Department of Health and Human Services

DEPARTMENTAL APPEALS BOARD

Civil Remedies Division

In the Case of:	)	
	)	
Hawthorne Inn of Danville,	)	Date: June 11, 2008
	)	
Petitioner,	)	
	)	
- v. -	)	Docket Nos. C-07-746
	)	C-08-10
Centers for Medicare & Medicaid Services.	)	Decision No. CR1801
	)	

DECISION

In this case, I consider a long term care facility's responsibilities when it receives inconsistent, ambiguous, or otherwise irregular medication orders.

Petitioner, Hawthorne Inn of Danville (Petitioner or facility), is a long term care facility located in Danville, Illinois, that is certified to participate in the Medicare program as a provider of services. Petitioner challenges the Centers for Medicare & Medicaid Services' (CMS's) determination that, based on a July 19, 2007 survey, it was not in substantial compliance with program participation requirements. CMS asks for summary affirmance of its determination.

I grant CMS's motion. Based on the undisputed evidence, I conclude that the facility was not in substantial compliance with requirements governing medication errors (42 C.F.R. § 483.25(m)(2)) and pharmacy services (42 C.F.R. § 483.60), and I affirm the imposition of two $5,000 per instance civil money penalties (CMPs).

I. Background

The Social Security Act (Act) sets forth requirements for nursing facility participation in the Medicare program, and authorizes the Secretary of Health and Human Services to promulgate regulations implementing those statutory provisions. Act, § 1819. The

Secretary's regulations are found at 42 C.F.R. Part 483. To participate in the Medicare program, a nursing facility must maintain substantial compliance with program requirements. To be in substantial compliance, a facility's deficiencies may pose no greater risk to resident health and safety than "the potential for causing minimal harm." 42 C.F.R. § 488.301.

The Secretary contracts with state survey agencies to conduct periodic surveys to determine whether skilled nursing facilities are in substantial compliance with program participation requirements. Act, § 1864(a); 42 C.F.R. § 488.20. The regulations require that each facility be surveyed once every twelve months, and more often, if necessary, to ensure that identified deficiencies are corrected. Act, § 1819(g)(2)(A); 42 C.F.R. §§ 488.20(a); 488.308.

Here, following a July 19, 2007 complaint investigation survey, CMS determined that the facility was not in substantial compliance with Medicare participation requirements, and that its deficiencies posed immediate jeopardy to resident health and safety. Based on these determinations, CMS imposed against the facility two $5,000 per instance CMPs ($10,000 total).

Petitioner requested a hearing and the case was assigned to me. I issued an initial pre-hearing order which directed the parties to file pre-hearing exchanges, including briefs and proposed exhibits, that included the written direct testimony of all proposed witnesses. The parties complied, filing their initial briefs and exhibits. CMS filed 63 proposed exhibits (CMS Ex 1 – CMS Ex. 63) but later withdrew CMS Exs. 14 - 19 and 51, and Petitioner filed 57 proposed exhibits (P. Ex. 1 – P. Ex. 55, P. Ex. 57, and P. Ex. 58, with P. Ex. 56 intentionally omitted). CMS subsequently moved for summary judgment, which Petitioner opposes (P. Opp. Br.).

II. Issues

I consider first whether summary judgment is appropriate.

On the merits, the case presents the following questions:

- whether, at the time of the July 19, 2007 survey, the facility was in substantial compliance with program participation requirements, specifically 42 C.F.R. § 483.25(m)(2) (medication errors), and 42 C.F.R. § 483.60 (pharmacy services);

- if the facility was not then in substantial compliance, are the two $5,000 per instance CMPs reasonable?

III. Discussion

A. Summary judgment is appropriate because Petitioner has not brought forth evidence sufficient to establish a genuine factual dispute.[1]

"To defeat an adequately supported summary judgment motion, the non-moving party may not rely on the denials in its pleadings or briefs, but must furnish evidence of a dispute concerning a material fact . . . ." *Livingston Care Center*, DAB No. 1871, at 5 (2003). The moving party may show the absence of a genuine factual dispute by showing that the non-moving party has presented no evidence "sufficient to establish the existence of an element essential to that party's case, and on which that party will bear the burden of proof at trial." *Livingston Care Center v. Dep't of Health and Human Services*, 388 F.3d 168, 173 (6th Cir. 2004). To avoid summary judgment, the non-moving party must then act affirmatively by tendering evidence of specific facts showing that a dispute exists. *Matsushita Elec. Indus. Co. v. Zenith Radio Corp.*, 475 U.S. 574, 586 n.11 (1986). *See also Vandalia Park*, DAB No. 1939 (2004); *Lebanon Nursing and Rehabilitation Center*, DAB No. 1918 (2004).

Here, CMS has come forward with evidence – the facility's own records – establishing that:

- a facility resident, identified as R3, was admitted to the facility from an acute care hospital;
- R3's transfer documents included two different orders for a powerful chemotherapy drug, one calling for daily administration of the medication, the other calling for weekly administration;
- facility staff forwarded to the facility's consulting pharmacist one of those medication orders, but did not mention the other;
- the consulting pharmacist contacted facility staff, questioning the medication order;
- staff confirmed the order for daily administration, but again neglected to mention the order for weekly administration;

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[1] My findings of fact and conclusions of law are set forth, in italics and bold, in the discussion captions of this decision.

- with the pharmacist's approval, staff continued to administer the daily dose, which proved to be a significant drug overdose; and

- R3 became acutely ill, was hospitalized, and died.

In CMS's view, these facts lead to the inescapable conclusion that the facility did not ensure that each resident was free of any significant medication error (as required by 42 C.F.R. § 483.25(m)(2)), and that a licensed pharmacist review each resident's drug regimen and report irregularities to the attending physician and to the director of nursing (as required by 42 C.F.R. § 483.60).

Petitioner tenders no evidence suggesting a dispute over any of these facts upon which CMS bases its case. Instead, Petitioner challenges CMS's legal conclusions, and provides a list of questions, which it characterizes as "material issues of fact in dispute" (whether the two orders were "conflicting and uninterpretable;" whether staff misinterpreted the order; whether staff committed a medication error; whether staff could rely upon the review of the consultant pharmacist; whether, and to what degree, the facility was culpable for the incorrect order; whether R3 died as a result of the medication error; whether R3's symptoms were consistent with his prior condition; what R3's condition was upon readmission to the hospital). But most of Petitioner's questions do not describe factual disputes; they call for legal conclusions. Those that involve facts, or inferences to be drawn from facts – such as the potentially dispositive question as to the appropriate standard of care – are not material. For purposes of summary judgment, I resolve them in Petitioner's favor, and Petitioner still does not prevail.

Because the undisputed facts establish deficiencies that are sufficient to sustain the penalties imposed, CMS is entitled to summary judgment.

B. The facility was not in substantial compliance with 42 C.F.R. § 483.25(m)(2) nor with 42 C.F.R. § 483.60.

Under the statute and the "quality of care" regulation, each resident must receive, and the facility must provide, the necessary care and services to allow a resident to attain or maintain the highest practicable physical, mental, and psychosocial well-being, in accordance with the resident's comprehensive assessment and plan of care. Act, § 1819(b); 42 C.F.R. § 483.25. To this end, the regulation specifically requires that the facility "ensure" that its residents are free of any significant medication errors. 42 C.F.R. § 483.25(m)(2).

The facility also must employ or obtain the services of a licensed pharmacist who, among other responsibilities, consults "on all aspects of the provision of pharmacy services in the facility." 42 C.F.R. § 483.60(b)(1). A licensed pharmacist must review the drug regimen of each resident at least monthly, and "must report any irregularities *to the attending physician* and the director of nursing, and these reports must be acted upon." 42 C.F.R. § 483.60(c)(1) and (2) (emphasis added).

In this case, R3 was an 86-year-old man suffering from a multitude of impairments, including Alzheimer's disease, anxiety, rheumatoid arthritis, urinary tract infection, dehydration, and muscle weakness. P. Exs. 6, 42. He was admitted to the facility on June 3, 2007, transferring from an acute-care hospital. P. Ex. 3. At the time of his admission, the hospital sent his medication orders to the facility. These orders cover three pages. One page is labeled "Patient Home Medications" and two are labeled "Current Active Medications." P. Ex. 7. Among the many medications listed is methotrexate, a chemotherapy drug that may also be used to treat rheumatoid arthritis. P. Ex. 38. The page labeled "Patient Home Medications" calls for a dose of 2.5 mg, by mouth, 3 times daily (hereafter, I will refer to this order as "daily dose order"). P. Ex. 7, at 1. One of the pages labeled "Current Active Medications" also calls for 2.5 mg doses of methotrexate by mouth, but, under the frequency section, the order reads: "Fr@09", followed by the following comments:

> Comments: **MAY BE GIVEN ON A WEEKLY BASIS
> AT HIGHER DOSES - VERIFY DOSING FREQUENCY.**

(Emphasis in original) (hereafter, I will refer to this order as "weekly dose order"). R3's attending physician signed each page and his signature is dated June 6. P. Ex. 7, at 2.

An error in transcription obviously caused the two different orders. The hospital's Medication Administration Record indicates that hospital staff had been administering the drug weekly. P. Ex. 2. And, in the hospital's discharge summary, R3's attending physician left no doubt that he had ordered a *weekly* dose:

> methotrexate 2.5 mg. q. 12 hours X 3 doses, all done on
> Fridays. In other words, he takes 3 doses per week, a total of
> 7.5 mg./week taken on Friday in 3 divided doses.

P. Ex. 9, at 2. Nevertheless, a Medication Reconciliation Sheet lists the daily dose order. P. Exs. 4, 5. It seems that the attending physician discovered the error, and attempted to correct it. On a medication list he signed on June 4, 2007, the "3 times daily order" is scratched out, and "weekly" is written in with an emphatic note: "this is incorrect!

Should be q week, not q day." P. Ex. 8. Unfortunately, the correction was not reflected in the transfer orders.[2]

Facility staff opted to administer the drug three times daily. Licensed Practical Nurse (LPN) Leslie Brown made that decision. She points out that the three times daily order "was clear:" she had no difficulty interpreting or understanding it. P. Ex. 49, at 3 (Brown Decl. ¶ 7). On the other hand, in her view, the weekly dose order was "not a standard accepted notation" so she thought that it was not a complete, correct order. P. Ex. 49, at 3 (Brown Decl. ¶ 10). After confirming that methotrexate may be prescribed for one of R3's conditions (rheumatoid arthritis), she transcribed the order into the facility's computer system, and forwarded the list of prescribed medications – absent the weekly dose order – to the facility's consulting pharmacist. P. Ex. 49, at 4 (Brown Decl. ¶ 12).

Soon thereafter, the facility's consulting pharmacist called the facility and questioned another nurse, LPN Betty Creasy, about the methotrexate order. LPN Creasy read to him the daily dose order, and told him that it had been signed by the physician. P. Ex. 50, at 1-2 (Creasy Decl. ¶¶ 2,3). The pharmacist told her that the medication could be given once a week in a higher dose, but after LPN Creasy confirmed the daily order, he did not inquire further. LPN Creasy did not tell him about the weekly dose order. P. Ex. 50, at 2 (Creasy Decl. ¶ 4). Neither the pharmacist nor facility staff reported any irregularity to R3's attending physician.

Facility staff continued to administer methotrexate according to the daily dose order until June 23, 2007, when R3 was hospitalized. P. Exs. 10, 11, 12. He died on June 26, 2007. His death certificate lists as the cause of death Pancytopenia[3] due to methotrexate toxicity. P. Ex. 22.

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[2] Petitioner argues that the hospital and R3's attending physician were at fault for not providing accurate and understandable orders. Without doubt, there is much blame to go around in this sad situation, but the culpability of others is wholly irrelevant to the question of whether the facility met its responsibilities under the regulations. *See Rosewood Care Center of Peoria*, DAB No. 1912 (2004).

[3] Pancytopenia is an abnormal reduction in the number of red and white blood cells and blood platelets. As discussed below, Petitioner challenges these conclusions as to the cause of R3's death, and, for summary judgment purposes, I resolve the issue in Petitioner's favor.

1. Facility staff did not ensure that R3 would be free of medication errors because they did not clarify ambiguous medication orders and they did not provide to the consulting pharmacist a complete account of R3's medication orders.

The facility concedes that R3 was administered an incorrect medication dose, but argues that it should not be held accountable for the errors because its nursing staff followed a signed physician order, and relied on the approval of the facility's consulting pharmacist. Petitioner defines the standard of care as follows:

> A nurse may rely upon an order that she receives when the order *is clear* and has been signed off by the physician and has been reviewed by the consultant pharmacist.

P. Opp. Br. at 5 (emphasis added). For purposes of summary judgment, I accept this definition. But facility staff did not meet this standard of care. First, the orders sent to the facility were not clear. The presence of two different orders created ambiguity, and, as is implicit in Petitioner's definition of standard of care, a nurse may not rely on ambiguous orders, but must obtain clarification. *See* CMS Ex. 58, at 3-4; CMS Ex. 59, at 4.

Second, the orders were not, in fact, reviewed by the consultant pharmacist because staff did not provide him with a complete account of the physician's orders. LPN Brown selected what she recognized and understood, but disregarded what she did not understand. Not only does this violate the standard of care, it violates the facility's own policies. The facility's medication administration policy requires that *all* physician orders be given to the pharmacy "*exactly as stated by the physician*." P. Ex. 23 (emphasis added). The nurse was not free to withhold the order simply because she did not understand it.

The facility had an opportunity to correct this error when the consulting pharmacist called expressing his concerns about what he considered irregularities in the methotrexate order. But, again, staff told him about the daily dose order, and did not mention the weekly dose order. At a minimum, the pharmacist's inquiry should have alerted them that this drug might not be prescribed in a way that they recognized.

Petitioner argues that, with respect to medication orders, a nurse should not be held to the same standard of care as a pharmacist. P. Ex. 53, at 5 (Chizek Decl. ¶ 7). I agree. Nurses are simply not expected to possess anywhere near a pharmacist's level of expertise about medications and medication orders. (If they did, there would be little need for review of medication orders by a licensed pharmacist). For this very reason, a nurse may not

disregard a medication order that she does not recognize or understand. At a minimum, she must pass the unintelligible order on to the pharmacist, who presumably has the expertise to determine its validity. The failure of the facility nurses to do so in this case violated the standard of care and put the facility out of compliance with 42 C.F.R. § 483.25(m)(2).

2. Neither the facility staff nor the consulting pharmacist conferred with R3's attending physician about the irregular methotrexate orders, in contravention of the regulations, FDA warnings, and the facility's own policies.

Because a high number of fatalities have resulted from the mis-administration of oral methotrexate, the Food and Drug Administration (FDA) characterizes it as "a high alert medication" and has issued multiple warnings about its dangers. P. Ex. 38, at 1. When prescribed for conditions such as rheumatoid arthritis (as opposed to cancer treatment), the dose is generally administered weekly instead of daily. The FDA warns that the expectation of daily dosing "has led to serious and sometimes fatal mistakes." P. Ex. 38, at 1. To reduce the risk of error, the FDA recommends (among other measures) that prescribers include the clinical indication within the prescription directions. "That way, if daily dosing is ordered for an autoimmune disease, the pharmacist will be alert to the possibility of error." P. Ex. 38, at 1. If such indication is not included, the pharmacist "should speak directly with the prescriber to determine the reason for use of methotrexate, and to verify the proper dosing schedule." P. Ex. 38, at 1; *see also* P. Ex. 39.

As noted above, the facility's consulting pharmacist recognized the irregularity of prescribing a daily dose of methotrexate for rheumatoid arthritis, and he brought that fact to the attention of the facility's nursing staff. But neither he nor the facility staff reported it to the attending physician, as recommended by the FDA, and required by both the regulation (42 C.F.R. § 483.60(c)(2)) and the facility's pharmacy consultant agreement. ("[the pharmacist] will . . . report in writing any irregularity to the facility's Administrator, Medical Director, the resident's physician, and the Director of Nursing Services.") P. Ex. 21, at 1.

The facility also suggests that it should not be accountable for the errors of its consulting pharmacist. However, to comply with the regulations, the *facility* must ensure that its residents are free of drug errors and the *facility* is responsible for the performance of its pharmacist, without regard to whether he is an employee or a consultant. Here, the facility's contract with its consulting pharmacist echoed the requirements of the regulations. The facility was responsible for ensuring that its consultant met those terms. 42 C.F.R. § 483.20(k)(3)(i) ("the services provided or arranged by the facility *must* . . .

meet professional standards of quality.") (emphasis added); *see*, *Emerald Oaks*, DAB No. 1800, at 7 n.3 (2001).

C. The $5,000 per instance penalties are reasonable.

CMS has imposed two penalties of $5,000 per instance – one for the facility's failure to ensure that its residents were free of medication errors, and one for its failure to comply with requirements for pharmacy services. Such penalty is toward the mid-range for per instance situations ($1,000 – $10,000). 42 C.F.R. § 488.438(a)(2).

The parties have provided me little assistance on the issue of the reasonableness of the penalties. At most, Petitioner has only marginally raised the issue, arguing only that the facility was not culpable.

In determining whether penalties imposed are reasonable, I consider the factors listed in 42 C.F.R. § 488.438(f): 1) the facility's history of noncompliance; 2) the facility's financial condition; 3) factors specified in 42 C.F.R. § 488.404; and 4) the facility's degree of culpability, which includes neglect, indifference, or disregard for resident care, comfort or safety. The absence of culpability is not a mitigating factor. 42 C.F.R. § 488.438(f)(4). The factors in 42 C.F.R. § 488.404 include: 1) the scope and severity of the deficiency; 2) the relationship of the deficiency to other deficiencies resulting in noncompliance; 3) the facility's prior history of noncompliance in general and specifically with reference to the cited deficiencies.

I have no information about the facility history. Petitioner has not suggested that its financial condition affects its ability to pay the penalty.

With respect to the other factors, I consider the severity of the deficiencies significant enough to warrant a substantial penalty. Petitioner challenges the hospital records and death certificate conclusion that the mis-administration of methotrexate caused R3's death. *Compare* P. Exs. 12, 13 *with* P. Ex. 19; *see also*, P. Ex. 24. For summary judgment purposes, I accept Petitioner's position that the medication overdoses did not cause R3's death. However, as the FDA warning establishes, methotrexate can be a very dangerous drug. P. Ex. 38. Unquestionably, administering on a daily basis what should have been a weekly dose of methotrexate is likely to cause serious injury, harm, impairment, or death to a resident, which means that the deficiencies posed immediate jeopardy to R3's health and safety. 42 C.F.R. § 488.301.

Moreover, the facility was culpable. As discussed above, at multiple points facility nurses and the consulting pharmacist could have prevented serious error, had they adhered to the standards of care and the facility policies. That they failed to do so at each

point makes the facility culpable. I find that this level of culpability, as well as the severity of the deficiencies, justify the penalties imposed.

IV. Conclusion

For all of the reasons discussed above, I uphold CMS's determination that Petitioner was not in substantial compliance with program participation requirements, and I find reasonable the imposition of two $5,000 per instance CMPs.

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/s/
Carolyn Cozad Hughes
Administrative Law Judge