Department of Health and Human Services

DEPARTMENTAL APPEALS BOARD

Civil Remedies Division

Consolidated Home Health
(CCN: 26-7468),

Petitioner,

v.

Centers for Medicare & Medicaid Services

Docket No. C-16-16

Decision No. CR4923

Date: August 15, 2017

DECISION

Consolidated Home Health (Petitioner) challenges the Centers for Medicare & Medicaid Services' (CMS) determination to terminate its participation in the Medicare program as a home health agency (HHA) and to impose a civil money penalty (CMP) of $8,500 per day for the period of August 7, 2015, until Petitioner's termination on August 30, 2015. For the reason set forth below, I affirm CMS's determination to terminate Petitioner's participation and its imposition of a CMP.

I. Background

The Social Security Act (Act) sets forth requirements for HHAs to participate in the Medicare program and authorizes the Secretary of Health and Human Services (Secretary) to promulgate regulations implementing the statutory provisions. 42 U.S.C. §§ 1395x(m), (o), 1395bbb. The Secretary's regulations governing HHA participation in the Medicare program are found at 42 C.F.R. part 484.

In order to participate in the Medicare program and obtain reimbursement for services provided to beneficiaries, an HHA must comply with all applicable conditions of participation specified in 42 U.S.C. § 1395bbb(a) and 42 C.F.R. part 484. 42 U.S.C.

§ 1395x(o)(6). Each HHA must sign a Medicare provider agreement and that agreement must specify that the HHA is subject to unannounced surveys performed by state or local government agencies. 42 U.S.C. §§ 1395cc(a), 1395bbb(c)(1); 42 C.F.R. § 488.10. "The survey process is the means to assess compliance with Federal health, safety, and quality standards." 42 C.F.R. § 488.26(c)(1). The state agency will normally conduct a standard survey; however, "[e]ach home health agency that is found, under a standard survey, to have provided substandard care shall be subject to an extended survey to review and identify the policies and procedures which produced such substandard care and to determine whether the agency has complied with the conditions of participation." 42 U.S.C. § 1395bbb(c)(2). Based on the survey results, the state agency certifies whether the HHA is complying with the conditions of participation. 42 C.F.R. §§ 488.20, 488.24, 488.26.

The state agency will certify that an HHA is not complying with the conditions of participation when the deficiencies are "of such character as to substantially limit the provider's . . . capacity to furnish adequate care or which adversely affect the health and safety of patients." 42 C.F.R. § 488.24(b). Whether or not there is compliance with a condition of participation depends upon "the manner and degree to which the provider . . . satisfies the various standards within each condition." 42 C.F.R. § 488.26(b). State surveyors are required to "directly observe the actual provision of care and services to residents and/or patients, and the effects of that care, to assess whether the care provided meets the needs of individual residents and/or patients." 42 C.F.R. § 488.26(c)(2).

CMS may terminate an HHA's Medicare provider agreement when the HHA no longer meets the requirements of the Act, the conditions of participation, or other requirements in the regulations. 42 U.S.C. §§ 1395cc(b)(2), 1395bbb(e); 42 C.F.R. § 489.53(a). Notably, CMS may terminate an HHA's provider agreement if the HHA has a single condition-level deficiency, and CMS's decision to do so is discretionary. *United Medical Home Care, Inc.*, DAB No. 2194 at 13-14 (2008); *Comprehensive Professional Home Visits*, DAB No. 1934 (2004). In addition to termination, CMS may impose a CMP on HHAs that will not exceed $10,000 for each day of noncompliance. 42 U.S.C. § 1395bbb(f)(2)(A)(i); 42 C.F.R. § 488.485. If CMS imposes termination and/or a CMP on an HHA, the HHA may request a hearing before an administrative law judge (ALJ) to dispute CMS's action. 42 U.S.C. §§ 405(b), 1320a-7a(b)(2), 1395cc(h)(1), 1395bbb(c)(1); 42 C.F.R. §§ 488.845(c)(2), 498.3(b)(8), (13), 498.5(b).

The hearing before an ALJ is a *de novo* proceeding. *CarePlex of Silver Spring*, DAB No. 1683 (1999) (holding that ALJs hold *de novo* hearings based on issues permitted under the regulations and ALJ review is not a quasi-appellate review); *see also Claiborne-Hughes Health Ctr. v. Sebelius*, 609 F.3d 839, 843 (6th Cir. 2010) (The Departmental Appeals Board (DAB) "reviewed the finding under the *de novo* standard that the ALJ would have applied."). On appeal to an ALJ, CMS must make a *prima facie* case that the HHA failed to comply substantially with federal participation requirements and, if this

occurs, the HHA must, in order to prevail, prove substantial compliance by a preponderance of the evidence. *See Hillman Rehab. Ctr.*, DAB No. 1611 at 8 (1997); *see Batavia Nursing & Convalescent Inn*, DAB No. 1911 (2004); *Batavia Nursing & Convalescent Ctr.*, DAB No. 1904 (2004); *Emerald Oaks*, DAB No. 1800 (2001); *Cross Creek Health Care Ctr.*, DAB No. 1665 (1998).

Petitioner is a HHA based in Missouri that participated in Medicare until the termination of its provider agreement on August 30, 2015. From August 3-7, 2015, surveyors from the Missouri Department of Health and Senior Services (state agency) conducted a Medicare recertification survey, which turned into an extended survey. CMS Exhibit (Ex.) 1 at 1; CMS Ex. 4 at 1; CMS Ex. 10 ¶ 5. The surveyors completed a Statement of Deficiencies in which they documented the reasons why Petitioner was not in compliance with six conditions of participation:

- 42 C.F.R. § 484.12 Compliance with Federal, State and Local Laws
- 42 C.F.R. § 484.14 Organization, Services and Administration
- 42 C.F.R. § 484.16 Group of Professional Personnel
- 42 C.F.R. § 484.18 Acceptance of Patient, Plan of Care, and Medical Supervision
- 42 C.F.R. § 484.48 Clinical Records
- 42 C.F.R. § 484.52 Evaluation of Agency's Program

CMS Ex. 1; *see also* CMS Ex. 11 ¶ 8. Most significantly, the surveyors found that Petitioner's noncompliance with § 484.18 constituted immediate jeopardy.[1] CMS Ex. 1 at 1. The surveyors determined that Petitioner was not in compliance with the standards for this condition (Tags G157, G158, G159, G164, G165) because it failed to: ensure patients are accepted for treatment on expectation that the patient's medical, nursing, and social needs can be adequately met by the agency in the patient's home; ensure staff follow the written plan of care as ordered by the physician; ensure development of a complete and accurate plan of care for each patient receiving home health services; ensure agency staff promptly alert the physician to any changes that suggest a need to alter the plan of care; and ensure drugs and treatments are administered by agency staff only as ordered by the physician. CMS Ex. 1 at 16-40.

In an August 12, 2015 initial determination, CMS informed Petitioner that it was terminating its Medicare provider agreement effective at the close of business on August 30, 2015. CMS Ex. 3 at 1. CMS also informed Petitioner that "[t]ermination can only be

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[1] The term "immediate jeopardy" is defined to mean "a situation in which the . . . [home health agency's] noncompliance with one or more requirements of participation has caused, or is likely to cause serious injury, harm, impairment or death to a patient(s)." 42 C.F.R. § 488.805.

averted by correction of the deficiencies that constitute an immediate jeopardy to patient safety" and that it could submit a plan of correction to the state agency in order to obtain a revisit survey. CMS Ex. 3 at 2. CMS also advised Petitioner that it was imposing an $8,500 per day CMP due to the finding of immediate jeopardy. CMS Ex. 3 at 2.

Petitioner submitted a plan of correction (POC) in relation to § 484.18, which the state agency received on August 13, 2015. CMS Ex. 6. However, in an email on that same day, the state agency informed Petitioner that the POC was deficient for a variety of reasons, including a failure to provide a date by which Petitioner would complete the corrections. CMS Ex. 8. On August 14, 2015, Petitioner submitted an addendum to the POC in which Petitioner stated it would complete its corrective action on August 21, 2015. CMS Ex. 7. Surveyors conducted a revisit survey on August 27-28, 2015, to determine if the deficiencies were corrected and if the immediate jeopardy had been abated. CMS Ex. 2; CMS Ex. 12 ¶ 5. The surveyors found that Petitioner remained out of compliance with all six conditions listed in the original Statement of Deficiencies and that Petitioner's noncompliance with the condition at § 484.18 was still at the immediate jeopardy level. CMS Ex. 2; CMS Ex. 12 ¶¶ 10-13.

In an August 28, 2015 letter, CMS notified Petitioner that due to its failure to correct the deficiencies from the August 7, 2015 survey, CMS was terminating its Medicare provider agreement on August 30, 2015. CMS Ex. 4. On September 9, 2015, it notified Petitioner of the imposition of the CMP of $8,500 per day for the period August 7 through August 30, 2015, (24 days) for a total CMP of $204,000. CMS Ex. 5.

On October 9, 2015, Petitioner requested a hearing before an ALJ to dispute CMS's initial determination. Petitioner attached eight exhibits to the hearing request (P. Exs. 1-8). I issued an Acknowledgement and Pre-Hearing Order that provided a prehearing exchange submission schedule for the parties. CMS submitted a brief (CMS Br.) and 12 proposed exhibits, CMS Exs. 1-12.[2] Petitioner submitted its brief (P. Br.) and 30 additional proposed exhibits (P. Exs. 9-38).[3]

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[2] CMS counsel unhelpfully and unprofessionally grouped all of the survey documents and medical records for each of the surveys conducted in this case under two exhibit numbers (i.e., CMS Ex. 9 for the first survey and CMS Ex. 10 for the second survey). CMS Exhibit 9 consists of 695 pages and CMS Exhibit 10 is 446 pages. The records for each patient ought to have been made separate exhibits and, by listing those individual exhibits on the exhibit list, Petitioner and I could have located documents relevant to each deficiency expeditiously, rather than rummaging through large exhibits.

[3] Some 47 days after Petitioner submitted its prehearing brief, CMS objected to it, claiming it was single-spaced and 19 pages, contrary to my PHO, which directed no more than 25 pages, double-spaced. I overrule CMS's objection. Petitioner does not have an

II. Decision on the Record

Neither party objected to any of the proposed exhibits. Therefore, I admit CMS Exs. 1-12 and P Exs. 1-38.

Petitioner requested that I issue a decision based on the written record. CMS did not object to this request. Therefore, I render this decision on the record without holding an oral hearing. 42 C.F.R. 498.66.

III. Issues:

1. Whether Petitioner failed to comply with one or more conditions governing Medicare participation of HHAs at a level of noncompliance that constituted immediate jeopardy for patients under Petitioner's care;

2. Whether CMS's had a legitimate basis to terminate Petitioner's provider agreement and impose a CMP; and

3. Whether a CMP in the amount of $8500 per day is reasonable.

IV. Findings of Fact and Conclusions of Law, and Analysis

I set forth my findings of fact and conclusions of law in bold and italics font.

1. ***Petitioner was not in substantial compliance with the condition of participation required by 42 C.F.R. § 484.18, Petitioner's noncompliance amounted to immediate jeopardy, and Petitioner did not return to compliance before termination of its provider agreement.***

Here, the applicable regulation requires as a condition for participation that patients of a home health agency be "accepted for treatment on the basis of a reasonable expectation that the patient's medical, nursing, and social needs can be met adequately by the agency in the patient's place of residence" and that the care provided follow a "a written plan of care established and periodically reviewed by a doctor . . . ." 42 C.F.R. § 484.18. The standards under this condition set forth requirements for the plan of care, periodic review of the plan of care, and conformance with physician orders.

The record supports the findings in the initial survey that Petitioner was not in compliance with the conditions of participation under 42 C.F.R. § 484.18 for Acceptance of Patients, Plan of Care, and Medical Supervision and that the noncompliance with this

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attorney; its action was *de minimus*, and CMS filed its objection well after the 15-day period I specified for filing objections.

condition caused or was likely to cause serious injury, harm, impairment, or death to a patient or patients. The Statement of Deficiencies stated:

> One condition level deficiency, 418.18 [sic] Acceptance of Patients, Plan of Care, and Medical Supervision resulted in a finding of immediate jeopardy (IJ). As of the date of the exit findings, 08/07/15, the agency failed to abate, or remove, the immediate jeopardy[4] potential for future patients.

CMS Ex. 1 at 1.

CMS argues that Petitioner's failure to comply with five standards under the § 484.18 condition shows that Petitioner was out of compliance with the entire condition. CMS Br. at 7-8. Petitioner disputes the condition-level deficiency and provided argument and explanation as to the five standards. P. Br. at 9-11.

Based on the following, I conclude that CMS met its prima facie case. As a result, I conclude that Petitioner was not in compliance with § 484.18. I also conclude that its noncompliance posed immediate jeopardy to Petitioner's patients.

a. Petitioner failed to comply with 42 C.F.R. § 484.18 (Tag G157) – Patients are accepted for treatment on the basis of a reasonable expectation that the patient's medical, nursing, and social needs can be met adequately by the agency in the patient's place of residence.

HHAs may only "accept patients for treatment on the basis of a reasonable expectation that the patient's medical, nursing, and social needs can be met adequately by the agency in the patient's place of residence." 42 C.F.R. § 484.18. In the present case, two patients were accepted for treatment without a reasonable expectation that the Petitioner could adequately meet the needs of the patient.

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4 Petitioner misconstrues the Statement of Deficiencies and CMS's findings. Petitioner seems to believe that the immediate jeopardy relates only to the findings with respect to Patient #3. That is not the case. The immediate jeopardy relates to the entire condition-level deficiencies cited with respect to § 484.18 under several tags and with respect to several other patients. Petitioner also failed to dispute most of CMS's findings under § 484.18.

Patient #1

Petitioner accepted Patient #1 because the patient's mother was a respiratory therapist and she was going to take care of Patient #1's ventilator care. However, the plan of care includes physician orders related to ventilator and respiratory assessments to be completed by the home health skilled nurse and also to instruct and assess the caregiver's ability to maintain the patient's ventilator and respiratory care. There is nothing to show Petitioner did this. CMS Ex. 2 at 5-8.

Patient #5

In the case of Patient #5, the patient's July 1, 2015 referral to home health directed the agency to provide a home health nurse **and** chore worker services. The clinical record showed that that while a nurse made visits three days a week, Petitioner did not provide a chore worker and the agency did not notify the physician that, even as of the first survey in August 2015, no chore worker had been provided. Petitioner accepted the patient even though it could not provide, and failed to provide, the chore services this blind patient critically needed. CMS Ex. 1 at 17-18.

Petitioner did not address or specifically dispute these issues in its brief; therefore, I find that Petitioner failed to substantially comply with § 484.18.

b. Petitioner failed to comply with 42 C.F.R. § 484.18 (Tag G158) – Care provided to the patient follows a written plan of care established and periodically reviewed by a doctor of medicine, osteopathy, or podiatric medicine.

The care that an HHA provides to a patient must "follow[] a written plan of care established by a doctor of medicine, osteopathy, or podiatric medicine." 42 C.F.R. § 484.18.

CMS asserts that Petitioner violated this standard based on the August 7, 2015 survey, which noted Petitioner failed to follow care plans for several patients.

Patient #1

CMS asserts that clinical records showed that Patient #1 had an order for a skilled nurse three times a week for nine weeks. CMS Ex. 1 at 19. However, from July 12 to July 19, 2015, Petitioner only provided skilled nursing services twice a week. CMS Ex. 1 at 19. During the revisit survey, a surveyor observed one of Petitioner's nurses tend to and place new dressings on multiple pressure ulcers that Patient #1 had. The surveyor noted that the nurse failed to comply with physician orders to implement standard infection control precautions and to treat and dress the wounds. CMS Ex. 2 at 12-20; CMS Br. at

10-11. Petitioner did not address or specifically dispute this issue in its brief (*Cf.* P. Br. at 9); therefore, I find that Petitioner failed to follow the care plan regarding Patient #1 and did not substantially comply with § 484.18.

Patient #2

For Patient #2, the home health referral by the physician ordered skilled nurse visits twice a week for nine weeks. CMS Ex. 1 at 19. The surveyor's review revealed no skilled nursing visits for three of those weeks and only one visit per week was documented for two of those weeks. CMS Ex. 1 at 19-20. During the revisit survey, a surveyor observed one of Petitioner's nurses tend to Patient #2 while failing to follow the physician's order to implement standard infection control precautions. CMS Ex. 2 at 20-23; CMS Br. at 11. Petitioner did not address or specifically dispute this issue in its brief. (*Cf.* P. Br. at 9); therefore, I find that Petitioner failed to follow the care plan regarding Patient #2 and did not substantially comply with § 484.18.

Patient #3

Patient #3 was discharged from a hospital on July 7, 2015, and Petitioner began providing home health services for Patient #3 on July 9, 2015. CMS Ex. 9 at 251; P. Ex. 10 at 2. Patient #3's primary diagnosis was acute venous embolism and thrombosis of deep vein (DVT). CMS Ex. 9 at 251-52. At that time Patient #3's prognosis was "fair." CMS Ex. 9 at 251. The plan of care directed a skilled nurse to "[i]mplement and instruct" the medication regimen, including dosage, side effects, name route, frequency, desired action, and adverse actions for this patient. CMS Ex. 9 at 251. The plan of care showed the patient's medications included Warfarin, a blood thinner, by mouth daily, and Lovenox, another blood thinner, by injection twice a day. CMS Ex. 1 at 21; CMS Ex. 9 at 251. One of the care plan's stated goals was for Patient #3 to "verbalize understanding of medications as evidenced by recall of action/dose/side effects within cert[ain] period of time." CMS Ex. 9 at 252. In order to implement this plan, the hospitalist caring for Patient #3 at the hospital ordered skilled nursing for two days a week for the first two weeks and once a week thereafter for the next seven weeks. CMS Ex. 9 at 251; *see also* P. Ex. 9 at 6.

A nurse employed by Petitioner saw Patient #3 on July 9, 2015. Although the hospital had ordered the Lovenox for Patient #3, the medication had not been delivered by July 9. P. Ex. 10 at 2. The nurse communicated with Patient #3 during the following days, but the medication was not delivered. P. Ex. 10 at 2; P. Ex. 11 at 2. The nurse saw Patient #3 on July 13, 2015, at 1:30 p.m. and waited until 3:30 p.m. for the delivery of the Lovenox, but it did not arrive. P. Ex. 10 at 2. The Lovenox was delivered to Patient #3 later on July 13, 2015, and Patient #3 injected two doses into himself by the time the nurse returned on July 14, 2015. P. Ex. 10 at 2; P. Ex. 13 at 4.

CMS's position is that the nurse's conduct violated § 484.18 because the nurse failed to notify Patient #3's doctor when the Lovenox was not available for several days. CMS Br. at 9; CMS Ex. 1 at 21. Citing the Mayo Clinic's website, CMS points out that:

> Deep vein thrombosis (DVT) occurs when a blood clot (thrombus) forms in one or more of the deep veins in your body, usually in your legs. Deep vein thrombosis can develop if you have certain medical conditions that affect how your blood clots. Deep vein thrombosis can also happen if you don't move for a long time, such as after surgery, following an accident, or when you are confined to a hospital or nursing home bed. Deep vein thrombosis is a serious condition because blood clots in your veins can break lose, travel through your bloodstream and lodge in your lungs, blocking the blood flow (pulmonary embolism).

CMS Br. at 8-9 n. 3.

Judy Morris, RN, the survey team leader, testified about Patient #3 with regard to DVT.

> Although there were several examples given of deficient practices, I was very concerned about the care provided to one patient in particular, identified in the Statement of Deficiencies as Patient #3. This patient had Deep Vein Thrombosis (DVT) which is a condition that carries great risk to a patient's health and must be treated and monitored properly. The patient's anticoagulation medication was delayed several days because the pharmacy was out and the nurse failed to notify the physician about this situation in a timely manner. Additionally, the nurse did not seem to know much about DVT and did not properly assess the patient for the presence of DVT. This put the patient at increased risk of possible death by pulmonary embolism.

CMS Ex. 11 at 2.

Petitioner disputes that it violated the regulations. Petitioner argues that the:

> [d]eficiency with respect to patient #3 was mischaracterized with confusion/inaccuracies cited by regulators with respect to the administration of Warfarin, Lovenox, and PT/INR testing . . . . Actions within the plan of correction specific to the IJ citation with patient #3 were properly followed . . . .

> The one agency fault . . . with patient #3 pertained to the nurse for not documenting her communication with the physician pertaining to the non-delivery of Lovenox. We openly admit the nurse's failure to document this call . . . . However, the characterization that this nurse or the agency had a reluctance to contact the physician is grossly inaccurate. The nurse's lack of documentation does correlate to the record and her personal statement [P. Ex. 10.] The nurse did correspond with the hospitalist who prescribed Lovenox. He did not respond to her call. She did correspond with the patient on delivery of Lovenox [P. Ex. 11] . . . . While there is no definitive proof for communication with the doctor, we request the [ALJ] to consider the preponderance of evidence of the situation to conclude that the interest of the patient and his safety was at the forefront.

P. Br. at 18-19. Petitioner also asserts that the nurse for patient #3 followed the physician order to perform the PT/INR tests and communicated the results to the physician. P. Br. at 7. As support for its position, Petitioner submitted a written statement from Patient #3's nurse. The nurse confirmed that Lovenox was ordered by the hospital from which Patient #3 had been discharged. P. Ex. 10 at 2. The nurse asserted that she called the hospitalist who was Patient #3's physician in the hospital, but did not receive a call back from the doctor. P. Ex. 10 at 2. The nurse admits that she did not document this call, but states she did document that she followed up "with the patient on the medication on 7/10/15, 7/11/15, 7/13/15 and 7/14/15." P. Ex. 10 at 2; P. Ex. 11. The nurse stated the following: "The meds were ordered by the hospital. They should have known that the pharmacy never delivers on the weekend (7/11 and 7/12). I am not sure when they ordered the meds. In my opinion, they should have been held responsible and not me. I followed the protocol. The only mistake I made was to not document the call to [the hospitalist]." P. Ex. 10 at 2. The nurse also stated that the Lovenox was delivered late on July 13, 2015, after she had waited from 1:30 p.m. to 3:30 p.m. for the medication to arrive. Finally, the nurse asserted, "I did not have to go back since the patient had been in-serviced by the hospital on the technique to give himself the injection. Before I left that day, I gave the patient some additional handouts to assist him in giving the injection." P. Ex. 10 at 2.

The facts in the record, along with Petitioner's position, as stated above, show that Petitioner failed to implement the care plan for Patient #3. The primary reason for the hospitalist to order home health services for Patient #3 was due to the "DVT [diagnosis] requiring Lovenox" and that "P[atien]t needs assistance" administering the medication. P. Ex. 9 at 6. Patient #3 needed Lovenox injections until "Coumadin [Warfarin] levels are therapeutic." P. Ex. 9 at 5. Patient #3 was in grave danger from DVT, having been discharged from the hospital on July 7, but when Petitioner's nurse arrived on July 9,

Lovenox was not present to be administered. Although Petitioner's nurse asserts that she called Patient #3's hospitalist concerning the medication, the nurse and Petitioner admit that she did not document this call. P. Br. at 7.

I do not find that the nurse called the hospitalist on July 9, 2015, concerning Patient #3's failure to receive Lovenox. Although the nurse stated this in a written statement submitted in this proceeding, the nurse's failure to document the call is at variance with her detailed documentation of her calls to Patient #3 concerning the patient's efforts to obtain Lovenox, and her call on July 14, 2015, to Patient #3's physician. P. Exs. 11-13. Further, the nurse's written statement manifests a view that it was the hospital's responsibility to deal with the failure of the pharmacy to timely deliver the Lovenox, indicating it is more likely that she took no action when the Lovenox was not present for her to inject into Patient #3 on July 9, 2015. The nurse also seemed unconcerned that Patient #3 ultimately had to inject the Lovenox by himself, without her instruction or supervision, because the hospital supposedly trained Patient #3. Regardless as to any alleged instruction by the hospital, Patient #3 injecting himself with the medication without the nurse present was a violation of the care plan.

Petitioner also argues in its defense that the prescription for Lovenox came from a hospitalist and not Patient #3's regular physician, and that Patient #3's regular physician did not know of the hospitalist's order regarding Lovenox. Therefore, the nurse acted properly to contact the hospitalist and not the physician. P. Br. at 5-6. As I found above, there is insufficient evidence that the nurse even contacted the hospitalist. However, the reason for the nurse to provide home health services to Patient #3 was to assist him with matters covered by the plan of care. Most certainly, when Patient #3 was in danger from his DVT condition, the nurse ought to have contacted Patient #3's physician in an effort to ensure Patient #3's health, regardless as to whether the physician or hospitalist ordered the Lovenox. Petitioner's nurse was the only health care provider on the scene to coordinate his care under the care plan, which was in fact her job as a home health nurse. Perhaps it is unsurprising that the nurse did not assist Patient #3 given the attitude Petitioner displayed in its brief in this matter. Petitioner essentially blames the hospital and the pharmacy for the lack of Lovenox while stating "[w]e believe that our RN did all she could under the circumstances with the exception that she did not document her call to . . . the hospitalist." P. Br. 5-6. This view shows a complete lack of responsibility for the patient that Petitioner had under its care.

Therefore, I conclude that Petitioner failed to comply with the plan of care related to Patient #3 and did not substantially comply with § 484.18.

I also conclude that the evidence of record supports that Petitioner placed Patient #3 in immediate jeopardy. The term "immediate jeopardy" is defined to mean "a situation in which the . . . [home health agency's] noncompliance with one or more requirements of participation has caused, or is likely to cause serious injury, harm, impairment or death to

a patient(s)." 42 C.F.R. §.488.805. Allowing Patient #3 to be without the prescribed Lovenox for five days following a stay in the hospital without contacting Patient #3's physician could have resulted in serious harm due to blood clots.[5]

Patient #4

For Patient #4, the plan of care ordered skilled nursing visits twice a week for two weeks. CMS Ex. 1 at 23. The record revealed that the skilled nurse provided only one skilled nurse visit during the first week. Similarly, no skilled nurse visits were made for the next week even though two visits were supposed to be provided. Later, when skilled nursing visits were resumed in July 2015 for one week, with the physician ordering two visits per week, the skilled nurse visited only once. CMS Ex. 1 at 24. Petitioner did not dispute CMS's findings; therefore, I conclude that Petitioner failed to comply with the plan of care for Patient #4 and failed to substantially comply with § 484.18.

Patient #5

Patient #5 had diagnoses including recent pneumonia, chronic airway obstruction, blindness in one eye, and reduced vision in the other eye. CMS Ex. 1 at 24. For Patient #5, the plan of care showed that the patient was on medication to rid the body of excess fluids and the skilled nurse was to weigh the patient daily and notify the physician of any weight variation of 5-7 pounds in a week. CMS Ex. 1 at 24-25. Also, the skilled nurse was to do a pulse oxygen level test as needed according to symptoms with the goal being that the patient's pulse oxygen saturation levels would be above 90%. The patient was using continuous oxygen at 4 liters. CMS Ex. 1 at 24-25. During the home visit, the surveyor observed the skilled nurse giving the patient a bath. However, the skilled nurse failed to have the patient wear the oxygen during the bath. The surveyor observed that the patient became visibly short of breath. The skilled nurse failed to check the patient's pulse oxygen level during or after the bath. The patient also indicated that he/she was not weighed daily and the skilled nurse verified that the patient was not weighed at each visit, stating that the patient's weight has been "stable," but did not explain how she would know this when no daily weights were taken. CMS Ex. 1 at 25. Petitioner did not dispute CMS's findings; therefore, I conclude that Petitioner failed to comply with the plan of care for Patient #5 and failed to substantially comply with § 484.18. I also conclude that the evidence of record supports that Petitioner placed Patient #5 in immediate jeopardy.

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[5] A skilled nursing facility has the burden of showing that CMS cleared erred in regard to its determination that noncompliance is at the immediate jeopardy level. 42 C.F.R. § 498.60(c)(2). This high standard of review does not apply to HHAs. However, even applying a preponderance of the evidence standard, I conclude that Petitioner's actions placed Patient #3 in immediate jeopardy.

<u>Continued noncompliance with § 484.18 (Tag G158)</u>

Petitioner remained out of compliance with Tag G158 at the follow up survey on August 28, 2015. Petitioner's POC for this deficiency listed, among other things, several duties for the Quality Improvement (QI) Nurse, including reviews of patient status, services provided, and medications and discussion of interim orders written during the week. CMS Ex. 7 at 2. The POC also provided that the QI nurse would review all discipline notes and notify staff members of missing paperwork. *Id.* Corrections were to be submitted immediately to the QI nurse and the QI nurse was to review all active charts and discharges "with the newly updated QI tool." The POC promised that Petitioner would complete these corrective actions by August 21, 2015. When the surveyor returned for the revisit survey and requested the result of the chart audits, the Director of Nursing (DON) provide only three chart audits: one completed by the DON and two completed by a staff nurse who was helping out in the evening. CMS Ex. 2 at 9. When the surveyors asked why the record review had not been completed by the QI nurse and why all discipline notes were not reviewed by August 21, 2015, as Petitioner had indicated they would be in the POC, the DON stated that the QI nurse had never showed up or been back to the agency since the time of the original survey exit on August 7, 2015. CMS Ex. 2 at 9-10. Therefore, Petitioner failed to comply with its own plan of correction. CMS Ex. 12 at 3. The revisit also revealed that Petitioner did not have the nurses use a care plan book to develop a personalized care plan on each patient as it stated it would in its POC. CMS Ex. 2 at 10-11; CMS Ex. 7 at 2. And, finally, the revisit survey found that with respect to two patients, Patient #1 and Patient #2, the skilled nurses caring for the patients failed to follow the patients' written plans of care when it failed to "implement and instruct" the patients with respect to standard precautions and infection control. The surveyors observed multiple instances with respect to both patients where the skilled nurse failed to follow proper infection control and standard precautions. As a result, these patients were at risk for contamination and infection. CMS Ex. 2 at 11-23.

In concluding Petitioner failed to return to compliance, I note the testimony of Lila Hamlet, RN, who helped to conduct the revisit survey from August 27-28, 2015. CMS Ex. 12 at 1-2.

> Having carefully reviewed the [Petitioner's POC], I expected some significant measures would have been taken toward achieving compliance. For example, [Petitioner] had indicated that it would train its nurses and medical staff on the subject of Deep Vein Thrombosis (DVT). It appeared that the training consisted of handing out a 19 page document from the Merck Manual website on the subject of DVT. No effort had been made to go over this document with staff and when asked whether their comprehension of the document had been

> tested, I was told that they thought I would be the one responsible for such assessment. When I did interview the nurses to assess their comprehension of DVT, their answers were usually incorrect, not consistent, and below the standard for competent patient care. This lack of knowledge of the risks of and care for patients with DVT went all the way up to the Director of Nursing who did not seem to understand the difference between thrombosis and phlebitis.

CMS Ex. 12 at 2-3.

Petitioner asserted that it did provide DVT training and provided a written statement from its DON that she performed two in service trainings on this subject as well as documents purporting to prove that training. P. Br. at 9; P. Ex 18 at 2; P. Ex. 36 at 20-63. However, reviewing Petitioner's submission, I credit Nurse Hamlet's testimony that Petitioner did not provide sufficient training and that the instructor, Petitioner's DON, was insufficiently informed of DVT to train others. Nurse Hamlet's testimony was detailed while Petitioner's evidence less clear. It is significant that Petitioner did not comply with its POC related to DVT due to the fact that this training was needed to abate the immediate jeopardy level noncompliance involving Patient #3.

c. I do not need to further evaluate the deficiencies under Tags G159, G164, and G165 because the substantial noncompliance under Tags G157 and G158 is sufficient for me to conclude that Petitioner is noncompliant, at the immediate jeopardy level, with the entire condition of participation at § 484.18.

The deficiencies related to two standards under § 484.18 discussed above are sufficient to show Petitioner's noncompliance with the entire condition of participation. Further, as discussed above, some of Petitioner's noncompliance was at the immediate jeopardy level. Therefore, I need not continue to evaluate all of the deficiencies noted by the state agency in order to uphold the sanctions CMS imposed on Petitioner.

2. CMS's imposition of a per-day CMP of $8500 was authorized under the applicable regulations.

The regulations regarding imposition of CMPs for home health agencies allow for the imposition of CMPs in the upper range of $8500 to $10,000 per day for a condition-level deficiency that constitutes immediate jeopardy. 42 C.F.R. § 488.845(b)(3). The regulations further provide that the per-day CMP will continue until compliance can be determined based on a revisit survey. 42 C.F.R. § 488.845(b)(3). The term immediate jeopardy is defined to mean "a situation in which the . . . [home health agency's]

noncompliance with one or more requirements of participation has caused, or is likely to cause serious injury, harm, impairment or death to a patient(s)." 42 C.F.R. § 488.805.

An $8,500 per day CMP is meant for an isolated incident of noncompliance. (In contrast, a per-day CMP of $10,000 is for a deficiency or deficiencies that are immediate jeopardy and result in actual harm.) *See* 42 C.F.R. § 488.845(b)(3)(i) and (iii). There are additional regulatory factors that may be considered in determining the appropriate amount of a civil money penalty. 42 C.F.R. § 488.845(b)(1). These include: the extent to which deficiencies pose immediate jeopardy; the nature, incidence, manner, degree, and duration of deficiencies or noncompliance; the agency's overall compliance history and the presence of repeat deficiencies; the extent to which deficiencies are directly related to the failure to provide quality patient care; the extent to which an agency is part of a larger organization with performance problems; and, an indication of any system-wide failure to provide quality care. 42 C.F.R. § 488.815(a)-(f).

Petitioner argues that the CMP should be significantly reduced because under the regulatory factors at 42 C.F.R. § 488.845(b), it is a small agency with annual revenues under one million dollars and with no access to legal counsel; it has had only one instance of a condition level deficiency in its history and that deficiency was properly addressed and resolved; it is not part of a larger organization with performance problems; and it claims it has a built-in, self-regulating quality assessment and performance improvement system. P. Br. at 17. Petitioner however did not argue that it did not have the financial resources to pay the CMP.

I conclude that the deficiencies here posed immediate jeopardy and that jeopardy was not abated because the agency failed to provide the requisite training to its staff after the survey. Moreover, Petitioner's failure to implement its plan of correction and its repeated deficiencies at the revisit survey indicate that Petitioner's deficiencies were of such a character and extent that it affected its ability to provide quality patient care. The surveyors found an agency that was in complete disarray; its records were chaotic and the DON did not appear to be able to effectively manage the agency. Therefore, I find the per-day CMP is reasonable.

3. CMS's imposition of termination was authorized under the applicable regulations.

CMS may terminate an HHA's Medicare provider agreement when the HHA no longer meets the requirements of the Act, the conditions of participation, or other requirements in the regulations. 42 U.S.C. §§ 1395cc(b)(2), 1395bbb(e); 42 C.F.R. § 489.53(a). Notably, CMS may terminate an HHA's provider agreement if the HHA has a single condition-level deficiency, and CMS's decision to do so is discretionary. *United Medical Home Care, Inc.*, DAB No. 2194 at 13-14 (2008); *Comprehensive Professional Home Visits*, DAB No. 1934 (2004). If there is a finding of immediate jeopardy-level

noncompliance, then CMS must terminate a HHAs participation in Medicare no more than 23 days from the last day of the survey at which the finding of immediate jeopardy was made. 42 C.F.R. § 488.825(a).

As discussed above, I have concluded that Petitioner was out of compliance with a condition of participation at the immediate jeopardy level and Petitioner did not return to compliance within the time stated by CMS. Therefore, CMS was authorized to terminate Petitioner's Medicare provider agreement.

V. Conclusion

I affirm CMS's determination to impose a CMP on Petitioner and to terminate Petitioner's provider agreement. I further conclude that the CMP of $8500 per day was reasonable.

/s/
Scott Anderson
Administrative Law Judge