Department of Health and Human Services

DEPARTMENTAL APPEALS BOARD

Civil Remedies Division

In the Case of:	)	
	)	
ManorCare at Palos Heights – West, (CCN: 14-5893),	)	Date: September 24, 2008
	)	
Petitioner,	)	
	)	
- v. -	)	Docket No. C-07-626
	)	Decision No. CR1847
Centers for Medicare & Medicaid Services.	)	
	)	

DECISION

In this case, we revisit the question of a long term care facility's responsibilities when it receives irregular medication orders.

Petitioner, ManorCare at Palos Heights-West (Petitioner or facility), is a long term care facility located in Palos Heights, 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 survey completed May 29, 2007, it was not in substantial compliance with program participation requirements.

I conclude that the facility was not in substantial compliance with requirements governing unnecessary drugs (42 C.F.R. § 483.25(l)(1)); medication errors (42 C.F.R. § 483.25(m)(2)) and drug regimen review (42 C.F.R. § 483.60(c)), and that its deficiencies posed immediate jeopardy to resident health and safety. I also affirm the civil money penalties (CMPs) imposed, $3050 per day for one day of immediate jeopardy, and $50 per day for 27 days of noncompliance that was not immediate jeopardy ($4400 total), which are the minimum amounts authorized by the statute and regulations.

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, section 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, section 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, section 1819(g)(2)(A); 42 C.F.R. §§ 488.20(a); 488.308.

Here, following an extended complaint investigation survey, completed May 29, 2007, 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 CMPs of $3050 per day for one day of immediate jeopardy, and $50 per day for 27 days of substantial noncompliance that was not immediate jeopardy ($4400 total). CMS Exhibits (Exs.) 1-4.

Petitioner requested a hearing and the case was assigned to me. I held a hearing in Chicago, Illinois on April 8, 2008. Mr. Nicholas J. Lynn and Mr. Mark J. Silberman appeared on behalf of Petitioner, and Mr. John E. Bizot appeared on behalf of CMS. During the hearing, I admitted into evidence CMS Exs. 1-54, and P. Exs. 1-24. Tr. 4-5, 72. With its reply brief (CMS Reply), CMS offered an additional exhibit as rebuttal evidence, CMS Ex. 55. Petitioner has belatedly objected to the admission of this document.[1] My pre-hearing order allows a party to supplement its exchanges based on a

[1] CMS submitted the proposed document in a filing dated June 18, 2008. Petitioner did not file an objection until August 21, 2008. The regulations afford a party "20 days from the date of mailing . . . to submit any rebuttal statement or additional evidence." 42 C.F.R. § 498.17(b); *see also* Pre-hearing Order at 8 (¶ 22) (August 7, 2007) (time limit to answer motions is 20 days from date of receipt). So Petitioner's

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showing of good cause and the absence of prejudice to the opposing party. However, I find it unnecessary to determine good cause/prejudice with respect to CMS Ex. 55, since the document is not necessary to my resolution of the case. I therefore decline to admit CMS Ex. 55.

The parties have also filed opening briefs (Br.), closing briefs (Cl. Br.) and reply briefs (Reply).

II. Issues

This case presents the following questions:

- whether, from May 24 through June 20, 2007, the facility was in substantial compliance with the program participation requirements, specifically 42 C.F.R. § 483.25(l)(1) (unnecessary drugs), 42 C.F.R. § 483.25(m)(2) (medication errors), and 42 C.F.R. § 483.60(c) (pharmacy services – drug regimen reviews);

- if the facility was not in substantial compliance on May 24, 2007, did its deficiencies pose immediate jeopardy to resident health and safety?

Because CMS has imposed the statutory and regulatory minimum per day CMP amounts, the penalty is reasonable as a matter of law. *See, e.g., Hermina Traeye Memorial Nursing Home*, DAB No. 1810, at 16 (2002).

III. Discussion

A. The facility was not in substantial compliance with 42 C.F.R. §§ 483.25(l)(1), 483.25(m)(2) and 483.60(c).[2]

Under the Act 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, section

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[1](...continued)
objections are not timely. For the reasons stated, I nevertheless decline to admit CMS Ex. 55.

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

1819(b); 42 C.F.R. § 483.25. To this end, each resident's drug regime must be free from unnecessary drugs. Unnecessary drugs include drugs used in excessive doses; drugs used for an excessive duration; drugs that are not adequately monitored; drugs used without adequate indications for their use; and drugs used in the presence of adverse consequences indicating that their dose should be reduced or discontinued. 42 C.F.R. § 483.25(l)(1). 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).

In the regulation's preamble, the drafters explained how medication errors are judged. The surveyors consider three factors: 1) drug category (did the error involve a drug that could result in serious consequences for the resident); 2) resident condition (was the resident compromised in such a way that he/she could not easily recover from the error); and 3) frequency of error (is there any evidence that the error occurred more than once). The drafters then offered an example of a significant medication error: three times in one week staff administer twice the correct dosage of digoxin, a potentially toxic drug, to a resident who already had a slow pulse rate that the drug would further lower. 56 Fed. Reg. 48826, 48853 (September 26, 1991).

The facility also must employ or obtain the services of a licensed pharmacist who, among other responsibilities, 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).

In this case, Resident 1 (R1) was a 68-year-old woman, admitted to the facility on January 15, 2007, transferring from an acute-care hospital. CMS Ex. 27. She was a small woman, weighing only 102 pounds. CMS Ex. 37, at 1. R1 had a history of multiple cerebrovascular accidents, and suffered from a multitude of impairments, including dementia, an anxiety disorder, chronic obstructive pulmonary disease, anemia, and hypertension. CMS Exs. 24; 27; 29, at 3; 30. She had swallowing difficulties. CMS Ex. 29, at 2; CMS Ex. 34, at 3. On the other hand, a January 19, 2007 psychology assessment found that R1 was able to perform simple calculations; her general knowledge was accurate; her immediate memory was intact; her thought processes were logical and organized; and her judgment was only minimally impaired; she had no hallucinations or delusions. She was, however, depressed and in need of close supervision. CMS Ex. 41.

While hospitalized, her medication orders included Risperidone (Risperdal)[3] ***0.5 mg*** BID (twice a day). CMS Ex. 43, at 3; CMS Ex. 53; CMS Ex. 54. But a very serious error occurred on her discharge/transfer medication reconciliation form: the transcribing nurse

[3] Risperidone is sold under the trade name Risperdal in the United States.

omitted a decimal point, writing "Risperdal ***5 mg*** BID." CMS Ex. 43, at 1; P. Ex. 10. Apparently, no one at the facility looked beyond the transfer order; at least, no one noticed the error. R1's January 15 medication order form called for "Risperdal 5 mg PO [orally] BID." CMS Ex. 43, at 1; P. Ex. 10. At some point (his signature is not dated) R1's physician, not recognizing the error in transcription, signed off on the orders. CMS Ex. 32, at 1; P. Ex. 13.[4]

At the time of her admission to the facility, no recorded diagnosis supported the order for Risperdal. *See, e.g.,* CMS Ex. 36. Uncorrected, this omission would have violated 42 C.F.R. § 483.25(l)(1), which considers "unnecessary" any drugs "used without adequate indications for their use." The facility allegedly remedied this omission with a physician telephone order, dated January 17, which indicates that the Risperdal was prescribed for anxiety, and Ativan was prescribed for psychosis. CMS Ex. 33, at 2; P. Ex. 3. But there are two major problems with this "correction." First, the individual who wrote in the diagnoses apparently made a transcription error, reversing the medication/diagnoses. Risperdal is not an approved treatment for anxiety; it is prescribed to treat psychosis. Ativan is a treatment for anxiety. Tr. 106-107; 132; CMS Ex. 36, at 3. More serious, the "correction" came too late. When the facility's consulting pharmacist reviewed R1's drug regimen she had no idea what, if any, diagnosis justified the administration of Risperdal. She nevertheless failed to question the order, claiming that the facility's request for a psych evaluation provided the necessary "indications for [its] use." Tr. 154.

On January 25, facility staff conducted the required assessment, in which they noted that R1 was taking three psychotropic medications: Zoloft, Risperdal, and Ativan, putting her at risk for adverse side effects. The assessment directed that her care plan require staff monitoring and physician notification of any adverse affects from these drugs. CMS Ex. 29 at 3, 21-22.

Throughout R1's stay, the facility nurses administered to her ***5 mg*** of Risperdal twice daily. CMS Ex. 40, at 2. No one questioned the order or the dosage.

On January 26, R1 suffered cardiac arrest, and was sent to the emergency room. CMS Ex. 23; CMS Ex. 34, at 8-9; P. Ex. 16. She died in the hospital on February 4, 2007. CMS Ex. 26.

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[4] It appears that the same nurse also mis-transcribed R1's 0.5 mg order for Ativan, writing 5.0 mg instead. CMS Ex. 43, at 1, 3. However, someone apparently caught that error, because her admission order for Ativan was corrected; someone wrote in a decimal point and, in bold, a zero prior to the decimal point: "Ativan **0**.5 mg PO." CMS Ex. 32, at 1.

1. R1's drug regime was not free from unnecessary drugs because she repeatedly received excessive doses of the powerful antipsychotic drug, Risperdal.

Risperdal is a powerful antipsychotic medication used to treat schizophrenia and acute manic or mixed episodes associated with bipolar disorder. CMS Ex. 20, at 1-2; CMS Ex. 47, at 1. Although physicians are apparently not precluded from prescribing the drug for dementia-related psychosis (as occurred here), it has not been approved for that purpose, and administering the drug to elderly patients with dementia-related psychosis presents significant risks. CMS Ex. 47, at 1. Risperdal's package insert includes the following black box warning:[5]

> **WARNING: INCREASED MORTALITY IN ELDERLY PATIENTS WITH DEMENTIA-RELATED PSYCHOSIS**
>
> **Elderly patients with dementia-related psychosis treated with atypical antipsychotic drugs are at an increased risk of death compared to placebo . . . Although the causes of death were varied, most of the deaths appeared to be either cardiovascular (e.g., heart failure, sudden death) or infectious (e.g., pneumonia) in nature. RISPERDAL® (risperidone) is not approved for the treatment of patients with Dementia-Related Psychosis. *[See Warnings and Precautions (5.1)]***

CMS Ex. 47, at 5; *see also* CMS Ex. 20, at 2; CMS Ex. 48, at 5; P. Ex. 18, at 1, 2; Tr. 116, 165-166, 169-170.

This warning puts physicians, pharmacists, and other health care workers on notice that great care must be exercised where, as here, Risperdal is prescribed for an elderly, demented patient.[6] At a minimum, these responsible parties should ensure that the

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[5] The United States Food and Drug Administration mandates that pharmaceutical companies include within a drug's package insert information about its adverse effects. The "black box warning" is the strongest warning required by the FDA and its use indicates that the drug carries significant – even life threatening – adverse effects.

[6] I reject as frivolous Petitioner's argument that this 68-year old woman who suffered from dementia and had a significant history of strokes was not "elderly." *See* CMS Ex. 45, at 4; CMS Ex. 48, at 12 (defining "geriatric" as individuals over age 65).

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dosages administered are not excessive, and should carefully monitor the resident for any adverse effects.

Here, comparing R1's hospital orders with her transfer order leads to the inescapable inference that an undetected transcription error – the omitted decimal point – resulted in facility staff administering to R1 ten times more Risperdal than she should have received. Petitioner nevertheless suggests that the twice daily 5 mg dosage of Risperdal was appropriately ordered by R1's physician, for his own, unarticulated, reasons. Petitioner's position is both poorly supported, and, as discussed in section 2 below, marginally relevant. It is poorly supported because the evidence (and common sense) overwhelmingly establish that the administered dosage was neither appropriate nor intended by R1's physician. Ten milligrams of Risperdal per day to treat psychotic dementia in a small elderly resident is unquestionably grossly excessive and dangerous. CMS Ex. 52, at 4 (Guay Decl. ¶ 11). A sudden ten-fold increase in dosage is also contrary to fundamental principles of medication administration and places the resident at increased risk. CMS Ex. 52, at 8-9 (Guay Decl. ¶¶ 21, 22); Tr. 121-122.

The pharmacological literature emphasizes special considerations in administering Risperdal to the elderly and debilitated. CMS Exs. 20, 45, 46, 47, 48. "In all cases, the lowest effective dosage should be determined for each patient." CMS Ex. 20, at 1. Dosages for this population are set as follows: initially 0.5 mg twice per day, to be increased in increments of no more than 0.5 mg once or twice per day, as tolerated. Increases above 1.5 mg twice per day should occur at no more than weekly intervals. In some patients, slower titration may be needed. CMS Ex. 20, at 1, 2; CMS Ex. 45, at 8; CMS Ex. 47, at 6.

Federal OBRA[7] guidelines for nursing homes recommend that the dosage not exceed 2 mg per day given in 1–2 divided doses. If higher doses are necessary to maintain or

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[6](...continued)
Moreover, nothing in this record suggests that facility staff had any questions as to whether R1 fell into this risk category, and if they had any doubts about who would be considered "elderly" for purposes of evaluating risks, it was incumbent upon them to resolve those doubts. For her part, Pharmacist Garcia showed that she considered the facility residents to be elderly when, after reviewing the drug regimens, including R1's, she reported that "[e]ach month the charts are reviewed for medications which are considered to be inappropriate for the elderly . . . ." CMS Ex. 13, at 2.

[7] Federal Nursing Home Reform Act (from the Omnibus Budget Reconciliation Act of 1987).

improve the resident's functional status, "the use of a higher dose must be documented per OBRA guidelines." CMS Ex. 20, at 2; *see* CMS Ex. 46, at 6; CMS Ex 52, at 3 (Guay Decl.¶ 8); Tr. 141-142.

Finally, the smaller a person is, the smaller the dose necessary to achieve the desired result. Tr. 128. At 102 pounds, R1 was very small.

Thus, the overwhelming medical evidence does not support the proposition that a 10 mg daily dose of Risperdal is an appropriate dosage for a small, elderly woman being treated for dementia-related psychosis.

In fact, the only suggestion in this record that a 10 mg per day dosage would be appropriate came from the facility's consultant pharmacist, Heidi Garcia, who testified that she noted no irregularities in R1's drug regimen because that dosage fell within the manufacturer's recommendations and the recommended dosage range as set forth in the Lexi-Comp Geriatric Dosage Handbook 2004-2005 (4 mg to 16 mg). P. Ex. 17, at 1, 2 (Garcia Decl. ¶¶ 3, 5, 6, 7); CMS Ex. 45; *see* Tr. 168 (CMS Ex. 45 is from the Lexi-Comp Geriatric Dosage Handbook). In fact, that publication reiterates the initial twice daily 0.5 mg dosage with slow titration of no more than 0.5 mg twice daily. CMS Ex. 45, at 8; Tr. 168-169.

None of the other medical references in this record approve administering such high doses of the antipsychotic medication to geriatric patients treated for dementia-related psychosis. At most, a chart included in an appendix to a pharmacological drugs handbook lists maximum adult dosages at 4-16 mg. CMS Ex. 19, at 3; *but see* CMS Ex. 19, at 2 (listing the daily oral dosage at 2 mg).

If it is ever appropriate, the dosage range Pharmacist Garcia cites refers to treatment of schizophrenia in adults. CMS Ex. 47, at 5. As Dr. David Guay explained, these large doses might be appropriate for a young adult schizophrenic.[8] Tr. 110. For reasons that are not fully understood, patients suffering from schizophrenia have increased tolerance for antipsychotic medications. But the drug's manufacturer notes that, even though "[e]fficacy has been demonstrated in a range of 4-16 mg/day," doses above 6 mg per day are not demonstrated to be more efficacious than the lower doses, and "are generally not recommended." CMS Ex. 47, at 5. And for geriatric patients, defined as those over 65,

[8] Dr. Guay, CMS's expert witness, has a doctorate in pharmacology and has practiced for more than 30 years. CMS Ex. 50. He testified that he has *never* seen a dose this high. Tr. 139.

doses exceeding 3 mg per day are not recommended. CMS Ex. 45, at 4; CMS Ex. 48, at 12.

> Because elderly patients are more likely to have decreased renal function, caution should be taken in dose selection and titration. . . . In schizophrenic patients, doses exceeding 3 mg per day are not recommended. In patients with behavioural disturbances due to severe dementia the optimal dose is 0.5 mg. b.i.d. (1.0 mg per day) . . .

CMS Ex. 48, at 12.

Notwithstanding the overwhelming pharmacological evidence, Petitioner maintains that the dosage was intended because R1's physician signed the questionable order. CMS Ex. 32. I note first that on January 14, 2007 – the day before R1's admission to the facility – Dr. Razzaque signed a medication order calling for 0.5 mg. Risperdal. CMS Ex. 53. A January 15 hospital medication sheet calls for 0.5 mg Risperdal. CMS Ex. 54, at 4. It would indeed have been strange for a physician intentionally to have so suddenly increased the dosage ten-fold without any apparent reason or explanation.

Moreover, Surveyor Annette Hodge interviewed R1's physician, Dr. Razzaque, on May 24, at noon. He told her that the change from 0.5 to 5.0 mg had been a "goof-up" and that he had not realized that 5 mg BID was excessive. He noted that he had not initially ordered the drug, but had simply continued the order of a prior physician. Dr. Razzaque conceded his lack of knowledge about proper dosage levels for psychotropic medications. Tr. at 54; CMS Ex. 7, at 7.[9]

Dr. Razzaque did not testify, and Petitioner has presented no evidence refuting the proposition that the January 15 medication order, including the physician signature, was an unintentional "goof-up."[10] Moreover, as discussed below, even if R1's physician had

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[9] Dr. Razzaque's comments well illustrate the wisdom of requiring facility (and pharmacist) oversight of all medications administered to facility residents.

[10] Petitioner listed Dr. Razzaque as a witness, but did not submit his written declaration, as called for by my pre-hearing order. Petitioner notes that Dr. Razzaque is embroiled in litigation related to this incident and would not willingly cooperate. Had Petitioner considered Dr. Razzaque's testimony necessary for the full presentation of its case, it could have asked that he be subpoened to testify at the hearing. 42 C.F.R.

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deliberately ordered the excessive dosage, the regulations compel the facility to identify such an aberrant order, and bring it to the physician's attention.

2. Neither the facility's licensed pharmacist nor anyone else reported any drug irregularities as required by the regulations.

This matter is not about whether the physician erred; it is about the *facility's* responsibility to question any apparent irregularity that could result in a resident's receiving unnecessary drugs. 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, at 8-9 (2004). To comply with the regulations, the *facility* must ensure that its residents are free of drug errors and, in this regard, the *facility* is responsible for the performance of its pharmacist. 42 C.F.R. § 483.20(k)(3)(i) ("the services provided or arranged by the facility *must* . . . [m]eet professional standards of quality."); *see Emerald Oaks*, DAB No. 1800, at 7 n.3 (2001)); *see also* Tr. 129 (In the face of what appears to be a valid physician order that is nevertheless unusual, the pharmacist should contact the physician to ensure that the order reflects what the physician wanted.)

Petitioner nevertheless suggests that physician orders are sacrosanct and may not be questioned by anyone other than another physician. Quoting Aristotle, Petitioner argues "a physician ought to be judged by the physician. . . ." P. Cl. Br at 10. But 42 C.F.R. § 483.60(c) *mandates* that a facility pharmacist question every "irregular" medication order and that the facility then take action based on the pharmacist's concerns. The consulting pharmacist well understood that her role included reviewing charts for medications "considered to be inappropriate for the elderly" because she indicated in her January 2007 consultation report that she had done so. CMS Ex. 13, at 2.

In her testimony, however, Pharmacist Garcia emphasized that the January 15 order, signed by the physician "was a valid order." When directly asked whether she had any responsibility beyond verifying the existence of a physician's order, she was evasive:

> I'm afraid, I see the way the questions are going. And everybody's like trying to like, and I'm afraid I'm going to say the wrong thing. And I'm – my words are going to be twisted against me.

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[10](...continued)
§ 498.58. However, Petitioner did not ask that Dr. Razzaque be subpoened.

Tr. 153.

When asked whether a prescription for 10 mg of Risperdal daily should have raised a red flag, she replied, (not inconsistent with Dr. Guay's opinion) that it depends on the patient's individual diagnosis. Tr. 154. But she admitted that when she reviewed R1's drug regimen, she did not know why the Risperdal had been prescribed. Tr. 154. So all she knew was that R1 was being given a very large dose of Risperdal, but she did not know why. She nevertheless justified her approval of the dosages because someone had asked for a "psych consult." Tr. 154. But Pharmacist Garcia should not have approved any drug in the absence of an acceptable indication for its use. The possibility that a future evaluation might justify a drug is insufficient to satisfy the requirement of 42 C.F.R. § 483.25(l)(1) that no drug be administered without an adequate indication for its use. And, of course, R1's diagnosis – dementia-related psychosis – would not have justified the dosages. Unfortunately, Pharmacist Garcia apparently did not learn of the diagnosis in time to halt the multiple instances of drug over-dosing.

Pharmacist Garcia testified that, had she known of R1's hospital dosage (0.5 mg), she would have requested clarification of the 5.0 mg dosage. Tr. 162-163. Whether she saw the hospital orders is an open question. In her declaration she claimed to have reviewed "R1's medications and all medication-related documentation available from the Hospital when she was transferred to ManorCare." P. Ex. 17, at 1 (Garcia Decl. ¶ 4). This suggests that she looked at more than the one-page transfer order containing the erroneous order. But her direct testimony does not specify what documentation she reviewed, and, in her responses to cross-examination questions, she would only admit to reviewing the one-page transfer order. Referring to the hospital's medication orders, CMS Ex. 43, at 2-4, CMS counsel asked whether they were "available" to her at the time of her review. She replied "I don't know," and in response to the follow-up question, replied "I didn't see it, and I don't know if it was available to me." Tr. 162.

According to Surveyor Hodge, the facility obtained those hospital orders, along with the transfer order, on the day of R1's admission. CMS Ex. 51, at 3 (Hodge Decl. ¶ 9); Tr. 56; *see* CMS Ex. 43, at 2-4. No one from the facility challenged that testimony, so I accept it. *See*, *e.g.*, P. Ex. 17 (Garcia Decl.); P. Ex. 22 (Tomer Decl.); P. Ex. 23 (Barnas statement); P. Ex. 24 (Saggese Decl.). Either the facility shared the hospital orders with Pharmacist Garcia and she neglected to review them properly; or she reviewed them but failed to recognize the extreme increase in dosages; or the facility failed to share those critical orders with Pharmacist Garcia. Under any one of these scenarios, the facility and/or its pharmacist failed in their responsibilities.

Finally, a pharmacist is not the only medical professional responsible for monitoring the appropriateness of medications administered. Nurses are trained in pharmacology, and are required to clarify any order that seems improper. As Dr. Guay testified,

> Thus, if a nurse is the least bit unclear about the dose of a medication to be administered, (s)he should clarify the dose to be given using all necessary means, including referral to appropriate medication reference materials, seeking assistance from supervisory nursing staff, and contacting the resident's attending physician. I consider it a deviation from one of the most basic standards of medication administration for a nurse to administer a medication without verifying the correct dosage.

CMS Ex. 52, at 5 (Guay Decl. ¶ 15); *see* Tr. 131-132. Here, at least six to eight nurses did not recognize their obligations. Tr. 131, 137.

3. Notwithstanding the recognized need for careful monitoring and reporting of adverse effects from her psychotropic medications, facility staff failed to respond to R1's significant symptoms.

In addition to an increased risk of death from cardiac arrest, use of Risperdal presents a multitude of other potential adverse reactions. Among the most common reactions are somnolence (sleepiness), fatigue, and anxiety. CMS Ex. 47, at 7. The State Operations Manual warns that using antipsychotic medications without monitoring for adverse consequences may be considered use of unnecessary medications. Falls and lethargy are among the symptoms that require such monitoring. CMS Ex. 46, at 7-8.

As noted above, the facility recognized the risks. R1's assessment says that her care plan must require monitoring and physician notification of any adverse affects from her psychotropic medications (Zoloft, Risperdal, and Ativan). CMS Ex. 29, at 3, 22. Her care plan – which, unfortunately was not initiated until ten days after the excessive dosing began (January 25) – recognized the risk for adverse effects related to Zoloft, Risperdal, and Ativan and required staff to monitor and report signs of adverse reactions such as a decline in mental status, lethargy, and complaints of dizziness. They were supposed to monitor R1's interaction with others for appropriateness, as well as her mood and behaviors. They were also supposed to evaluate the effectiveness and side effects of the medications for possible decrease/elimination of the drugs. CMS Ex. 44, at 19.

During her stay at the facility, R1 exhibited alternating symptoms of lethargy and agitation. CMS Ex. 34, at 4, 6. Nursing staff described her to Surveyor Hodge as moving "from being very lethargic to very agitated," "sleeping all the time," "always lethargic," and often "out of it." CMS Ex. 7, at 3, 4. She experienced multiple falls throughout her stay at the facility. CMS Ex. 34, at 2, 7. But I see no evidence that anyone even considered whether these symptoms were related to her medications.

Petitioner argues that such symptoms could have been caused by R1's underlying condition, and that CMS has not proven a relationship between her medications and her symptoms. This misses the point. Since she had been on psychotropic medications since before her admission, the cause of her symptoms was not readily apparent. It was incumbent upon facility staff to recognize that her symptoms could have been related to her medications, to monitor them, and to consult her physician about that potential relationship. *See* Tr. 124-125. But they failed to do so.

4. R1's discharge and death did not correct the facility's deficiencies with respect to unnecessary drugs, medication errors, and pharmacy services.

Petitioner points out that R1 left the facility on January 26, 2007, and argues that, since CMS has not presented evidence of facility deficiencies for any period thereafter, notably from May 24 through June 20, 2007, it has not demonstrated the facility's substantial noncompliance for the period in question. P. Cl. Br. at 5.

While I agree that CMS could have imposed a penalty from the date facility staff administered the first excessive dose of Risperdal (January 15, 2007) through the date the facility demonstrated substantial compliance (June 20, 2007), I do not agree that CMS's determination to impose penalties for only part of this period (beginning on the first day of the survey) means that it may not impose any penalties at all.

Petitioner's argument disregards the well-settled principle that once a facility has been found to be out of substantial compliance (as Petitioner was here), it remains so until it affirmatively demonstrates that it has achieved substantial compliance once again. *Premier Living and Rehab Center*, DAB No. 2146, at 23 (2008); *Lake City Extended Care Center*, DAB No. 1658, at 12-15 (1998). Substantial compliance means not only that the specific cited instances of substandard care were corrected, and that no other instances have occurred, but also that the facility has implemented a plan of correction designed to ensure that no such incidents occur in the future. No findings that the facility violated the standard of care between these dates are required in order to find the facility out of substantial compliance, nor can evidence of other incidents in which the facility met the standard of care change the fact that it was out of substantial compliance. *Barn*

Hill Care Center, DAB No. 1848, at 10, 14 (2002)*; Lake City*, DAB No. 1658, at 15 (1998); s*ee also Hermina Traeye Memorial Nursing Home*, DAB No. 1810, at 17-18 (2002) ("The burden is on the facility to prove that it has resumed complying with program requirements, not on CMS to prove that deficiencies continued to exist after they were discovered."); *Asbury Center at Johnson City*, DAB No. 1815, at 19-20 (2002) ("[A] facility's return to substantial compliance must usually be established through a resurvey, and in a situation involving inadequate supervision requiring such a resurvey appears wise."); *Cross Creek Care Center*, DAB No. 1665 (1998).

Petitioner has not established that an effective plan of correction was implemented any earlier than CMS has found. In fact, until the time of the survey, facility staff did not even seem to have been aware of its drug-related deficiencies.

B. CMS's determination that the facility's deficiencies posed immediate jeopardy to resident health and safety is not clearly erroneous.

I next consider whether CMS's immediate jeopardy finding was "clearly erroneous."

Immediate jeopardy exists if the facility's noncompliance has caused or is likely to cause "serious injury, harm, impairment, or death to a resident." 42 C.F.R. § 488.301. CMS's determination as to the level of a facility's noncompliance (which would include an immediate jeopardy finding) must be upheld unless it is "clearly erroneous." 42 C.F.R. § 498.60(c).

Petitioner here misapprehends the standard for review of an immediate jeopardy finding. Relying on the Administrative Law Judge decision in *Daughters of Miriam*, DAB CR1357 (2005), Petitioner argues that CMS has failed to meet its burden of coming forward with evidence sufficient to establish that the facility's noncompliance posed immediate jeopardy to resident health and safety. P. Cl Br at 7-9.

The Departmental Appeals Board reversed the ALJ decision in *Daughters of Miriam*. *Daughters of Miriam*, DAB No. 2067 (2007). The Board noted that the language of the regulation – CMS's determination as to the level of noncompliance must be upheld unless it is "clearly erroneous" – requires that the ALJ and the Board presume that CMS's determination is correct unless the facility demonstrates that the determination is clearly erroneous. To hold otherwise "would effectively eviscerate the review limitation in [42 C.F.R. §] 489.60(c)(2)." *Daughters of Miriam*, DAB No. 2067, at 7; *see also Liberty Commons Nursing and Rehab Center - Johnston*, DAB No. 2031 (2006), *aff'd, Liberty Commons Nursing and Rehab Center - Johnston v. Leavitt*, No. 07-1329, 2008 WL 2787675 (4th Cir. July 18, 2008).

The facility is thus charged with rebutting that presumption "with evidence and argument showing that the harm or threatened harm did not meet any reasonable definition of 'serious.'" *Daughters of Miriam*, DAB No. 2067, at 9. As the Board has observed repeatedly, the "clearly erroneous" standard imposes on facilities a "heavy burden" to show no immediate jeopardy. Determinations of immediate jeopardy are sustained if CMS presents evidence "from which '[o]ne could reasonably conclude' that immediate jeopardy exists." *Barbourville Nursing Home*, DAB No. 1962, at 11 (2005) (quoting *Florence Park Care Center*, DAB No. 1931, at 27-28 (2004) (citing Koester Pavilion, DAB No. 1750 (2000))).

Here, R1 died from heart failure, and elderly individuals suffering from dementia-related psychosis who are treated with Risperdal face an increased likelihood of death from heart failure. Tr. 114, 132-133; CMS Ex. 26, at 2; CMS Ex. 47, at 5. Nevertheless, I agree that this relationship does not establish that R1's death was caused by her over-medication. But I need not make that connection in order to sustain CMS's immediate jeopardy finding. So long as the facility's noncompliance "is likely to cause serious injury, harm [or] impairment," its deficiencies pose immediate jeopardy.

Petitioner argues that the odds of dying or suffering irreversible harm from an overdose of Risperdal are relatively small so CMS has not established a "likelihood" of harm. In *Daughters of Miriam*, the Board addressed the "likelihood" standard in the context of medication errors. The Board found the administration of contraindicated medication to be among the deficiencies likely to have a direct, immediate, and serious adverse effect on a resident's health. DAB No. 2067, at 10. As here, Petitioner there argued that the probability that residents could have been seriously harmed by their medications belied the immediate jeopardy finding. But the Board rejected this argument, noting the Petitioner had not provided evidence needed to undertake "such a complex and exacting medical inquiry." DAB No. 2067, at 11. Further, the Board noted that the problem was not limited to these individuals, but to the "weakness of Petitioner's system for protecting its residents demonstrated by the series of errors that occurred in providing care to [a single resident]." DAB No. 2067, at 11 (quoting *Liberty Commons Nursing and Rehab Center – Johnston*, DAB No. 2031, at 18-19 (2006), *aff'd, Liberty Commons Nursing and Rehab Center - Johnston v. Leavitt*, No. 07-1329, 2008 WL 2787675 (4th Cir. July 18, 2008)).

I note also that R1 suffered from swallowing difficulties. CMS Ex. 29, at 2; CMS Ex. 34, at 3. Excessive dosages of Risperdal can also cause extra pyramidal symptoms within the swallowing mechanism (the muscles of deglutition) increasing the risk of aspiration. A 10 mg daily dose would increase that risk "dramatically." Tr. 133.

On multiple occasions, facility nurses administered to a vulnerable resident massively excessive doses of a potentially dangerous medication. The warnings of potentially dire consequences went unheeded. The consulting pharmacist posed no questions about it, even though she had no idea why the drug had been prescribed. Neither the pharmacist nor any staff member questioned the dosage. Although the resident showed symptoms that are associated with the medication's side effects, no one even considered whether those symptoms were related to the medication.

In light of these significant facts, I do not find "clearly erroneous" CMS's immediate jeopardy determination.

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 that the deficiency posed immediate jeopardy to resident health and safety.

/s/
Carolyn Cozad Hughes
Administrative Law Judge