Department of Health and Human Services

DEPARTMENTAL APPEALS BOARD

Civil Remedies Division

Asistencia Villa Rehabilitation and Care Center,
(CCN: 55-5379),

Petitioner,

v.

Centers for Medicare & Medicaid Services.

Docket No. C-16-13

Decision No. CR4947

Date: October 5, 2017

DECISION

Petitioner, Asistencia Villa Rehabilitation and Care Center, is a long-term care facility located in Redlands, California, that participates in the Medicare program. Based on a survey completed July 24, 2015, the Centers for Medicare & Medicaid Services (CMS) determined that the facility was not in substantial compliance with multiple Medicare requirements, including those that govern pharmaceutical services and medication errors. CMS also determined that the facility's deficiencies posed immediate jeopardy to resident health and safety. It has imposed civil money penalties (CMPs) of $6,200 per day for one day of immediate jeopardy and $250 per day for 39 days of substantial noncompliance that was not immediate jeopardy ($9,750). Petitioner limits its appeal to the deficiencies cited at the immediate jeopardy level, one additional citation, and the immediate jeopardy determination itself.

CMS has moved for summary judgment, which Petitioner opposes.

I grant CMS's motion.

Based on the determinations Petitioner does not challenge, the facility was not in substantial compliance with Medicare program requirements from July 4 through September 7, 2015, and the penalty imposed for that period ($250 per day) is reasonable. As discussed below, the undisputed evidence also establishes that the facility was not in substantial compliance with the regulations governing pharmacy services and medication errors; those deficiencies posed immediate jeopardy to resident health and safety; and the penalty imposed for the one day of immediate jeopardy ($6,200) is reasonable.

Background

The Social Security Act (Act) sets forth requirements for nursing facilities to participate 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 survey skilled nursing facilities in order to determine whether they are in substantial compliance. Act § 1864(a); 42 C.F.R. § 488.20. Each facility must be surveyed annually, with no more than fifteen months elapsing between surveys, and must be surveyed 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. The state agency must also investigate all complaints. Act § 1819(g)(4).

In this case, on July 24, 2015, surveyors from the California Department of Public Health (state agency) completed the facility's annual recertification survey. Based on their findings, CMS determined that the facility did not comply substantially with the following program requirements:

- 42 C.F.R. §§ 483.20(m) and (e) (Tag F285 – resident assessment: pre-admission screening and coordination) at scope and severity level D (isolated instance of noncompliance that causes no actual harm with the potential for more and minimal harm);

- 42 C.F.R. § 483.25 (Tag F309 – quality of care) at scope and severity level D;

- **42 C.F.R. § 483.25(m)(2) (Tag F333 – quality of care: medication errors) at scope and severity level K (pattern of noncompliance that poses immediate jeopardy to resident health and safety)**; [1]

[1] I highlight, in bold, the deficiencies that Petitioner appealed.

- **42 C.F.R. § 483.35(i) (Tag F371 – dietary services: sanitary conditions) at scope and severity level F (widespread substantial noncompliance that causes no actual harm with the potential for more than minimal harm)**;

- 42 C.F.R. § 483.40(b) (Tag F386 – physician services: visits) at scope and severity level E (pattern of noncompliance that causes no actual harm with the potential for more than minimal harm);

- 42 C.F.R. § 483.40(c)(1)-(2) (Tag F387 – physician services: frequency of visits) at scope and severity level D;

- **42 C.F.R. § 483.60(a) and (b) (Tag F425 – pharmacy services: procedures and consultation) at scope and severity level K**;

- 42 C.F.R. § 483.60(c) (Tag F428 – pharmacy services: drug regimen review) at scope and severity level E;

- 42 C.F.R. § 483.60(b)(d) and (e) (Tag F431 – pharmacy services: service consultation, labeling, and storage) at scope and severity level E; and

- 42 C.F.R. § 483.75(*l*)(1) (Tag F514 – administration: clinical records) at scope and severity level E.

P. Ex. 1; *see* CMS Ex. 1.

Thereafter, CMS determined that the facility returned to substantial compliance on September 8, 2015. CMS has imposed against the facility penalties of $6,200 per day for one day of substantial noncompliance that posed immediate jeopardy to resident health and safety (July 24) and $250 per day for 39 days of substantial noncompliance that did not pose immediate jeopardy (July 25 – September 7), for penalties totaling $15,950. CMS Ex. 2.

Petitioner appealed but has limited its appeal to just three of the deficiency findings: 42 C.F.R. §§ 483.25(m); 483.35(i); and 483.60(a) and (b). CMS Ex. 1; Consent Motion for Partial Dismissal.

CMS now moves for summary judgment. Petitioner opposes. With its motion for summary judgment (CMS MSJ), CMS submitted nine exhibits (CMS Exs. 1-9). Petitioner submitted its opposition to summary judgment (P. Opp.) with 17 exhibits (P. Exs. 1-17).

Issues

As a threshold matter, I consider whether summary judgment is appropriate.

Based on the uncontested issues, from July 24 through September 7, 2015, the facility was not in substantial compliance with Medicare program requirements and a $250 per day penalty is reasonable. *See* 42 C.F.R. § 498.20(b); *Blossom South Nursing and Rehab Ctr*, DAB No. 2578 at 10-11 (2014) (affirming that CMS may impose a remedy whenever a facility is not in substantial compliance with program requirements).

The issues remaining are:

1. Was the facility in substantial compliance with 42 C.F.R. §§ 483.25(m)(2) and 483.60(a) and (b); [2]

2. If the facility was not in substantial compliance with sections 483.25(m)(2) and 483.60(a) and (b), did those deficiencies pose immediate jeopardy to resident health and safety; and

3. Is the penalty imposed for the period of immediate jeopardy – $6,200 for one day – reasonable.

Discussion

Summary judgment. Summary judgment is appropriate if a case presents no genuine issue of material fact, and the moving party is entitled to judgment as a matter of law. *Bartley Healthcare Nursing & Rehab.*, DAB No. 2539 at 3 (2013), *citing Celotex Corp.*

[2] Because it would serve no purpose, I decline to review the deficiencies cited under 42 C.F.R. § 483.35(i). The deficiency was not cited at the immediate jeopardy level, so it does not affect the immediate jeopardy finding. I have no authority to review the F-level scope and severity finding. 42 C.F.R. § 498.3(b)(14). Petitioner has not challenged the $250 per day penalty imposed from July 25 through September 7, so resolving the section 483.35(i) issue would not affect the penalty. In any event, the multiple deficiencies that Petitioner concedes more than support the $250 per day penalty. *See Perry Cty. Nursing Ctr. v. U.S. Dep't. of Health & Human Servs*, 603 F. App'x. 265, 271 (2015); *Claiborne-Hughes Health Ctr. v. Sebelius*, 609 F.3d 839, 847 (2010); *Carrington Place of Muscatine*, DAB No. 2321 at 20-21 (2010); *Senior Rehab. & Skilled Nursing Ctr.*, DAB No. 2300 at 6 n.5 (2010), *aff'd Senior Rehab. & Skilled Nursing Ctr. v. HHS*, No. 10-60241 (2011); s*ee also* 42 C.F.R. § 498.3(b)(13) (limiting review to findings that result in CMS imposing a penalty).

v. Catrett, 477 U.S. 317, 322-25 (1986); *Ill. Knights Templar Home*, DAB No. 2274 at 3-4 (2009), and cases cited therein.

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. v. Dep't of Health & Human Services*, 388 F.3d 168, 173 (6th Cir. 2004) (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. *Matsushita Elec. Indus. Co. v. Zenith Radio Corp.*, 475 U.S. 574, 586 n.11 (1986); s*ee also Vandalia Park*, DAB No. 1939 (2004); *Lebanon Nursing & Rehab. Ctr.*, DAB No. 1918 (2004). The non-moving party may not simply rely on denials, but must furnish admissible evidence of a dispute concerning a material fact. *Ill. Knights Templar*, 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 172; *Guardian Health Care Ctr.*, DAB No. 1943 at 8 (2004); *but see Brightview*, DAB No. 2132 at 10 (entry of summary judgment upheld 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. *Cf. 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.").

1. ***CMS is entitled to summary judgment because the undisputed evidence establishes that facility staff administered to two residents an unsafe combination of drugs; they stored fentanyl patches in emergency kits, violating state law; and supervisory nursing staff did not know that fentanyl patches must <u>never</u> be administered to any resident before insuring that he/she is opioid-tolerant. These deficiencies put the facility out of substantial compliance with 42 C.F.R. §§ 483.60(a) and (b) and 483.25 (m)(2).***[3]

<u>Program requirements</u>. The facility must provide routine and emergency drugs to its residents. Its pharmaceutical services (including procedures that assure the accurate

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

acquiring, receiving, dispensing, and administering of all drugs and biologicals) must meet the needs of each resident. 42 C.F.R. § 483.60(a). To this end, the facility must employ or obtain the services of a licensed pharmacist who: 1) consults "on all aspects" of providing pharmacy services in the facility; 2) establishes a system of records showing the receipt and disposition of all controlled drugs "in sufficient detail to enable an accurate reconciliation"; and 3) determines that drug records are in order and that an account of all controlled drugs is maintained and reconciled periodically. 42 C.F.R. § 483.60(b)

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

Unsafe drug combination. Resident M suffered from hypertension, diseases of the esophagus, spinal cord injury, and the late effects of cardiovascular disease. CMS Ex. 3 at 2. Resident N, who had suffered a cerebrovascular accident (stroke), was also diagnosed with the late effects of cerebrovascular disease, hemiplegia (paralysis) affecting the dominant side, dysphagia (difficulty swallowing), hypertension, esophageal reflux, and osteoarthritis. CMS Ex. 4 at 2.[4]

CMS maintains – and Petitioner does not dispute – that facility staff concurrently administered two drugs – the proton-pump inhibitor omeprazole (Prilosec/Prilosec OTC) and the blood thinner clopidogrel (Plavix) – to Residents M and N. CMS Exs. 3 and 4. In doing so, the facility was administering an unsafe combination of drugs, particularly since these residents were at risk for heart attacks or strokes.

The Food and Drug Administration mandates that pharmaceutical companies include with a drug's package insert information warning about its adverse effects. A "black box warning" is the strongest of the mandated warnings, and its use indicates that the drug carries significant – even life threatening – adverse effects. P. Ex. 1 at 80.

In an announcement dated November 18, 2009, the Food and Drug Administration warned to avoid using Plavix with Prilosec. CMS Ex. 6 at 1. "Patients at risk for heart attacks or strokes who use clopidogrel to prevent blood clots will not get the full effect of this medicine if they are also taking omeprazole." CMS Ex. 6 at 3. The FDA warned

[4] In an apparent effort to protect privacy, CMS has obliterated information, including age and gender, from these residents' records. Such information is often relevant in determining the risks medications might pose to the individual.

that patients taking clopidogrel should not take even over-the-counter forms of omeprazole. CMS Ex. 6 at 4. These warnings are included with clopidogrel's packaging insert as black box warnings. CMS Ex. 6 at 4. Since issuing the warnings, the FDA has repeated them in "drug safety communications." CMS Ex. 6 at 10, 12. The facility's written policies echo the warning. P. Ex. 1 at 71-72.

Notwithstanding the FDA warnings and the facility's own policy, for more than three years, the facility administered this unsafe combination of drugs to Resident M. CMS Ex. 3 at 2. Both drugs were prescribed to Resident N on the same day, January 29, 2015, so, by the time the surveyors caught the problem, that resident had been taking the unsafe combination for more than seven months. CMS Ex. 4 at 2; P. Ex. 1 at 71. I consider these significant medication errors. Further, the facility was not meeting the pharmaceutical needs of either Residents M or N – in fact, it was jeopardizing their health and safety. By repeatedly failing to catch such a basic error, the facility's licensed pharmacist was not providing the level of consultation required by the regulation. The facility was therefore out of substantial compliance with 42 C.F.R. § 483.60(a) and (b), as well as § 483.25(m)(2).[5]

Violation of state law in storing the narcotic, fentanyl. Fentanyl is a potent narcotic analgesic. Transdermal fentanyl (Duragesic) comes as a patch that is applied to the skin. CMS Ex. 8.

An emergency kit is a sealed container of medications that a facility may use if required medications are not available. By regulation, California limits a facility's emergency kit usage. With limited exceptions, "legend" (i.e., prescription) drugs may *not* be stored in emergency supply kits. For analgesics, such as fentanyl, the kit may have "[n]ot more than six emergency drugs in solid, oral dosage form or suppository dosage form. . ." The drugs must be in sealed containers, and "[n]ot more than four doses of any one drug may be so stored." Cal. Code Regs. Tit. 22 § 72377; CMS Ex. 7 at 3.

CMS maintains that the facility stored two 50 mcg/hr (micrograms per hour) and two 25 mcg/hr fentanyl patches in its emergency kit, violating state law. CMS Ex. 5 at 3; CMS MSJ at 2, 16 n. 2; P. Ex. 1 at 51, 80. Petitioner has not come forward with any evidence suggesting that it disputes that it stored fentanyl patches in the kit, and, in fact, has not denied doing so. A fentanyl patch is not an oral dose nor a suppository dose and, under the California regulation, may not be stored in an emergency kit. Indeed, it is difficult to imagine any justification for storing this potent drug – which is generally used for chronic (not acute) pain that is not well-controlled by other medications (CMS Ex. 9 at 1) – in an

[5] Petitioner concedes that it was also out of substantial compliance with section 483.60(c), which mandates that the pharmacist report any irregularities to the attending physician and director of nursing and that the facility act upon the pharmacist's report.

emergency kit, and Petitioner has offered none. That the facility did so again shows that the facility's pharmacist was not providing the level of service required by sections 483.60(a) and (b), which put the facility out of substantial compliance with those provisions. *See also* 42 C.F.R. § 483.60(e).[6]

Administering fentanyl patches without determining resident tolerance. Fentanyl is a powerful drug, and the patches – called the "fentanyl transdermal system (Duragesic) – administer it in significant doses. Not surprisingly, the package insert includes a black box warning. Highlighting that black box warning is the caption: "**FOR USE IN OPIOID-TOLERANT PATIENTS ONLY**." CMS Ex. 1 at 1 (emphasis in original). The warning explains that Duragesic contains a high concentration of "a Schedule II opioid agonist, fentanyl," which has the highest potential for abuse and associated risk of fatal overdose. CMS Ex. 8 at 1. The black box warning emphasizes how dangerous it is to administer the drug to individuals who are not known to be opioid-tolerant and posts that warning three additional times:

- **DURAGESIC® should ONLY be used in patients who . . . have demonstrated opioid tolerance . . . .**

- **Because serious or life-threatening hypoventilation could occur, DURAGESIC® (fentanyl transdermal system) is contraindicated:**

    - **in patients who are not opioid-tolerant . . . .**

- **DURAGESIC® is ONLY for use in patients who are already tolerant to opioid therapy of comparable potency. Use in non-opioid tolerant patients may lead to fatal respiratory depression.**

CMS Ex. 8 at 1-2 (emphasis in original); *see* CMS Ex. 9. The facility had in place written policies that echo these warnings. P. Ex. 1 at 80-81.

CMS asserts that, notwithstanding these dire warnings, the facility's nurse supervisor confirmed that staff would administer the drug so long as they had a physician order, without regard to whether the resident was opioid-tolerant. CMS MSJ at 19-20; P. Ex. 1 at 82. Petitioner has not challenged the allegation, much less come forward with evidence suggesting any dispute over its underlying facts. Nor has Petitioner suggested that it had in place any system to ensure that fentanyl patches (which were, after all, available to staff in the emergency kits) were administered only to those who could safely tolerate them. Supervisory staff were unaware of the dangers posed by administering the

[6] Petitioner also concedes that it was out of substantial compliance with section 483.60(e), which mandates that, in storing drugs and biologicals, facilities comply with federal and state laws.

drug without screening for opioid-tolerance. This put residents at serious risk. Under section 483.60(a), the facility should have assured that its staff understood and followed the procedures it had in place to prevent such errors in the dispensing and administering of drugs. Because it did not, the facility was not in substantial compliance with that regulation.[7]

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

Immediate jeopardy. Immediate jeopardy exists if a 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). The Board has observed repeatedly that the "clearly erroneous" standard imposes on facilities a "heavy burden" to show no immediate jeopardy and has sustained determinations of immediate jeopardy where CMS presented evidence "from which '[o]ne could reasonably conclude' that immediate jeopardy exists." *Barbourville Nursing Home*, DAB No. 1931 at 27-28 (2004), *citing Koester Pavilion*, DAB No. 1750 (2000); *Daughters of Miriam Ctr.*, DAB No. 2067 at 7, 9 (2007).

Here, through ignorance or indifference, the facility's pharmacist and nursing staff simply disregarded the Food and Drug Administration's black box warnings on medications. As a result, two residents, who were at serious risk for heart attacks or stroke, were administered a medication known to diminish the effectiveness of the medication prescribed to protect them from blood clots. That these individuals had apparently not been seriously harmed is fortuitous. Nevertheless, administering this combination of drugs without considering the black box warnings is likely to cause the residents serious harm.

Equally disturbing, facility staff did not appreciate the dangers posed by Duragesic. It was stored and available in the emergency kit, even though it is used for chronic, not acute, pain and should be administered only to those residents who are opioid-tolerant. But the supervisory nursing staff were unaware of that. The availability of the drug combined with the supervisory nurse's ignorance and the general absence of meaningful oversight by the facility's pharmacist created a situation that was likely to cause serious harm to a resident.

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[7] Although CMS cited multiple additional instances of facility errors under pharmacy services and medications, for summary judgment purposes, it did not rely on any allegations that Petitioner challenged.

Because the facility's deficiencies were likely to cause serious harm to vulnerable facility residents, CMS's determination that the deficiencies posed immediate jeopardy to resident health and safety is not clearly erroneous.

3. The $6,200 penalty imposed for one day of immediate jeopardy is reasonable.

To determine whether a civil money penalty is reasonable, I apply 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.

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 section 488.438(f) 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).

Here, CMS imposes a $6,200 penalty for one day of immediate jeopardy, which is in the mid-range for a per day CMP ($3,050 to $10,000). 42 C.F.R. §§ 488.408(e)(1)(iii), 488.438(a)(1)(i). Considering the relevant factors, the penalty is reasonable.

First, except to argue that its deficiencies did not pose immediate jeopardy so CMS should not have imposed a higher-range penalty, Petitioner does not challenge the amount of the penalty.

With respect to the regulatory criteria, CMS does not argue that the facility's history justifies a higher CMP. Petitioner does not claim that its financial condition affects its ability to pay the penalty.

Applying the remaining factors, I find deeply troubling the facility's disregard for something as vital as a black box warning. Its pharmacist was not paying attention to drug combinations; and its nurses had not been properly trained to heed those warnings. Moreover, storing Duagesic in an emergency kit, making it accessible to staff and implying that it was an appropriate emergency medication, when it is not, represented serious shortcomings with the facility's pharmacy services, for which the facility is culpable.

Finally, the facility had multiple additional instances of substantial noncompliance (scope and severity levels D and E), which Petitioner has not challenged and which, combined with the immediate jeopardy deficiencies, justify a penalty above the minimum for that one day.

Conclusion

For these reasons, I grant CMS's motion for summary judgment. The facility was not in substantial compliance with program requirements from July 4 through September 7, 2015. The undisputed evidence establishes that its deficiencies posed immediate jeopardy to resident health and safety. The penalties imposed – $6,200 per day for one day of immediate jeopardy and $200 per day for 39 days of substantial compliance that did not pose immediate jeopardy – are reasonable.

/s/
Carolyn Cozad Hughes
Administrative Law Judge