Department of Health and Human Services

DEPARTMENTAL APPEALS BOARD

Appellate Division

In the Case of:	DATE: May 17, 2010
Maysville Nursing & Rehabilitation Facility, Petitioner,	Civil Remedies CR2032 App. Div. Docket No. A-10-34
- v. -	Decision No. 2317
Centers for Medicare & Medicaid Services.	

FINAL DECISION ON REVIEW OF ADMINISTRATIVE LAW JUDGE DECISION

Maysville Nursing & Rehabilitation Facility (Maysville), a Kentucky long-term care facility certified to participate in both Medicare and Medicaid, appeals the November 29, 2009 decision of Administrative Law Judge Keith W. Sickendick, Maysville Nursing & Rehabilitation Facility, DAB CR2032 (2009) (ALJ Decision). At issue before the ALJ was a determination by the Centers for Medicare & Medicaid Services (CMS), based on a survey of Maysville on November 7, 2007 and two revisit surveys, that Maysville was not in substantial compliance with multiple regulatory requirements for long-term care facilities participating in the Medicare and Medicaid programs. After a hearing, the ALJ concluded that (1) Maysville was not in substantial compliance with program participation requirements at 42 C.F.R. §§ 483.25(l) (unnecessary drugs) and 483.60(c) (drug regimen review); (2) CMS's determination that Maysville's noncompliance with these requirements posed immediate jeopardy was not clearly erroneous; (3) Maysville was not in substantial

compliance with program participation requirements at 45 C.F.R. §§ 483.15(a), 483.25(d), and 483.25(h) at the non-immediate jeopardy level; (4) Maysville's noncompliance posed immediate jeopardy from July 31, 2007 through November 1, 2007, and continued at the non-immediate jeopardy level through November 22, 2007; and (5) a civil money penalty (CMP) of $3,050 per day for the period of immediate jeopardy and $250 per day for the period of non-immediate jeopardy was reasonable, and CMS had a basis for imposing a discretionary denial of payment for new admissions (DPNA) from November 17 through 22, 2007.[1]

On appeal, Maysville disputes the ALJ's conclusion that it failed to comply substantially at the immediate jeopardy level with section 483.25(l). Maysville also disputes that it failed to comply substantially with section 483.60(c) before September 28, 2007 and argues that any noncompliance with this section before or after that date did not pose immediate jeopardy.

For the reasons discussed below, we affirm the ALJ's conclusions that Maysville was not in substantial compliance with sections 483.25(l) and 483.60(c) at the immediate jeopardy level and uphold the imposition of the $3,050 per-day CMP for the period July 31 through November 1, 2007. We uphold without any discussion the imposition of a $250 per-day CMP from November 2 through 22, 2007, which Maysville conceded was properly imposed based on the uncontested noncompliance findings.

Background

In order to participate in Medicare, a long-term facility must comply with the participation requirements set forth in 42 C.F.R. Part 483, subpart B. 42 C.F.R. § 483.1. State agencies under contract with CMS perform onsite surveys to assess compliance with these requirements. 42 C.F.R. §§ 488.300, 488.305. Deficiencies – or failures to meet participation requirements – are reported by the state survey agency on a standard form called a "Statement of Deficiencies" (SOD). State Operations Manual (SOM), Appendix P – Survey Protocol for Long-Term Care Facilities (accessible at http://cms.gov/manuals/Downloads/som107ap_p_ltcf.pdf).

CMS may impose enforcement remedies (including CMPs) when it determines, on the basis of survey findings, that a facility is not in "substantial compliance" with one or more participation

[1] The ALJ also stated that, pursuant to 42 C.F.R. §§ 483.151(b)(2) and (e)(1), the state agency was required to withdraw Maysville's approval to conduct a nurse aide training program (NATCEP) for a period of two years because the total CMP exceeded $5,000. See ALJ Decision at 15.

requirements. 42 C.F.R. § 488.402. "Substantial compliance" means 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." 42 C.F.R. § 488.301. Under the regulations, the term "noncompliance" refers to "any deficiency that causes a facility to not be in substantial compliance." Id.

CMS determines the amount of a CMP based on the "seriousness" (scope and severity) of the facility's noncompliance. 42 C.F.R. § 488.404(a). The most serious type of noncompliance is one that places residents in "immediate jeopardy." Section 488.404(b). 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. The minimum per-day amount for a CMP in the case of immediate jeopardy is $3,050. 42 C.F.R. § 488.438(a)(1). A per-day CMP of $50 to $3,000 may be imposed for noncompliance at less than the immediate jeopardy level. Id.

On November 7, 2007, state agency surveyors completed a complaint and partial-extended survey of Maysville and thereafter issued an SOD containing the survey's findings (CMS Exhibit 46). The SOD identified nine findings of noncompliance, including several that the surveyors found posed immediate jeopardy. ALJ Decision at 6-7. The SOD for a November 27, 2007 revisit survey (CMS Exhibit 53) cited Maysville with the same deficiencies identified in the SOD for the previous survey but found that immediate jeopardy had been abated on November 2, 2007, although Maysville did not return to substantial compliance at that time. Id. at 2.

CMS imposed a CMP in the amount of $4,550 per day beginning July 31, 2007. CMS lowered the amount of the per-day CMP to $250 beginning November 2, 2007 after determining that the immediate jeopardy was abated on that date. The state agency subsequently accepted Maysville's allegation that it had returned to substantial compliance no later than November 23, 2007; however, following a January 4, 2008 revisit survey, both the state agency and CMS determined, instead, that Maysville did not return to substantial compliance until January 4, 2008. ALJ Decision at 2-3. Since the ALJ concluded that Maysville returned to substantial compliance November 23, 2007, the $250 per-day CMP imposed by CMS, and found reasonable by the ALJ, covers the period November 2, 2007 through November 22, 2007.[2]

[2] CMS did not appeal the ALJ's conclusions that a $3,050 per-day CMP was reasonable, instead of the $4,550 per-day CMP

(Continued. . .)

The ALJ Decision

The ALJ made 11 numbered findings of fact and conclusions of law (FFCLs). See ALJ Decision at 7, 8, 13, 14, 16. On appeal, Maysville takes exception to FFCLs 1-3, in which the ALJ concluded that Maysville violated sections 483.25(l) and 483.60(c) and that CMS's finding of immediate jeopardy based on those violations was not clearly erroneous. Maysville also argues that the ALJ erred in concluding that it was unnecessary to address four other findings of noncompliance.

Section 483.25(l) provides in pertinent part:

> *Unnecessary drugs*—(1) *General.* Each resident's drug regimen must be free from unnecessary drugs. An unnecessary drug is any drug when used:
>
> * * * * *
>
> (iii) Without adequate monitoring;
>
> * * * * *

Section 483.60(c) provides:

> *Drug regimen review*. (1) The drug regimen of each resident must be reviewed at least once a month by a licensed pharmacist.
>
> (2) The pharmacist must report any irregularities to the attending physician and the direction of nursing, and these reports must be acted upon.

The ALJ's conclusion that Maysville failed to comply substantially with sections 483.25(l) and 483.60(c) was based on the examples of two residents, referred to as Residents 1 and 7, who were prescribed the anticoagulant medication Coumadin. The following facts are undisputed.[3] Hemorrhage, necrosis, death or permanent disability can result when Coumadin is not in a therapeutic range. Laboratory tests for Prothrombin Time and International Normalized Ratio (PT/INR) are used to determine whether Coumadin is in a therapeutic range and should be performed at least monthly. Resident 1 had a PT/INR test on

(Continued. . .)

CMS imposed, or that Maysville returned to substantial compliance on November 23, 2007 instead of January 4, 2008.

[3] This factual background is drawn primarily from undisputed facts found at pages 9-13 of the ALJ Decision. We cite to evidence in the record for additional details that are also undisputed.

July 31, 2007. A July 31 nurse's note indicates that "[c]urrent lab results" were faxed to Resident 1's physician that day. P. Ex. 1, at 150. An August 1 nurse's note states: "MD return call NNO [no new orders] R/T [related to] Lab." Id. A "consultant pharmacist" who conducted a drug regimen review for Maysville on August 29, 2007 noted that there were "no irregularities" in Resident 1's drug regimen. P. Ex. 1, at 226. Another consultant pharmacist conducted a drug regimen review on September 28, 2007, reporting that Resident 1's "last lab result for an INR was dated 7/31/07" and stating that Maysville should "follow up on these lab reports" since "[i]t is recommended to check the protime/INR monthly at a minimum." Id. and CMS Ex. 45, at 22. Maysville failed to act on the pharmacist's report. Resident 1 did not receive another PT/INR test until October 10, 2007, when he was hospitalized for a subdural hematoma and tested high for INR. Resident 7 had an August 10, 2007 physician order that PT/INR testing be done in three days. No PT/INR test was done until August 16, when the charge nurse asked the physician to order an immediate PT/INR because Resident 7 had a skin tear that was bleeding "quite a bit more than a normal skin tear." Tr. at 212. Resident 7's INR tested high on August 16.

Standard of Review

We review a disputed finding of fact to determine whether the finding is supported by substantial evidence on the record as a whole, and a disputed conclusion of law to determine whether it is erroneous. Departmental Appeals Board, *Guidelines - Appellate Review of Decisions of Administrative Law Judges Affecting a Provider's Participation in the Medicare and Medicaid Programs*, http://www.hhs.gov/dab/divisions/appellate/guidelines/index.html.

Analysis

Below, we discuss each of the two noncompliance findings on which the ALJ relied in upholding the imposition of the immediate jeopardy level CMP. The first of these noncompliance findings involves Residents 1 and 7. As the Board has previously noted, however, "[n]oncompliance as to any one resident cited under a tag is sufficient to support a finding of noncompliance under the tag even if the surveyors cited other examples of noncompliance under the tag." Jewish Home of Eastern Pennsylvania, DAB No. 2254, at 7 (2009). In addition, immediate jeopardy exists if noncompliance with one or more participation requirements "has caused, or is likely to cause serious injury, harm, impairment, or death to a resident." 42 C.F.R. § 488.301. Here we conclude that Maysville failed to comply substantially with section 483.25(l) at the immediate

jeopardy level with respect to Resident 1 from July 31 through November 1, 2007. That conclusion, without more, is sufficient to affirm the ALJ's conclusion that a $3,050 per-day CMP was reasonable for that period. However, we also conclude that for part of that period, Maysville was out of compliance with section 483.25(l) with respect to Resident 7 as well as with section 483.60(c) and that this additional noncompliance was at the immediate jeopardy level.[4]

A. The ALJ's conclusion that Maysville failed to comply substantially with section 483.25(l) is supported by substantial evidence and free of error.

Resident 1

Maysville does not dispute the ALJ's finding that a resident for whom Coumadin is prescribed should have a PT/INR test at least monthly to monitor the level of Coumadin. See ALJ Decision at 9, citing CMS Ex. 45, at 22 (9/28/07 pharmacist's report stating that "[i]t is recommended to check the protime/INR monthly at a minimum" and citing the Institute for Clinical Systems Improvement 2001 Anticoagulation Therapy Supplement); see also ALJ Decision at 11 (finding credible the pharmacist's opinion).[5] Nor does Maysville dispute that Resident 1 had no physician orders for, and did not receive, PT/INR testing for more than one month following a test on July 31, 2007. However, Maysville takes the position that it was not responsible for the fact that Resident 1 did not have PT/INR testing monthly after that date. Maysville asserts that nurses in Kentucky have no authority to order laboratory tests and have no duty to compel physicians to order tests. Thus, in Maysville's view, it fulfilled its

[4] The ALJ did not make separate findings regarding the duration of the noncompliance under section 483.25(l) with respect to Residents 1 and 7 or the duration of the noncompliance under section 483.60(c). See ALJ Decision at 13. While the facts found by the ALJ regarding Resident 1 support finding immediate jeopardy level noncompliance under section 483.25(l) from July 31 through November 1, 2007, the facts found by the ALJ do not appear to provide a basis for finding noncompliance under section 483.25(l) with respect to Resident 7 prior to August 13, 2007 or for finding noncompliance under section 483.60(c) prior to August 29, 2007.

[5] In addition, Maysville's administrator acknowledged that standing orders for laboratory tests are needed for certain drugs, including Coumadin. CMS Ex. 45, at 76 (11/7/07 surveyor notes).

responsibilities under section 483.25(l) by identifying and monitoring Resident 1 for the observable side effects of excessive Coumadin and by ensuring monthly visits from Resident 1's attending physician, who, Maysville notes, had the authority to order PT/INR tests. RR at 8-12.[6]

The ALJ rejected Maysville's argument that its monitoring duties did not include alerting Resident 1's physician to the absence of physician orders that would ensure that the laboratory tests needed to monitor the level of Coumadin were performed at least monthly. The ALJ stated in part:

> The regulation squarely places the burden upon Petitioner to ensure there is adequate monitoring and Petitioner does not have the option of hiding behind . . . the physician's . . . failure to act. I take no issue with Petitioner's assertion that nursing staff may not order laboratory tests or substitute its judgment for that of the physician. However, Petitioner does have the burden under the regulation to ensure that monitoring is done. When monitoring is not done, Petitioner has the burden to show that it took action to ensure the monitoring was done or that the clinical evidence reflects a reasonable explanation for why it was not.

ALJ Decision at 13.

We agree with the ALJ that the regulation imposes a substantial responsibility on the facility to adequately monitor a resident's drug regimen. The lead-in language to section 483.25 makes clear that it is the facility's responsibility to ensure that each quality of care requirement in section 483.25 is met, stating: "Each resident must receive and the facility must provide the necessary care and services to attain or maintain the highest practicable physical, mental, and psychosocial well-being, in accordance with the comprehensive assessment and plan of care." (Emphasis added.) There is nothing in the language of section 483.25(l) suggesting that a facility is responsible only for monitoring it can provide directly or that exempts a facility from alerting a physician when an integral part of that monitoring – an order for laboratory testing – appears to be missing.

The preamble to the final rule adopting section 483.25(l) supports the ALJ's reading of this section. The preamble notes

[6] Maysville does not contend that monitoring Resident 1 for observable side effects of Coumadin would always be adequate to detect excessive levels of the drug.

that numerous commenters "believed that the regulation inappropriately holds facilities responsible for controlling drug use when it is physicians who prescribe drugs and control their use. They argue that under State Law only the physician may prescribe and discontinue drugs, order laboratory monitoring tests for drug use, and generally arrange the drug therapy of the resident." 56 Fed. Reg. 48,826, 48,852 (Sept. 26, 1991). In response to these comments, the preamble cites provisions in titles XVIII and XIX of the Social Security Act, as well as the regulations at section 483.75(h)(2)(i), all of which, the preamble says, "clearly make the facility responsible for the quality of drug therapy provided in the facility. They do not require the facility to act in place of the physician, but they do, in accordance with the statute, hold the facility responsible for the health and safety of the resident."[7] Id. The preamble also addresses comments that section 483.25(l) "will require nursing facilities to exercise medical judgments that would interfere with a physician's treatment decisions." Id. The preamble states that the regulation requires instead "that facilities enforce Medicare and Medicaid standards for the use of drugs on residents and ensure that physicians make reasonable medical judgments that these standards have been met before prescribing drugs to the facility's residents." Id.

Contrary to what Maysville argues, moreover, it is entirely consistent with Kentucky law to require that a facility ensure that physicians make reasonable medical judgments that Medicare and Medicaid standards for the use of drugs have been met. A February 2005 Advisory Opinion Statement issued by the Kentucky Board of Nursing states that a nurse has "the responsibility and the obligation . . . to question a patient care order that is deemed inappropriate by a nurse according to his/her educational preparation and clinical experience." CMS Ex. 31, at 4. The opinion further provides that in "any situation where . . . a nurse questions the appropriateness, accuracy, or completeness of an order, the nurse should not implement the order until it is verified for accuracy with the physician/provider." Id.

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[7] Sections 1819(d)(4)(A) and 1919(d)(4)(A) (42 U.S.C. §§ 1395i-3(d)(4)(A) and 1396r(d)(4)(A)) provide that a facility "must operate and provide services in compliance . . . with accepted professional standards and principles which apply to professionals providing services in such a facility." Section 483.75(h)(2)(i) provides that agreements for services furnished by outside resources must specify that the facility assumes responsibility for "[o]btaining services that meet professional standards and principles that apply to professionals providing services in such a facility."

Under the facts on which Maysville relies, Maysville's nursing staff was clearly required by this Advisory Opinion to question the physician's failure to order further PT/INR testing. From May 8, 2007 (when Resident 1 was readmitted to the facility) through July 23, 2007, Resident 1's physician issued a total of five orders for future PT/INR testing – one order each time the physician received the results of a PT/INR test.[8] See RR at 5 (citing pages from P. Ex. 1). Based on this history of physician orders for PT/INR testing for Resident 1 and the undisputed standard of care for Coumadin therapy (PT/INR testing at least monthly), Maysville's nursing staff should have questioned Resident 1's physician if he gave no orders for another PT/INR test after receiving the results of the July 31 test. As noted above, an August 1 entry in the nurses notes reads: "MD return call NNO [no new orders] R/T [related to] Lab." P. Ex. 1, at 150. Maysville's charge nurse testified that this note "meant we continue the same dose" of Coumadin. Tr. at 184. She further testified that there was no order from the physician for any additional laboratory tests. Id. This evidence clearly indicates that Maysville was aware of the absence of a physician's order for further PT/INR testing for a resident still receiving Coumadin therapy. Yet, despite this awareness, there is no evidence that Maysville ever brought the absence of such an order to the physician's attention.

Maysville asserts in its request for review that the August 1 nurses note records the "fact" that Resident 1's physician "specifically indicated that he was issuing no new orders[.]" RR at 5. If Maysville means by this assertion that the physician specifically told the nurse who made notes on the conversation that he was not giving new orders for a repeat PT/INR test, such a meaning is inconsistent with the charge nurse's testimony regarding her understanding of what the physician meant (to continue the same dose), although Maysville itself relies on the same testimony.[9] In addition, the surveyor notes indicate that the physician told the surveyors he thought Resident 1 already had an order for repeat PT/INR tests. See CMS Ex. 45, at 72. Thus, there is no evidence to support a finding that Resident 1's physician specifically told the nurse on August 1 that he was not ordering any such tests or a finding that that is how Maysville's nursing staff understood the order at the time.

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[8] Resident 1 was transferred to a new physician on July 2, 2007. P. Ex. 1, at 71. The first two orders were issued before that date.

[9] Maysville cites to page 183 of the transcript; however, the relevant testimony appears on page 184.

Maysville mistakenly suggests that the Board's decision in Beverly Health and Rehabilitation-Spring Hill, DAB No. 1696 (1999), aff'd, Beverly Health & Rehab. Servs. v. Thompson, 223 F.Supp.2d 73 (D.D.C. 2002), supports its position that it was not required to question Resident 1's physician about the absence of an order for a repeat PT/INR. Maysville cites the Board's quoting with approval the ALJ's statement that "nurses are not required to challenge those judgments that physicians make which are 'uniquely within the skill and training of a physician.'" Beverly at 42-43. The Board's statement in Beverly is inapposite because the monitoring of Coumadin therapy, as opposed to prescribing the drug, is not "uniquely within the skill and training of a physician." As we have discussed, the regulation imposes substantial responsibility for that monitoring on the facility. Moreover, as discussed above, Maysville points to nothing in the record showing that Resident 1's physician either made or clearly communicated to Maysville an affirmative judgment that Resident 1 did not need a repeat PT/INR test.

Resident 7

Maysville admits that it did not arrange for a PT/INR test for Resident 7 at the time ordered by her physician. Nonetheless, Maysville takes exception to the ALJ's conclusion that it failed to comply substantially with section 483.25(l) with respect to Resident 7, characterizing this failure to follow the physician's orders as "a short delay of 3 days[.]" RR at 12. Maysville's reference to a "delay" in obtaining the PT/INR test is misleading. Maysville does not dispute that Resident 7's physician gave an order on August 10, 2007 to test the resident's PT/INR in three days, i.e., on August 13, and that no test was done on that date. The physician's order clearly reflects a determination that the resident's Coumadin level needed to be checked on that date. Thus, Maysville's admitted failure to ensure that the PT/INR test was done when ordered by the physician was on its face a violation of the requirement in section 483.25(l) that drugs prescribed for residents be adequately monitored.

Furthermore, that the "delay" was only three days was purely fortuitous. The PT/INR test was done on August 16 only because a nurse noticed that Resident 7 had more than normal bleeding from a skin tear. Had it not been for this incident, the "delay" might well have been much longer.

Accordingly, we uphold the ALJ's conclusion that Maysville failed to comply substantially with section 483.25(l) based on the findings with respect to both Residents 1 and 7.

B. The ALJ did not err in concluding that CMS's determination that Maysville's noncompliance with section 483.25(l) posed immediate jeopardy was not clearly erroneous.

In concluding that CMS's determination that Maysville's noncompliance with section 483.25(l) posed immediate jeopardy was not clearly erroneous, the ALJ relied on the undisputed facts that 1) Resident 1's INR was high when he was hospitalized on October 10, 2007; 2) Resident 7's INR was high when she sustained a skin tear on October 16, 2007; and 3) excessive Coumadin levels (indicated by the high INR) may lead to serious harm or death. ALJ Decision at 13. The ALJ found that Maysville "has not shown that serious harm or death was not likely due to its failure to monitor Coumadin therapy." Id.

The regulations provide that "CMS's determination as to the level of noncompliance . . . must be upheld unless it is clearly erroneous." 42 C.F.R. § 498.60(c)(2). The ALJ recognized this and also correctly stated that a determination of immediate jeopardy is a determination as to the level of noncompliance and, thus, subject to the "clearly erroneous" standard. ALJ Decision at 5. Under the clearly erroneous standard, CMS's immediate jeopardy finding is presumed to be correct, and the facility has a heavy burden to overturn it. E.g., Stone County Nursing & Rehabilitation Center, DAB No. 2276, at 17 (2009), and cases cited therein. We conclude that Maysville has not met that burden here.

Maysville does not offer any reasons why CMS's determination that its noncompliance with respect to Resident 1 posed immediate jeopardy could be found clearly erroneous. Maysville merely contends that any noncompliance with respect to Resident 7 did not pose immediate jeopardy because its close monitoring of the resident for side effects of Coumadin "led to the discovery of the delay in obtaining the PT/INR lab test." RR at 12. However, Maysville does not dispute that Resident 7 suffered actual harm, in the form of more than normal bleeding, before the facility obtained a new order from the physician. Regardless of whether this actual harm was serious, the ALJ could reasonably conclude that Resident 7 faced a likelihood of serious harm without a timely PT/INR test precisely because, as the ALJ found, hemorrhaging, i.e., excessive bleeding, is one of the known dangerous side effects from Coumadin therapy. ALJ Decision at 9. Immediate jeopardy is defined as including a situation in which the facility's noncompliance is likely to cause serious harm. 42 C.F.R § 488.301.

Accordingly, we uphold the ALJ's conclusion that CMS's determination that Maysville's noncompliance with section 483.25(l) posed immediate jeopardy was not clearly erroneous.

C. The ALJ's conclusion that Maysville failed to comply substantially with section 483.60(c) is supported by substantial evidence and is free of error.

The ALJ found that Maysville failed to comply substantially with section 483.60(c) based on 1) the pharmacist's failure to "identify the irregularity" in Resident 1's drug regimen in August 2007, and 2) Maysville's failure "to act upon the consulting pharmacist's recommendation to obtain an order for testing" in September 2007. ALJ Decision at 12. Maysville concedes its failure to act on the latter recommendation and that it therefore failed to comply substantially with section 483.60(c) beginning September 28, the date the pharmacist reported the irregularity. RR at 14-15.

Maysville also does not dispute that there was an irregularity in Resident 1's drug regimen on August 29, when the first review of his drug regimen was conducted. According to the ALJ Decision, it was "undisputed that the pharmacist failed to identify the irregularity that Resident 1 had no order for a PT/INR within 30 days of his last PT/INR and no testing of PT/INR in nearly 30 days." ALJ Decision at 12. Maysville's comment that "another [PT/INR] test would not have been due until August 31, 2007" (RR at 8) does not constitute a denial that there was no order for any future testing even though Resident 1 needed testing at least monthly under the undisputed standard of care. The ALJ's finding that the absence of an order constituted an irregularity when the pharmacist conducted the drug regimen review on August 29 is especially reasonable since there were only two days left before the end of the maximum period between tests of one month and no test could be done until a physician's order was issued.

Maysville argues that, despite the pharmacist's failure to identify an irregularity, it complied with section 483.60(c) from August 29 to September 28. According to Maysville, subsection (c)(1) of section 483.60 requires a facility to ensure that a licensed pharmacist conducts a monthly review of each resident's drug regimen, while subsection (c)(2) requires that a facility act on irregularities reported by the pharmacist to the director of nursing. Maysville argues that it satisfied both requirements and that nothing in the regulation makes it responsible for the accuracy of the pharmacist's review. RR at 14-15, 17. In Maysville's view, in holding that the facility "has the burden to ensure that its records receive a competent pharmacist review" (ALJ Decision at 13 (emphasis added)), the ALJ in effect required "the nursing staff to substitute or question the judgment of a trained, licensed professional with expertise in the area of pharmacy." Id. at 14.

Maysville's reading of the regulation is unduly narrow. While subsection (c)(1) of section 483.60 does not specify that the required monthly review must be accurate, this subsection must be read in the context of the regulation as a whole, including section 483.60(a), which states that a facility must "provide pharmaceutical services (including procedures that assure the accurate . . . dispensing . . . of all drugs . . .) to meet the needs of each resident" (emphasis added). Thus, in context, it is clear that the monthly review required by subsection (c)(1) of section 483.60 must be an accurate review. [10]

Contrary to what Maysville suggests, finding it noncompliant with section 483.60(c) based on the fact that the pharmacist's review did not identify an irregularity does not imply that the facility was required to substitute its judgment for that of the pharmacist. It simply means that the facility is responsible for the consequences of the pharmacist's failure to conduct an accurate review. The Board has previously rejected a facility's similar argument that it was not "responsible for the professional judgment (or presumably lack thereof) exercised by licensed staff within the scope of their practice." Royal Manor, DAB No. 1990, at 12 (2005). The Board explained its rationale as follows:

> The facility acts through its staff, and is correspondingly responsible for their actions as employees. As the Board explained in a prior case, when a nurse acts within the scope of her employment, the "employer cannot disown the consequences of the inadequacy of the care provided by the simple expedient of pointing the finger at her fault, since she was the agent of her employer empowered to make and carry out daily care decisions." Emerald Oaks, DAB No. 1800, at 7, n.3 (2001). It is the facility that executes a provider agreement and undertakes to provide services of the quality mandated by the participation requirements. If the professional staff hired by the facility is, as proved to be the case here, not adequately skilled, trained, or equipped to provide those services, the facility must

[10] Maysville cites Pacific Regency Arvin, DAB CR792 (2001) for the proposition that compliance with subsection (c)(1) of section 483.60 can be established if the facility presents evidence of monthly reviews by a licensed pharmacist. RR at 14. ALJ decisions (such as DAB CR792) are not precedent binding on the Board. In any event, that case presented the issue of whether there was sufficient evidence that a monthly review had actually been conducted, not whether there is a violation of subsection (c)(1) where a monthly review fails to identify an irregularity.

> answer for, and correct, that failure through the survey and certification process[.]

Id. We find this rationale no less applicable here even if Maysville hired the pharmacist as a consultant rather than an employee.[11] Maysville is responsible for the inadequacy of the pharmacist's drug regimen review because an accurate review was part of the services Maysville was required to provide to ensure that residents received quality care. Moreover, as previously noted, section 483.75(h)(2)(i) specifically makes a facility responsible for the quality of the services provided by "outside resources," which would include the consultant pharmacists who conducted the drug regimen reviews.

Accordingly, we uphold the ALJ's conclusion that Maysville failed to comply substantially with section 483.60(c) based on the pharmacist's failure to report an irregularity on August 29 as well as Maysville's failure to act on the September 28 report of an irregularity.

D. The ALJ did not err in concluding that CMS's determination that Maysville's noncompliance with section 483.60(c) posed immediate jeopardy was not clearly erroneous.

The ALJ concluded that CMS's determination that Maysville's noncompliance with section 483.60(c) posed immediate jeopardy was not clearly erroneous. On appeal, Maysville states that "with respect to . . . the violation of 42 CFR 483.60(c), there is no evidence to support a conclusion that immediate jeopardy existed at any time prior to September 28, 2007." RR at 16. Thus, Maysville does not dispute that its admitted noncompliance with section 483.60(c) from September 28 through November 1 posed immediate jeopardy, only that any noncompliance with section 483.60(c) before that period (which the ALJ concluded, and we agree, existed) constituted immediate jeopardy.

As stated above, Maysville had the burden of showing that CMS's determination of immediate jeopardy was clearly erroneous. Maysville offers no reasons why CMS's determination that its noncompliance with section 483.60(c) prior to September 28 posed

[11] Section 483.60(b) provides that a facility "must employ or obtain the services of a licensed pharmacist . . . . ." It appears that the pharmacists who conducted the reviews in question here were not employed by Maysville since the form they filled out showing for each review either that no irregularities were noted or that a report was made is captioned "Med Care Pharmacy Consultant Pharmacist Medication Regimen Review." P. Ex. 1, at 226.

immediate jeopardy could be found clearly erroneous. Accordingly, we uphold the ALJ's conclusion without further discussion. We note in any event that it is immaterial whether there was immediate jeopardy under section 483.60(c) before September 28 since, as discussed above, Maysville's noncompliance with section 483.25(l) posed immediate jeopardy from July 31 through November 1, 2007.

E. The ALJ did not err in determining that it was unnecessary to address four findings of noncompliance.

The ALJ did not address noncompliance findings under sections 483.20(k)(3)(ii), 483.25, 483.75, or 483.75(o)(1), all of which were originally cited at the immediate jeopardy level.[12] According to the ALJ, it was unnecessary to address these findings because Maysville's noncompliance under sections 483.25(l) and 483.60(c) amply justified a $3,050 per-day CMP (the lowest amount that may be imposed for immediate jeopardy level noncompliance) and the other enforcement remedies (a discretionary DPNA and the denial of approval for a NATCEP). ALJ Decision at 8-9.

Maysville argues that the ALJ should have addressed these noncompliance findings, none of which, it asserts, show immediate jeopardy level noncompliance. RR at 17-21. This argument appears to assume that the Board would reverse the ALJ's conclusions that Maysville failed to comply substantially with section 483.25(l) and, until September 28, 2007, with section 483.60(c). Had we done so, there would have been no basis in the ALJ Decision for upholding the immediate jeopardy level CMP, and we would have been required to consider, or remand the case to the ALJ to consider, the findings of immediate jeopardy level noncompliance that the ALJ did not address. However, we have concluded above that substantial evidence in the record supports the ALJ's findings that Maysville failed to comply substantially with sections 483.25(l) and 483.60(c) at the immediate jeopardy level and that it was out of compliance with the requirements of one or both of these sections at the immediate jeopardy level during the entire July 31 through November 1, 2007 period. We therefore agree with the ALJ that it was unnecessary to address the remaining noncompliance findings.

[12] CMS stated at the hearing that it accepted the results of the state agency's informal dispute resolution reducing the scope and severity of two of the four noncompliance findings to the non-immediate jeopardy level. ALJ Decision at 7.

Conclusion

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

_____/s/_____
Judith A. Ballard

_____/s/_____
Stephen M. Godek

_____/s/_____
Sheila Ann Hegy
Presiding Board Member