Department of Health and Human Services

DEPARTMENTAL APPEALS BOARD

Appellate Division

In the Case of:	DATE: February 3, 2009
Hallmark House Nursing Center,	
Petitioner,	Civil Remedies CR1814 App. Div. Docket No. A–08-132
	Decision No. 2226
- v. -	
Centers for Medicare & Medicaid Services.	

FINAL DECISION ON REVIEW OF ADMINISTRATIVE LAW JUDGE DECISION

Hallmark House Nursing Center (Hallmark), a skilled nursing facility (SNF) located in Pekin, Illinois, requested review of the decision of Administrative Law Judge (ALJ) Steven T. Kessel in Hallmark House Nursing Center, DAB CR1814 (2008) (ALJ Decision). The ALJ sustained the determination of the Centers for Medicare & Medicaid Services (CMS) imposing $22,000 in civil money penalties (CMPs) against Hallmark. The ALJ upheld CMS's findings that Hallmark failed to comply substantially with the medication error regulation at 42 C.F.R. § 483.25(m)(2) and that the noncompliance posed immediate jeopardy to the health and safety of facility residents. The ALJ also upheld CMS's determination that Hallmark failed to comply substantially with a Life Safety Code requirement governing facility egress from November 2, 2006 through January 30, 2007. The ALJ concluded that the CMPs assessed by CMS were reasonable.

For the reasons discussed below, we affirm the ALJ Decision.

Legal Background

To participate in the Medicare program, a SNF must comply with the program participation requirements in 42 C.F.R. Part 483, subpart B. A SNF's compliance with the participation requirements is determined through surveys performed by state health agencies. Section 1819 of the Social Security Act[1] (Act); 42 C.F.R. Parts 483, 488, and 498.

A facility's "failure to meet a participation requirement" is called a "deficiency." 42 C.F.R. § 488.301. A facility is in "substantial compliance" with the participation requirements if "any identified deficiencies pose no greater risk to resident health or safety than the potential for causing minimal harm." Id. "Noncompliance" means "any deficiency that causes a facility to not be in substantial compliance." Id.

CMS may impose remedies against a facility that is not in substantial compliance with the participation requirements. 42 C.F.R. §§ 488.408, 488.440(a). Each deficiency found during a survey is assigned a level of "seriousness" for the purpose of selecting the appropriate remedies, if any, to impose on the facility. See 42 C.F.R. § 488.404. The level of seriousness is based on an assessment of scope (whether the deficiency is isolated, a pattern, or widespread) and severity (the degree of harm, or potential harm, to resident health and safety posed by the deficiency). Id.

The highest level of severity is "immediate jeopardy," defined at section 488.301 of the regulations as "a situation in which the provider's noncompliance . . . has caused, or is likely to cause, serious injury, harm, impairment, or death to a resident." On appeal to an ALJ, a determination by CMS that a deficiency posed immediate jeopardy must be upheld unless the facility proves that CMS's determination was "clearly erroneous." 42 C.F.R. § 498.60(c)(2).

Section 488.401 of the regulations states that a "plan of correction" (POC) is a plan developed by the facility and approved by CMS or the state agency describing the actions the

[1] The current version of the Social Security Act can be found at www.ssa.gov/OP_Home/ssact/comp-ssa.htm. Each section of the Act on that website contains a reference to the corresponding United States Code chapter and section. Also, a cross-reference table for the Act and the United States Code can be found at 42 U.S.C.A. Ch. 7, Disp Table.

facility will take to correct its deficiencies. The POC also specifies the date by which the deficiencies will be corrected. Id.

Standard of review

Our standard of review on a disputed finding of fact is whether the ALJ decision is supported by substantial evidence on the record as a whole. Our standard of review on a disputed conclusion of law is whether the ALJ decision is erroneous. Guidelines for Appellate Review of Decisions of Administrative Law Judges Affecting a Provider's Participation in the Medicare and Medicaid Programs, http://www.hhs.gov/dab/guidelines/prov.html.

The ALJ Decision

The ALJ made the following findings of fact and conclusions of law (FFCLs):

> 1. On November 6, 2006 Petitioner failed to comply with the requirements of 42 C.F.R. § 483.25(m)(2);
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> 2. CMS's determination that Petitioner manifested an immediate jeopardy level deficiency on November 6, 2006 is not clearly erroneous;
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> 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; and
>
> 4. CMS's remedy determinations are reasonable.
>
> a. CMS's determination to impose a $5,000 CMP for Petitioner's immediate jeopardy level noncompliance on November 6, 2006 is reasonable.
>
> b. CMS's determination to impose CMPs 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.
>
> c. Petitioner did not prove that its financial condition precludes it from paying the civil money penalties that I sustain.

d. Petitioner is not entitled to an offset against the civil money penalties for fines that it paid to the State of Illinois.[2]

ALJ Decision at 3-10.

Analysis

Hallmark's appeal of the ALJ Decision contests FFCLs 2, 3 and 4(a)-(c). Hallmark Br. at 1-2. We address Hallmark's exceptions to each of the contested FFCLs below.

A. FFCL 2 of the ALJ Decision is supported by substantial evidence on the record as a whole and free of legal error.

Hallmark does not contest the ALJ's threshold finding (FFCL 1) that the facility failed to comply with 42 C.F.R. § 483.25(m)(2), which requires facilities to ensure that residents are "free of any significant medication errors." Hallmark Br. at 4, n.1. Hallmark does not deny that at approximately 8:30 p.m. on October 14, 2006, a facility employee, Nurse Neff, made a significant medication error in administering 100 units of Lantus to an 80 year-old, female resident (Resident 1) with diagnoses of diabetes mellitus and senile dementia.[3] Hallmark Ex. 2, at 5; CMS Ex. 6, at 2, 4-9; CMS Ex. 7, at 7-8. Lantus is a long-acting hypoglycemic agent and human insulin analog used to treat diabetes. CMS Ex. 27, at 5-11. The amount of Lantus administered by Nurse Neff, Hallmark also concedes, was ten times the amount that had been prescribed by Resident 1's treating physician, Dr. C. William Fisher. Hallmark Ex. 2, at 5 (Declaration of Administrator Lynn Brady); CMS Ex. 10, at 9 (October 2006 Physician Order); CMS Ex. 10, at 62-63 (October 2006 Diabetes Mellitus Medication Administration Record).

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[2] The ALJ did not address the other deficiencies cited in CMS's determination since, the ALJ concluded, the deficiencies addressed in his decision were sufficient to support the assessed remedies. ALJ Decision at 3. We concur in this conclusion and, consequently, our decision also does not reach the additional noncompliance findings. We note, however, that CMS has not waived these other findings as additional grounds to support its determination and the assessed CMPs. CMS Br. at 2, n.1.

[3] In its appeal of the ALJ Decision, Hallmark states that "there were no disputes of fact." Hallmark Br. at 2.

Hallmark argues, however, that the ALJ erred in upholding CMS's determination of the severity level of the deficiency (FFCL 2). Hallmark contends that its noncompliance did not involve either of the two types of situations that pose "immediate jeopardy" under 42 C.F.R. § 488.301. That is, Hallmark claims (1) that the medication error did not cause serious harm to Resident 1, and (2) that the facility's noncompliance with the medication error regulation was not likely to cause serious injury, harm, impairment or death to any resident. To support its contentions, Hallmark relies on the ALJ decision in Daughters of Miriam Center, CR1357 (2005). In that decision, the ALJ defined "serious" to mean "something that is dangerous, grave, grievous or life threatening . . . that requires extraordinary care, or which has lasting consequences. An injury that requires, for example, hospitalization or which produces long-term impairment, or which causes severe pain, is a 'serious' injury." CR1357, at 3. The ALJ also held in his Daughters of Miriam Center opinion that CMS was required to make a prima facie showing of actual or likely serious injury, harm, impairment or death to sustain an immediate jeopardy determination.

With respect to its argument that the Lantus overdose did not cause Resident 1 serious harm, Hallmark claims that there "was no proof that the injury if any suffered by R-1 was [ir]reversible, left R-1 incapacitated or caused pain." Hallmark Br. at 3. When the overdose was discovered, Hallmark argues, Resident 1 "was awake and lucid," and within an hour her blood sugar level was normal. Id. Hallmark further cites the declarations and testimony of Dr. Fisher and Administrator Brady that Resident 1 "did not suffer any harm." Id. Hallmark argues that the Lantus-induced hypoglycemia in Resident 1 was not serious because it was "only a temporary low blood sugar reading," did not cause severe pain, and was easily reversed with "only one medication glucagon [and] sugar." Hallmark Br. at 2, 5.

To support its claim that the facility's noncompliance with the medication error regulation also was not likely to have caused serious injury, harm, impairment or death to Resident 1 or any other resident, Hallmark cites the declarations and testimony of Dr. Fisher, Hallmark's Administrator, and the surveyor. According to Hallmark, the evidence and testimony establish that the facility had procedures in place, including an hourly bed check policy, that would have prevented serious harm from any medication overdose. Hallmark Reply at 3-4, citing Hallmark Ex. 1, at 3; Hallmark Ex. 9; Tr. at 109. Further, Hallmark contends, it "had no idea that [N]urse Neff would make such a significant medication error" and that there was "no potential [for] harm to re-occur in the very near future as Nurse Neff was immediately

discharged." Hallmark Br. at 4; Hallmark Reply at 4. Thus, Hallmark concludes, the noncompliance was an "isolated instance involving one nurse" that caused neither actual harm nor a probability of serious injury, harm or death. Hallmark Reply at 5.

Hallmark's arguments are unavailing. At the outset, Hallmark's reliance on the ALJ decision in Daughters of Miriam Center, DAB CR1357, is misplaced. As the Board stated in reversing that decision, the ALJ's exercise in defining the term "serious" was unnecessary since, under the clear error standard of review, an immediate jeopardy determination by CMS "is presumed to be correct" and the petitioner has the burden to show that the harm or injury "did not meet **any reasonable definition of 'serious.'**" DAB No. 2067, at 9 (2007)(emphasis added). The Board further noted in Daughters of Miriam Center that when CMS issued the survey, certification and enforcement regulations, it acknowledged that "distinctions between different levels of noncompliance . . . do not represent mathematical judgments for which there are clear or objectively measured boundaries." Id. at 14-15, citing 59 Fed. Reg. 56,116, 56,179 (1994).[4] "This inherent imprecision" the Board observed, was "precisely why CMS's immediate jeopardy determination, a matter of professional judgment and expertise, [was] entitled to deference." Id.

Here, substantial evidence and testimony support the ALJ's conclusion that CMS reasonably found Hallmark's noncompliance to have caused serious harm to Resident 1 and to have posed a likelihood of serious injury, harm, impairment or death to facility residents. According to the medical literature and testimony in the record, excessive amounts of Lantus can cause hypoglycemia, a condition characterized by blood sugar levels falling below 70 to 80 milligrams per deciliter (mg/dL). CMS Ex. 27; Tr. at 155; CMS Ex. 18, at 2-3. Severe hypoglycemia, the record further establishes, can cause brain damage, seizures, lack of consciousness, coma, and even death. CMS Ex. 18, at 2-4, 6; CMS Ex. 27, at 8-9, 11; CMS Ex. 28, at 5; CMS Ex. 29, at 4; Tr. at 22, 43-44, 160-61. According to the Physician's Desk Reference (PDR), the effect profile of Lantus is "relatively constant with no pronounced peak," and it can remain in effect for up to 24 hours after it is administered. CMS Ex. 27, at 5. An overdosage of Lantus "may lead to severe and sometimes long-

[4] Appendix Q of the CMS State Operations Manual (SOM), Guidelines for Determining Immediate Jeopardy, describes the procedures followed by surveyors to determine if particular circumstances pose immediate jeopardy.

term and life-threatening hypoglycemia. . . . More severe episodes with coma, seizure or neurologic impairment may be treated with intramuscular/subcutaneous glucagon or concentrated intravenous glucose. Id. at 7-8; see also CMS Ex. 18, at 3. Further, the PDR description of Lantus states that "after apparent clinical recovery from hypoglycemia, continued observation and additional carbohydrate intake may be necessary to avoid reocurrence of hypoglycemia." Id.

The record also includes testimony and medical literature explaining how "[m]ultiple risk factors underlie [an] increased susceptibility to hypoglycemia in the elderly." CMS Ex. 29, at 4; see also CMS Ex. 18, at 3; CMS Ex. 28, at 6. Among those risk factors is the fact that the first presenting symptoms of hypoglycemia in the elderly can be neuroglycopenic (confusion, delirium, dizziness) rather than adrenergic (palpitation, sweating, tremors), and thus difficult to detect in patients with cognitive impairment. Id. Those with cognitive impairment also may not recognize their condition or be able to communicate about it with caregivers. Id. Moreover, elderly patients with diabetes "may be at even greater risk for morbidity from hypoglycemia due to superimposed defective hypoglycemic counterregulatory responses and advanced atherosclerosis." CMS Ex. 28, at 6. According to Surveyor Pappas, a registered nurse with expertise in the causes and treatment of diabetes, elderly individuals often are "less sensitive to the physiological changes that occur when they become hypoglycemic," and "some of the early warning symptoms may also become less pronounced" after multiple hypoglycemic episodes. CMS Ex. 18, at 3. Elderly patients also face risk of injury from falls associated with hypoglycemic episodes.

In this case, the facility administered ten times the prescribed amount of Lantus to Resident 1 at approximately 8:30 p.m. on October 14, 2006. The overdose was not discovered, however, until approximately 2:30 a.m. on October 15, 2006. At that time, Resident 1 was found "diaphorietic, cold and clammy," and with a blood sugar level of 32. CMS Ex. 7, at 1, 8; CMS Ex. 10, at 23. Surveyor Pappas testified that when the overdose was discovered, Resident 1's "blood sugar was down to 32. That is very close to being incompatible with life, . . . anything below like 10 or 15, somewhere in that range can lead to brain cell death and lack of any activity in those brain cells." Tr. at 22; CMS Ex. 18, at 6. The surveyor later added that "when a person's blood sugar is down to 32, they're diaphoretic, they're sweaty. They're oftentimes not responsive, and it's just a serious emergency situation." Tr. at 42-43; see also CMS Ex. 6, at 5. Hallmark's POC for the medication error characterized the Lantus

overdose as "causing a **critical** condition." CMS Ex. 6, at 9 (emphasis added).

The evidence and testimony also support the conclusion that the danger posed by the Lantus overdose was compounded by the presence in Resident 1 of another diabetes medication that had been administered earlier in the day. Specifically, Resident 1 had been given Novolin R, a short-acting hypoglycemic agent, at approximately 4:30 p.m. on October 14, pursuant to Dr. Fisher's order. CMS Ex. 10, at 9, 18, 62-63; CMS Ex. 18, at 3. The effects of Novolin R begin approximately ½ hour after injection and peak between 2-1/2 - 5 hours after injection. CMS Ex. 26, at 4. Thus, according to the evidence of record, the Novolin R administered to Resident 1 at 4:30 p.m. on October 14 was at its peak effect, already working to lower Resident 1's blood sugar level, when the Lantus overdose was administered. CMS Ex. 26, at 4; Tr. at 165-166.

The severity of the actual harm to Resident 1 caused by the Lantus overdose is further evidenced in facility records, summaries of the surveyor's interviews with facility staff, and testimony addressing Resident 1's condition and treatment in the hours following the discovery of the overdose. The records and testimony show that once Resident 1's hypoglycemia was discovered, supervising registered nurse Beaver immediately gave Resident 1 a tube of glucose and called Dr. Fisher. CMS Ex. 7, at 7-8; CMS Ex. 10, at 19, 23; see also CMS Ex. 6, at 4-6. Dr. Fisher responded to the patient's reported condition and the overdose information by ordering the facility to administer a vial of intramuscular glucagon to Resident 1 and to send Resident 1 to the hospital emergency room. Id. Nurse Beaver then called 911. CMS Ex. 7, at 3; CMS Ex. 10, at 23. In the emergency room of Pekin Hospital, Resident 1 "was again found to have low blood sugars in the 60's." CMS Ex. 10, at 78. Following treatment in the emergency room, Resident 1 was admitted overnight to Pekin Hospital, where she was monitored and documented as having two additional blood sugar readings at hypoglycemic levels. CMS Ex. 10, at 74, 78; P. Ex. 1, ¶ 4; Tr. at 19-20.

Thus, substantial evidence and testimony in the record about the known effects of Lantus, the heightened risk factors for hypoglycemia in cognitively impaired, elderly patients, and Resident 1's condition and treatment once the overdose was discovered, support the ALJ's finding that CMS reasonably determined the medication error to have caused Resident 1 serious harm. Together the evidence and testimony establish that the significant medication error did not simply result in an easily reversed "temporary low blood sugar reading" in Resident 1, as

Hallmark submits. Rather, Dr. Fisher's orders to administer intramuscular glucagon and send Resident 1 to an emergency room, Nurse Beaver's 911 call, and Resident 1's emergency room treatment and subsequent hospitalization demonstrate that the Lantus overdose required extraordinary medical care, close monitoring, and intervention as needed during the 24-hour period in which the medication was in effect.

Hallmark claims that Resident 1 "was not hospitalized because she needed to be hospitalized," but only for observation. Hallmark Br. at 5. But this claim is wholly belied by Resident 1's documented condition and by the actions and orders of the medical professionals attending to her in the hours after the medication error was discovered. Indeed, had Resident 1's hypoglycemic condition at 2:30 a.m. not been recognized as the result of a significant Lantus overdose, but observed and treated simply as a single, limited, episode of hypoglycemia, Resident 1 would have been at continued risk of coma, seizure or neurologic impairment during the remaining part of the 24-hour period in which the 100 units of Lantus remained in effect.

Moreover, Hallmark's argument that the harm Resident 1 suffered was not "serious" because the Lantus overdose did not cause irreversible, or permanent injury has no merit. At the outset, we note that the evidence of record does not conclusively establish whether Resident 1 did, or did not, sustain any permanent neurological damage from the Lantus overdose. Resident 1 had a diagnosis of senile dementia, and it appears that no objective measures were taken to assess whether the Lantus-induced hypoglycemia caused Resident 1 any permanent long-term impairment. Even if we were to assume, however, that the facility's noncompliance did not cause Resident 1 any long-term impairment, Hallmark cites to no authority restricting immediate jeopardy findings to circumstances involving permanent or irreversible injury or harm.

We further reject Hallmark's argument that the ALJ's finding should be reversed since Resident 1's treating physician and Hallmark's Administrator testified that Resident 1 did not suffer any harm and that there was no potential for more than minimal harm from the facility's noncompliance with the medication error regulation. Hallmark Br. at 3, citing Hallmark Ex. 1, ¶ 6; Hallmark Ex. 2, at 5. It is well-settled that, absent clear error, we defer to the findings of the ALJ on weight and credibility of testimony. Koester Pavilion, DAB No. 1750, at 21 (2000). In this case, despite Dr. Fisher's and Administrator Brady's general conclusions, Dr. Fisher acknowledged that he ordered Resident 1 to be sent to the hospital emergency room in

part because the Lantus would continue to act as a hypoglycemic agent in Resident 1 during the 24-hour period following the overdose and that, consequently, Resident 1 would require treatment during that entire timeframe. Tr. at 166-68. Indeed, on Hallmark's October 15, 2006 medication error report documenting the overdose, which was signed by Administrator Brady, the facility answered "yes" to the question whether the error could have "endangered the life or welfare of the patient," explaining that "Lantus will continue to drop the blood sugar for 24 [hours] after administration." CMS Ex. 10, at 74. Further, neither Administrator Brady nor Dr. Fisher observed Resident 1 during the six-hour period between the administration of the Lantus and the time the overdose was discovered, when the Lantus and Novolin R together would have been acting to lower Resident 1's blood sugar level. In addition, like the testimony of Dr. Fisher, Administrator Brady's testimony addressed whether Resident 1's long-term condition had changed as a result of the medication error, not whether the condition of having the Lantus overdose in her system could itself be considered serious harm. Finally, while Dr. Fisher's opinions about the harm caused by the medication error favored the facility, he acknowledged that he has received numerous patient referrals from Hallmark, thus revealing a potential bias or interest in favor of Hallmark. Tr. at 150. In light of these factors, we defer to the ALJ's discretion as to the relative plausibility of Administrator Brady's and Dr. Fisher's testimony.

We also find unpersuasive Hallmark's contention that "the three essential components of immediate jeopardy" described in the SOM – harm, immediacy, and culpability – were not satisfied since Hallmark had no reason to know that Nurse Neff would make such a significant medication error as the Lantus overdose and, consequently, Hallmark lacked culpability for the noncompliance. Hallmark Br. at 4, citing SOM App. Q. During her brief, three-month tenure as a part-time employee at Hallmark, Nurse Neff made an additional medication error when, on July 30, 2006, she administered Resident 2's medications to Resident 2's roommate, Resident 3. CMS Ex. 11, at 4, 10; CMS Ex. 12, at 5; Tr. at 38-39, 47, 104, 119. Although the types of medications involved in the July 30 error did not result in serious harm to Residents 2 or 3, the type of error made – the administration of medication to the wrong resident – plainly could have involved drugs with more serious consequences. As the Board has previously observed, "[a]dministering medications not ordered by the resident's physician or not following the doctor's order with respect to dosage or the method of administration may have a direct, immediate, and serious adverse effect on a resident's health." Daughters of Miriam Center, DAB No. 2067, at 10, citing SOM,

Appendix P, Part II (discussing "significant" and "nonsignificant" medication errors and indicating that some medication errors have a "high potential" for problems for the typical long term care facility resident). Thus, while Nurse Neff may have been in-serviced in the proper administration of medications after the July 30, 2006 incident, Hallmark had reason to know that Nurse Neff was capable of making significant medication errors.

In addition, as CMS argues, CMS's determination of the likelihood of serious harm posed by the facility's noncompliance with the medication error regulation is supported by evidence showing that Nurse Neff was not the only employee to have administered the wrong amounts of insulin to Resident 1 in the Fall of 2006, as well as evidence that Resident 1 was not the only facility resident receiving insulin injections. Previously, the Board has concluded that the term "likely" in the immediate jeopardy regulation is synonymous with "probable," and suggests that the degree of probability that an event may occur is greater than "possible" or "potential." Daughters of Miriam Center, DAB No. 2067, at 10; Innsbruck Healthcare Center, DAB No. 1948 (2004). Further, the Board has "emphasized . . . that a reviewer should consider the nature of the noncompliance and decide whether it was likely to result in serious harm, not only to the resident . . . whose circumstances triggered the immediate jeopardy determination, but to the facility's population at large." Daughters of Miriam Center, DAB No. 2067, at 12, citing Liberty Commons Nursing and Rehab Center - Johnston, DAB No. 2031 (2006), aff'd, Liberty Commons Nursing & Rehab Ctr.-Johnston v. Leavitt, 241 F. App'x 76 (4th Cir. 2007).

In this case, the medication administration records for September and October 2006 show multiple instances wherein Resident 1 was administered either too little, or too much, insulin according to her physician's sliding scale order. CMS Ex. 10, at 48-50, 62-63; see also Tr. at 33. At 6:00 a.m. on October 1, 3 and 4, 2006, Resident 1 had blood sugar levels of 152, 186, and 162 respectively. CMS Ex. 10, at 62. According to the sliding scale order, she should have received four units of Novolin R. Id. at 63. Yet, in each instance, no insulin was administered. Id. In contrast, on September 5, 2006, Resident 1 had a blood sugar level of 138, in response to which no insulin should have been administered. Id. at 48-49. Yet, the records show four units were given at that time. Id. Further, the record shows that there were six additional residents with diabetes who had orders for insulin injections at the time of the survey. CMS Ex. 6, at 4; CMS Ex. 14, at 24. Together, this evidence supports the conclusion that "the mis-administration of Lantus insulin to

Resident 1 was not entirely an isolated event" and the determination that the facility's noncompliance was likely to cause serious harm, injury, impairment or death to facility residents was not clearly erroneous. ALJ Decision at 4.

We also find no merit in Hallmark's argument that its noncompliance did not pose a likelihood of serious harm to residents from significant medication errors because it had policies and procedures in place, including a regular bed check policy, to prevent serious harm. Hallmark Reply at 3. As discussed above, evidence in the record shows that the initial presenting symptoms of hypoglycemia in the elderly can include confusion or delirium, and that the visible adrenergic symptoms of hypoglycemia (palpitation, sweating tremors) may not be presented until after the condition has caused serious injury or harm. Further, Hallmark's Administrator acknowledged that she did not know how thorough the bed checks were on the night of October 14-15. Tr. at 109. She additionally confirmed that early signs of hypoglycemia, including confusion, delirium or dizziness, would not be observed if a resident was asleep during a bed check. Tr. at 111. Furthermore, even with the bed check policy in effect, the overdose of Lantus to Resident 1 was not recognized until six hours after it had been administered, at 2:30 a.m. It is unclear, however, whether these symptoms were presented any earlier, and there is no evidence that Resident 1 was in fact checked before that time. Moreover, although Nurse Neff had reported earlier in the evening to Nurse Beaver the amount of Lantus she had given to Resident 1, Nurse Beaver admittedly failed to recognize at that time that the amount was an overdose of ten times the prescribed amount of the medication. CMS Ex. 7, at 8; Tr. at 74. Thus, the evidence contradicts Hallmark's claim that the facility had effective procedures in place to timely prevent any serious injury, harm, impairment or death from a significant medication error. Indeed, in light of the known effects of Lantus and Novolin R, it is reasonable to conclude, as Surveyor Pappas did, that Resident 1 "suffered the effects of the insulin overdose for hours without any treatment whatsoever." CMS Ex. 18, at 6 (Declaration of Betty Pappas, R.N.).

Finally, we reject Hallmark's argument that its noncompliance with the medication error regulation did not pose immediate jeopardy since it involved an "isolated" event, which the facility timely investigated and fully corrected by immediately firing Nurse Neff. Hallmark Reply at 5; see also Hallmark Br. at 4-5. As discussed above, substantial evidence supports the ALJ's conclusion that the facility's noncompliance with the medication error regulation was not limited to the actual harm caused

Resident 1 by the single Lantus overdose. Rather, Hallmark's noncompliance posed a likelihood of serious injury, harm, impairment or death to other facility residents who had been at risk of similar significant medication errors.

We recognize that the survey concluded that the scope of the medication error deficiency was "isolated." CMS Ex. 6, at 4. Under the CMS regulations and SOM, however, the term "isolated" is not used synonymously with single event, as Hallmark suggests. Under the regulations and manual, the word "isolated" is used as a term of art, meaning "when one or a very limited number of residents are affected and/or one or a very limited number of staff are involved, and/or the situation has occurred only occasionally or in a very limited number of locations." 42 C.F.R. § 488.404(b)(2); SOM, Appendix P, Survey Protocol for Long-Term Care Facilities, IV. Deficiency Categorization, C. Guidance on Scope Levels. Thus, when, as in this case, a facility's noncompliance is assessed as isolated in scope, the assessment does not necessarily reflect a conclusion that an error occurred only once and involved only a single resident. Further, even where, as in this case, a deficiency's scope is categorized as "isolated," immediate jeopardy may nevertheless be found if the facility's noncompliance either caused or was likely to cause serious injury, harm, impairment or death to any resident.

Nor does Hallmark's prompt termination of Nurse Neff after the Lantus overdose was discovered provide a basis for reversing the immediate jeopardy determination. It is well-settled that the statutes and regulations permit CMS to impose a CMP for a "past noncompliance," i.e., a noncompliance that occurred after the last standard survey and before the current survey. See, e.g., Aase Haugen Homes, DAB No. 2013 (2006). That Hallmark quickly took action to correct the noncompliance after the Lantus overdose had been administered "does not alter the nature of the noncompliance or diminish the threat it posed prior to its discovery." Daughters of Miriam, DAB No. 2067, at 14. Finally, Hallmark's POC for the medication error shows that correction of the noncompliance was not limited to firing Nurse Neff, as Hallmark suggests. Rather, the correction involved numerous additional measures, including: In-servicing every nurse individually on glucose parameters and physician notification requirements; developing a new blood glucose documentation form and policy/procedure; and highlighting actual insulin orders on resident MARs "to insure this does not happen again." CMS Ex. 6, at 9-13.

Accordingly, we conclude that the ALJ's finding that CMS's immediate jeopardy determination was not clearly erroneous is supported by substantial evidence on the record as a whole and free of legal error.

B. FFCL 3 of the ALJ Decision is supported by substantial evidence on the record as a whole and free of legal error.

Life Safety Code (LSC) requirements for fire safety are incorporated into the participation requirements for long term care facilities at 42 C.F.R. § 483.70(a)(1). LSC chapters 7 and 19 set forth the criteria for "means of egress," defined as "path[s] of egress travel to a public way." CMS Ex. 20, at 11 (LSC § 7.1.2.). "A basic principle of the Code requires that every component of a means of egress be operable by and under the control of the occupants attempting egress." Id. Consistent with this principle, the LSC requires that all means of egress be unobstructed, and any doors or gates along an exit path or passageway must not have latches or locks that "require[] the use of a tool or key from the egress side." CMS Ex. 20, at 48 (LSC §§ 19.2.2.2.4, 7.2.1.5.1.). One exception to this requirement states that a locked gate or door "shall be permitted . . . where the clinical needs of the patients require specialized security measures for their safety, provided that staff can readily unlock such doors at all times." CMS Ex. 20, at 49 (LSC § 19.2.2.2.4, Exception 1; LSC § 7.2.1.6.1). A second exception permits a delayed-egress lock that meets certain technical requirements, including an unlocking mechanism triggered by pressure on the gate which produces an alarm, and a posted sign explaining how to use the system. CMS Ex. 20, at 49 (LSC § 19.2.2.2.4, Exception 2; LSC § 7.2.1.6.1).

In this case, it is undisputed that a November 2, 2006 survey found that an outside fence gate along an exit path from the Hallmark facility had a lock that was noncompliant with LSC § 19.2.2.2.4 and met neither of the two exceptions to the rule. ALJ Decision at 6-7, citing CMS Ex. 3, at 5-7; CMS Ex. 5, at 5-7; CMS Ex. 19, at 3. There was no showing at the time of the survey that the clinical needs of residents required such a lock or that all staff could readily unlock the gate at all times. Further, while the gate had a lock which the surveyor treated as a delayed-egress lock, it did not meet the technical requirements of the second exception to LSC § 19.2.2.2.4. Specifically, the lock required a key code to release the gate, and there was no sign stating how to use the mechanism. CMS Ex. 4, at 18; CMS Ex. 5, at 5-7; CMS Ex. 19, at 3. The surveyor found that this deficiency posed a risk of more than minimal harm. CMS Ex. 5, at

5-7; CMS Ex. 19, at 4. He determined that the gate was a significant obstacle that "could affect 71 of 71 residents if evacuation via a deficient means of egress was necessary." CMS Ex. 5, at 6.

Following the survey, Hallmark acknowledged the noncompliance and developed a POC for it based on the first exception of LSC § 19.2.2.2.4. The POC stated that on November 28, 2006, the Quality Assurance Committee reviewed the status of the facility residents and found that no resident "was independent mentally and/or physically" and that the "residents' clinical needs require[d] a specialized security measure on the fence gate for their safety." CMS Ex. 5, at 27. "A resident with physical or mental deficits," the POC stated, "would be in great jeopardy with a busy street and a deep wooded gully a few yards from the gate." Id. To support this conclusion, the POC provided that all "attending physicians will give orders for this secured gate due to residents' safety," and stated that such physician orders would be obtained for all future admissions. Id. The POC further provided that a full staff in-service would be given on November 8, 2006 to provide the code and instructions to all staff. Id. The POC stated that the corrections would be implemented by January 31, 2007. Id.

Hallmark argues that, while the POC for the deficiency listed a completion date of January 31, 2007 as "when all of the clinical files of the residents included a physician's order," the noncompliance should be considered corrected once all staff members were given the unlock code, on November 8, 2006. Hallmark Br. at 6; see also Hallmark Post-hearing Br. at 14. Hallmark contends that, notwithstanding the POC provision that the facility would obtain individualized physician orders establishing that the clinical needs of the residents required the locked gate, the LSC exception does not in fact require such physician orders. Hallmark also argues that "only a finding that the clinical needs of a resident require a locked door" to justify the exception. Hallmark Br. at 6.

We reject Hallmark's argument and conclude that the ALJ's determination that Hallmark's noncompliance with the LSC requirement continued through January 30, 2007 is free of legal error and supported by substantial evidence on the record. Under the regulations, the duration of a per-day CMP is computed for the number of days of noncompliance (or until the facility is terminated), and it accrues until the date of correction determined by an on-site revisit or by "written credible evidence" which CMS or the State agency receives and accepts. 42 C.F.R. §§ 488.440, 488.454; Jennifer Matthew Nursing and

Rehabilitation Center, DAB No. 2192, at 41-42 (2008), citing Cross Creek Health Care Center, DAB No. 1665, at 3 (1998). Once a facility's noncompliance with a participation requirement has been established, the facility bears the burden of showing that it implemented its plan of correction and achieved substantial compliance to end the application of remedies. See, e.g., Briarwood Nursing Center, DAB No. 2115, at 17 (2007), quoting Lake Mary Health Care, DAB No. 2081, at 28 (2007).

Here, the ALJ did not err in sustaining CMS's determination of the duration of the noncompliance. First, while Hallmark suggests that an exception to the LSC egress rule would be justified if only one resident had a clinical condition necessitating special security measures, the plain language of the LSC exception uses the plural term "residents." This wording clearly indicates that the exception is premised upon the assessed needs of the resident population at large. Furthermore, as CMS points out, if only a single or limited number of residents have such needs, there may be better and less restrictive measures, such as the use of a WanderGuard alarm system for residents at risk of elopment, that could be used to protect those residents while the rest of the facility occupants would retain the ability to control and operate the means of egress.

The ALJ also did not err in rejecting Hallmark's contention that the physician orders were not needed under the "clinical needs" exception of LSC § 19.2.2.2.4 and Hallmark's approved POC. The LSC sets forth the fundamental principle that, generally, all means of egress should "be operable by and under the control of the occupants attempting egress" to ensure occupant safety. The LSC recognizes, however, that an exception to the general rule is warranted where the safety benefits of unfettered egress are outweighed by the potential harm (such as risk of elopement) to residents whose clinical needs (such as dementia) require special security measures that pose obstacles to egress. As the ALJ stated, "[i]mplicit 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." ALJ Decision at 7. Thus, the ALJ reasonably concluded, to justify an exception, a sufficient number of determinations in *"individual cases"* was required to establish that, on balance, the clinical needs of residents requiring specialized security measures for their safety outweighed the benefits of the general prohibition against impediments to egress. Id. (italics in original).

Moreover, Hallmark's POC explicitly stated that to correct the noncompliance *"all attending physicians"* would provide orders stating that the lock was necessary to ensure residents' safety. CMS Ex. 5, at 27 (emphasis added). Hallmark's Administrator acknowledged in testimony that physician approval was "absolutely" required for the locked gate. Tr. at 116. "[T]o have a locked gate," the Administrator testified, "you have to have a physician's order that states that the resident would be in danger if it wasn't locked, and they could get out on their own." Tr. at 117. Consequently, Hallmark's argument that the generalized finding by its Quality Assurance Committee that the clinical conditions of residents required the extra security measure was sufficient to justify the exception has no merit. Indeed, if the "clinical needs" exception could be satisfied merely by a quality assurance committee's general determination that the clinical conditions of residents required a lock on an egress gate, the basic LSC principle supporting unfettered egress could easily be nullified.

As noted above, it is well-settled that once noncompliance has been established, the facility must show that it attained substantial compliance with the participation requirements in order to end the duration of a per-day CMP. Further, "[i]t is not enough that some steps have been taken, but rather the facility must prove that the goal has been accomplished." Briarwood at 17, quoting Lake Mary Health Care, DAB No. 2081, at 28 (2007). In this case, Hallmark's Administrator testified that the physicians "agreed" that the residents required the locked gate. Tr. at 116. Yet, Hallmark offered no evidence that it obtained any physician orders earlier than January 31, 2007. CMS subsequently accepted Hallmark's representation that it had obtained the physician orders by January 31st. In the absence of proof that sufficient orders were secured prior to January 31, 2007 to justify use of the lock, rather than some alternative means of protecting the residents from elopement and other risks, the ALJ properly concluded that substantial compliance was not achieved until January 31, 2007.

Accordingly, the ALJ's determination that Hallmark's failure to comply with the LSC requirement continued through January 30, 2007 is free of legal error and supported by substantial evidence on the record as a whole.

C. FFCL 4 of the ALJ Decision is supported by substantial evidence on the record as a whole and free of legal error.

CMS may impose CMPs in the range of $3,050 to $10,000 per day for deficiencies constituting immediate jeopardy. 42 C.F.R. § 488.438(a)(1)(i). CMPs for deficiencies that do not constitute immediate jeopardy but either caused actual harm or caused no actual harm, but had the potential for more than minimal harm, may be imposed in the range of $50 to $3,000 per day. 42 C.F.R. § 488.438(a)(1)(ii). To determine the amount of a CMP, CMS considers the following factors: The facility's history of noncompliance (including repeated deficiencies), its financial condition, its degree of culpability for the cited deficiencies, the seriousness of the noncompliance, and the relationship of one deficiency to the other deficiencies resulting in noncompliance. 42 C.F.R. §§488.404, 488.438(f).

An ALJ must make an "independent determination" about whether the amount of a CMP imposed by CMS is reasonable. CarePlex of Silver Spring, DAB No. 1683, at 16 (1999). In assessing whether a CMP is reasonable, the ALJ may not consider any factors other than those (described above) that CMS is to consider. 42 C.F.R. § 488.438(e)(3).

In this case, Hallmark argues that the Board should reverse the ALJs' determination to sustain the CMP of $5,000 for the facility's noncompliance with the medication error regulation since the facility's noncompliance did not pose immediate jeopardy. Hallmark further argues that "even if an immediate jeopardy finding was proper, there certainly was no reason" to assess more than the minimum CMP amount of $3,050, since the facility had a history of no prior fines or CMPs, and since Hallmark lost over $21,000 during the first eight months of 2007. Hallmark Br. at 7.

Hallmark also contests the ALJ's determination to uphold the CMP of $200 per day for the period November 7, 2006 through January 30, 2007, for the LSC violation. Hallmark argues that "[m]ost of the Life Safety Code deficiencies were corrected immediately or within a few days." Id. at 8. Hallmark further claims that the ALJ failed to address the ambiguity of notices from the state agency as to when penalties would be imposed, indicating that the facility "was given three months for completion of corrective actions." Id. at 8. In addition, Hallmark argues that the ALJ mischaracterized the facility's compliance history and failed to take into account Dr. Fisher's testimony that "Hallmark gives the best nursing home care in the Pekin area." Id. at 8, citing Hallmark Ex. 1, at 4.

Hallmark's contentions are unavailing. As discussed in detail above, the ALJ's conclusion that CMS's immediate jeopardy

determination was not clearly erroneous is supported by substantial evidence on the record and free of legal error. Consequently, it was appropriate for the ALJ to sustain a CMP in the upper range for the facility's noncompliance with the medication error regulation.

Further, the ALJ's determination to uphold the $5,000 amount of the CMP for the immediate jeopardy violation is supported by the record evidence and properly took into account the factors to be considered in making such a determination. First, the ALJ's assessment of the seriousness of the deficiency is well-founded. Hallmark's noncompliance with the medication error rule was, as previously discussed, extremely serious, causing dangerous hypoglycemia in Resident 1. The critical condition resulting from Hallmark's noncompliance required hospitalization of Resident 1, extraordinary medical care and careful monitoring while the Lantus overdose remained in effect. It additionally posed a likelihood of further serious harm to other facility residents. Similarly, the noncompliance with the LSC was at a level of seriousness that could justify more that the minimum penalty amount. CMS Ex. 3, at 5-6 (scope and severity level E, and notation that "deficient practice could affect 71 of 71 residents if evacuation via a deficient means of egress was necessary").

Moreover, while Hallmark alleges that it had a history of no prior fines or CMPs, it is the facility's history of noncompliance, not its history of assessed remedies, that CMS and the ALJ must consider in determining and evaluating the amount of the penalty. 42 C.F.R. § 488.438(f)(1). In Hallmark's case, the evidence in the record addressing the facility's noncompliance history supports the ALJ's finding that the facility's noncompliance with the medication error rule "was not the first blight on an unblemished record." ALJ Decision at 9. The record shows that surveys conducted between 2003 and 2005 found that Hallmark had eight health deficiencies, seven of which were at a scope and severity level (D to G) constituting noncompliance, and 22 LSC deficiencies. CMS Ex. 2, at 2-4. The 2005 survey found the facility's noncompliance with the regulation governing nutritional status to have caused actual harm. Id. at 2. Hallmark claims and CMS does not deny that the 22 LSC violations consisted of seven repeated claimed deficiencies that were structural in nature and did not require correction. Even if we were not to take into account those seven deficiencies, Hallmark's history of noncompliance provides some support for a CMP greater than the minimum amount.

We also reject Hallmark's contention that its "financial condition of losing over $21,000 in only the first eight months of 2007 . . . does not support more than the minimum penalty." Hallmark Br. at 7. While the Administrator testified that Hallmark's financial condition was "grave," she simultaneously admitted that the facility had cash and other assets and that, at the time of the April 2008 hearing, she did not actually know the facility's specific financial condition. Tr. at 92-93. Further, Hallmark submitted no other evidence to show that it did not have adequate assets to pay the CMPs. Moreover, as the ALJ observed "during the period in 2007 when [Hallmark] claimed to have lost money it paid to its owner $120,000 in management fees." ALJ Decision at 10, citing Hallmark Ex. 7, at 5; Tr. 92. But for this payment, the document provided by Hallmark would have shown a "Net Income" profit of over $88,000 for the period. Hallmark Ex. 7, at 5.

In addition, there is no merit in Hallmark's contention that the ALJ erred in failing to address what Hallmark alleges to be an ambiguity in the November 21, 2006 notice from the state agency indicating that Hallmark was given three months to complete the corrective actions for the LSC deficiencies. The notice at issue plainly states that Hallmark was required to include in its LSC POC "a **specific** date when corrective action will be completed not later than 12/17/06 for any deficiency at Level 'D' or higher." CMS Ex. 1, at 6 (emphasis in original). Moreover, "there is nothing in the regulations that precludes the imposition of a CMP based on a continuing deficiency before the facility has an opportunity to correct that deficiency pursuant to its approved plan of correction." Lakeridge Villa Health Care Center, DAB No. 1988, at 9 (2005), aff'd, Lakeridge Villa Health Care Ctr. v. Leavitt, 202 F. App'x 903 (6th Cir. 2006).

Finally, Hallmark's contention that it promptly corrected "most" of the LSC deficiencies and its criticism of the ALJ for failing to take into account Dr. Fisher's statement about the general quality of care provided at Hallmark, are irrelevant. As noted above, the ALJ is limited to considering only the objective factors identified in the regulations for evaluating the amount of a penalty.

Accordingly, we conclude that the ALJ's findings sustaining the $22,000 in CMPs assessed by CMS are supported by substantial evidence on the record as a whole and free of legal error.

Conclusion

For the reasons stated above, we affirm the ALJ Decision.

/s/
Leslie A. Sussan

/s/
Constance B. Tobias

/s/
Judith A. Ballard
Presiding Board Member