Department of Health and Human Services

DEPARTMENTAL APPEALS BOARD

Civil Remedies Division

Golden Living Center – Colonial Manor
(CCN: 52-5309),

Petitioner

v.

Centers for Medicare and Medicaid Services.

Docket No. C-11-398

Decision No. CR2504

Date: February 22, 2012

DECISION

Petitioner, Golden Living Center – Colonial Manor (Petitioner or facility), is a long term care facility located in Glendale, Wisconsin, that participates in the Medicare program. Based on a survey completed on January 12, 2011, the Centers for Medicare and Medicaid Services (CMS) determined that Petitioner was not in substantial compliance with Medicare participation requirements. CMS imposed against Petitioner a civil money penalty (CMP) of $700 per day effective January 12 through February 14, 2011, for a total CMP of $23,800.

Petitioner appealed, and CMS moves for summary judgment.

For the reasons set forth below, I grant summary judgment. The undisputed facts establish that the facility was not in substantial compliance with 42 C.F.R. §§ 483.25(l) (Tag F329 unnecessary drugs), 483.60(a), (b) (Tag F425 pharmaceutical services), and 483.75(l)(1) (Tag F514 clinical records). I also find that the $23,800 CMP that CMS imposed is reasonable.

I. Background

The Social Security Act (Act) sets forth requirements for nursing facilities' participation in the Medicare program and authorizes the Secretary of Health and Human Services (Secretary) 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 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 12 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.

Surveyors from the Wisconsin Department of Health Services conducted a survey of Petitioner that ended on January 12, 2011. Based on their findings, CMS determined that the facility was not in substantial compliance with numerous Medicare requirements and imposed a CMP of $700 per day effective January 12 through February 14, 2011, for a total CMP of $23,800. After a revisit survey, CMS found that the facility returned to substantial compliance on February 15, 2011.

On April 15, 2011, Petitioner timely requested a hearing contesting all findings of noncompliance and related sanctions set forth in the CMS notices issued on February 17 and March 16, 2011. The case was assigned to me for hearing and decision. On April 20, 2011, I issued an Acknowledgement and Initial Pre-Hearing Order establishing a briefing schedule. In accordance with the schedule, on July 1, 2011, CMS submitted a motion for summary judgment and memorandum (CMS Br.), along with 28 exhibits (CMS Exs. 1-28). On August 2, 2011, Petitioner submitted a response in opposition to CMS's motion for summary judgment (P. Br.) and 15 exhibits (P. Exs. 1-15).

II. Issues

- Whether, from January 12 through February 14, 2011, the undisputed facts establish that Petitioner was in substantial compliance with 42 C.F.R. §§ 483.25(l), 483.60(a), (b), and 483.75(l)(1); and

- If Petitioner was not in substantial compliance, whether the $700 per day CMP CMS imposed is reasonable.

III. Discussion

Summary judgment is appropriate when a case presents no issue of material fact, and its resolution turns on questions of law. *See Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 247-48 (1986); *Livingston Care Ctr. v. United States Dep't of Health and Human Servs.*, 388 F.3d 168, 173 (6th Cir. 2004). *See also Illinois Knights Templar Home*, DAB No. 2274, at 3-4 (2009) (*citing Kingsville Nursing Ctr.*, DAB No. 2234, at 3-4 (2009)). The moving party may show the absence of a genuine factual dispute by presenting evidence so one-sided that it must prevail as a matter of law, or 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 Ctr.*, 388 F.3d 168, 173 (*quoting Celotex Corp. v. Catrett*, 477 U.S. 317, 323-24 (1986)). To avoid summary judgment, the non-moving party must then act affirmatively by tendering evidence of specific facts showing that a dispute exists. *See 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 Rehab. Ctr.*, DAB No. 1918 (2004). To defeat an adequately supported summary judgment motion, the non-moving party may not rely on the denials in its pleadings or briefs, but it must furnish evidence of a dispute concerning a material fact. *Illinois Knights Templar Home*, DAB No. 2274, at 4; *Livingston Care Ctr.*, DAB No. 1871, at 5 (2003).

In examining the evidence for purposes of determining the appropriateness of summary judgment, I must draw all reasonable inferences in the light most favorable to the non-moving party. *Brightview Care Ctr.*, DAB No. 2132, at 2, 9 (2007); *Livingston Care Ctr.*, 388 F.3d at 168, 172; *Guardian Health Care Ctr.*, DAB No. 1943, at 8 (2004); *but see Cedar Lake*, DAB No. 2344, at 7; *Brightview Care Ctr.*, DAB No. 2132, at 10 (upholding summary judgment where inferences and views of non-moving party are not reasonable). However, drawing factual inferences in the light most favorable to the non-moving party does not require that I accept the non-moving party's legal conclusions. *Cedar Lake*, DAB No. 2344, at *7; Guardian Health Care Ctr.*, DAB No. 1943, at 11 ("A dispute over the conclusion to be drawn from applying relevant legal criteria to undisputed facts does not preclude summary judgment if the record is sufficiently developed and there is only one reasonable conclusion that can be drawn from those facts.").

Petitioner failed to tender sufficient evidence allowing me to draw reasonable inferences in its favor creating a genuine dispute of material fact regarding the deficiencies at issue here. Petitioner relies mainly on the declaration of Jameie Williams, R.N., Petitioner's Director of Nursing (DON), to challenge the material facts that CMS alleges, which are that (CMS Br. at 3): 1) the facility continued to administer an antipsychotic to a resident without adequate indications documented in the resident's clinical record to justify its continued administration; 2) the facility did not monitor for the need, reduction, or discontinuation of the administration of the antipsychotic; 3) the facility did not dispense

and administer medications to three residents in accordance with their medical professionals' orders; 4) the facility did not come forward with any proof of an accurate pharmaceutical reconciliation for these three residents; and 5) the facility did not maintain clinical records on these three residents that it *completely* and *accurately* documented. Even when I construe DON Williams' declaration and Petitioner's other exhibits in the light most favorable to the Petitioner, Petitioner was not able to come forward with sufficient evidence to dispute the fact that for 24 days a resident continued to receive an antipsychotic without proper monitoring, and the facility did not reconcile records showing that three residents did not receive their medications as their medical professionals ordered.

My findings and conclusions are set forth in the bold italicized headings and supported by the discussions in the sections below.

A. CMS is entitled to summary judgment that Petitioner was not in substantial compliance with 42 C.F.R. § 483.25(l) because the undisputed evidence establishes that Petitioner did not monitor for the need, reduction, or discontinuation of the administration of the antipsychotic drug Haldol to Resident 8.

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. 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*. *See* 42 C.F.R. § 483.25(l)(1).

Additionally, special rules apply to the use of antipsychotic drugs. Based on a 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 must also ensure that it gradually reduces doses and implements behavioral interventions to discontinue the antipsychotics.[1] 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

[1] Petitioner's own Policy & Procedure Manual regarding Medication Management mirrors the language set out in subsections 1 and 2 of this regulation. *See* CMS Ex. 6.

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.* 48,826, 48,851-52 (Sept. 26, 1991).

CMS cited Petitioner for an unnecessary drug deficiency involving the administration of the antipsychotic drug Haldol (haloperidol). Haldol is used to treat the symptoms of delirium and is usually prescribed for a short period of time in order to stabilize a patient's cognitive state. CMS Ex. 8, at 6. In all patients, response to antipsychotics should be monitored at least every 24 hours. *Id.* Once a patient's cognitive state stabilizes, Haldol should be administered over the next few days, then tapered, and then discontinued. *Id.* For over three weeks the facility administered the antipsychotic to one resident, identified as Resident 8 (R8).

R8, a 70-year-old female, was admitted to the facility on November 2, 2010, suffering from a number of conditions, including congestive heart failure, chronic obstructive pulmonary disease, hypertension, diabetes, obesity, sleep apnea, and osteoarthritis. CMS Ex. 7, at 33. R8's treatment regimen included several medications but did not include Haldol. *Id.* On December 6, 2010, R8 experienced respiratory distress and was admitted to a hospital with sepsis and hypoxia. CMS Ex. 7, at 8, 12-13, 42. R8 began exhibiting confusion and agitated behaviors, such as repeated attempts to get out of bed. CMS Ex. 7, at 8; P. Br. at 11. A hospital psychiatrist evaluated R8 and diagnosed her with "[d]elirium secondary to sepsis and hypoxia."[2] CMS Ex. 7, at 9. The psychiatrist recommended a range of Haldol as needed for agitation "so as to allow diminishing doses as she medically clears." CMS Ex. 7, at 9.

After more than a week in the hospital, R8 was prepared for discharge. Her final hospital evaluation noted that her delirium had "improved today" and ordered the continuation of 0.5 milligrams (mg.) of Haldol each day at bedtime. CMS Ex. 7, at 10. The hospital discharge summary indicated that R8 "did experience prolonged episodes of delirium and agitation throughout her stay" and required Haldol, as needed, for her agitation. CMS Ex. 7, at 13. The discharge summary included a list of R8's medications at discharge that included a notation of 0.5 mg. of Haldol as a handwritten addition to the otherwise typed list. CMS Ex. 7, at 11, 14.

On December 13, 2010, the hospital discharged R8, and the facility readmitted her. The facility's orders beginning on that date included 0.5 mg. Haldol at bedtime every day. CMS Ex. 7, at 15. The facility completed an "Immediate Plan of Care" for alteration of skin integrity, the use of oral anticoagulants, and the following risks: pain; skin

[2] Delirium is a temporary condition resulting from a co-existing condition such as an infection. CMS Ex. 10. Haldol is a drug approved to treat delirium. CMS Ex. 5, at 41.

breakdown; respiratory problems; cardiovascular problems; and falls. CMS Ex. 7, at 21-27. There was no Immediate Plan of Care for R8's use of antipsychotics. *See* CMS Ex. 7. A "Behavior Monthly Flow Sheet," dated December 2010, was present in R8's file. CMS Ex. 7, at 28. The form is a pre-printed checklist that states it should be used when a resident is administered certain classes of medication, including antipsychotics, such as Haldol. The form lists possible behaviors to monitor, possible staff interventions, and provides space to document resident responses to those interventions. However, other than R8's name, physician's name, and date, the form is completely blank. CMS Ex. 7, at 28.

Petitioner's staff began administering 0.5 mg. of Haldol to R8 after readmission. Petitioner claims it continued administering Haldol until a psychologist, Dr. Heimler, evaluated R8 24 days later on January 6, 2011. P. Ex. 3; P. Br. at 13. On that date, Dr. Heimler discussed the antipsychotic with Nurse Practitioner (NP) Lisa Lockwood. NP Lockwood discontinued the medication on that same date. CMS Ex. 7, at 30. This was also the same day that the surveyor inquired about the status of R8's treatment with Haldol. CMS Ex. 1, at 65.

To defeat CMS's motion for summary judgment, Petitioner must do more than deny the allegations. It must *furnish evidence* of specific facts showing that a dispute exists. Petitioner claims that–consistent with the regulatory requirements and its own policy–(1) a nurse practitioner appropriately assessed, evaluated, and monitored R8 upon readmission; and (2) Haldol was medically necessary–for 24 days–to treat R8's delirium, and the administration of Haldol was appropriately discontinued in a timely manner. Petitioner, however, has not come forward with clinical records supporting its assertions. Further, Petitioner has not provided an affidavit from NP Lockwood disputing that R8 failed to receive a proper assessment for the administration of the antipsychotic drug. Based on the evidence presented, the only reasonable inference that can be drawn from the undisputed facts is that, prior to the survey, the facility did not properly assess R8 for unnecessary drugs or implement interventions to assure that R8 was not unnecessarily medicated or experiencing adverse reactions to administered antipsychotic medication.

Petitioner argues that, the same day that R8 was readmitted, NP Lockwood evaluated R8, "noted the Haldol order, determined that she did not want to change it until she could be sure that the delirium did not recur at the nursing facility and a mental health professional conducted a more thorough evaluation, and so she ordered the medication continued, and a mental health evaluation as soon as possible." P. Br. at 13; *see* P. Ex. 1, at 6. To support its position, Petitioner cites only a computer printout progress note authored by NP Lockwood. P. Ex. 2. This progress note, dated January 6, 2011, 24 days after R8's readmission, simply states:

> Resident seen by [behavioral health consultant psychologist] today. Resident has been on scheduled Haldol at bedtime since readmission secondary to delirium. Delirium issues are resolved at this time.

P. Ex. 2. NP Lockwood does not reference a previous evaluation, assessment, order, or referral–all of which Petitioner alleges were performed. P. Br. at 13. Before the date of discontinuation, nowhere in the record did Petitioner provide any clinical records reflecting NP Lockwood's assessment upon readmission, let alone one that contains a review of R8's signs or symptoms of delirium and whether they indicated the continued need for the antipsychotic.

Again, Petitioner has not come forward with any clinical records showing NP Lockwood ordered the continued administration of Haldol. There are no clinical records that NP Lockwood ordered Petitioner's staff to monitor R8 to assure the medication was effective in treating signs and symptoms of delirium or to monitor R8 for possible side effects. The only proffered evidence of a clinical record in defense of this cited deficiency is the progress note, written more than three weeks after the purported readmission evaluation, which does not support Petitioner's position that it was necessary to continue to administer Haldol to R8 after her readmission.

The only support Petitioner offers for NP Lockwood's purported readmission evaluation is DON Williams' declaration. P. Br. at 13; P. Ex. 1. She asserts that:

> The same day the Resident returned [December 13, 2010], a Nurse Practitioner named Lisa Lockwood evaluated her, noted the Haldol order, determined that she did not want to change it until she could be sure that the delirium did not recur at the nursing facility, and a mental health professional conducted a more thorough evaluation, and so she ordered the medication continued, and a mental health evaluation as soon as possible. That evaluation took place on January 6, 2011, which is as soon as it was possible to arrange the consultation during the holiday season.

P. Ex. 1, at 6. For the purposes of summary judgment, I am not required to accept as true inferences that are unreasonable. And considering there is no clinical documentation of NP Lockwood's purported December 13, 2010 assessment, or an affidavit from NP Lockwood, I will not infer that this assessment took place. Nevertheless, even if I were to accept as true that NP Lockwood did assess R8's need for continued Haldol upon readmission, nowhere in Petitioner's clinical records is there evidence to show the facility properly *monitored* R8 for potential side effects or signs or symptoms of delirium to justify the drug's use *for 24 days* after the facility readmitted R8.
Interestingly, although Petitioner argues that Haldol was medically necessary to treat R8's delirium and, as such, the facility administered the drug upon R8's December 13, 2010 readmission and continued it until January 6, 2011, the Medication Administration

Record (MAR)[3] inexplicably reflects that the facility did not administer Haldol to R8 on December 13, December 29, or at any time in January 2011. *See* CMS Ex. 7.

Considering Petitioner has not come forward with evidence establishing a factual dispute as to whether the facility kept R8 free from unnecessary drugs, whether it be by not showing adequate continued indications for administration of Haldol nor adequate monitoring of the Haldol under the terms of 42 C.F.R. § 483.25(l), I find the facility is not in substantial compliance with this deficiency, and CMS is entitled to summary judgment.

As I discuss later, I find the seriousness of this violation alone substantiates the $700 per day CMP that CMS imposed upon the facility. Nonetheless, I also consider the other violations CMS alleges in its motion for summary judgment.

B. CMS is entitled to summary judgment that Petitioner was not in substantial compliance with 42 C.F.R. § 483.60(a) and (b) because the undisputed evidence establishes Petitioner did not accurately dispense and administer drugs to meet the needs of Resident 10 and Resident 32 nor did Petitioner come forward with an accurate reconciliation for these residents' drug records.

42 C.F.R. § 483.60(a) and (b) require the following:

> (a) Procedures. A facility must provide pharmaceutical services (including procedures that assure the accurate acquiring, receiving, *dispensing, and administering of all drugs* and biologicals) to meet the needs of each resident.
>
> (b) Service consultation. The facility must employ or obtain the services of a licensed pharmacist who--
>
> > (1) Provides consultation on all aspects of the provision of pharmacy services in the facility;
> > (2) *Establishes a system of records of receipt and disposition of all controlled drugs in sufficient detail to enable an accurate reconciliation*; and

[3] A MAR is the facility document that specifies how each mediation is administered to a resident.

> (3) *Determines that drug records are in order and that an account of all controlled drugs is maintained and periodically reconciled.*

42 C.F.R. § 483.60(a) , (b) (Emphasis added).

Resident 10

R10 was a 70-year old male whose diagnoses included fungal lumbar spinal discitis, chronic kidney disease, bilateral knee replacement, chronic obstructive pulmonary disease, chronic ischemic heart disease, osteoarthritis, a left heel ulcer, and mild cognitive impairment. CMS Ex. 13, at 1, 7. He needed pain management and monitoring related to his left foot/heel wound, fungal lumbar spinal discitis, and peripheral vascular disease. CMS Ex. 13, at 15.

R10 was admitted to Petitioner's facility on October 14, 2010. *See* CMS Ex. 1, at 94; P. Ex. 5, at 3. The record shows that on October 18, 2010, R10 had a nurse practitioner's order for Oxycontin, 10 mg. by mouth every eight hours, and oxycodone, 10 mg. by mouth every four hours, as needed. P. Ex. 5, at 1. Oxycontin is a trade name for a long-acting, extended release narcotic pain medication containing oxycodone. Oxycodone is a short-acting narcotic pain medication. On October 27, 2010, the nurse practitioner changed R10's Oxycontin order, increasing the dosage to 20 mg. by mouth every eight hours. P. Ex. 5, at 2. Following a hospital stay for exacerbation of his cardiac and respiratory ailments, R10 was readmitted to Petitioner's facility on December 1, 2010. On that date, the nurse practitioner gave a new order for Oxycontin, 20 mg. by mouth every 12 hours, and continued the previous order for oxycodone, 10 mg. by mouth every four hours, as needed for pain. *See* CMS Ex. 1, at 94; CMS Ex. 13, at 17.

The record shows that the nurse practitioner's new order for Oxycontin every 12 hours was not entered into R10's December 2010 MAR, and instead, the old order for Oxycontin every eight hours was incorrectly entered. CMS Ex. 13, at 18-19.

As alleged in the SOD, on the following dates, R10's Individual Narcotic Record (INR), a log on which nursing staff signed-out the narcotics, shows that nursing staff gave R10 Oxycontin three times a day, instead of every 12 hours as ordered:

> December 16, 2010 - Petitioner administered 20 mg. of Oxycontin to R10 at 6 a.m., 12 p.m., and 8 p.m. *See* CMS Ex. 1, at 95; CMS Ex. 13, at 18, 22.

> December 28, 2010 - Petitioner administered 20 mg. of Oxycontin to R10 at 5 a.m., 2 p.m., and 10 p.m. *See* CMS Ex. 1, at 95; CMS Ex. 13, at 23, 24.

> December 29, 2010 - Petitioner administered 20 mg. of Oxycontin to R10 at 5 a.m., 2 p.m., and 9 p.m. *See* CMS Ex. 1, at 95; CMS Ex. 13, at 23.
>
> December 30, 2010 - Petitioner administered 20 mg. of Oxycontin to R10 at 6 a.m., 2 p.m., and 9 p.m. *See* CMS Ex. 1, at 95; CMS Ex. 13, at 23, 24.
>
> January 1, 2011 - Petitioner administered 20 mg. of Oxycontin to R10 at 6 a.m., 9 a.m., and 9 p.m. *See* CMS Ex. 1, at 95; CMS Ex. 13, at 23, 24, 25.

On the following date, Petitioner administered a double dose of Oxycontin to R10:

> January 4, 2011 - 20 mg. of Oxycontin was administered to R10 at 6 a.m., and then two doses (40 mg. total) were administered at 9 p.m. (R10's order is for one 20 mg. tablet, not two). *See* CMS Ex. 1, at 95; CMS Ex. 13, at 23.

Moreover, the MAR and INR show that on the following dates, Petitioner failed to administer to R10 his morning or evening does of Oxycontin, 20 mg., as prescribed:

> December 15, 2010 - Petitioner failed to administer R10 his morning dose.
>
> January 3, 2011 - Petitioner failed to administer R10 his evening dose.
>
> January 5, 2011 - Petitioner failed to administer R10 his evening dose.
>
> January 6, 2011 - Petitioner failed to administer R10 his morning dose.

CMS Exs. 1, at 96; 13, at 18, 21, 22, 23, 24, 25.

Irregularities also existed with respect to the administration of oxycodone. CMS notes that staff wrote in the wrong medication name and strength at the top of some of R10's INR log sheets, so that, instead of writing "oxycodone 10 mg.," they incorrectly wrote in "Oxycontin 10 mg." CMS Br. at 14. Under the nurse practitioner's order, R10 was supposed to receive 10 mg. of oxycodone by mouth every four hours as needed for pain. However, the INR shows that staff did not follow this order.

The record reflects that Petitioner's staff administered either too much oxycodone to R10 or administered it more frequently than ordered:

> December 25, 2010 - Petitioner administered oxycodone, 20 mg., at 2p.m.. CMS Ex. 1, at 96; CMS Ex. 13, at 30.
>
> December 27 and 31, 2010 - Petitioner administered two tablets of oxycodone (10 mg. x 2 = 20 mg.), at 2 p.m. CMS Ex. 1, at 96; CMS Ex. 13, at 30.
>
> December 15 and 18, 2010 - Petitioner administered one dose of oxycodone to R10 at 2 p.m. and another dose at 4 p.m., which is every two hours, not every four hours as ordered. CMS Ex. 1, at 96; CMS Ex. 13, at 28-29.
>
> December 26, 2010, Petitioner administered two 10 mg. tablets of oxycodone, instead of one, at 1 p.m., and again gave him two tablets of oxycodone at 6 p.m. CMS Ex. 1, at 96; CMS Ex. 13, at 29.
>
> January 4, 2011 - Petitioner administered two 10 mg. tablets of oxycodone at 8 a.m. CMS Ex. 1, at 96; CMS Ex. 13, at 29.

Petitioner concedes that a transcription error occurred when a nurse mistakenly reentered the old medication order for Oxycontin on R10's December MAR, instead of entering the nurse practitioner's new December 1, 2010 order, which prescribed 20 mg. of Oxycontin every twelve hours rather than every eight hours. P. Response at 20; *see* P. Ex. 1, at 9. Petitioner, however, downplays this error and cites the statements DON Williams made that it was not a "significant" medication error. According to Ms. Williams' declaration, the pharmacy correctly filled the December 1, 2010 Oxycontin order and delivered only two 20 mg. doses of Oxycontin each day. Ms. Williams acknowledges that "[R10's] December MAR indicates that the Resident was administered three 20 mg. doses on most days in December," but then states that she "determined that the nurses actually were administering two of the 10 mg. oxycodone tablets from the "PRN" (as needed) supply on those days." Ms. Williams states that she "also determined that our narcotic reconciliation records correctly documented and accounted for every such dose." P. Ex. 1, at 9. As a further attempt to justify that the error was not significant, Ms. Williams contends that R10 did not suffer any harm because he "never actually received more medication on any day in December than was permissible under the Nurse Practitioner's Orders." P. Ex. 1, at 10.

Ms. Williams' testimony alone is not enough to defeat CMS's motion for summary judgment. Although Ms. Williams refers to "narcotic reconciliation records" as proof that every dose was "accounted for," Petitioner has not indicated what these documents

are, nor has Petitioner proffered them as evidence. Therefore I do not have to accept her unsupported and unreasonable inference as true for summary judgment purposes. *See Brightview Care Ctr.*, DAB No. 2132, at 10.

CMS has offered Petitioner's own records in support of findings that the surveyors made based on review of those records documenting that Petitioner's staff made multiple errors in the administration of Oxycontin, 20 mg., and oxycodone, 10 mg., to R10. On some days, R10 received too many doses of these medications. On other days, R10 did not receive the correct number of doses. Other than the declaration of Ms. Williams, who concedes some errors, Petitioner has not come forward with any evidence establishing a dispute over any of the facts set forth in the MAR and INR documentation regarding the administration of Oxycontin and oxycodone during the relevant time frame. The only reasonable inference for me to draw is that Petitioner's staff did not dispense and administer Oxycontin and oxycodone to R10 in accordance with the nurse practitioner's orders.

Despite the DON's conclusion that Petitioner's errors were not significant, Petitioner's own training documents recognize that Oxycontin and oxycodone must be properly administered and closely regulated. A training document for nursing staff from January 2010 states, among other instructions, "Oxycodone and Oxycontin are 2 different medications. They are the same drug type but Oxycontin is long acting and oxycodone is short acting. They CANNOT be interchanged." The document also states that "[n]arcotics are to be counted at the end of your shift with oncoming nurse." CMS Ex. 13, at 35.

The Mayo Clinic states the following regarding oxycodone:

> Do not take more of it, do not take it more often, and do not take it for a longer time than your doctor ordered. This is especially important for elderly patients, who may be more sensitive to the effects of pain medicines. If too much of this medicine is taken for a long time, it may become habit-forming (causing mental or physical dependence).

CMS Ex. 14, at 10. Regarding missed doses, the Mayo Clinic states, "[i]f you miss a dose of this medicine, take it as soon as possible. However, if it is almost time for your next dose, skip the missed dose and go back to your regular dosing schedule. Do not [take] double doses." CMS Ex. 14, at 12.

The fact that Petitioner alleges R10 did not suffer any actual harm does not precludemy finding it out of substantial compliance with participation requirements. For a facility to be found not in "substantial compliance" with participation requirements, all that is required is a finding that the deficiency has the potential for more than minimal harm. 42

C.F.R. §§ 488.301, 488.402(c), 488.430(a). Here, Oxycontin and oxycodone are powerful narcotic pain medications that can pose serious risks to a resident's health and safety if improperly administered. As Schedule II narcotics having strong potential for abuse or addiction, they are controlled substances subject to additional regulations that do not apply to other medications. 42 C.F.R. § 483.60(b)(2), (3), and (e)(2). With controlled substances, facilities must establish a system to ensure that their receipt and disposition is recorded with sufficient detail to enable an accurate reconciliation and have an account of all controlled drugs that is maintained and periodically reconciled. 42 C.F.R. § 483.60(b)(2), (3). Additionally, a facility must provide separately locked, permanently affixed compartments for storage of Schedule II controlled drugs and other drugs subject to abuse, except when the facility uses single unit package drug distribution systems where the quantity is minimal and missing doses can be readily detected. 42 C.F.R. § 483.60(e)(2).

The errors by Petitioner's staff clearly had the potential for more than minimal harm. The improper administration of these powerful narcotics could potentially have led to serious complications, including dependency issues and untreated pain symptoms for R10. For the purposes of this deficiency, even if Petitioner were to have shown it administered the narcotics to R10 as ordered, its consistent failure to have accurate and reconciled documentation of what narcotic was administered, and when, also constitutes a violation under this regulation.

Resident 32

R32 was a 75-year-old woman diagnosed with hypertension, heart disease, schizophrenia, periodic fainting, and chronic fatigue. CMS Ex. 16, at 7. She regularly took almost two dozen medications. CMS Ex. 16, at 7, 9.

CMS alleges support for a deficiency under 42 C.F.R. § 483.60(a) and (b) because R32's records reflect missing doses of Acular, Spiriva, and Zestril. Acular is used to treat itchy eyes caused by allergies. It is also used to treat swelling and redness that can occur after cataract surgery. CMS Ex. 17. Spiriva is inhaled medication used to prevent wheezing, shortness of breath, and difficult breathing in patients with chronic obstructive pulmonary disease. CMS Ex. 21. Zestril is a blood pressure medication. CMS Br. at 15; P. Ex. 1, at 11.

R32 had physician orders originally dated November 4, 2010, for Acular eye drops administered twice a day, every day, to the right eye; for a Spiriva inhaler, one puff once a day, every day; and for Zestril, one tablet by mouth once a day, every day. CMS Ex. 1, at 99, 101; CMS Ex. 16, at 7. According to R32's January 2011 MAR, Acular was not given as prescribed on January 3-5, 2011. CMS Ex. 1, at 100; CMS Ex. 16, at 30. On January 3, 2011, R32 was not provided the 9 a.m. dose of Acular. Although R32 was provided her 5 p.m. dose as prescribed, she was not provided the medication at all on

January 4 and 5. CMS Ex. 1, at 100; CMS Ex. 16, at 30. The MAR also indicates that Spiriva was not administered to R32 on January 4, 2011. CMS Ex. 1, at 100; CMS Ex. 16, at 27. With respect to Zestril, R32's MARs show that she received this medication once a day from November 5-12, 2010 (CMS Ex. 16, at 19), then did not receive it again until January 1, 2011 (CMS Ex. 16, at 10, 27-28). R32 then did not receive Zestril again from January 2-5, 2011, even though the order for daily administration was renewed monthly. CMS Ex. 16, at 27-28. According to the SOD, a nurse had mistakenly noted on the MAR that R32's Zestril was discontinued. CMS Ex. 1, at 100-01.

In addition, CMS alleges that R32's records show that Petitioner administered R32 too many doses of Zocor, a medication to control high levels of cholesterol in the blood. R32 was supposed to receive Zocor on Mondays, Wednesdays, and Fridays, as her prescriber ordered, but Petitioner's staff documented that Zocor was administered every day. CMS Ex. 1, at 102-03.

Petitioner has conceded that some pharmaceutical errors occurred. In a Medication Error Reporting Form dated January 1, 2011, Petitioner's staff stated that Acular and Spiriva were not given to R32 because the facility ran out of these medications. Staff also noted that these medications were ordered too late. CMS Ex. 16, at 5. Another Medication Error Reporting Form, dated January 4, 2011, states that Petitioner did not administer Zestril to the resident from November 12 through December 31, 2010, nor did Petitioner administer it on January 2 and 3, 2011. The form indicates also that Petitioner administered Zocor to R32 every day from November 5 through November 30, 2010, when it was supposed to be administered only on Mondays, Wednesdays, and Fridays. CMS Ex. 16, at 4. Staff noted that there was a documentation error that started as a transcription error. In explaining these errors, Petitioner's staff wrote on the form, "[n]urse yellowed out Zestril by mistake. Zestril was just above Zocor and Zocor was rewritten on the day Zestril was yellowed out. [I] [f]eel the nurse yellowed Zestril by mistake. End of month order check did NOT catch this mistake."[4] CMS Ex. 16, at 4.

Petitioner's DON, Ms. Williams, concedes that staff made several errors with respect to R32's medications. P. Ex. 1, at 11. However, she asserts that none of the errors harmed, or had the potential to cause more than minimal harm to R32, and that the errors "plainly represent human errors and do not reflect some inadequacy in Petitioner's pharmacy

[4] Petitioner asserts that it is universally recognized that highlighting an order in yellow means that the order has been discontinued. P. Br. at 23.

systems". [5] *Id.* at 12.

Although Ms. Williams admits that "Zocor continued to be administered per the now-incorrect MAR every day through November," she claims that the December MAR correctly showed "X's" in the boxes for Sunday, Tuesday, Thursday, and Saturday, indicating that Zocor was to be administered only on Mondays, Wednesdays, and Fridays, and that Zocor was, in fact, administered correctly in December. *See* P. Ex. 13, at 1. Ms. Williams states further that a nurse who noticed that the phrase "at bedtime" had been incorrectly written in the Zocor box intended to correct this error, but instead mistakenly highlighted in yellow the order for Zestril, which is above the order for Zocor on the MAR. As a result, nursing staff believed that Zestril had been discontinued and stopped administering this medication to R32 through December. Ms. Williams stated that this error was caught and corrected before the survey. According to Ms. Williams, "there is no indication that too much Zocor or too little Zestril caused any harm to [R32]" (P. Ex. 1, at 12; P. Ex. 15), and she claims that she confirmed that R32's blood pressure remained under control even though she did not receive Zestril for several weeks. P. Ex. 1, at 12.

As for the alleged missed doses of Acular and Spiriva, Ms. Williams questions whether this was actually the case based on R32's MAR. P. Ex. 1, at 13. She acknowledges that the MAR does reflect that R32 did not receive some doses of Acular during January 1-5, 2011, but she claims that it also shows that some doses were administered, which would suggest that Acular was not unavailable. P. Ex. 1, at 13. Ms. Williams concedes that, on January 4, 2011, one dose of Spiriva was missed but gave no reason to explain why, and there were no missed doses documented in December 2010 or January 2011.

For summary judgment purposes, I accept Ms. Williams' claims as true. However, her statements, even when interpreted in a light most favorable to Petitioner, do not dispute CMS's allegations that Petitioner's staff committed numerous pharmaceutical errors with respect to R32. Petitioner has conceded that its staff made numerous pharmaceutical errors: R32 received more Zocor than she was prescribed; she received less Zestril than she was prescribed (in fact, it was discontinued for several weeks); and, on certain dates, she did not receive her prescribed doses of Spiriva and Acular because the facility ran out of the medication. It is clear that Petitioner's pharmacy system was not accurate in

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[5] While Petitioner concedes that there were medication errors, it consistently attempts to analyze them under the requirements of section 483.25(m) and not the pharmaceutical deficiency at issue here under section 483.60. Nonetheless, the Board has found that it is a facility's burden under 483.60(a) to rebut CMS's showing that a drug was not available to a resident who was taking it regularly. *See Western Care Management Corp., d/b/a Rehab. Specialties Inn*, DAB No. 1921 (2004).

assuring that its residents received medications as ordered and required to meet their needs.

Moreover, I reject Ms. Williams' conclusions that none of Petitioner's pharmaceutical errors harmed or had the potential for causing more than minimal harm to R32. To the contrary, R32 could have experienced adverse effects and potentially serious harm as a result of Petitioner's staff's failure to give her the medications she had been prescribed. For example, she could have untreated symptoms including breathing problems from a missed dose of Spiriva and increased blood pressure due to missing Zestril from November 12 through December 31, 2010, and on January 2 and 3, 2011. With respect to Zocor, R32 could have suffered serious adverse effects from the fact that she received it every day instead of her prescribed dose, which was only on Mondays, Wednesdays, and Fridays. Zocor is a prescribed drug, and the Mayo Clinic warns that one of its side effects may include difficulty with breathing. CMS Ex. 24, at 7. Especially considering R32 was prescribed Spiriva for existing breathing problems, this error had the potential for causing more than minimal harm.

In Petitioner's view, the pharmaceutical errors resulted from "human errors" and not from inadequacies in Petitioner's pharmacy system. P. Br. at 15 and 17. As noted in *Barn Hill Care Ctr.*, DAB No. 1848, at 18 (2002), the regulatory requirements offer no "human error" exception:

> Indeed, it is difficult to imagine any deficiency that is not, at its core, attributable to "human error." A facility, therefore, puts in place systems that minimize the chance for "human error."

As with R10, Petitioner's staff committed multiple pharmaceutical errors with respect to R32 and these errors establish that Petitioner failed to ensure that systems were in place to accurately dispense and administer drugs to meet R32's needs, in violation of 42 C.F.R. § 483.60(a) and (b). Additionally, Petitioner failed to have a system in place to reorder prescribed medications, and it failed to promptly remedy this situation. These errors had the potential for more than minimal harm to both R10 and R32. Based on the undisputed facts above, I find that Petitioner was not in substantial compliance with 42 C.F.R. § 483.60(a) and (b).

C. CMS is entitled to summary judgment that Petitioner was not in substantial compliance with 42 C.F.R. § 483.75(l)(1) because the undisputed evidence establishes Petitioner did not maintain clinical records on R8, R10, and R32 that were complete and accurately documented.

42 C.F.R. § 483.75(l)(1) requires a facility to maintain clinical records on each resident, in accordance with accepted professional standards and practices that are complete, accurately documented, readily accessible, and systematically organized.

CMS principally relies on the same facts that I have already discussed for the deficiencies under 42 C.F.R. §§ 483.25 and 483.60(a) and (b). With respect to R8, CMS cites the inaccurate and incomplete facility records created when Petitioner administered Haldol to the resident. CMS Ex. 1, at 115, 125-26. With respect to R10's clinical record, CMS refers to the missed doses and other errors relating to the administration of Oxycontin and oxycodone. CMS Ex. 1, at 115-20. As for R32's record, CMS cites the missed doses of Acular, Spiriva, and Zestril, as well as the fact that the resident received too many doses of Zocor. CMS Ex. 1, at 120-24.

CMS alleges also that R8's records regarding receipt of the drug Remeron, used to treat depression, were not accurate. CMS Ex. 1, at 115. According to the SOD, R8 had a physician's order, dated December 28, 2010, for 7.5 mg. of Remeron every evening. However, staff transcribed this order as "75" mg., not "7.5" mg. and entered "Remeron 75 mg." every evening on the December 2010 and January 2011 MAR. As alleged in the SOD, Petitioner's staff initialed the administration of 75 mg. of Remeron every night to R8 from December 29, 2010. CMS Ex. 1, at 124-25. CMS notes, however, that according to the SOD, Petitioner's staff apparently did provide the correct dose by cutting 15 mg. tablets of Remeron in half. CMS Ex. 1, at 125; CMS Br. at 18.

In its hearing request, Petitioner acknowledges that errors existed in the medical records, but attempts to attribute any discrepancies to "software glitches." P. Hearing Request at 12. To support its assertion that none of the errors in the medical records constitute a violation of 42 C.F.R. § 483.75(l)(1), Petitioner points to DON Williams' statements that clinical records are to serve as "ongoing guidance to the variety of caregivers who interact with each resident over time . . . and a historical record of the resident's condition, status . . . over time." P. Response at 26; P. Ex. 1, at 13-14.

As already discussed above with the other two deficiencies, the undisputed evidence shows that the clinical records of R8, R10, and R32 were neither complete nor accurate and contained significant documentation errors. With respect to R10 and R32, Petitioner's staff committed numerous documentation errors in their medication records, which resulted in missed doses, under-dosing, and excessive doses.

R8's records were not accurate or complete because Petitioner did not monitor R8 to assure the Haldol was effective in treating R8's symptoms or for adverse effects. The alleged readmission assessment that NP Lockwood conducted is also not contained in R8's clinical record. Further, the MAR reflects that R8 was only provided Haldol from December 14-28 and December 30-31, 2010. CMS Ex. 7, at 32. Although Petitioner argues that R8 medically required Haldol upon readmission through January 6, 2011, when NP Lockwood discontinued it, there is no evidence, either in the MAR or in the progress or nursing notes, that Petitioner administered Haldol to R8 on December 13, December 29, or at any time in January. Nor does the record contain any explanation as

to whether the Haldol was provided as ordered, and not documented, or whether it simply was not provided at all. *See* CMS Ex. 7.

Petitioner failed to maintain clinical records on R8, R10, and R32 that were complete and accurately documented. The inaccurate, incomplete, and error-filled records had the potential for causing more than minimal harm to R8, R10, and R32, as I previously discussed for the underlying deficiencies. Based on the undisputed facts above, I find that Petitioner was not in substantial compliance with 42 C.F.R. § 483.75(l)(1).

D. The penalty CMS imposed is reasonable.

I next consider whether the CMP is 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.

Unless a facility contends that a particular regulatory factor does not support the CMP amount, the ALJ must sustain it. *Coquina Center*, DAB No. 1860 (2002). In its hearing request, Petitioner simply makes a general assertion that it "specifically challenges the amount of the CMP." P. Hearing Request at 13. However, in its response in opposition to CMS's motion for summary judgment, Petitioner provides no further information or details as to the basis of this challenge. Petitioner does not contest the length of time during which CMS imposed the CMP or claim that its financial condition affects its ability to pay.

As previously noted, I find that the administration of unnecessary drugs violation (42 C.F.R. § 483.25(l)) alone justifies the amount of the CMP. Administering an antipsychotic drug without adequate monitoring in an elderly patient for an extended period of time is a serious deficiency, for which I find the facility culpable. The additional violations further support the $700 per day CMP imposed from January 12 through February 14, 2011.

I note that the $700 penalty is at the lower end of the lower range of penalties, which varies from $50 - $3,000. 42 C.F.R. § 488.438(a)(1)(ii). Further, the facility has a long history of noncompliance. In the past two years alone, various surveys of Petitioner – annual health certification surveys, complaint surveys, and Life Safety Code surveys – have resulted in findings of numerous deficiencies. CMS Ex. 27. Among other surveys finding deficiencies, a December 10, 2009 annual recertification survey resulted in a

finding of immediate jeopardy under Tag F323 (accidents and supervision) for which Petitioner was assessed a CMP of $11,400. CMS Ex. 27, at 3. I note that at a complaint survey conducted on April 7, 2009, Petitioner was cited, among other things, for failing to be in substantial compliance with Tag F425 (pharmacy services), at the "D" level of scope and severity. CMS Ex. 27, at 4. This tag is one of the deficiencies discussed above. Petitioner has thus demonstrated repeated noncompliance under Tag F425, a fact that supports an aggravated penalty amount.

For the reasons set forth above, I grant summary judgment in favor of CMS and find that the remedy imposed is reasonable.

/s/
Joseph Grow
Administrative Law Judge