that the error was arguably isolated doesn't diminish its significance. The error in this case had life-threatening potential.[2] Moreover, and as CMS points out, the nurse who administered the overdose to Resident #1 had a history of committing medication errors. CMS Ex. 12, at 3. So, in fact, the mis-administration of Lantus insulin to Resident #1 was not entirely an isolated event.

2. CMS's determination that Petitioner manifested an immediate jeopardy level deficiency on November 6, 2006 is not clearly erroneous.

The evidence offered by CMS strongly supports a finding that Petitioner's noncompliance was at the immediate jeopardy level. The harm that the insulin overdose caused Resident #1 was obvious and extremely serious. The overdose made the resident gravely ill,

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[1] Petitioner does not reiterate this argument in its post-hearing brief.

[2] I discuss the seriousness of the error in more detail in Finding 2.

necessitating that she be hospitalized. There was a likelihood of even more serious harm. An insulin overdose in the amount administered to Resident #1 easily could have caused her to sustain permanent brain injury and it could have killed her.

Furthermore, the likelihood of harm resulting from the nurse's error was heightened by the failure of Petitioner to have systems in place that detected and redressed the error quickly. At the end of her shift the nurse who mis-administered the Lantus insulin to Resident #1 told a coworker that she had administered 100 units of the medication instead of the 10 that had been prescribed. CMS Ex. 7, at 8. That admission was not immediately recognized by Petitioner's staff as a serious medication administration error. Indeed, the mis-administration of Lantus to Resident #1 was not recognized by Petitioner's staff as a medication administration error until six hours after it had occurred. By then, the resident was in acute distress, necessitating that she be hospitalized.

I find to be unpersuasive Petitioner's arguments that CMS's determination of an immediate jeopardy level deficiency is clearly erroneous. Petitioner's arguments are that:

> • The mis-administration of Lantus insulin to Resident #1 was only an "isolated, one-time occurrence." Petitioner's post-hearing brief at 1.
>
> • Resident #1 did not suffer a serious injury as a consequence of the insulin overdose but, rather, a "potential for injury" that was "only a possibility." Petitioner's post-hearing brief at 6.

As I discuss above, even an isolated error by a facility's staff can constitute noncompliance with Medicare participation requirements. The fact that the medication error in this case was arguably isolated does not diminish its significance. Indeed, the harm resulting from an error of the type committed here is not diminished one iota if the error is an isolated one.

But, in fact, the medication error in this case was not isolated. The nurse who mis-administered Lantus insulin to Resident #1 had committed a similar error a few weeks previously when she gave medications to the wrong resident. CMS Ex. 12, at 5. So, Petitioner had on its staff a nurse with a propensity to commit medication errors. All of Petitioner's residents – not just Resident #1 – were at risk so long as this nurse's tendency to commit errors remained unaddressed.

Petitioner places great emphasis on the fact that the resident's reaction to the Lantus insulin was ameliorated by the care she received after the overdose was discovered. Its central argument is that there was no more than a potential for harm to the resident. According to Petitioner there was no likelihood that the resident would suffer serious injury or worse in light of her subsequent recovery from the overdose's effects.

But, such retrospective analysis ignores the fact that the resident indeed suffered serious injury. Her condition deteriorated so gravely in the hours after the administration of the insulin overdose that she needed to be hospitalized. When the overdose was discovered her blood sugar level was at 32, and she was cold, diaphoretic, and clammy. That these effects were reversed by medical care in no way diminishes their seriousness. A serious injury does not need to be a permanent injury to rise to the level of an immediate jeopardy level deficiency.

Furthermore, that *this resident* may have been saved by emergency treatment measures in no way diminishes the probability of serious injury harm or even death caused by Petitioner's medication errors. Petitioner had on its staff a nurse with a propensity to commit egregious medication errors. So long as that situation persisted there was a high probability that someone would eventually suffer grievous harm. Petitioner's – and the resident's - good fortune in this case in no respect diminishes that probability.

3. Petitioner failed to comply with a Life Safety Code requirement during the period that began on November 2, 2006 and which continued through January 30, 2007.

As I discuss above the November 2 survey identified several failures by Petitioner to comply with Life Safety Code requirements. Here I address Petitioner's failure to comply with the Life Safety Code requirement governing exit access. CMS Ex. 3, at 5-7; CMS Ex. 19, at 3.

Petitioner's facility has a paved exit path running from a corridor near the facility's dining room and ultimately leading to a street that is adjacent to the facility. CMS Ex. 19, at 3. The exit from the corridor opens to a fenced in area. The exit path runs alongside of the facility through the fenced-in area and to the street. At one point the path is interrupted by a gate. *Id.*

At the time of the November 2 survey this gate was locked. CMS Ex. 19, at 3. The surveyor who conducted the November 2 survey found that the gate had a delayed egress lock that did not comply with Life Safety Code requirements. *Id.*

Section 7.2.1.6.1(c) of the Life Safety Code requires that locked exit gates must have a release device that is actuated by pressure. For there to be compliance a locked exit gate release device must respond to pressure lasting no more than three seconds which in turn opens the gate within 15 seconds. CMS Ex. 3, at 6; CMS Ex. 19, at 3. Additionally, Section 7.2.1.6.1(d) of the Life Safety Code requires that a facility post a sign by a locked exit gate which instructs the user to push the release device until an alarm sounds. The sign must advise the user that the gate may be opened within 15 seconds of the alarm sounding. *Id*. The surveyor found that Petitioner's gate would not open unless the staff input a code on a keypad. CMS Ex. 19, at 3. In addition, there was no sign instructing the user to push on the gate until an alarm sounded. *Id.*

The evidence offered by CMS establishes a failure by Petitioner to comply with the Life Safety Code as it governed the maintenance of exit gates. Petitioner did not have a pressure release device that conformed to the code's requirements nor did it post the required sign. These are significant departures from code requirements because they potentially make it difficult or impossible for individuals seeking to escape Petitioner's premises in the event of an emergency to use the exit path.

Petitioner does not deny this deficiency. It asserts, however, that it corrected it by November 8, 2006. I do not find Petitioner's argument to be persuasive.

Petitioner submitted a plan of correction addressing the exit gate among other things. CMS Ex. 5, at 27. In the plan of correction it averred that its residents' clinical needs required a special security measure on the gate in order to protect the residents' safety. *Id*. It proposed that all of the residents' attending physicians would give admission orders for residents for the secured gate. *Id.* It represented that this measure would be completed by January 31, 2007.

The plan of correction is consistent with an exception to the Life Safety Code at section 19.2.2.2.4 that allows a facility to implement specialized security measures for its residents involving exit gates where such measures are required by residents' clinical needs and provided that the staff can readily unlock the gates at all times. Implicit in this exception is recognition that the need to protect some residents against their unauthorized exit from a facility may trump a need for a readily accessible exit. However, that exception is not a blanket exception to the general requirement that exit gates be able to be opened with pressure release devices. Rather, it contemplates an exception based on determinations made in *individual cases* that residents' needs to be denied easy access to the outside of a facility supersede general safety requirements.

Good faith qualification by Petitioner under the exception meant that it was absolutely necessary that it obtain assurances from the residents' physicians, made on an individualized basis, that these residents' needs for security required that they be denied

easy access to the outside of the facility. Tr. 67-68, 116. Petitioner represented that it would not be able to accomplish that prior to January 31, 2007 and it has offered no evidence that it achieved it at an earlier date.

Now, however, Petitioner contends that "all that was needed [to correct the Life Safety Code deficiency] was that the gate be locked and all staff given the unlock code, which was done by November 8, 2006." Petitioner's post-hearing brief at 14. This plainly misstates what Petitioner was required to do to qualify for the exception and does not establish that Petitioner attained compliance at a date earlier than January 31, 2007.

4. CMS's remedy determinations are reasonable.

a. CMS's determination to impose a $5,000 civil money penalty for Petitioner's immediate jeopardy level noncompliance on November 6, 2006 is reasonable.

Regulations provide that civil money penalties for immediate jeopardy level deficiencies must fall within a range of from $3,050 to $10,000 per day. 42 C.F.R. § 488.438(a)(1)(c). The regulations establish criteria for determining where within a penalty range a penalty amount should be established. The regulatory criteria include: the seriousness of a facility's noncompliance; its compliance history; its culpability; and its financial condition. 42 C.F.R. §§ 488.438(f)(1) - (4); 488.404 (incorporated by reference into 42 C.F.R. § 488.438(f)(3)).

I have applied those criteria to the evidence in this case and I conclude that the $5,000 civil money penalty that CMS determined to impose for one day of immediate jeopardy level noncompliance is reasonable. I find that the penalty amount of $5,000 is justified in this case both by the seriousness of Petitioner's noncompliance and its compliance history. I do not find that Petitioner's financial condition precludes it from paying this penalty or the other civil money penalties that CMS determined to impose against it.[3]

Petitioner's noncompliance was extremely serious. The medication administration error committed by Petitioner's nursing staff easily could have killed Resident #1. It is fortuitous that the error was discovered in time to administer emergency medical treatment to the resident. Nevertheless, by the time the error was discovered by Petitioner's staff the resident was in acute distress and her blood sugar level had plummeted to a level that was life-threatening.

[3] I discuss Petitioner's assertions about its financial condition at subpart c. of this Finding.

Furthermore, Petitioner's compliance history shows that this episode was not the first blight on an unblemished record. The nurse who mis-administered Lantus insulin to Resident #1 had previously committed another potentially serious medication error. Also, Petitioner has a history of noncompliance with Medicare and Life Safety Code requirements. These include a total of eight health deficiencies and 22 Life Safety Code deficiencies identified at surveys conducted between 2003 and 2005. CMS Ex. 2, at 2-4. These include findings of deficiencies that caused actual harm to residents. *Id.* at 2.

I find a civil money penalty of $5,000 actually to be quite modest given the gravity of Petitioner's immediate jeopardy level deficiency and its history of noncompliance. Indeed, CMS could have begun the period of immediate jeopardy at an earlier date than November 6, 2006 given that the medication error at issue in this case occurred on October 14, 2006 and that the nurse who mis-administered medication on that date had committed a serious medication error previously.

b. CMS's determination to impose civil money penalties of $200 per day for each day of a period that began on November 7, 2006 and which ran through January 30, 2007 is reasonable.

Civil money penalties for deficiencies that are not at the immediate jeopardy level must fall within a range of from $50 - $3,000 per day. 42 C.F.R. § 488.438(a)(1)(ii). The same criteria that govern immediate jeopardy level penalty amounts apply to decide where a penalty should be set within the non-immediate jeopardy level penalty range. 42 C.F.R. §§ 488.438(f)(1) - (4); 488.404 (incorporated by reference into 42 C.F.R. § 488.438(f)(3).

The penalty amount that CMS determined to impose to remedy Petitioner's Life Safety Code noncompliance is minimal in that it is less than ten percent of the maximum allowable amount. I conclude that the single Life Safety Code deficiency that I sustain in this decision is more than enough to justify this minimal penalty amount. Failure by Petitioner to maintain its exit gate in compliance with Life Safety Code requirements certainly posed a threat of more than minimal harm to Petitioner's residents. Furthermore, Petitioner had previously been cited for Life Safety Code noncompliance. CMS Ex. 2, at 2-3.

c. Petitioner did not prove that its financial condition precludes it from paying the civil money penalties that I sustain.

Petitioner describes its financial condition as being "grave." Petitioner's post-hearing brief at 5. It asserts that it lost more than $21,000 in the first eight months of 2007. *Id.*; P. Ex. 7, at 5. Evidently, Petitioner contends that it should be excused from paying at least some of the civil money penalties because of its condition.

I am unpersuaded that Petitioner's arguments about its financial condition justify reducing the civil money penalty amounts. Petitioner has not shown that it lacks the cash reserves or the overall financial health to pay the penalties that I sustain. Nor has it shown that paying these penalties would jeopardize its ability to provide care of an acceptable quality to its residents. The financial losses Petitioner contends it sustained occurred about a year ago. That is a point in time that is too remote to be meaningful evidence of Petitioner's present financial condition. Financial losses in any given brief period of time are not necessarily a valid marker of a facility's overall financial condition. *Kenton Healthcare, LLC*, DAB CR1666, at 44 (2007).

Furthermore, there is evidence to show that Petitioner's financial condition is actually robust. In cost report data that Petitioner submitted for the fiscal year ending December 31, 2006 Petitioner asserted that it had earned a net profit of over $260,000. CMS Ex. 2, at 1. And, it claimed a total equity of over $760,000. *Id.* I note, moreover, that during the period in 2007 when Petitioner claimed to have lost money it paid to its owner $120,000 in management fees. P. Ex. 7, at 5; Tr. 92.

d. Petitioner is not entitled to an offset against the civil money penalties for fines that it paid to the State of Illinois.

Petitioner asserts that it paid a fine of $5,000 to the State of Illinois as a consequence of the medication administration error that is the basis for my finding of an immediate jeopardy level deficiency. Evidently, Petitioner contends that I should offset this amount against the civil money penalties that I impose.

I have no authority to do so. The regulations governing civil money penalty amounts do not provide for offsets.

/s/
Steven T. Kessel
Administrative Law Judge