**Department of Health and Human Services**

**DEPARTMENTAL APPEALS BOARD**

**Civil Remedies Division**

St. Clair's Home Health, Incorporated,
(CCN: 557025),

Petitioner

v.

Centers for Medicare and Medicaid Services.

Docket No. C-11-50

Decision No. CR2341

Date: March 18, 2011

# DECISION

Petitioner, St. Clair's Home Health, Incorporated, is a home health agency (HHA) located in Inglewood, California, that, until its termination on November 5, 2010, was certified to participate in the Medicare program. Following surveys completed April 30, 2010 and June 21, 2010, the Centers for Medicare and Medicaid Services (CMS) terminated St. Clair's program participation because it failed to maintain substantial compliance with three conditions of participation, 42 C.F.R. sections 484.18, 484.30, and 484.48, and because it failed to correct previously-cited deficiencies. Petitioner here appeals its termination, and CMS moves for summary judgment.

For the reasons discussed below, I grant summary judgment. The undisputed facts establish that St. Clair's failed to maintain substantial compliance with all Medicare conditions of participation, and CMS is therefore authorized to terminate its program participation.

**Background**

An HHA is a public agency or private organization that "is primarily engaged in providing skilled nursing services and other therapeutic services" to patients in their homes. Social Security Act (Act) § 1861(o). It may participate in the Medicare program as a provider of services if it meets that statutory definition and complies with certain requirements, called conditions of participation. Act §§ 1861(o), 1891; 42 C.F.R. Part 484; 42 C.F.R. § 488.3. But if the provider fails to comply with the provisions of section 1861 or the relevant regulations, CMS, acting on behalf of the Secretary of Health and Human Services, may terminate its provider agreement. Act § 1866(b)(2); 42 C.F.R. § 489.53(a)(1).

A "condition of participation" represents a broad category of home health services. Each condition is contained in a single regulation, which is divided into subparts called standards. 42 C.F.R. Part 484. Compliance with a condition of participation is determined by the manner and degree to which the provider satisfies the standards within the condition. 42 C.F.R. § 488.26(b). If deficiencies are of such character as to "substantially limit the [HHA's] . . . capacity to furnish adequate care or which adversely affect the health and safety of patients," the provider is not in compliance with conditions of participation. 42 C.F.R. § 488.24(b). CMS may terminate program participation if the HHA fails to meet even one condition of participation. Act §§ 1866(b)(2)(B), 1861(o)(6); 42 C.F.R. § 489.53(a)(3); *Cmty. Home Health*, DAB No. 2134 at 4 (2007).

CMS may also terminate an HHA that fails to correct its deficiencies within a reasonable time (ordinarily no more than 60 days), even if those deficiencies are at the standard (rather than the condition) level. 42 C.F.R. § 488.28.

To monitor compliance, CMS contracts with state agencies that periodically survey the HHAs. 42 C.F.R. § 488.10.

Here, the California Department of Public Health (State Agency) completed St. Clair's recertification survey on April 30, 2010. CMS Ex. 2. Based on those survey findings, CMS determined that the HHA was not in substantial compliance with five conditions of participation and that its deficiencies posed immediate jeopardy to patient health and safety. CMS Ex. 1. CMS thereafter authorized a follow-up survey, which the State Agency completed on June 21, 2010. Based on those survey findings, CMS determined that St. Clair's was not in substantial compliance with three conditions of participation: 42 C.F.R. § 484.18 (acceptance of patients, plan of care and medical supervision); 42 C.F.R. § 484.30 (skilled nursing services); and 42 C.F.R. § 484.48 (clinical records). CMS also determined that St. Clair's had failed to correct significant deficiencies cited during the April survey. CMS Ex. 1 at 2.

CMS terminated St. Clair's Medicare participation for two independent reasons: 1) at the time of the June survey, it was not in substantial compliance with all conditions of participation; and 2) it did not correct all of the deficiencies identified during the April survey.

Petitioner challenges the termination, and CMS now moves for summary judgment. With its motion, CMS has submitted 24 exhibits. (CMS Exs. 1-24). Petitioner responded in a letter dated December 21, 2010.

**Issues**

I consider first whether summary judgment is appropriate.

On the merits, the sole issue is whether CMS is authorized to terminate Petitioner's Medicare provider agreement.

**Discussion**

***A. CMS is entitled to summary judgment because the undisputed facts establish that St. Clair's failed to maintain substantial compliance with all Medicare conditions of participation and that it failed to correct previously-cited deficiencies; CMS is therefore authorized to terminate its program participation.[1]***

Summary judgment is appropriate if a case presents no genuine issue of material fact, and one party is entitled to judgment as a matter of law. 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 Servs.*, 388 F.3d 168, 173 (6th Cir. 2004) (quoting *Celotex Corp. v. Catrett*, 477 U.S. 317, 322 (1986)). To avoid summary judgment, the non-moving party must then act affirmatively by tendering evidence of specific facts showing that a dispute exists. *See Matsushita Elec. Indus. Co. Ltd. v. Zenith Radio Corp.*, 475 U.S. 574, 586 n. 11 (1986); *see also Vandalia Park*, DAB No. 1939 (2004); *Lebanon Nursing & Rehab. Ctr.*, DAB No. 1918 (2004).

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

***1. St. Clair's was not in substantial compliance with 42 C.F.R. § 484.18 because its staff did not follow written plans of care established by a doctor.***

Patients are accepted for treatment based on a reasonable expectation that the patient's medical, nursing, and social needs can be met adequately by the HHA at the patient's residence. The care follows a written plan of care established and reviewed periodically by a doctor. 42 C.F.R. § 484.18. The plan must be developed in consultation with agency staff and must cover *all* pertinent diagnoses, including mental status, types of services and equipment required, frequency of visits, prognosis, rehabilitation potential, functional limitations, activities permitted, nutritional requirements, medications and treatments, and safety measures to protect against injury, instructions for a timely discharge or referral, and any other appropriate items. 42 C.F.R. § 484.18(a) (emphasis added).

Here, CMS cites multiple instances in which St. Clair's staff did not follow the patient's written care plan:

- Patient 8 had an open wound on his right leg. His care plan listed the wound and "intractable pain" as his diagnoses. CMS Ex. 6 at 1. However, when Surveyor Debra Moore, RN, HFEN (health facilities evaluator nurse), accompanied Petitioner's skilled nurse to the patient's home on June 18, 2010, she observed him sitting in a chair, short of breath and using oxygen from a concentrator set at 2 liters per minute per nasal canula. CMS Ex. 4 at 7-8 (Moore Decl. ¶ 17); CMS Ex. 10 at 1-2. Surveyor Moore reviewed a history and physical examination report, dated February 18, 2010, from the acute care hospital to which Patient 8 was then admitted. The report documented Patient 8's history of T-cell lymphoma, an ulcerative lymphoma involving his right leg, chronic obstructive pulmonary disease (COPD), and congestive heart failure (CHF). His oxygen saturation level was very low – 60% on room air (normal oxygen saturation is 95-100%). CMS Ex. 11 at 1-2; CMS Ex. 4 at 8 (Moore Decl. ¶ 17). But, contrary to the requirements of 42 C.F.R. § 484.18(a), his care plan did not mention his respiratory impairments, nor any treatments ordered to address those problems. CMS Ex. 6.

  Apparently, at the exit conference, a non-licensed HHA employee told Surveyor Moore that she had added respiratory information to Patient 8's care plan. Of course, even if done properly, making such a correction at the time of the survey would not preclude termination. *See Cmty. Home Health*, DAB No. 2134 at 14 (finding irrelevant the HHA's claim that it took "swift and decisive action" to correct its deficiencies). Moreover, the unlicensed employee's undated handwritten note is plainly inadequate. Not only was it added by an unlicensed

employee, it also fails to include Patient 8's respiratory diagnoses and other factors required by the regulation. CMS Ex. 4 at 8 (Moore Decl. ¶18).

Patient 8's care plan directed the skilled nurse to cleanse his leg wound with normal saline and to apply Xeroform dressing, a sterile, non-adhering primary dressing that provides a moist environment conducive to healing. Yet, Surveyor Moore saw the skilled nurse apply Vaseline gauze instead of Xeroform. The care plan did not include any orders or directions for Vaseline. CMS Ex. 6 at 1; CMS Ex. 4 at 4 (Moore Decl. ¶ 9); CMS Ex. 10 at 1.

- Patient 12 had multiple pressure ulcers on his buttocks, feet, and legs. CMS Exs. 16, 22. His care plan directed the skilled nurse to cleanse wounds on his left foot and right knee with normal saline, apply a Hydrogel dressing,[2] cover the wound with gauze and Kerlix, and secure with tape. CMS Ex. 16. On June 16, Surveyor Moore accompanied the HHA skilled nurse to Patient 12's home. When the skilled nurse removed the soiled dressing from the patient's left leg, they saw that the prior skilled nurse had applied a Xeroform dressing, rather than the ordered Hydrogel. Surveyor Moore verified that the most recent physician order, dated June 14, 2010, called for Hydrogel. CMS Ex. 22. Neither the skilled nurse nor St. Clair's administrator provided a credible, satisfactory explanation for this deviation from the care plan and physician order. CMS Ex. 4 at 5 (Moore Decl. ¶ 11, 12).

- Patient 5 was diagnosed with sepsis and had decubitus ulcers on his legs and buttocks. CMS Ex. 4 at 7 (Moore Decl. ¶ 16). His care plan was purportedly effective from May 30, 2010 to July 28, 2010 (*but see* ¶ A3 below for a discussion of the irregularities involved in the plan's creation). Contrary to the requirements of 42 C.F.R. § 484.18(a), the plan did not mention decubitus ulcers among Patient 5's diagnoses or treatment. CMS Ex. 12 at 1-2. The plan finally mentions them in the 60-day summary, which would have been prepared at the end of the certification period: "[p]atient continues to have multiple decubitus ulcers on right/left leg and buttocks." CMS Ex. 12 at 2.

  Patient 5's care plan directed the skilled nurse to provide wound care to his wounds. On June 17, 2010, the HHA skilled nurse and Surveyor Moore observed that a new wound had developed on the patient's left leg. Obviously, since the wound was new, Patient 5's physician was not aware of it and had not established any treatment for it. Yet, without consulting Patient 5's physician, the skilled

[2] Hydrogel dressings provide a moist wound environment, which helps to clean and debride necrotic tissue. They are non-adherent and can be removed without trauma to the wound. CMS Ex. 3 at 6-7.

nurse treated the wound with a Xeroform dressing. CMS Ex. 4 at 6 (Moore Decl. ¶¶ 13, 14); CMS Ex. 15.

All home health care and services should derive from the patient's care plan. Those plans must be comprehensive, and staff must follow their instruction. Where, as here, the plan omits a serious diagnosis, the patient is unlikely to receive necessary care. Where, as here, nursing staff disregard plan instructions or provide care in the absence of instructions, the patient is put at risk. These circumstances substantially limit the HHA's capacity to furnish adequate care and adversely affect the health and safety of patients. St. Clair's was therefore not in substantial compliance with 42 C.F.R. § 484.18, and, on that basis alone, CMS rightfully terminated its program participation.

***2. St. Clair's was not in substantial compliance with 42 C.F.R. § 484.30 because skilled nurses did not evaluate patient needs as necessary.***

The facility furnishes skilled nursing services by or under the supervision of a registered nurse (RN) and in accordance with the plan of care. 42 C.F.R. § 484.30. Among other requirements, the RN must regularly re-evaluate the patient's nursing needs. 42 C.F.R. § 484.30(a).

As discussed above, Patient 8 suffered from COPD and CHF and required oxygen. He told Surveyor Moore that he needed oxygen continuously, but he did not have portable oxygen. When riding in a car to his doctor's appointments, he told her, he "[stuck] his head outside of the car window to get air." CMS Ex. 4 at 9-10 (More Decl. ¶ 21); CMS Ex. 10 at 1. He asked Surveyor Moore to request from the HHA portable oxygen for his wheelchair. As CMS observes, St. Clair's nurses completely disregarded Patient 8's respiratory needs. No one evaluated his needs for oxygen, his knowledge of the hazards related to oxygen use, his fire safety awareness, or his disease process. CMS Br. at 16-17; CMS Ex. 4 at 10-11 (Moore Decl. ¶ 23). The absence of an adequate assessment means that Patient 8's care needs were not identified and not addressed, which substantially limited St. Clair's capacity to furnish him adequate care and adversely affected his health and safety. St. Clair's was therefore not in substantial compliance with 42 C.F.R. § 484.30, and, on that basis alone, CMS rightfully terminated its program participation.

CMS also points out, accurately, that the RN failure to evaluate patient needs was cited during the April 30, 2010 survey. CMS Br. at 18. The report form for that survey sets forth in considerable detail RN failures to evaluate the nursing needs of two patients. CMS Ex. 2 at 51-60. Among other particularly disturbing deficiencies, an RN supervisor had not visited a patient but had signed an assessment form indicating that she had visited and assessed the individual. Needless to say, the comprehensive assessment for that patient was wholly inadequate. CMS Ex. 2 at 55. Petitioner promised to correct most of

its skilled nursing deficiencies no later than May 21, 2010.[3] Even if I concluded that the deficiencies cited under skilled nursing services did not put the HHA out of compliance at the condition level (which I emphatically do not), I would nevertheless sustain St. Clair's termination under 42 C.F.R. § 488.28 because Petitioner failed to correct a standard-level deficiency.

***3. St. Clair's was not in substantial compliance with 42 C.F.R. § 484.48 because a patient's clinical record did not contain vital documents.***

The HHA must maintain for each of its patients a clinical record containing pertinent past and current findings in accordance with accepted professional standards. Among other requirements, the record must contain appropriate identifying information: the physician's name; drug, dietary, treatment, and activity orders; signed and dated clinical and progress notes; copies of summary reports sent to the attending physician; and a discharge summary.

At the time of the June survey, Patient 5's current clinical record included neither a care plan nor a comprehensive assessment. CMS Ex. 4 at 12. St. Clair's office manager, a clerical employee, told Surveyor Moore that she could assist with Patient 5's missing documents. She apparently went into a separate office. After waiting for a few minutes, Surveyor Moore followed her into that office and caught her on the computer creating Patient 5's care plan. She printed it out and handed it to the surveyor. A few minutes later, the employee completed Patient 5's comprehensive assessment. CMS Ex. 4 at 12 (Moore Decl. ¶¶ 26, 27); CMS Ex. 12 at 3-4. I have discussed above some of the inadequacies of the care plan. Moreover, the plan was not signed by either a nurse or the attending physician, not surprising in light of the means by which it was generated. CMS Ex. 12 at 1.

Petitioner has not denied any of these assertions, although it points out that the office manager has since died and is "not here to defend herself." However, had these documents been properly prepared and maintained in Patient 5's clinical record, the responsible professionals should have come forward to say so. St. Clair's does not even assert, much less provide evidence, to establish any dispute over these facts. CMS has therefore shown that St. Clair's failed to maintain for each of its patients, in accordance with accepted professional standards, a clinical record containing critical documents.[4] The inadequacy of its clinical record absolutely compromised St. Clair's capacity to

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[3] For one deficiency, it promised a completion date of June 3. CMS Ex. 2 at 60.

[4] The irregular and inappropriate manner by which St. Clair's employee generated the care plan also violated 42 C.F.R. § 484.18, as well as 42 C.F.R. § 484.55 (comprehensive assessment of patients).

furnish adequate care, which justifies CMS's determination that it was not in substantial compliance with 42 C.F.R. § 484.48, and this deficiency alone justifies the termination.

***B. St. Clair's must meet requirements for program participation without regard to the quality of the survey or the alleged bias of a surveyor.***

As the above discussion shows, CMS presents compelling evidence – unrebutted by Petitioner – that St. Clair's was not in substantial compliance with the Medicare conditions of participation. Far from coming forward with evidence showing a dispute of any material fact, Petitioner has not even challenged CMS's factual allegations. Instead, Petitioner charges that one of the state surveyors is associated with its competitor and was therefore biased. Petitioner also complains that, until CMS included it with its exhibits, its administrator had not seen a one-page list of accusations that were made by an anonymous complainer. *See* CMS Ex. 21 at 7.

Petitioner has provided absolutely no evidence to support its allegations of surveyor misconduct. In any event, as CMS points out, the Board has repeatedly rejected, as irrelevant, such attacks on survey performance. *Comprehensive Prof'l Home Visits*, DAB No. 1934 at 13 (2004) (quoting *Beechwood Sanitarium*, DAB No. 1906 at 44 (2004) (holding that " 'the appeals process is not intended to review the conduct of the survey but rather to evaluate the evidence of compliance regardless of the procedures by which the evidence was collected.' . . . Consequently, the arguments concerning the surveyor's alleged attitude and knowledge of program requirements are unavailing.")).

**Conclusion**

Because Petitioner does not dispute any of the underlying facts, which establish that St. Clair's was not in substantial compliance with all conditions of participation at the time of the June 2010 survey, CMS had the authority to terminate its Medicare participation and is entitled to summary judgment. Independent of that finding, because the undisputed evidence establishes that St. Clair's did not correct deficiencies cited during the April 2010 survey, CMS had an alternative basis for terminating its program participation. I therefore grant CMS's motion for summary judgment.

/s/
Carolyn Cozad Hughes
Administrative Law Judge