Department of Health and Human Services

DEPARTMENTAL APPEALS BOARD

Civil Remedies Division

Washington Christian Village
(CCN: 14-5000),

Petitioner

v.

Centers for Medicare and Medicaid Services.

Docket Nos. C-10-456 and C-10-602

Decision No. CR2403

Date: July 27, 2011

DECISION

In this case, I consider a long term care facility's responsibilities when a physician prescribes for its residents questionable combinations and dosages of antipsychotic drugs.

Petitioner, Washington Christian Village (Petitioner or facility), is a long term care facility located in Washington, Illinois, that is certified to participate in the Medicare program. Petitioner concedes that, based on surveys completed December 17, 2009 and February 2, 2010, it was not in substantial compliance with Medicare program requirements. Petitioner nevertheless challenges the Centers for Medicare and Medicaid Services' (CMS's) determination that it was not in substantial compliance with one of the regulations cited, 42 C.F.R. § 483.25(l), which directs the facility to keep its residents free from unnecessary drugs.

For the reasons discussed below, I find that the facility was not in substantial compliance with 42 C.F.R. § 483.25(l) and find the penalty imposed reasonable.

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. Act § 1864(a); 42 C.F.R. § 488.20. The Act and 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 surveys completed on December 17, 2009 and February 2, 2010, CMS determined that the facility was not in substantial compliance with several Medicare requirements and imposed penalties of $300 per day for 47 days (December 17, 2009 – February 1, 2010) and $100 per day for 27 days (February 2–28, 2010). CMS Ex. 2 at 2. By stipulation dated July 7, 2010, the parties limited the scope of this appeal to the deficiencies cited under 42 C.F.R. § 483.25(l) (tag F329) during the December survey. Petitioner concedes the other deficiencies cited during that survey and the February 2, 2010 revisit.[1] CMS agrees that it based the $300 per day civil money penalty (CMP) solely on the deficiencies cited under section 483.25(l). Stipulation to Limit Scope of Hearing (July 7, 2010).

The parties agree that this matter may be decided based on the written record, without need for an in-person hearing. CMS Closing (Cl.) Brief (Br.) at 1; P. Cl. Br. at 1; 42 C.F.R. § 498.66.

---

[1] Based on the December survey, CMS found that the facility was not in substantial compliance with 42 C.F.R. §§ 483.25 (tag F309 – quality of care) and 483.25(h) (tag F323 – accidents and supervision), as well as section 483.25(l). CMS Ex. 6. Based on the February 2 survey, CMS found that the facility's substantial noncompliance continued, with the most serious deficiencies cited under 42 C.F.R. § 483.25. CMS Ex. 2. During this time, CMS also found that the facility was not in substantial compliance with Life Safety Code (LSC) requirements, based on a LSC survey completed December 23, 2009. CMS Ex. 1. CMS subsequently determined that the facility corrected its LSC deficiencies as of January 29, and it appears that CMS imposed no penalties for LSC deficiencies. CMS Ex. 2.

I admit into evidence CMS Exhibits (CMS Exs.) 1-22 and Petitioner's Exhibits (P. Exs.) 1-27. The parties have filed opening briefs (CMS Br.; P. Br.) and closing briefs (CMS Cl. Br.; P. Cl. Br.).

II. Issues

By agreement of the parties, the issues before me are:

- From December 17, 2009 through February 1, 2010, was the facility in substantial compliance with 42 C.F.R. § 483.25(l)?

- If the facility was not then in substantial compliance with 42 C.F.R. § 483.25(l), is the penalty imposed – $300 per day – reasonable?

III. Discussion

Statutory and regulatory requirements. 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 § 1819(b); 42 C.F.R. § 483.25. The Act also explicitly establishes the right of facility residents to be free from chemical restraints imposed for the purpose of discipline or convenience rather than for the treatment of medical symptoms. Act § 1819(c)(1)(A)(ii). To that 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 whose adverse consequences indicate that they should be reduced or discontinued. 42 C.F.R. § 483.25(l)(1).

Special rules apply to the use of antipsychotic drugs. Based on the resident's comprehensive assessment, the facility must ensure that a resident who has not used antipsychotic drugs is not given them unless necessary "to treat a specific condition as diagnosed and documented in the clinical record." Unless contraindicated, the facility should also attempt to discontinue antipsychotics by gradually reducing the doses and implementing behavior interventions. 42 C.F.R. § 483.25(l)(2).

Responding to comments, the drafters of the regulation explained that an "unnecessary drug" is "reserved for drug therapy circumstances" that CMS guidelines establish "are a potential threat to the resident's health and safety, and for which the facility is unable to justify why using a drug under such circumstances is in the best interest of the resident." The facility "can certainly rely on physician justification of the risk-benefit of the drug use," but it cannot simply claim that "the doctor ordered it." Requiring only a

physician's order to justify a questionable drug "would render the regulation, and the statutory underpinnings for it, meaningless." 56 *Fed. Reg.* 48826, 48851-52 (Sept. 26, 1991).

In its State Operations Manual (SOM), CMS has issued guidelines listing drug therapies that potentially threaten resident health and safety; if the facility administers these drugs, it must justify that use as in the best interest of the resident. CMS Ex. 13 at 27.

This case centers around the drugs ordered and administered to two facility residents, identified as Resident 21 (R21) and Resident 17 (R17).

R21 was a 78-year-old woman who, because of her worsening dementia, transferred to the facility from an assisted living center on November 2, 2009. In addition to dementia, she suffered from diabetes, gastric esophageal disease, and fibromyalgia. CMS Ex. 18 at 1, 2, 19, 37. Nurses described her as "very anxious" and "nervous," and she exhibited significant behavior problems. She did not sleep the night following her admission, but stayed up, claiming that the "authorities were looking for her." CMS Ex. 8 at 14. Thereafter, the nurses' notes alternately describe her as "restless" and "very pleasant [and] cooperative," although, problematically, she repeatedly tried to transfer and walk by herself. CMS Ex. 8 at 15.

At the time of her admission, R21 was prescribed the antipsychotic drug, Haldol (haloperidol), but Mark D. Canty, M.D., the facility's medical director who became R21's attending physician, discontinued that drug on the day of her admission. CMS Ex. 8 at 13; P. Ex. 1 at 2. He prescribed Zoloft (sertraline), 100 mg, twice a day for depression.[2] CMS Ex. 18 at 19, 40. On November 5, Dr. Canty prescribed Seroquel (quetiapine), 25 mg. twice a day, for "dementia/agitation." CMS Ex. 18 at 19.

Thereafter, R21's restlessness and agitation continued. CMS Ex. 8 at 16. By November 10, she was regularly walking with the assistance of a merry walker.[3] She would refuse to rest, even when visibly fatigued, and fell several times. CMS Ex. 8 at 17-23. She sometimes refused to eat or take her medications. CMS Ex. 8 at 24.

---

[2] The parties describe the prescription as 100 mg. *once* a day, citing page 40 of CMS Exhibit 18 – a December 8, 2009 hospital transfer record that lists R21's medications. That document says "Zoloft 100 mg twice a day."

[3] A merry walker is an assistive device designed to enable individuals with impaired balance to ambulate. The device envelops the individual in a frame with a base wider than the area occupied by the individual's legs. *See Lake Park Nursing and Rehab. Ctr.*, DAB CR1341 at 6 n.4 (2005), *aff'd* DAB No. 2035 (2006).

By December 5, R21's daughter was so concerned about her mother's apparent decline that she asked staff to withhold the Seroquel until her doctor "returned." CMS Ex. 8 at 24. Staff contacted Dr. Canty, who ordered the drug held until December 7. P. Ex. 5.

On December 7, test results showed that R21 had critically high sodium levels. CMS Ex. 8 at 27. High sodium levels can cause seizures, confusion, irritability, and coma. CMS Ex. 8 at 29. Dr. Canty directed staff to send her to the hospital for evaluation. CMS Ex. 8 at 25. She was admitted to the hospital with complaints of an altered mental status, decreased food intake, and high sodium (hypernatremia). CMS Ex. 18 at 37. Initially, the hospital planned to withhold all of her medications "until she is more awake and responsive." CMS Ex. 18 at 38. Thereafter, the physician prescribed Seroquel, 25 mg. twice a day, Zoloft, 100 mg. twice a day, and Haldol, 1 mg. as needed. CMS Ex. 8 at 31-32.

When R21 returned to the facility on December 10, the nurse's note describes her as "lethargic" and "disoriented." CMS Ex. 18 at 26. Her physician continued her on Seroquel, 25 mg. twice a day, for "dementia [with] agitation." CMS Ex. 18 at 35. On December 11, he discontinued the Zoloft and prescribed Zyprexa (olanzapine), 5 mg. twice a day, for depression. CMS Ex. 18 at 26, 36.

On December 12, R21 was admitted to hospice care. CMS Ex. 18 at 27; P. Ex. 20. Her problematic behaviors continued, however, and she suffered additional falls. CMS Ex. 18 at 27-30.

R17 was a 96-year-old woman, originally admitted to the facility in December 2007 and readmitted on November 4, 2009, apparently following a hospital stay. Her diagnoses included pelvic fractures and dementia with physically aggressive behaviors. CMS Ex. 16 at 9, 19, 26. According to her care plan, she was easily agitated with staff and exhibited behaviors such as crying and anger following her son's visits. CMS Ex. 16 at 26. In September 2009, Dr. Canty prescribed Seroquel, 12.5 mg. twice a day, which he later increased to 25 mg. twice a day. P. Exs. 10, 12. At the time of her readmission, he renewed the prescription for Seroquel, 25 mg. twice a day, and added Zyprexa, 2.5 mg. daily. CMS Ex. 16 at 19. Nurses' notes document multiple episodes of aggressive and other problematic behaviors, including throwing items, cursing, elopement, biting, and scratching. CMS Ex. 16 at 15-16. In one instance, she fell off the edge of her bed while attempting to slap a nurse aide. CMS Ex. 16 at 16.

A. The facility was not in substantial compliance with 42 C.F.R. § 483.25(l) because it did not adequately justify its use of questionable combinations and dosages of antipsychotic drugs.[4]

As a threshold matter, I reject Petitioner's suggestion that CMS must prove that the facility administered unnecessary drugs. The statute and regulations explicitly place the burden on the *facility* to show that only necessary drugs are administered to its residents.

I also emphasize that I see no indication that Dr. Canty was anything other than a conscientious physician trying to manage his challenging patients. Whether the drugs he prescribed were appropriate or even beneficial is not the issue. As explained below, CMS properly identified the drugs he prescribed as potentially very dangerous, so the facility had an independent responsibility to question him about their risks and benefits and, ultimately, to justify their use as in the resident's best interests. That justification had to be documented in the resident's clinical record. In these proceedings, Dr. Canty explains his reasons for ordering the drugs he ordered. But such after-the-fact justifications do not satisfy the facility's obligations to ensure that its residents are free from unnecessary drugs.

Seroquel (quetiapine) and Zyprexa (olanzapine) are antipsychotic medications. Neither is approved for the treatment of patients with dementia-related psychoses, and their labels warn that administering the drugs to elderly people "who have lost touch with reality (psychosis) due to confusion and memory loss (dementia) can raise the risk of death."[5] *See* Zyprexa Prescribing Information, http://www.Zyprexa.com; *see also* http://www.Seroquelxr.com.[6] Not surprisingly, the SOM includes these drugs among its list of medications "that have the potential to cause clinically significant adverse

---

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

[5] The United States Food and Drug Administration (FDA) 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. Dr. Canty concedes that he was aware of the black box warning for Seroquel, although he does not mention the similar warning for Zyprexa. P. Ex. 24 at 8 (Canty Decl. ¶ 29).

[6] Petitioner complains that CMS "introduced new evidence" because, in its closing brief, it cited to the drug manufacturers' websites. Although the sites contain additional information, CMS refers only to the manufacturers' instructions and FDA approvals, undisputed facts that underpin the issues in this case. I do not consider the references "new evidence," and, even if CMS had not cited the websites, I could have done it on my own. Judges regularly and appropriately cite to such public information.

consequences, that may have limited indications for use, require specific monitoring, and . . . warrant careful consideration of relative risks and benefits." The SOM does not preclude use of the listed drugs but emphasizes that facilities must use them cautiously. CMS Ex. 13 at 27.

Not all conditions justify the use of antipsychotic medications, and the SOM lists situations for which antipsychotic medications are *not* indicated: wandering; poor self care; restlessness; impaired memory; mild anxiety; insomnia; unsociability; inattention or indifference to surroundings; fidgeting; nervousness; uncooperativeness; and certain verbal expressions or behaviors that do not represent a danger to the resident or others. CMS Ex. 13 at 43.

Petitioner challenges CMS's reliance on the SOM, citing *Foxwood Springs Living Center*, DAB No. 2294 (2009), a case in which the Departmental Appeals Board held that CMS's questionable interpretation of a SOM provision did not alter the regulatory provisions that govern how and when a facility can establish that it has corrected its deficiencies. As the *Foxwood* panel observed, the SOM provides state survey agencies with CMS's interpretive guidelines, standards of practice, and internal policies. I agree with Petitioner that the SOM does not have the same effect as the statute or regulations (by which I am bound) and that a manual provision does not alter the plain meaning of a regulation. However, I do not agree that manual provisions have no effect. As explained above, the regulations' drafters explicitly directed CMS to provide necessary guidance by identifying drugs that potentially threaten resident health and safety. 56 *Fed. Reg.* at 48,851-52. Because these SOM provisions "reasonably interpret the Act and regulations," they are entitled to considerable deference. *See, e.g., Heartland Manor at Carriage Town*, DAB No. 1664 at 19 (1998). Indeed, even assuming that an Administrative Law Judge is authorized to disregard the SOM's listing of problematic drugs, I could not do so here where the evidence (including the black box warnings) of the drugs' dangers is so substantial and the evidence challenging the SOM's drug provisions is so weak.

In challenging the SOM provisions, Petitioner has submitted two articles. The first is a short report describing a study funded by the drug's manufacturer, which concludes that Seroquel (prescribed by itself, not in combination with another second generation atypical antipsychotic – see discussion below) "can effectively control agitation in elderly patients with Alzheimer's disease without increasing risk of stroke or other cerbrovascular events." P. Ex. 21 at 1.[7] I agree with CMS that the funding of this study

[7] CMS questions the relevance of the study to R17 and R21, neither of whom suffered from Alzheimer's disease. The report is confusing as to the study's application to demented individuals not suffering from Alzheimer's. The above quote suggests that it applies solely to Alzheimer's sufferers, but the study purportedly included patients with vascular dementia as well. P. Ex. 21 at 1.

raises questions about objectivity, and I see no evidence that the study's conclusions are widely accepted within the scientific community. In any event, even the study's senior investigator discouraged the use of Seroquel to treat agitation. He pointed out that no medication has FDA approval for treating agitation associated with dementia and cautioned that "pharmacological interventions should be the last choice in treating agitation – not the first choice." P. Ex. 21 at 1, 2. If anything, these words of caution support the SOM provisions requiring facilities to justify their use of the drug.

In the second article, which is from an on-line publication called *Pharmacotherapy* and was posted in the year 2000, researchers from the University of Texas reviewed studies evaluating the efficacy and safety of antipsychotics administered to patients with "dementia of Alzheimer's type" associated with psychotic symptoms. The article points out that problems associated with the use of antipsychotics (among other classes of drugs) led Congress, in the Omnibus Budget Reconciliation Act of 1987 (Public Law 100-203), to restrict their use. The article also notes that data is lacking on the safety and efficacy of atypical antipsychotics on elderly patients with dementia and concludes that "[s]election of alternative antipsychotics should be based on research data as they become available, clinical experience, and side effect profiles. All antipsychotics should be given at the lowest effective dosage to ensure minimal side effects and optimal outcomes." P. Ex. 22 at 10. Again, this article recognizes problems associated with antipsychotic drugs, as well as the absence of reliable research data for guidance. It thus does not undercut – in fact, it effectively supports – the SOM provisions requiring facilities to justify their use.

Inadequate justification. CMS charges that the facility violated 42 C.F.R. § 483.25(l)(2) when it administered Seroquel and Zyprexa to R17 and R21 because it did not document in their clinical records specific, diagnosed conditions that justify the use of the antipsychotic drugs.

This is certainly the case for **R17**, whose clinical record includes drug orders without accompanying diagnoses. In his declaration, Dr. Canty says that, on September 5, 2009, he ordered Seroquel, 12.5 mg. twice a day and that his order is in the record as Petitioner Exhibit 10. He now explains that he ordered Seroquel due to R17's "increased agitation/behaviors." P. Ex. 24 at 6 (Canty Decl. ¶ 6). But his order includes neither a diagnosis nor any other justification for the drug, and nothing in this record suggests that the facility questioned him about that omission. P. Ex. 10.

At the time of R17's November 4 readmission to the facility, Dr. Canty prescribed Seroquel, 25 mg. twice a day, and Zyprexa, 2.5 mg. daily. CMS Ex. 16 at 19. Again, these orders include no justification, and, again, nothing in the record suggests that the facility brought this to the doctor's attention.

Petitioner has submitted an old order for Zyprexa, dated April 11, 2008, which includes the diagnosis "dementia with physically aggressive behaviors." CMS Ex. 16 at 9, 19; P. Ex. 7. But that order can hardly justify administering the drug more than a year and a half later, particularly since Dr. Canty discontinued the April 11, 2008 order on March 11, 2009. P. Ex. 9.

The facility thus regularly administered antipsychotic drugs to R17 without ensuring and documenting in her clinical record that the drugs were necessary to treat a specific condition. It was therefore not in substantial compliance with 42 C.F.R. § 483.25(l).

Petitioner has come forward with a partial justification for administering one of the drugs to R17 – an order dated September 18, 2009, which increases the dosage of Seroquel from 12.5 mg. to 25 mg. twice a day "[because] of continued abusive behavior to staff." P. Ex. 12. This "justification" does not change my finding. First, it does not explain the purposes of the September 5 and November 4 drug orders. Second, it is highly questionable whether it is ever appropriate to administer antipsychotic medications based solely on a resident's behavior toward staff. According to Surveyor Beverly A. Asbury, R.N., elderly patients with dementia are often combative with care givers, but caregivers

> should possess the skills and training necessary to manage these behaviors. So long as the patient is not combative with other residents or a danger to herself, there is then no justification for the use of antipsychotic medications.

See CMS Ex. 21 at 2 (Asbury Delc. ¶ 9); *see also* CMS Ex. 13 at 43 (noting use of antipsychotics not indicated to treat uncooperativeness). Petitioner, however, suggests that R17's behaviors could have caused injury to herself or other residents. P. Br. at 10. But the facility did not justify the antipsychotics by claiming that they were necessary to protect R17 or any other resident from injury. Moreover, no evidence shows that she ever attacked any other resident, and her care plan did not identify as problems potential injury to herself or aggression toward other residents. CMS Ex. 16 at 26.

From the record before me, I cannot determine whether administering antipsychotic drugs to R17 could have been justified, but I need not answer that question to resolve this case. At a minimum, the facility should have brought to Dr. Canty's attention that he had not justified the drugs he ordered on September 5 and November 4, and, with respect to the September 18 order, they should have questioned whether it was appropriate to prescribe an antipsychotic based solely on R17's behavior toward staff. These failures, not the underlying question of whether the drugs could ultimately be justified, put the

facility out of substantial compliance.[8]

CMS also finds inadequate the facility's documented reason for prescribing antipsychotic drugs to **R21**. Dr. Canty prescribed Zyprexa for R21's depression. CMS Ex. 18 at 36. However, Zyprexa is not approved for treatment of depression. CMS Ex. 20 at 3 (McDorman Decl. ¶ 14). According to the 2007 Drug Information Handbook for Nursing, which is apparently still in use by CMS and the state survey agencies, Zyprexa is moderately to highly sedating, so it should be used "with caution" in treating disorders featuring depression. CMS Ex. 14 at 1. Because of these considerations, the facility was obliged to get the physician's written justification, explaining why the drug's benefits outweighed the risks to R21. The record includes no evidence that anyone at the facility even considered this contraindication, much less brought it to Dr. Canty's attention.

Similarly, according to the physician's orders, R21 took Seroquel for dementia with agitation. CMS Ex. 18 at 35. A nurse's note says that R21 is on Seroquel "for agitation." CMS Ex. 8 at 18. Prescribing Seroquel for this purpose is also questionable, and I see no evidence that facility staff asked Dr. Canty to document why the advantages of her taking this drug for this purpose outweighed the risks.

Duplicate therapy. The SOM defines "duplicate therapy" as "multiple medications of the same pharmacological class/category" or any medication therapy that "substantially duplicates a particular effect of another medication that the individual is taking." CMS Ex. 13 at 4. Seroquel and Zyprexa are both second generation atypical antipsychotic drugs, so administering both would be considered duplicate therapy. CMS Ex. 13 at 39 (SOM); CMS Ex. 18 at 33; CMS Ex. 22 at 3.

> Duplicate therapy is generally not indicated, unless current clinical standards of practice and documented clinical rationale confirm the benefits of multiple medications from the same class or with similar therapeutic effects.

CMS Ex. 13 at 20. Consistent with these provisions of the SOM, the 2007 Drug Information Handbook for Nursing warns that "co-administration of two or more antipsychotics does not have any pharmacological basis or clinical advantages and

[8] Conspicuously missing from this case is any reference to the facility's licensed pharmacist. The facility must employ or obtain the services of a licensed pharmacist who, among other duties, reviews at least monthly each resident's drug regimen and reports any irregularities to the attending physician and director of nursing, who must "act upon" the pharmacist's report. 42 C.F.R. § 483.60(b), (c). It seems that CMS cited no deficiencies under section 483.60, but, assuming that the facility retained the services of a pharmacist who approved the residents' drug regimens, I would have expected to hear from him/her. CMS Exs. 2, 6.

increases the potential for side effects." CMS Ex. 14 at 3; *accord* P. Ex. 22 at 10 (pointing out that "minimal data exist to support the superiority of combinations regimens over monotherapy" and warning that "complex drug regimens increase the risk of adverse reactions and drug interactions").

Petitioner makes much of the fact that the appendix to the 2009 Drug Information Handbook for Nursing omitted language addressing duplicate therapy, from which Petitioner infers that such warnings "are no longer consistent with current best practices in administration of antipsychotic medication." P. Br. at 12. I draw no such inference. If, in fact, practice standards regarding duplicate therapies have changed, some medical literature should highlight that fact. But Petitioner has come forward with no such evidence showing that standards of practice have changed in this regard, and the SOM still mandates a justification for duplicate therapy.

Again, I do not resolve the question of whether duplicate therapy could have been justified in the cases of R17 and R21. However, the practice is highly controversial, and, as the SOM provides, "documentation is necessary to clarify the rationale for and benefits of duplicate therapy and the approach to monitoring for benefits and adverse consequences," and that documentation should be available in the resident's clinical record. CMS Ex. 13 at 20. Because the facility did not provide that documentation, it was not in substantial compliance with 42 C.F.R. § 483.25(l).

Dosages. The SOM directs facilities to administer the "lowest possible [dosage] to achieve the desired therapeutic effects," when the drugs are used for long-term treatment. CMS Ex. 13 at 43. These instructions are consistent with acceptable standards of medical practice. P. Ex. 22 at 10 (declaring that "all antipsychotics should be given at the lowest effective dose"). The SOM also lists dosages, which the facility may exceed "if it provides evidence to show why the higher doses were necessary to maintain or improve the resident's function and quality of life." CMS Ex. 13 at 27.

According to both the SOM and the facility's own documents, the daily dosage threshold for Zyprexa (olanzapine), when used to manage behavioral symptoms related to dementia, is 7.5 mg. *See* CMS Ex. 13 at 43; CMS Ex. 18 at 33; *see also* CMS Ex. 22 at 3 (listing the "usual" dose ranges for Zyprexa at 2.5 to 10 mg./day). The 2009 Drug Information Handbook for Nursing recommends a low starting dose of 2.5-5 mg. per day, increasing as clinically indicated and tolerated. CMS Ex. 8 at 38.[9] Yet, on December 11, when Dr. Canty first ordered Zyprexa for R21, his order totaled 10 mg. daily, well above the recommended daily dosage threshold. And, in addition to administering the highest

[9] In defending the ordered dosage, Petitioner cites to the wrong category of patients. For the non-elderly with agitations associated with bipolar disorder or schizophrenia, an initial dosage of up to 10 mg. per day can be appropriate. CMS Ex. 8 at 38. Obviously, neither R17 nor R21 fell within that category.

dosage of Zyprexa, the facility was also giving her a duplicate drug, Seroquel. Prescribing this dosage, particularly in combination with a similar medication, should have raised eyebrows within the facility, but I see no indication that the facility questioned the order, or otherwise justified its administration. Again, whether or not these dosages could have been justified, the facility's failure to ensure that they were necessary put it out of substantial compliance with the regulation.

Petitioner argues that this result precludes physicians from ever prescribing medications in excess of recommended dosages. P. Cl. Br. at 6. To the contrary, a physician may prescribe an unorthodox drug, combination of drugs, or dosages of drugs, but the facility must ensure that he does so knowingly. The facility cannot know if a prescription results from the physician's "reasoned medical judgment" or from the physician's ignorance. Moreover, under Petitioner's theory, so long as the facility receives a valid physician's order, it need inquire no further, a result that renders the regulation meaningless, since obviously the facility can administer no drugs (or other medical treatments) without a valid physician's order.

Finally, although Dr. Canty seems to have made adjustments in his drug orders over time, I see no evidence of systematic facility efforts to reduce the drug dosages. R17's care plan does not even mention making an effort to reduce the dosages of the two antipsychotic drugs. CMS Ex. 16 at 26. R21's care plan says to "gradually decrease doses of medications [Seroquel and Zoloft] as ordered by MD," but the facility does not appear to have acted on that plan. CMS Ex. 18 at 44.

Petitioner claims "ample justification" for administering antipsychotic medications but offers none, except the physician order and the physician's after-the-fact declaration that his orders were justified. Because it has not shown that it justified, as in the residents' best interests, administering to R17 and R21 a questionable dosage and combination of powerful antipsychotic drugs, it was not in substantial compliance with 42 C.F.R. § 483.25(l).

B. The facility was not in substantial compliance with 42 C.F.R. § 483.25(l) because, having administered the drugs, it did not adequately monitor the affected residents 1) for side effects and other adverse consequences of the drugs; or 2) to determine the effectiveness or feasibility of reducing dosages.

Monitoring. Without question, a facility must monitor, for side effects and other adverse consequences, any resident taking antipsychotic drugs. It must also monitor the resident's behaviors to determine the drug's effectiveness and the feasibility of reducing the dosages. 42 C.F.R. § 483.25(l)(1). Careful monitoring would have been especially important for R21. Not only was she taking high dosages and unorthodox drug

combinations, she also exhibited symptoms consistent with side effects associated with antipsychotic drugs like Seroquel and Zyprexa – loss of appetite, lethargy, restlessness,[10] and uncontrolled muscle movements.[11] CMS Ex. 13 at 44-45; CMS Ex. 20 at 2 (McDorman Decl. ¶ 10); CMS Ex. 22 at 3-7.

Consistent with the regulatory requirements the care plans for both R17 and R21 directed staff to monitor behaviors and document their observations. Specifically, R17's care plan directed staff to "document in behavior tracking and report any mood or behaviors to [social services] or [doctor]" and to "assess for effectiveness to medication with MD notification of behaviors or side effects or ineffective regimen." CMS Ex. 16 at 26. R21's care plan required staff to review her medication for effectiveness and side effects and to report concerns to her physician. All staff were to monitor her behaviors on a tracking form and to attempt non-prescription interventions "per mood behavior tracking." They were also to observe her for mental status changes attributable to the meds and to notify her physician if the medication did not produce the desired results. CMS Ex. 18 at 44.

The facility had in place a "monthly flow record," on which staff were supposed to document behavioral symptoms and medication side effects. *See* CMS Ex. 18 at 32-33. The record contains no evidence that staff used these flow records or any other system to document R17's symptoms and behaviors. With respect to R21, the flow sheets seem to have been in place, but, for the entire month of December, the document contains just one entry, which was made on the December 7 night shift, reporting "movement sided effects" (motor restlessness, pelvic thrusting, increased agitation, and loss of independent mobility). CMS Ex. 18 at 32. This document is troublesome for two reasons. First, we know that R21 exhibited significant behaviors throughout this period, and the absence of entries shows that facility staff were not consistently monitoring and documenting as required by the regulation and her own care plan. Second, these behaviors occurred when R21's Seroquel had been discontinued. According to the authors of "Side Effects of Antipsychotic Drugs," published in *Postgraduate Medicine*, tardive dyskinesia (TD) is

[10] Akathisia refers to a "distressing feeling of internal restlessness that may appear as constant motion, the inability to sit still, fidgeting, pacing or rocking." CMS Ex. 13 at 4. It is among the neurological side effects of antipsychotic medications that can occur at any time from the first few days of treatment to years later. CMS Ex. 13 at 4.

[11] Tardive dyskinesia (TD) refers to abnormal, recurrent, involuntary movements that may be irreversible and typically present as lateral movements of the tongue or jaw, tongue thrusting, chewing, frequent blinking, brow arching, grimacing, and lip smacking. The trunk or other parts of the body may also be affected. CMS Ex. 13 at 6. When symptoms of tardive dyskinesia present, the physician should consider lowering or discontinuing the antipsychotic drug, although such change may exacerbate the symptoms, at least temporarily.

most likely first observed when the dose is lowered or stopped, because antipsychotic drugs may suppress TD movements. CMS Ex. 22 at 8. Thus, that the hip thrusting appeared after R21stopped taking Seroquel may have been significant.

Finally, this lack of systematic monitoring defeats Petitioner's claim that the residents benefitted from these medications. No reliable evidence suggests that their symptoms were alleviated.[12] Nursing notes indicate that R17's combative behavior continued. CMS Ex. 16 at 16. R21was still restless, still wandered through the facility, and still suffered falls. CMS Ex. 18 at 27-30. This suggests that the drugs were not effective and that the residents were exposed to their risks without obtaining the desired benefits. In any event, the absence of careful monitoring makes it impossible to tell where they benefitted or suffered as a result of the medications.

C. The penalties imposed are reasonable.

I next consider whether the CMPs are reasonable by applying 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. 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; and 3) the facility's prior history of noncompliance in general and specifically with reference to the cited deficiencies.

In reaching a decision on the reasonableness of the CMP, I consider whether the evidence supports a finding that the amount of the CMP is at a level reasonably related to an effort to produce corrective action by a provider with the kind of deficiencies found, and in light of the above factors. I am neither bound to defer to CMS's factual assertions, nor free to make a wholly independent choice of remedies without regard for CMS's discretion. *Barn Hill Care Ctr.*, DAB No. 1848, at 21 (2002); *Cmty. Nursing Home*, DAB No. 1807, at 22 *et seq*. (2002); *Emerald Oaks*, DAB No. 1800, at 9 (2001); *CarePlex of Silver Spring*, DAB No. 1638, at 8 (1999).

CMS imposed a penalty of $300 per day, which is at the low end of the penalty range for per-day CMPs ($50-$3,000). 42 C.F.R. §§ 488.408(d), 488.438(a)(1).

The facility has a history of substantial noncompliance, and this is not the first time that it has been found noncompliant with 42 C.F.R. § 483.25(l). Based on its last annual survey, completed in February 2009, the facility was not in substantial compliance with 42 C.F.R. § 483.25(l) at scope and severity level D (isolated instance that caused no

[12] Indeed, these symptoms can be side effects of the medications.

actual harm with the potential for more than minimal harm). During both surveys, the facility was not in substantial compliance with 42 C.F.R. § 483.25(h) (tag F323). In February 2009, the deficiency was cited at scope and severity level G (actual harm that is not immediate jeopardy), and, during this survey, it was cited at scope and severity level E (a pattern of noncompliance that causes no actual harm with the potential for more than minimal harm). In February 2009, the facility was also not in substantial compliance with 42 C.F.R. § 483.35(i) (tag F371 – dietary services, sanitary conditions) at scope and severity level D. CMS Ex. 3 at 1.

Nor was the facility in substantial compliance during its two earlier annual surveys. In February 2008, it was not in substantial compliance with one requirement, 42 C.F.R. § 483.20(k)(3)(i) (tag F281 – comprehensive care plans – services must meet professional standards). In January 2007, it was not in substantial compliance with five requirements, which included an E level deficiency under section 483.25(h).

The facility's history, by itself, more than justifies the relatively modest CMP of $300 per day.

Petitioner does not claim that its financial condition affects its ability to pay the CMP.

With respect to the remaining factors, I consider the deficiencies cited significant. It seems that the facility took no independent steps to ensure that its residents were free from unnecessary drugs. So long as a physician ordered the drugs, the facility administered them. Of particular concern was staff's failure to monitor, in any systematic way, the effects or effectiveness of the drugs, for which it must be held culpable.

For these reasons, I conclude that a $300 per day penalty is reasonable.

IV. Conclusion

From December 17, 2009 through February 1, 2010, the facility was not in substantial compliance with 42 C.F.R. § 483.25(l), and the penalty imposed ($300 per day) is reasonable.

/s/
Carolyn Cozad Hughes
Administrative Law Judge