Department of Health and Human Services

DEPARTMENTAL APPEALS BOARD

Civil Remedies Division

Orange Tree Nursing Center,
(CCN: 55-5017),

Petitioner,

v.

Centers for Medicare & Medicaid Services.

Docket No. C-15-3981

Decision No. CR4936

Date: September 15, 2017

DECISION

Petitioner, Orange Tree Nursing Center ("Orange Tree" or "the facility"), challenges, *inter alia*, the determination by the Centers for Medicare & Medicaid Services (CMS) that it was not in substantial compliance with the Medicare program participation requirement that each resident of a skilled nursing facility (SNF) must receive and the facility must provide the necessary care and services to attain or maintain the highest practicable physical, mental, and psychosocial well-being, in accordance with the comprehensive assessment and plan of care. 42 C.F.R. § 483.25. Petitioner also challenges the imposition of a per-instance civil money penalty (CMP) of $3,000. For the reasons discussed below, I affirm CMS's determination.

I. Background

The Social Security Act (Act) establishes requirements for SNF participation in the Medicare program and authorizes the Secretary of Health and Human Services ("the Secretary") to promulgate regulations implementing those statutory provisions. *See* 42 U.S.C. § 1395i-3; 42 C.F.R. parts 483 and 488. To participate in the Medicare program, an SNF must maintain substantial compliance with program participation requirements. In order to be in substantial compliance, an SNF's deficiencies may "pose no greater risk

to resident health or safety than the potential for causing minimal harm." 42 C.F.R. § 488.301. "Noncompliance" means "any deficiency that causes a facility to not be in substantial compliance." 42 C.F.R. § 488.301.

The Secretary contracts with state agencies to conduct periodic surveys to determine whether SNFs are in substantial compliance with program participation requirements. 42 U.S.C. § 1395aa(a); 42 C.F.R. § 488.10. The Act also authorizes the Secretary to impose enforcement remedies against SNFs that are not in substantial compliance with the program participation requirements, and these regulations specify the enforcement remedies that can be imposed. 42 U.S.C. § 1395i-3(h)(2); 42 C.F.R. § 488.406. Among other enforcement remedies, CMS may impose a per-day CMP for the number of days an SNF is not in substantial compliance or a per-instance CMP for each instance of the SNF's noncompliance. 42 C.F.R. § 488.430(a). At the time of the February 2014 survey, a per-day CMP could range from $50 to $3,000 for noncompliance that did not pose immediate jeopardy to the health and safety of residents.[1] 42 C.F.R. § 488.438(a)(2). At the time of the survey, a per-instance CMP could range from $1,000 to $10,000.[2] 42 C.F.R. § 488.438(a)(2).

If CMS imposes a CMP based on noncompliance, then the facility may request a hearing before an administrative law judge (ALJ) to challenge the noncompliance finding and enforcement remedy. 42 U.S.C. §§ 1320a-7a(c)(2), 1395i(h)(2)(B)(ii)); 42 C.F.R. §§ 488.408(g), 488.434(a)(2)(viii), 498.3(b)(13).

Petitioner is an SNF located in Riverside, California that participates in the Medicare and Medicaid programs. The California Department of Public Health (survey agency) completed an abbreviated standard survey to investigate two complaints at Petitioner's facility on February 25, 2014. CMS Exhibits (Exs.) 1, 3. In a June 16, 2015 initial determination, CMS stated that it concurred with the state survey agency's findings, based on the February 25, 2014 survey, that determined that Petitioner was not in substantial compliance with two program requirements cited at the "D" and "G" levels of scope and severity.[3] CMS Ex. 3 at 1; *see* CMS Ex. 1. The deficiencies cited were as follows:

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[1] "Immediate jeopardy" exists when "the provider's noncompliance with one or more requirements of participation has caused, or is likely to cause, serious injury, harm, impairment, or death to a resident." 42 C.F.R. § 488.301.

[2] CMP amounts increased, effective February 3, 2017, for violations occurring after November 2, 2015. *See* 82 Fed. Reg. 9,174 (February 3, 2017).

[3] Scope and severity levels are used by CMS and state survey agencies when selecting remedies. The scope and severity level is designated by letters A through L. Pub. 100-7, State Operations Manual, § 7400.5.1 (Factors That Must be Considered

1. 42 C.F.R. § 483.10(b)(11), F157 (Physician Consultation and Notification) at the "D" level of scope and severity (s/s) (no actual harm with potential for more than minimal harm that is not immediate jeopardy);

2. 42 C.F.R. § 483.25, F309 (Quality of Care) at the "G" level of s/s (actual harm that is not immediate jeopardy).

CMS Ex. 1 at 1, 9. CMS advised Petitioner that it was imposing an enforcement remedy based only on Petitioner's failure to substantially comply with 42 C.F.R. § 483.25. CMS Ex. 3 at 2. CMS imposed a per-instance CMP of $3,000 for that deficiency. CMS Ex. 3 at 2.

Petitioner submitted a request for hearing dated August 13, 2015, that was received on August 19, 2015. I issued an Acknowledgment and Pre-Hearing Order on September 14, 2015, establishing a schedule for filing briefs and pre-hearing exchanges.

CMS filed a pre-hearing brief (CMS Br.) and 10 exhibits (CMS Exs. 1-10), and Petitioner filed a pre-hearing brief (P. Br.) and 29 exhibits (P. Exs. 1-29). In an Order dated May 3, 2016, I admitted CMS Exs. 1-10 and P. Exs. 1-2, 3 (pages 1 and 2 only), 4, 6-14, 16, 18, 20-22, and 25-29.[4] In a subsequent Order dated June 2, 2016, I admitted CMS Ex. 13, which had been submitted immediately prior to the hearing.

On May 9, 2016, I convened a hearing to give the parties an opportunity to cross-examine the witnesses who provided written direct testimony. CMS cross-examined Director of Nursing Linda Blankenship and "RN Supervisor" Carolina Montoya. *See* P. Exs. 10, 12. Petitioner cross-examined CMS's witness, state surveyor Omar Fausto. *See* CMS Ex. 7. The parties submitted post-hearing briefs (CMS Post-Hearing Br.; P. Post-Hearing Br.) and post-hearing reply briefs (CMS Reply; P. Reply).

When Selecting Remedies), "Assessment Factors Used to Determine the Seriousness of Deficiencies Matrix" (table), *https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/som107c07.pdf* (last visited August 29, 2017); *see* 42 C.F.R. § 488.408. As relevant here, a scope and severity level of D, E, or F indicates a deficiency that presents no actual harm but has the potential for more than minimal harm that does not amount to immediate jeopardy. A scope and severity level of G, H, or I indicates a deficiency that involves actual harm that does not amount to immediate jeopardy.

[4] In my Order, I provisionally admitted CMS Ex. 7 and P. Exs. 10 and 12 pending the appearance of the witnesses for cross-examination. All witnesses appeared for cross-examination.

II. Issues

The issues presented are:

1. Whether Petitioner failed to be in substantial compliance with the Medicare program participation requirement at 42 C.F.R. § 483.25.

2. If so, whether the $3,000 per-instance CMP for violating 42 C.F.R. § 483.25 is reasonable.

Although Petitioner challenges the "factual findings" underlying the deficiency cited under 42 C.F.R. § 483.10(b)(11), CMS imposed a CMP based only the deficiency cited under 42 C.F.R. § 483.25 (CMS Ex. 3 at 2). An SNF has a right to a hearing before an ALJ when CMS has "made an adverse 'initial determination' of a kind specified in 42 C.F.R. § 498.3(b)." 42 C.F.R. § 498.3(a)(1). However, it is only after CMS makes a finding that an SNF is noncompliant and imposes a remedy under 42 C.F.R. § 488.406, that the SNF has received an initial determination subject to further review. 42 C.F.R. § 498.3(b)(13); *Columbus Park Nursing & Rehab. Ctr.*, DAB No. 2316 at 6 (2010); *see also* 42 C.F.R. §§ 488.330(e)(3), 488.408(g)(1), 498.3(a)(1), 498.3(a)(3)(ii). Consistent with this, an SNF "has no right to an ALJ hearing to contest survey deficiency findings where CMS has not imposed any of the remedies specified in section 488.406 based on those findings, or where CMS imposed, but subsequently rescinded, any such remedies." *Southpark Meadows Nursing & Rehab. Ctr.*, DAB No. 2703 at 5 (2016), citing *Columbus Park*, DAB No. 2316 at 7. Therefore, I only have jurisdiction to adjudicate the alleged violation of 42 C.F.R. § 483.25 from the February 25, 2014 survey because it is the only deficiency for which CMS proposed an enforcement remedy.

III. Discussion[5]

A. The facility did not ensure that Resident A received and that it provided the necessary care and services to attain or maintain the highest practicable physical, mental, and psychosocial well-being as required by 42 C.F.R. § 483.25.

1. Petitioner's policy requires that facility staff notify, among others, a resident's physician if a resident has a significant change in condition.

2. Resident A had poor food consumption at nine consecutive meals on October 24-26, 2013, and then refused two meals on October 27, 2013.

[5] Findings of fact and conclusions of law are in bold and italics.

3. ***The facility telephonically contacted Resident A's son on October 25, 2013, to inform him that Resident A had not been eating well for a few days.***

4. ***Resident A's Minimum Data Set (MDS), dated October 5, 2013, assessed that she was "occasionally incontinent" with less than a total of seven episodes of incontinence in the week-long assessment period.***

5. ***Nursing notes document that Resident A was incontinent of urine 16 times in the 3½ day period from October 24 to 27, 2013.***

6. ***Resident A's son visited the facility on October 27, 2013, at which time he requested that Resident A be sent to the hospital for evaluation.***

7. ***Nursing staff from the facility discouraged Resident A's son's request for a transfer to the hospital and informed the son that Resident A's increased weakness could be due to the flu vaccine and that the facility could perform in-house diagnostic tests rather than transferring Resident A to the hospital.***

8. ***Nursing staff from the facility contacted Resident A's physician on October 27, 2013, at approximately 12:30 p.m., to communicate Resident A's son's request that she be transferred to a hospital, which was the first communication with the physician regarding Resident A since the physician ordered a flu vaccine on October 21, 2013.***

9. ***Resident A was transferred to an acute care hospital at the request of her son on October 27, 2013, and remained in the hospital for six days, until November 2, 2013.***

10. ***The hospitalization discharge diagnoses included sepsis secondary to urinary tract infection, suspected aspiration pneumonia, anemia, and candida esophagitis. Resident A's treatment included a blood transfusion and intravenous antibiotics.***

CMS asserts that Petitioner was not in substantial compliance with 42 C.F.R. § 483.25 with regard to Resident A. Specifically, CMS claims that the facility failed to identify

changes in Resident A's condition, which delayed her receipt of "treatment of a life threatening condition." CMS Br. at 7. Petitioner argues in its brief that "Resident A's alleged generalized weakness is not an unexpected change of condition, but a common result of a flu vaccine." P. Br. at 15.

The facility has a policy for reporting a change in a resident's condition, to include that "[i]t is the policy of this facility to ensure that the resident's physician and responsible party are notified in the event of a significant change in the resident's physical, mental, or psychosocial status, and to ensure that appropriate care and documentation occurs subsequent to such change." CMS Ex. 10 at 1. The facility's definition of a change of condition lists a number of "sudden or marked changes in," to include changes in vital signs, behavior, appetite ("refusing meals, decreased appetite"), and level of functioning. CMS Ex. 10 at 3.

Resident A was admitted to the facility on June 1, 2012. CMS Ex. 5 at 1. Resident A's medical history included diagnoses of leukocytosis, renal insufficiency, anemia, hypertension, diabetes mellitus, hypothyroidism, gastroesophageal reflux disease, osteoarthritis, cardiac arrhythmia, and hypercholesterolemia. CMS Ex. 5 at 1. Resident A was assessed as having a Brief Interview for Mental Status (BIMS) score of 15 in October 2013, which means that Resident A was "cognitively intact." CMS Ex. 5 at 10; *see* Long-Term Care Facility Resident Assessment Instrument 3.0 User's Manual, Chapter 3, Section C0050 (Summary Score), *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/NursingHomeQualityInits/Downloads/MDS-30-RAI-Manual-V113.pdf* (last visited August 29, 2017).

Resident A's MDS[6] completed on October 5, 2013, indicates that she was "occasionally incontinent" of bladder, meaning that "during the 7-day look-back period the resident was incontinent less than 7 episodes." Long-Term Care Resident Assessment Instrument 3.0 User's Manual, Section H0300; CMS Ex. 5 at 17. Nursing notes indicate that during the period from October 17 to 24, Resident A was incontinent of bladder nine times, which is consistent with the recent MDS assessment that she was "occasionally incontinent." CMS Ex. 5 at 51-53. However, Resident A was incontinent of bladder 16 times during the 3½ day period from October 24 to 27, 2013, with three episodes of incontinence on October 24, four episodes of incontinence on October 25, five episodes of incontinence on October 26, and four episodes of incontinence prior to her midday transfer to the hospital on October 27. CMS Ex. 5 at 41-42, 51-53.

An October 2013 food consumption log indicates that Resident A had poor food consumption at meals (defined by the facility as consumption of less than 50 percent of the meal) for all three meals offered on October 24, 25, and 26, and after nine meals with

[6] The MDS is an assessment of the resident's functional capacity. *See* 42 C.F.R. § 483.315.

poor food consumption, Resident A then refused both her breakfast and lunch on October 27. CMS Ex. 5 at 54. Further, of the 17 meals offered between October 22 and 27, Petitioner had poor consumption or refused 15 of those 17 meals. CMS Ex. 5 at 54. While there are earlier occasions on which Resident A had poor consumption of her meals, there is no similar period in which she had poor consumption or refused so many meals for such a prolonged period of time. CMS Ex. 5 at 54-56. In fact, on only two other days in the three-month period from August to October did Resident A have poor food consumption for all three meals in a single day (September 19 and October 19), and on only one occasion did Resident A have poor food consumption for as many as four consecutive meals (September 23-24).[7] CMS Ex. 5 at 54-56. In addition, Resident A did not outright refuse a meal at any time during the three-month period, except for on October 27. CMS Ex. 5 at 54-56. Petitioner's poor consumption or refusal of meals for eleven consecutive meals, and her poor consumption or refusal of 15 of 17 meals served over six days, is unquestionably a change in her pattern of food consumption and is a clear indication of a change in her appetite.

On October 25, 2013, Petitioner's staff took notice of Resident A's recent poor food consumption.[8] CMS Ex. 5 at 41. By that afternoon, Resident A had poor food consumption of nine of the previous 11 meals (including lunch), with poor consumption of her breakfast and lunch on October 22 and 23, and poor consumption of all meals on October 24 and 25. CMS Ex. 5 at 54. A 3:30 p.m. nursing note on October 25, 2013, indicates the following: "Resident not eating well few days. [Director of Nursing] informed, she stated that they will start on weekly weights. [Responsible Party] made aware, he is concern[ed] about it [and] he stated that he will come to visit as soon as possible." CMS Ex. 5 at 41. Another nurse who cared for Resident A, RN Supervisor

[7] Petitioner argues that "Resident A routinely ate poorly" and that her decreased appetite was "within her baseline condition." P. Reply at 5. Petitioner explained that when Resident A had a period of decreased food consumption in September 2013, it notified Resident A's physician. P. Reply at 5. Upon notification, Dr. Pfeifle ordered ferritin level testing and increased nutritional supplements. P. Reply 5; *see* CMS Ex. 5 at 48. However, when Resident A had a far more significant period of decreased food consumption in October 2013, Petitioner did not contact Resident A's physician.

[8] Petitioner contends that "the relevant time frame in this case is no longer than three days, from October 25 to 27, 2013." P. Reply, at 3. Petitioner ignores that, on October 25, 2013, it observed that Resident A had not been eating well for the past few days. CMS Ex. 5 at 41.

Carolina Montoya, stated the following, apparently with respect to the October 25, 2013 nursing note: "During the week when the resident had a change of condition, stop eating, is when the facility contacted [the] resident's son."[9] Transcript (Tr.) at 156.

Despite the fact that the facility notified Resident A's son that she was eating poorly and the Director of Nursing speculated that "they will start weekly weights," the facility did not notify Resident A's physician of her change in appetite or initiate any medical intervention. After the October 25 afternoon nursing note entry, Resident A continued to have poor food consumption, with poor consumption of her dinner that same evening, and poor consumption of all three meals the following day, on October 26, 2013. CMS Ex. 5 at 54. And then on October 27, 2013, Resident A refused her breakfast and lunch. CMS Ex. 5 at 54.

Resident A's son visited the facility on October 27, 2013, at which time he observed she was weak and insisted that Resident A be transferred to the hospital. CMS Ex. 5 at 41-42; Tr. at 153 (testimony of Ms. Montoya that "the son insist for the patient to be transferred to the hospital."). A 12:30 p.m. nursing note by Ms. Montoya on October 27, 2013, indicates the following:

> Resident's son stated resident is getting [illegible] week [sic] and he will like for the resident to be sent at the hospital for an evaluation. Resident told this RN, that she feels weak but has no pain. Just generalize[d] weakness. This RN explained to resident's son that resident refused to eat for past 2 days and also she got a flu vaccine few days ago and could be that the reason why she is feeling weak. Resident's son stated that he wants something done now and to send resident to hospital. Dr. Pfiefle paged and made aware about son's request. Dr. Pfiefle ok[ay] to send resident to Parkview Community Hospital for an evaluation . . .

CMS Ex. 5 at 41-42.

Ms. Montoya explained, in her written direct testimony that "[a]ll of Resident A's vital signs were within normal limits. I advised Resident A's son that she did not appear to need to be transported to the hospital because she was alert and able to communicate her needs, yet displayed no signs or symptoms of pain or acute distress, and because her vital

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[9] Counsel for CMS asked Ms. Montoya the following on cross-examination: "So when the resident had a change of condition, they contacted the son. Why didn't they contact the physician?" Ms. Montoya responded: "I don't know. I cannot answer that. I wasn't there." Tr. at 157.

signs were normal. I also told Resident A's son that we would transfer her to the hospital if he still wanted her to be transferred, regardless of whether or not Resident A appeared to be in acute distress."[10] P. Ex. 10 at 2-3.

Ms. Montoya testified that "[b]ased on [her] assessment of Resident A's condition . . . and the lack of signs or symptoms to indicate that Resident A had suffered a significant change in physical, mental or psychosocial status, I determined that Resident A was not in any acute or serious distress, and appeared not to need to be transferred to Parkview Hospital's emergency room." P. Ex. 10 at 3. Ms. Montoya testified that she "contacted Dr. Pfiefle and made him aware of Resident A's son's request" to transfer her to the hospital.[11] P. Ex. 10 at 4. On cross-examination, Ms. Montoya explained that she first contacted Dr. Pfiefle after Resident A's son requested that Resident A be transferred to the hospital. Tr. at 152.

Both the RN Supervisor, Ms. Montoya, and the Director of Nursing, Ms. Blankenship,[12] attributed Resident A's symptoms to her receipt of a flu vaccine on October 24, 2013. CMS Ex. 5 at 41 (nursing note documenting that Resident A received the flu vaccine on October 24, 2013); P. Ex. 12 at 3-4 (stating "it is not uncommon for residents like Resident A to display no adverse side effects from a flu vaccine for several days. As a result, that Resident A displayed increased weakness and tiredness several days after the flu vaccine is not inconsistent with an opinion that such symptoms derived from the vaccine."); P. Ex. 10 at 3 ("While Resident A was not documented to have exhibited

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[10] Ms. Montoya stated in her nursing note that when she spoke with Resident A, Resident A reported she was weak but had no pain. CMS Ex. 5 at 41. However, in her written direct testimony, she stated that "I first asked Resident A how she was doing" and "Resident A told me that she felt fine." P. Ex. 10 at 2.

[11] Ms. Montoya did not contact the doctor for the purpose of reporting Resident A's weakness and lack of appetite.

[12] Ms. Blankenship testified that she learned, for the first time at the hearing, that Resident A had received intravenous antibiotics and a blood transfusion during a nearly week-long hospitalization. Tr. at 191-93; *see* CMS Ex. 5 at 60-69. This is inconsistent with her written direct testimony, in which she cited to P. Ex. 19, which is a copy of records involving Resident A's treatment at the hospital. Ms. Blankenship denied knowledge of important details of Resident A's hospitalization, despite the fact that she previously stated that she had reviewed Resident A's hospital records including "her chest x-ray reports, laboratory results, and emergency department notes" and had also "participated in Orange Tree's Quality Assistance & Assessment Committee, and in alliance with the interdisciplinary team . . . helped develop and implement written policies and procedures for the provision of nursing care." P. Ex. 12 at 1-2, 5.

earlier signs of adverse side effects from the flu vaccine, it is not uncommon for a delay in the appearance of adverse side effects in elderly recipients."). Interestingly, the records from Resident A's hospitalization do not reference her receipt of the flu vaccine, even though Petitioner's staff thought it was a significant factor in her reports of weakness and change in appetite. CMS Ex. 5 at 60-69; P. Ex. 19.

The quality of care regulation at 42 C.F.R. § 483.25 requires that "[e]ach resident must receive and the facility must provide the necessary care and services to attain or maintain the highest practicable physical, mental, and psychosocial well-being, in accordance with the comprehensive assessment and plan of care."[13] An SNF's failure to provide necessary care and services under 42 C.F.R. § 483.25 can be evidenced by a facility's failure to immediately notify a resident's physician when the resident has experienced a significant change in condition. *Magnolia Estates Skilled Care*, DAB No. 2228 at 21 (2009) ("Failure to notify a physician about a clinical condition that required immediate physician consultation and intervention in order to mitigate a risk of infection and more serious physical injury is clearly a failure to provide 'necessary care and services' to ensure that a resident attains or maintains her highest practicable well-being.").

In the statement of deficiencies (SOD), CMS contends that Petitioner failed to provide the necessary care and services to Resident A, to include failing to recognize a change in condition and consulting Resident A's physician. CMS Ex. 1; *see Magnolia Estates*, DAB No. 2228 at 21. In fact, the only reason that Petitioner contacted the physician is because Resident A's son insisted that she be transferred to a hospital; nursing notes reflect that "Dr. Pfiefle [was] paged and made aware about son's request." CMS Ex. 5 at 42; *see* CMS Ex. 5 at 46 (Dr. Pfiefle's Order stating "as per son request send resident to Parkview ER for evaluation [secondary] [to] resident [increased] weakness."); P. Ex. 10 at 4 ("I offered these in-house treatment options to Resident A's son, but he insisted that we send her to the hospital. I then contacted Dr. Pfiefle and made him aware of Resident A's son's request . . . Dr. Pfiefle approved the transfer of Resident A to Parkview Hospital."). Ms. Montoya contacted Resident A's physician, but only to communicate the request from Resident A's son that Resident A be sent to the hospital. CMS Ex. 5 at 41.

The question, for purposes of determining whether Petitioner was substantially noncompliant with 42 C.F.R. § 483.25, is whether Resident A received and the facility provided her with the necessary care and services for her to attain or maintain the highest practicable physical, mental, and psychosocial well-being. Resident A had poor or no food consumption at 15 out of the 17 meals preceding her transfer to a hospital at the

[13] Federal nursing home regulations substantially changed effective October 4, 2016. Based on the date of the survey, which preceded the regulatory revisions, I refer to the regulations that were in effect at the time of the survey.

insistence of her son, and had poor food consumption at nine consecutive meals and then refused two meals prior to her transfer. CMS Ex. 5 at 54. While the facility does not consider this nearly one-week period of poor food consumption to signal a significant change in her condition that could require medical intervention, Resident A's food consumption logs demonstrate that she had a change in appetite characterized by "refusing meals, decreased appetite" as stated in the facility's own policy. CMS Exs. 5 at 54; 10 at 3. Further, the facility clearly felt that Resident A had a change in appetite by October 25, 2013, two days prior to her transfer to the hospital; Petitioner called Resident A's son on that date to let him know that she was "not eating well [for a] few days." CMS Ex. 5 at 41.

Further, in addition to Resident A's significant change in appetite, the evidence shows that Resident A had a significant change in her level of urinary continence.[14] In October 2013, the facility assessed that Resident A was normally continent of urine and was only "occasionally" incontinent of urine, which as previously discussed, would be less than seven episodes of incontinence in a week-long period. CMS Ex. 5 at 17. Resident A, in the 3½ day period between October 24 and 27, was incontinent of urine on 16 occasions. CMS Ex. 5 at 51-53. The significant increase in the frequency of urinary incontinence should have been recognized as a change in condition, in that this was a significant decrease in Resident A's level of functioning. CMS Ex. 10 at 3. The drastic increase in the frequency of episodes of urinary incontinence is quite significant, in that upon her admission to the hospital, Resident A was diagnosed as having "*sepsis secondary to [a] urinary tract infection*." CMS Ex. 5 at 61 (emphasis added). Even to a layperson, it is far more likely, and obvious, that a urinary tract infection, rather than a flu vaccine, could cause a sudden increase in the frequency of urinary incontinence.

With respect to Petitioner's arguments and testimony that Resident A was suffering from the side effects of the flu vaccine and did not require medical intervention, Petitioner has not submitted any evidence that the flu vaccine would cause poor or no meal consumption at 15 of 17 meals, or that a flu vaccine would cause the resident to be suddenly and repeatedly incontinent of urine.[15] The only evidence Petitioner offers in support of its flu vaccine theory is the testimony of Ms. Blankenship and Ms. Montoya. Tr. at 149 (testimony of Ms. Montoya that side effects are "weakness, flu-like symptoms,

[14] Petitioner argues that Resident A did not exhibit any signs or symptoms of a urinary tract infection. P. Br. at 14-15; P. Post-Hearing Br. at 12-13. Although CMS has not addressed this basis in either the SOD or its briefing, I nonetheless address it in response to Petitioner's allegations that Resident A had no signs of urinary changes. P. Br. at 15.

[15] It is noteworthy that Resident A received the flu vaccine on October 24, 2013; her appetite notably changed beginning on October 22, 2013, two days *prior* to receiving the flu vaccine. CMS Ex. 5 at 41, 54.

and it can cause, you know, residents not to eat or drink because they feel very weak"); Tr. at 187 (Director of Nursing's testimony that she "would have considered the potential side effects and the potential ramifications from Resident A's receipt of the flu vaccine the day prior" when a nurse informed her that Resident A was eating poorly). There is a good reason why the facility's policy (CMS Ex. 10) and the Secretary's regulations (42 C.F.R. §§ 483.10(b)(11), 483.25) require nursing staff to consult a resident's physician if they notice a significant change in a resident's condition; nursing staff are not qualified to make medical diagnoses, and nursing staff should not deny residents essential medical care based on their unqualified assumptions regarding the cause of a resident's symptoms. In this case, the facility's nursing staff was aware that Resident A was eating poorly for nearly a week, yet they determined, without consulting the resident's physician, that the resident's receipt of a flu vaccine was the reason for her change in appetite. The facility's nursing staff was incorrect, and but for Resident A's son's advocacy, their inaction could have led to a far worse outcome for this resident.

Resident A had poor, or no, food consumption of 15 out of 17 meals between October 22 and 27, 2013, and had poor food consumption for nine consecutive meals on October 24, 25, and 26, followed by refusal of the meals preceding her transfer to the hospital on October 27. Resident A, who was only infrequently incontinent of bladder, was incontinent of urine 16 times in the same 3½ day period from October 24 to 27, 2013.[16] While Petitioner passes off these significant changes as side effects of the flu vaccine,[17] Petitioner is mistaken. Under Petitioner's own policy, Resident A unquestionably had a significant change in condition that warranted consultation with her physician and medical intervention. Petitioner's own policy indicates that a change in condition can include a sudden or marked change in appetite, to include refusing meals or decreased appetite, or a change in level of functioning. CMS Ex. 10 at 3. Petitioner clearly thought that Resident A's appetite had changed to warrant notification of her son, and Petitioner can point to no remotely similar instance showing such a prolonged and sustained period of poor food consumption. *See* CMS Ex. 5 at 54-56. Resident A only received the emergency medical care she needed because her son firmly advocated for her and was not convinced by a nurse's explanation that a flu vaccine was causing his mother's distress. CMS Ex. 5 at 41-42; Tr. at 152-153. Rather than consulting a physician and timely reporting Resident A's change in appetite that was first evident to nursing staff on October 25 (CMS Ex. 5 at 41), or taking note of the sudden increase in the frequency of episodes of urinary incontinence, the facility nurses relied on what amounts to unsupported hunches about the expected side effects of the flu vaccine and failed to ensure that Resident A received the medical care she needed. Resident A was

[16] Petitioner has not presented any evidence that urinary incontinence is a side effect of the flu vaccine.

[17] It does not appear that Petitioner ever recognized the increase in frequency of episodes of urinary incontinence.

hospitalized for six days and given intravenous antibiotics and a blood transfusion; her hospitalization records make no mention that her hospitalization was related to any side effects of the flu vaccine. CMS Ex. 5 at 60-69. There is no question that Resident A was hospitalized due to a urinary tract infection that led to sepsis, along with anemia, candida esophagitis, and suspected aspiration pneumonia, among other diagnoses. CMS Ex. 5 at 61. The failure to render medical treatment to Resident A, to include notifying her physician of her significant change in condition that was evident days prior to her transfer, undoubtedly delayed necessary medical treatment for this 91-year-old resident who had multiple acute illnesses. Petitioner's failure to immediately notify Resident A's physician about her significant change in appetite deprived her from receiving timely medical care, in violation of 42 C.F.R. § 483.25. In addition, Petitioner's failure to notify Resident A's physician about her change in function due to urinary incontinence also evidences a failure to recognize a serious medical condition. Petitioner, in failing to recognize that Resident A had a significant change in condition, failed to provide the necessary care and services to Resident A.

B. A per-instance CMP of $3,000 is a reasonable enforcement remedy for Petitioner's noncompliance with 42 C.F.R. § 483.25.

I have concluded that Petitioner violated 42 C.F.R. § 483.25. If a facility is not in substantial compliance with program requirements, CMS has the authority to impose one or more of the enforcement remedies listed in 42 C.F.R. § 488.406, including a CMP. Here, CMS chose to cite the deficiency at the G level of scope and severity and imposed a per-instance CMP based on Petitioner's failure to be in compliance with the program requirement at 42 C.F.R. § 483.25.[18]

In determining whether the per-instance CMP amount imposed against Petitioner is reasonable, I apply the factors listed in 42 C.F.R. § 488.438(f). 42 C.F.R.

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[18] An ALJ may review CMS's scope and severity findings only if a successful challenge would affect: (1) the range of the CMP amounts that CMS could collect; or (2) a finding of substandard quality of care that results in the loss of approval of a facility's nurse aide training program. 42 C.F.R. § 498.3(b)(14), (d)(10)(i)-(ii); *NMS Healthcare of Hagerstown*, DAB No. 2603 at 6-7 (2014). None of these factors are applicable. Although CMS cited the deficiency at the "G" level of scope and severity and that will stand, it likely would have been more appropriate to cite the deficiency at the immediate jeopardy level. Petitioner's failure to render medical care to Resident A is egregious, and even though it knew that her condition had changed two days earlier, it only contacted her physician after the resident's son insisted that she receive medical treatment. The seriousness of her medical condition is evident based on the duration of her hospitalization, along with the multiple diagnoses and treatment interventions. CMS Ex. 5 at 60-69.

§ 488.438(e)(3). These factors include: (1) the facility's history of noncompliance; (2) the facility's financial condition; (3) the factors specified at 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 at 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.

CMS proposed a per-instance CMP of $ 3,000 for the noncompliance with 42 C.F.R. § 483.25.[19] Petitioner has not challenged the reasonableness of the proposed CMP amount, and absent any evidence that Petitioner is unable to pay the CMP or that a particular regulatory factor does not support the CMP amount, I sustain it. *Coquina Ctr.*, DAB No. 1860 (2002).

Petitioner's failure to consult Resident A's physician until only after Resident A's son insisted that she receive medical treatment placed her at risk for serious harm, as evidenced by the six-day length of her hospitalization and the multiple diagnoses of acute conditions that required blood transfusion and intravenous antibiotic treatment. Petitioner had a duty to identify Resident A's deteriorating condition and consult her physician so that the physician could determine if medical intervention was necessary. Petitioner's staff, however, made no attempt to notify Resident A's physician because they had determined that her deteriorating condition was due to a flu vaccine administered on October 24, 2013. *See* CMS Ex. 5 at 41. Petitioner is culpable for its employees' inaction and its failure to provide the necessary care and services that Resident A required. I conclude that based on my review of the required factors, the per-instance CMP, which is quite low for the seriousness of the deficiency, is reasonable for Petitioner's noncompliance with Medicare requirements. *See* 42 C.F.R. §§ 488.408(d)(1)(iv), 488.438(a)(2).

[19] CMS argues that Petitioner had a history of noncompliance, stating that "Orange Tree has been out of compliance in each of its last four surveys." CMS Br. at 9, citing CMS Ex. 9 at 1-2. Owing to Petitioner's failure to challenge the CMP amount and CMS's assertion that Petitioner has a history of noncompliance, I accept CMS's assertion as true. However, even without consideration of this unfavorable factor, a $3,000 per instance penalty is reasonable. *See* 42 C.F.R. § 488.438(f).

IV. Conclusion

For the foregoing reasons, I conclude that Petitioner was not in substantial compliance with 42 C.F.R. § 483.25 (cited as tag F309). Further, I conclude that the per-instance CMP of $3,000 for noncompliance with 42 C.F.R. § 483.25 is a reasonable enforcement remedy.

_____/s/_____
Leslie C. Rogall
Administrative Law Judge