Department of Health and Human Services

DEPARTMENTAL APPEALS BOARD

Appellate Division

In the Case of:	
Daughters of Miriam Center,	DATE: February 9, 2007
Petitioner,	Civil Remedies CR1357 App. Div. Docket No. A-06-30
- v. -	Decision No. 2067
Centers for Medicare & Medicaid Services.	

FINAL DECISION ON REVIEW OF ADMINISTRATIVE LAW JUDGE DECISION

Daughters of Miriam Center (DMC), a New Jersey skilled nursing facility (SNF), appealed the September 29, 2005 decision of Administrative Law Judge (ALJ) Steven T. Kessel, Daughters of Miriam Center, DAB CR1337 (2005) (ALJ Decision). In that decision, the ALJ overturned a determination by the Centers for Medicare & Medicaid Services (CMS) that DMC's noncompliance with the Medicare participation requirement in 42 C.F.R. § 483.20(k)(3)(i) had put the SNF's residents in "immediate jeopardy." Because he found the immediate jeopardy determination to be clearly erroneous, the ALJ reduced the per instance civil money penalty (CMP) that CMS had imposed on DMC for the noncompliance from $3,100 to $1,000.

We conclude that by requiring CMS to make a prima facie showing of immediate jeopardy, the ALJ erroneously placed on CMS the burden of proving that its determination of immediate jeopardy was not clearly erroneous. We further conclude, based on our review of the record as a whole, that the ALJ erred in finding that CMS's determination of immediate jeopardy was clearly erroneous. Accordingly, we reverse the ALJ Decision and reinstate the $3,100 CMP.

Legal Background

To participate in the Medicare program, a SNF must comply with the requirements for participation in 42 C.F.R. Part 483, subpart B. Compliance with these participation requirements is verified by periodic surveys performed by state health agencies. See 42 C.F.R. Part 488, subpart E.

A survey's findings are reported in a Statement of Deficiencies. A "deficiency" is a "failure to meet a [Medicare] participation requirement." 42 C.F.R. § 488.301. Each deficiency finding in the Statement of Deficiencies includes a determination of the deficiency's level of "seriousness." See 42 C.F.R. § 488.404.

The level of seriousness is determined by assessing the deficiency's scope (whether the deficiency is isolated or widespread) and severity (the degree or magnitude of harm - or potential harm - to resident health and safety resulting from the deficiency). 42 C.F.R. § 488.404. A deficiency's severity is classified, from least to most severe, as: (1) no actual harm with a potential for minimal harm; (2) no actual harm with a potential for more than minimal harm that is not immediate jeopardy; (3) actual harm that is not immediate jeopardy; or (4) immediate jeopardy to resident health or safety. 42 C.F.R. § 488.404(b)(1). The highest level of severity – "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." 42 C.F.R. § 488.301.

CMS may impose enforcement remedies on a SNF, including a CMP, if the SNF is not in "substantial compliance" with Medicare participation requirements. 42 C.F.R. § 488.402(b), (c). A SNF is not in substantial compliance if it has one or more deficiencies severe enough to create at least the potential for more than minimal harm to resident health and safety. See 42 C.F.R. §§ 488.301 (defining substantial compliance as "a level of compliance . . . such that any identified deficiencies pose no greater risk to resident health or safety than the potential for causing minimal harm"); The Windsor House, DAB No. 1942, at 2-3, 61 (2004). The regulations (and we) use the term "noncompliance" to refer to "any deficiency that causes a facility to not be in substantial compliance. 42 C.F.R. § 488.301.

A SNF is entitled to an ALJ hearing to contest a finding of noncompliance that results in the imposition of an enforcement remedy. See 42 C.F.R. § 498.3(d)(13). A determination concerning the seriousness of a SNF's noncompliance must be

upheld unless it is "clearly erroneous." 42 C.F.R. § 498.60(c)(2).

Case Background[1]

During a February 2004 compliance survey, the New Jersey Department of Health and Senior Services (state survey agency) determined that a contract nurse working at DMC had failed to administer medications as ordered by a physician and in accordance with acceptable standards of nursing practice with respect to two residents identified as Resident 3 and Resident 4. CMS Ex. 2. The survey's Statement of Deficiencies, whose factual assertions DMC did not dispute before the ALJ,[2] indicates that, on February 11, 2004, the nurse in question administered Vancomycin (an antibiotic) to Resident 3 by intramuscular injection to the right thigh, even though a physician had ordered the drug to be administered by mouth. Id. at 2. That same day, the nurse mistakenly gave Resident 4 drugs — including Norvasc (an anti-hypertensive drug) and Dilantin (an anti-convulsant) — that had been prescribed for Resident 4's roommate. Id. at 2-3. The nurse also attempted to inject Resident 4 with the roommate's dose of insulin, but Resident 4 (a non-diabetic) refused the injection. Id. The errors were discovered on the day they occurred, and upon their discovery the nurse who committed them was immediately relieved of duty. Id. at 2-4.

Based on these facts, the state survey agency found that DMC was not in substantial compliance with the Medicare participation requirement at 42 C.F.R. § 483.20(k)(3)(i) on February 11, 2004. CMS Ex. 2, at 1; CMS Ex. 3. The state survey agency also determined that DMC's noncompliance had put residents in immediate jeopardy. CMS Ex. 3.

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[1] The information in this section is drawn from the ALJ Decision and the record before the ALJ, and is presented to provide a context for the discussion of the issues raised on appeal. Nothing in this section is intended to replace, modify, or supplement the ALJ's findings of fact or conclusions of law.

[2] As indicated below, CMS filed a motion for summary judgment before the ALJ. The motion was based partly on the facts described in the Statement of Deficiencies. DMC's response to the summary judgment motion did not place any of those facts in dispute. See Daughters of Miriam Center's Pre-Hearing Memorandum and Response to CMS' Motion for Summary Judgment (Dec. 15, 2004).

CMS accepted the state survey agency's findings and imposed a $3,100 per instance CMP on DMC. CMS Ex. 1. DMC requested a hearing before the ALJ to contest the enforcement action. CMS responded to the hearing request with a motion for summary judgment. The ALJ granted the motion in part, concluding that, on February 11, 2004, DMC was not in substantial compliance with one or more participation requirements, including section 483.20(k)(3)(i), which requires that "services provided or arranged by the facility . . . [m]eet professional standards of quality[.]" See Ruling Granting Partial Summary Disposition (Dec. 28, 2004) at 2-5. However, the ALJ found that an evidentiary hearing was needed to resolve DMC's challenge to CMS's immediate jeopardy determination and to decide whether the amount of the CMP was reasonable. Id. at 5-6. Accordingly, the ALJ conducted an in-person evidentiary hearing on those issues. Only one person gave testimony: Mary Ann Palmer, R.N., a surveyor who participated in the February 2004 survey.

After the hearing, the ALJ issued the decision now under appeal. The decision addresses the two issues that survived summary judgment: the validity of CMS's immediate jeopardy determination, and the reasonableness of the CMP amount. Regarding the first issue, the ALJ described what he believed to be the parties' respective evidentiary burdens:

> In any case where a finding of immediate jeopardy is at issue CMS has the burden of coming forward with sufficient evidence to establish prima facie proof that the regulatory definition of immediate jeopardy is satisfied. . . .
>
> If CMS meets its burden to establish a prima face case the burden then shifts to Petitioner to prove that immediate jeopardy is not present. In a case of immediate jeopardy the burden on Petitioner is heavy, assuming that CMS establishes its prima facie case. Petitioner must prove that CMS's immediate jeopardy determination is clearly erroneous in order to prevail.

ALJ Decision at 4 (citation omitted; emphasis added).

Applying these standards, the ALJ found that there was "no prima facie evidence" that DMC's noncompliance – namely, the nurse's medication errors on February 11, 2004 – had caused either death or "serious" actual harm to DMC's residents. ALJ Decision at 5-6. In addition, the ALJ found that, although DMC's noncompliance had created a "potential" for serious harm, CMS had "failed to offer prima facie proof that the *potential* for harm resulting

from the nurse's deficient performance translated into a *likelihood* that any resident would be harmed." Id. at 7 (italics in original; footnote omitted).

In its post-hearing brief, CMS asserted that the thwarted attempt to administer insulin to Resident 4 was "the most dangerous medication error." CMS Post-Hearing Br. at 4. However, the ALJ disagreed with CMS that this incident had created an immediate jeopardy situation:

> CMS observes that insulin is a potentially lethal drug when mis-administered. It argues that the consequences to the resident, had the drug been administered to her, could very well have been grave. Thus, according to CMS, the resident was placed at immediate jeopardy by the nurse's attempt to give her insulin.
>
> I find this reasoning to be unpersuasive. I agree with CMS that insulin is potentially a very dangerous drug when mis-administered. But, the problem with CMS's analysis is that it has provided nothing to establish that there was a likelihood that this resident would be harmed. In this case, the nurse was stopped by the resident's refusal to accept the medication. Conduct that might have been injurious or lethal, had it occurred, did not occur. It would be speculative, to say the least, to infer a likelihood of injury from a situation where no injurious conduct actually occurred.

ALJ Decision at 7 (footnotes omitted). In addition, the ALJ found that DMC's prompt discovery of the medication errors and termination of the error-prone nurse's employment rendered the likelihood of serious harm "speculative":

> The nurse who perpetrated the mis-administration and attempted mis-administration of medicines on February 11, 2004 was not a regular employee of Petitioner's facility but was, in fact, a temporary employee who had been assigned to work on that date by an outside agency. The misfeasances committed by the nurse became known to Petitioner very shortly after they were committed and Petitioner immediately terminated the nurse's service. The possibility that this nurse might have committed additional practice errors at Petitioner's facility ended immediately with the termination of her service. A continued presence of the nurse at Petitioner's facility after February 11 would have raised the issue of whether the *possibility*

> that the nurse might have perpetrated additional harm would have evolved into a *likelihood* of such happening. But, that issue is speculative here, because the nurse's service was terminated immediately by Petitioner's management.

Id.

Based on the foregoing analysis, the ALJ concluded that CMS's immediate jeopardy determination was clearly erroneous. ALJ Decision at 3-9. Finding the noncompliance "significant" but not at the level of immediate jeopardy, the ALJ reduced the CMP imposed by CMS from $3,100 to $1,000. Id. at 7-9.

CMS then filed this appeal, contending that the ALJ had erred in overturning its immediate jeopardy determination. At DMC's request, we held oral argument. During the argument, the Board questioned whether CMS has the burden of making a prima facie case regarding the level of seriousness of a SNF's noncompliance. The parties submitted written responses to this question following the oral argument, and we have considered those responses as well as relevant Board decisions.

Standard of Review

We review a disputed finding of fact to determine whether the finding is supported by substantial evidence, and a disputed conclusion of law to determine whether it 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; Golden Age Nursing & Rehabilitation Center, DAB No. 2026 (2006).

Discussion

The parties agree that the primary issue in this appeal is whether the ALJ erred in overturning CMS's immediate jeopardy determination.[3] We conclude that the ALJ Decision must be

[3] The ALJ addressed the merits of CMS's immediate jeopardy determination without indicating whether that issue was appealable. Under CMS's regulations, a determination concerning the seriousness of the SNF's noncompliance is appealable to an ALJ only if a successful challenge to the determination would affect (1) the range of CMP amounts that CMS could impose for the (continued...)

reversed for two reasons.

First, the ALJ erroneously required CMS to make a prima facie showing of immediate jeopardy. ALJ Decision at 4 (stating that "CMS has the burden of coming forward with sufficient evidence to establish prima facie proof that the regulatory definition of immediate jeopardy is satisfied"). The regulations at 42 C.F.R. § 498.60(c)(2) provide that a determination by CMS concerning the level of noncompliance must be upheld unless it is "clearly erroneous." In Liberty Commons Nursing and Rehab Center – Johnston, DAB No. 2031 (2006) (Liberty Commons), we held that this standard of review requires the ALJ and the Board in effect to presume that CMS's determination of immediate jeopardy is correct unless the SNF demonstrates that the determination is clearly erroneous. DAB No. 2031, at 18-19. As we indicated in that decision, requiring CMS to make a prima facie showing of immediate jeopardy would effectively eviscerate the review limitation in section 489.60(c)(2), which was intended to put the burden – a heavy one, in fact – on the SNF to upset a determination regarding the level of noncompliance.[4] Id.; see also Barbourville Nursing Home, DAB No. 1962 (2005) (stating that the "clearly erroneous" standard, as discussed in the preamble to the regulations, puts a heavy burden on providers to overturn

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[3](...continued)
SNF's noncompliance, or (2) a finding of substandard quality of care that has resulted in the loss of approval of the SNF's nurse aide training program. 42 C.F.R. § 498.3(b)(14). We note that because CMS imposed a "per instance" CMP, and because per instance CMPs are imposed within a single dollar range ($1,000 to $10,000), see 42 C.F.R. § 488.438(a)(2), a decision with respect to the validity of CMS's immediate jeopardy determination will have no effect on the range of CMP amounts that CMS may impose. In addition, we see no indication in the record that the noncompliance in this case resulted in loss of approval of DMC's nurse aide training program (assuming DMC had such a program). Although these circumstances suggest that the immediate jeopardy determination in this case was not appealable, we decline to address the appealability issue because CMS did not raise it below or before us.

[4] "To require CMS to make a prima facie case on the level of noncompliance would effectively and impermissibly convert what is clearly a limitation on the ALJ's scope of review under the regulations (and by extension a corresponding burden of proof on the SNF) into a burden of proof, or at least a burden of going forward, on CMS." Liberty Commons at 18-19.

CMS's determination regarding the level of noncompliance and requires that "survey team members and their supervisors" who make judgments about the level of noncompliance be accorded "some degree of flexibility, and deference, in applying their expertise . . . ."), aff'd Barbourville Nursing Home v. U.S. Dept. of Health and Human Servs., No. 05-3241 (6th Cir. April 6, 2006).

Our second reason for reversing the ALJ Decision is that DMC did not, in our view, carry its burden of showing clear error by CMS in determining the level of noncompliance. As indicated, immediate jeopardy is "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." 42 C.F.R. § 488.301. Under this definition, immediate jeopardy exists in either of the following two general circumstances. First, immediate jeopardy exists if the SNF's noncompliance has caused death or "serious" harm to one or more residents. (For discussion purposes, we use the word "harm" as shorthand for the regulatory terms "injury, harm, or impairment.") Second, immediate jeopardy exists if the SNF's noncompliance is or was "likely to cause" death or serious harm.

CMS has published guidelines in its State Operations Manual (SOM) to help surveyors make supportable immediate jeopardy determinations. SOM (CMS Pub. 7), Appendix Q, *Guidelines for Determining Immediate Jeopardy* ("CMS Immediate Jeopardy Guidelines").[5] With respect to noncompliance that presents a threat of harm, CMS's guidelines state that immediate jeopardy is "a crisis situation in which the health and safety of individual(s) are at risk." Id. at Q-3. The guidelines further state that immediate jeopardy exists when there is a "high potential" or "likelihood" that a SNF's noncompliance will cause death or serious harm "in the very near future." Id. at Q-3, Q-12. The guidelines stress that "Immediate Jeopardy procedures must not be used to enforce compliance quickly on more routine deficiencies." Id. at Q-4.

In view of these definitions and agency guidelines, the ALJ addressed two issues: Did DMC's noncompliance cause death or "serious" harm to one or more residents? If not, was the noncompliance "likely to cause" such outcomes"?

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[5] We cite to the paper-based version of the SOM that was in use during 2001 (CMS Pub. 7). In 2004, CMS issued an electronic version of the SOM (Pub. No. 100-07) that supplants the paper-based version.

In addressing the first issue, the ALJ endeavored to define the term "serious." He found that "[i]n ordinary parlance, 'serious' means something that is dangerous, grave, grievous, or life-threatening." ALJ Decision at 3. The ALJ further stated that the regulatory definition of immediate jeopardy makes it clear that "serious" harm is something "outside the ordinary," requiring "extraordinary care" or having "lasting consequences." Id. In addition, the ALJ stated:

> An injury that requires, for example, hospitalization, or which produces long-term impairment, or which causes severe pain, is a "serious" injury. That distinguishes the injury or harm from a situation that is temporary, which is easily reversible with ordinary care, which does not cause a period of incapacitation, which heals without special medical intervention, or which does not cause severe pain.

Id.

We think this definitional exercise was unnecessary insofar as its purpose was to set the framework for deciding whether CMS had proved a prima face case. As discussed, CMS had no such burden. Under the correct analytical framework, CMS's immediate jeopardy determination is presumed to be correct. In other words, it is presumed that the harm or threatened harm resulting from the noncompliance was in fact serious. DMC has the burden to rebut the presumption with evidence and argument showing that the harm or threatened harm did not meet any reasonable definition of "serious."[6]

In any event, we find it unnecessary to decide whether the noncompliance caused serious actual harm because we conclude that

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[6] In a footnote, the ALJ stated that his definition of "serious" was consistent with the definition of "serious health condition" in the Department of Labor (DOL) regulations that implement the Family and Medical Leave Act of 1993 (FMLA). ALJ Decision at 3, n.1. However, the ALJ provided no foundation to support an analogy to the FMLA. Furthermore, the DOL regulations define "serious health condition" largely with reference to a person's ability to work, a criterion that has no relevance in the nursing home context. See 29 C.F.R. § 825.114 (defining "serious health condition" to include "inpatient care" or treatment that involves a "period of incapacity" (defined as an "inability to work, attend school, or perform other regular daily activities")).

DMC failed to show that CMS lacked a basis for finding that the noncompliance was "likely to cause" serious harm. The term "likely" is ordinarily or commonly used to describe an outcome or result that is "probable" or "reasonably to be expected" though "less than certain." Webster's New World Dictionary (2nd College Ed.); see also The American Heritage Dictionary of the English Language (4th ed.); Black's Law Dictionary (5th ed.) (defining "likely" to mean "probable"). Also, the term "likely" – and its synonym "probable" – suggest a greater degree of probability that a particular event will occur than the terms "possible" or "potential." See Webster's New World Dictionary (2nd College Ed.) (definition of "probable"); Black's Law Dictionary (5th ed.) (defining "probable" as "having more evidence for than against," and defining "possible" as "capable of existing" and "free to happen or not"). In this regard, we have emphasized that a "mere risk" of serious harm is not equivalent to a "likelihood" of such harm. Innsbruck Healthcare Center, DAB No. 1948 (2004).

To be sure, the boundary between "likelihood" and mere "possibility" or "potential" is a matter of degree and may be difficult to discern in the context of a particular dispute. However, administering medication as ordered by the resident's doctor and in accordance with acceptable nursing standards of practice is a critical element of a resident's nursing home care. Administering medications not ordered by the resident's physician or not following the doctor's order with respect to dosage or method of administration may have a direct, immediate, and serious adverse effect on a resident's health. See SOM (CMS Pub. 7), Appendix P, Part II, *Guidance to Surveyors – Long-Term Care Facilities*, at PP-129-131 (discussing "significant" and "non-significant" medication errors and indicating that some medication errors have a "high potential" for problems for the typical long term care facility resident). According to CMS's immediate jeopardy guidelines, a failure to administer medication as prescribed, administration of contraindicated medication, and administration of medication to the wrong individual are errors that "trigger" scrutiny to determine whether residents were or are in immediate jeopardy. CMS Immediate Jeopardy Guidelines at Q-4, Q-6, Q-7.[7]

[7] CMS's guidelines list various immediate jeopardy "triggers" – that is, types of situations that may create immediate jeopardy and should prompt further investigation by surveyors. The guidelines instruct surveyors that they should use "professional judgment" to determine if in fact the situation at hand has caused or is likely to cause serious harm. CMS

(continued...)

DMC suggests that our immediate jeopardy analysis should focus on determining the probability that Residents 3 and 4 could have been seriously harmed by particular medication errors given their medical status, the medication dosages administered, and other resident-specific factors. Oral Argument Tr. at 7-9. However, DMC has not provided the evidence needed to undertake such a complex and exacting medical inquiry. Furthermore, the inquiry proposed by DMC (and performed by the ALJ) ignores the threat of harm that the noncompliance posed to residents other than Residents 3 and 4.

In Liberty Commons, the SNF was found noncompliant because it failed to follow or implement latex allergy precautions for a resident who it believed to be allergic to latex. CMS determined that the noncompliance was at the level of immediate jeopardy. The SNF objected to that determination, asserting that the resident was not in fact allergic to latex. The ALJ rejected the SNF's argument, and the Board sustained the ALJ. The Board stated:

> As the ALJ found, the validity of the immediate jeopardy finding in this case does not turn on whether there was "clinical evidence" of Resident 2's allergy to latex or whether CMS identified other residents with latex allergies. It lies, as the ALJ concluded, "in the weakness of Petitioner's system for protecting its residents demonstrated by the series of errors that occurred in providing care to Resident #2." ALJ Decision at 6. Liberty Commons undertook to care for a resident who it assumed was allergic to latex based on certain statements in his hospital records and his family's statements to facility staff. Based on the precautions Liberty Commons admits to taking based on this information, the urgent steps it took to seek medical help for Resident 2 after it became aware of the exposure and on its Latex Allergy Precautions policy, it is evident that Liberty Commons accepted during the relevant time period that it had an obligation to protect Resident 2 from exposure to latex and that a lapse in that protection posed a very real threat of likely serious harm and even death. Whether the threat it perceived with respect to Resident 2 existed in fact is not material. Immediate jeopardy exists if a SNF's noncompliance is the type of

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[7](...continued)
Immediate Jeopardy Guidelines at Q-4.

> noncompliance that would likely cause serious injury, harm, impairment, or death if not corrected, even if surveyors did not observe or identify a particular resident who was actually threatened with harm during the survey.

DAB No. 2031, at 18-19. Thus, we emphasized in Liberty Commons 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 or residents whose circumstances triggered the immediate jeopardy determination, but to the facility's population at large. This approach is consistent with CMS's immediate jeopardy guidelines, which instruct surveyors to consider whether the harm or potential harm is "likely to occur in the very near future to this individual or others in the entity, if immediate action is not taken." CMS Immediate Jeopardy Guidelines at Q-12.

In our view, CMS had ample reason to conclude that DMC's noncompliance would likely have caused death or serious harm to Resident 4 in the very near future, but for her fortuitous refusal to accept the insulin injection, or to other residents had the facility not stopped the nurse from administering medications when it did. The nurse's multiple errors occurred in the space of a single shift, and they suggested extreme carelessness or gross incompetence. The error regarding Resident 3 involved an apparent failure to read or interpret properly the physician's Vancomycin order as reflected in the resident's treatment records. DMC Ex. 4 (noting that the "cause of incident" was the nurse "did not properly read" the physician's order); DMC Ex. 13 (noting that Resident 3's medication administration record indicated that Vancomycin was to be administered by mouth). The errors involving Resident 4 stemmed from an inexplicable failure by the nurse to identify correctly the patient to whom she was giving the medications. There is no indication in the record that the nurse's deficient performance was atypical or an infrequent aberration.

There is also no indication that the nurse's responsibilities for administering prescription medication extended only to Residents 3 and 4, or that her work was being closely supervised. An incident report prepared by the supervising nurse on the shift when the errors occurred shows that she became aware of the errors only after the contract nurse who made them approached the supervisor to tell her she had made the mistake involving the injection of Vancomycin into Resident 3's thigh. DMC Ex. 13, at 1. The supervising nurse then told the Assistant Director of Nursing who, after asking the contract nurse to leave, discovered

the errors involving Resident 4. Id.; DMC Ex. 8, at 1; DMC Ex. 11, at 1; CMS Ex. 20, at 14. Thus, the facility's discovery of the contract nurse's errors and its ability to take action to prevent further errors was not due to its supervision of the contract nurse but, rather, to her own decision to alert staff to one of her errors. Had the contract nurse not recognized her mistake in injecting the Vancomycin and reported it, there is no reason for us to conclude, based on the record before us, that she would not have continued to make medication errors indefinitely while contracted to work at the facility.

At oral argument, DMC stated that it did not disagree with the ALJ's finding that one of the medications handled by the nurse — insulin — was "'potentially a very dangerous drug when mis-administered.'"[8] Oral Argument Tr. at 7. In addition, CMS's witness, Nurse Palmer, testified that the drugs administered to Residents 3 and 4 could have caused serious complications or dangerous side effects, including muscle necrosis and thrombophlebitis[9] (Vancomycin), hypotension and slow pulse (Norvasc), and drowsiness, dizziness and change in blood pressure (Dilantin). ALJ Hearing Tr. at 22, 25-26, 29-30. Given all these circumstances, CMS had reason to conclude that the noncompliance, had it continued, would likely have caused serious harm to *some* resident.

The reasons given by the ALJ for overturning the immediate jeopardy determination are unpersuasive. The ALJ first indicated that there was no likelihood of serious injury because Resident 4 prevented the insulin injection. See ALJ Decision at 7. However, it is reasonable to suppose that other residents would not have refused the injection under these circumstances. As CMS's regulations recognize, nursing home residents are a

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[8] One of our prior decisions indicates that dire outcomes from insulin administration errors are much more than just a theoretical possibility. In Barn Hill Care Center, DAB No. 1848 (2002), surveyors found that four diabetic residents received insulin overdoses. Resident 3 quickly became acutely ill and had to be hospitalized with profound hypoglycemia. Resident 1 was found unresponsive and foaming at the mouth. Resident 2 was found slumped in her chair with blood sugar level of 31. Resident 4 was found unresponsive in bed with a large skin tear caused by a fall against a door.

[9] Thrombophlebitis occurs when a blood clot causes inflammation in one or more veins, typically in the legs. See Dorland's Illustrated Medical Dictionary (28th ed.).

vulnerable population. Most have serious physical and mental impairments and conditions that render them totally or heavily dependent on the nursing staff for their care and survival. Some are so profoundly debilitated or impaired that they are unable to communicate their wishes or maintain awareness and understanding of what is happening to or around them. Such residents would be unlikely to discover that a drug is being given to them in error, much less have the ability to prevent the error once discovered. That Resident 4 refused the insulin injection was merely fortuitous given that she accepted other drugs (Dilantin and Norvasc) that she was not supposed to receive. We agree with CMS that its assessment of the level of noncompliance should not hinge on the fortuity of a single resident's intervention, particularly when the noncompliance posed risks to other residents under the nurse's care.

We also find immaterial the fact that DMC terminated the nurse's employment shortly after discovering the medication errors. Although DMC acted promptly to remove the contract nurse after discovering her medication errors, the regulations permit CMS to find immediate jeopardy and impose a CMP based on "past noncompliance" (that is, noncompliance that occurred but was corrected prior to the survey). See 42 C.F.R. § 488.438(a)(2), 488.438(b), 488.438(f)(2). For that reason, among others, it is appropriate to consider whether, prior to any corrective action, DMC's residents were exposed to noncompliance of the type likely to cause serious harm if not detected.[10] As discussed, CMS had a reasonable basis for concluding that Residents 3 and 4, and any other residents to whom the contract nurse administered medications, were directly exposed to such noncompliance during the contract nurse's work at DMC. The fact that DMC took prompt remedial action does not alter the nature of the noncompliance or diminish the threat it posed prior to its discovery. Furthermore, as previously discussed, there is no basis for concluding that the facility would have discovered the errors had the contract nurse herself not brought one of them to its attention.

In drafting the applicable regulations, CMS stated that

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[10] Apart from CMS's authority to cite prior noncompliance, considering what harm could have resulted to the specific residents at issue, or to other residents, but for the discovery and cessation of the professional practices causing the noncompliance seems logically to be an integral part of assessing the likelihood of serious harm. DMC certainly has not persuaded us otherwise.

"distinctions between different levels of noncompliance, whether measured in terms of their frequency or seriousness, do not represent mathematical judgments for which there are clear or objectively measured boundaries." *Medicare and Medicaid Programs; Survey, Certification and Enforcement of Skilled Nursing Facilities and Nursing Facilities*, 59 Fed. Reg. 56,116, 56,179 (Nov. 10, 1994). This inherent imprecision is precisely why CMS's immediate jeopardy determination, a matter of professional judgment and expertise, is entitled to deference. Id. ("Survey team members and their supervisors ought to have some degree of flexibility, and deference, in applying their expertise in working with these less than perfectly precise concepts"). In this proceeding, DMC introduced no testimony from any person qualified to question how CMS applied its professional judgment and expertise to determine the level of noncompliance. Although DMC suggests that the probability of future harm from particular medication errors was insufficiently great to constitute a "likelihood" of harm, DMC produced no evidence affirmatively supporting that position.

For all the reasons above, we conclude that the ALJ erred in finding that CMS's immediate jeopardy determination was clearly erroneous.

The ALJ reduced the amount of the CMP imposed by CMS from $3,100 to $1,000 based on his decision that the severity of the noncompliance was below the level of immediate jeopardy. ALJ Decision at 7-8. Because we now affirm the determination of immediate jeopardy, and because DMC does not contend that the amount of the CMP, as originally imposed, was unreasonable for that level of noncompliance, we reinstate the $3,100 CMP imposed by CMS.

Conclusion

For the reasons above, we reverse the ALJ Decision and reinstate the $3,100 per instance CMP imposed by CMS.

/s/
Judith A. Ballard

/s/
Leslie A. Sussan

/s/
Sheila Ann Hegy
Presiding Board Member