Department of Health and Human Services

DEPARTMENTAL APPEALS BOARD

Civil Remedies Division

In the Case of:	)	
	)	
Techota, LLC, d/b/a CV Home Health Services,	)	Date: January 12, 2009
	)	
Petitioner,	)	
	)	
- v. -	)	Docket No. C-08-445
	)	Decision No. CR1886
Centers for Medicare & Medicaid Services.	)	
	)	

DECISION

For the reasons stated below, I conclude that Techota, LLC, d/b/a CV Home Health Services (Petitioner or Techota), was not eligible to participate in the Medicare program because it did not meet the Medicare conditions of participation governing home health agencies. Accordingly, I find that the determination of Centers for Medicare & Medicaid Services (CMS) that Petitioner did not qualify as a home health agency was correct.[1]

I. Background

Petitioner operated a home health agency (HHA) in Vance, Alabama that applied to participate in the Medicare program. CMS Posthearing Brief (CMS Br.) at 2. The Alabama Department of Public Health (the survey agency) performed an initial Medicare certification survey of Petitioner on October 9-10, 2007. CMS Ex. 1. The survey agency

[1] At all times relevant during this appeal, Petitioner could have reapplied for participation in Medicare. In fact, it could have proceeded on this course simultaneously with this appeal. Petitioner, however, elected to pursue only this appeal of CMS's decision that it was not eligible to participate. CMS Exhibits (Exs.) 10, 11; Transcript (Tr.) 206-211; and CMS Br. at 3.

determined that Petitioner failed to meet at least two of the conditions of participation necessary for certification for participation in the Medicare program, namely 42 C.F.R. § 484.18 (Condition of participation: acceptance of patients, plan of care, and medical supervision) with respect to the administration of the HHA and 42 C.F.R. § 484.30 (Condition of participation: skilled nursing services) with respect to the HHA's furnishing of services to patients. On November 7, 2007, CMS notified Petitioner of its determination that Petitioner was not eligible to participate as an HHA in the Medicare program. CMS Ex. 10. It further informed Petitioner that it could take steps to correct the deficiencies found and to reapply to establish eligibility. CMS also informed Petitioner that it could request that CMS reconsider its determination. Petitioner sought reconsideration from CMS of its determination. By letter dated March 10, 2008, CMS notified Petitioner of its reconsideration decision. CMS Ex. 11. It determined that the deficiencies cited under the two conditions of participation were correct and that CMS's decision to deny participation was correct. CMS indicated that if Petitioner believed this decision was incorrect it could request a hearing.

By letter dated May 8, 2008, Petitioner appealed the denial of participation, and the matter was assigned to me for hearing and decision. I convened a hearing in Atlanta, Georgia on September 3, 2008. CMS offered offered 11 exhibits, CMS Exs. 1-11 were admitted. Petitioner offered 21 exhibits, Petitioner Exhibits (P. Exs.) 1-21 were admitted. The parties submitted posthearing briefs (CMS Br. and P. Br.) and posthearing reply briefs (CMS Reply and P. Reply).[2]

II. Analysis

A. Issue presented

This case presents the following issue for my determination-

- The sole issue before me is whether CMS properly determined that Petitioner was not qualified to participate as an HHA in the Medicare program.

[2] Petitioner titled its posthearing brief as its posthearing reply brief. I refer to it, however, as its posthearing brief (P. BR.) because Petitioner later sought leave to file a sur reply to CMS's posthearing reply brief, which I granted. That is referred to as P. Reply.

B. Applicable law

The Social Security Act (Act) sets forth requirements that a prospective provider of HHA services must meet in order to participate in the Medicare program, and authorizes the Secretary of Health and Human Services to promulgate regulations implementing the statutory provisions. Act, sections 1861(o) and 1891 (42 U.S.C. §§ 1395x(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 be eligible to participate in the Medicare program and obtain reimbursement, 42 C.F.R. § 488.3(a)(2) requires that an HHA must be in compliance with all applicable "conditions" as specified in 42 C.F.R. Part 484. An initial review of compliance with the conditions of participation is required and such reviews or surveys are conducted by the state survey agency. Based upon its survey, the state survey agency either certifies compliance or noncompliance of the surveyed provider. 42 C.F.R. § 488.20.

The state survey agency certifies that an HHA is not in compliance with the conditions for 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); *CSM Home Health Services*, DAB No. 1622, at 6-7 (1997). The state survey agency is to assess the provider's performance against the appropriate standards to determine and document the nature and extent of any deficiency and to assess the need for correction or improvement. Surveyors are required to "directly observe the actual provision of care and services to residents, and the effects of that care, to assess whether the care provided meets the needs of individual residents. . . ." 42 C.F.R. § 488.26(c). Furthermore, deficiencies, which considered individually might not constitute violation of a condition of participation, should also be considered collectively with all other deficiencies to determine whether a condition of participation has been violated. *CSM Home Health Services,* DAB No. 1622, at 7.

A prospective provider that is determined not to qualify as a provider by CMS, has a right to have the determination reviewed in accordance with the procedures of 42 C.F.R. Part 498.

CMS bears the burden of producing evidence sufficient to establish a prima facie case. CMS must set forth the basis for its determination with sufficient specificity for a petitioner to respond and come forward with evidence related to the disputed findings. The evidence set forth by CMS must be sufficient to establish a prima facie case that

CMS had a legally sufficient basis to determine that a prospective provider did not meet the participation requirements. In order for a petitioner to prevail, the petitioner must then prove by a preponderance of the evidence on the record as a whole that it was in substantial compliance with the relevant statutory and regulatory provisions. *Hillman Rehabilitation Center*, DAB No. 1611, *aff'd*, *Hillman Rehabilitation Center v. U.S. Dept. of Health and Human Services*, No. 98-3789 (D.N.J. May 13, 1999).

C. Discussion

The regulations in 42 C.F.R. Part 484 establish the conditions and standards by which HHA compliance with the Medicare program participation requirements is determined. The standards set forth in the regulations are essentially the yard sticks by which surveyors measure the level of compliance of the HHA. If HHA performance does not measure-up to the regulatory standard, a deficiency exists. If a deficiency is found, the question is whether that deficiency alone, or considered in combination with another deficiency, is "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). If the provider's capacity to furnish adequate care is substantially limited, or if the health and safety of patients is adversely affected, then a condition-level deficiency exists. Consequently, if I determine that Petitioner failed to meet even one condition of participation, I need go no further and I must affirm CMS's determination not to certify the provider for participation in the Medicare program.[3]

Prospective new providers must be in operation and providing services to patients when surveyed. This means that, at the time of the survey, the provider must be furnishing all services necessary to meet the applicable provider definition and demonstrate its operational capability in all facets of its operations. State Operations Manual (SOM), section 2008A. A new HHA applicant must be providing skilled home health services to a minimum of 10 patients before a survey is conducted and, at the time of the survey, the HHA must be providing care to at least seven of the 10 required patients. SOM, section 2008B. At the time of the certification survey of this HHA, it was treating 10 patients and the survey found deficiencies with respect to four of the 10 patients.[4]

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[3] I must point out that at all times relevant to this matter, Petitioner also had the option of correcting the particular deficiencies and reapplying for certification and participation in the Medicare program, but it chose not to pursue that course of action. Tr. 211.

[4] CMS contends deficiencies with respect to just less than half of the entire patient sample is indicative of serious systemic problems with the HHA. *See also* Tr. at 34-35.

1. Because Techota was not in compliance with one Medicare condition of participation, CMS appropriately decided not to certify Techota for participation as an HHA in the Medicare program.

a. Petitioner did not meet the condition of participation at 42 C.F.R. § 484.18 (Tags G 159 (plan of care) and G 165 (conformance with physician orders)).

The regulation on which this participation requirement is based states–

> **Condition of participation: Acceptance of patients, plan of care, and medical supervision.**
>
> 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. Care follows a written plan of care established and periodically reviewed by a doctor of medicine, osteopathy or podiatric medicine.
>
> (a) *Standard*: *Plan of care.* The plan of care developed in consultation with the agency staff covers 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, any safety measures to protect against injury, instructions for timely discharge or referral, and any other appropriate items. If a physician refers a patient under a plan of care that cannot be completed until after an evaluation visit, the physician is consulted to approve additions or modifications to the original plan. Orders for therapy services include the specific procedures and modalities to be used and the amount, frequency, and duration. The therapist and other agency personnel participate in developing the plan of care.

42 C.F.R. § 484.18(a).

Tag G 159 and Tag G165

The surveyors determined that Techota failed to meet these particular standards under the condition of participation for two of eight patient records reviewed. The surveyors first found that Petitioner failed to follow the patients' plans of care. All home health care services must be authorized and directed by the patient's physician. 42 C.F.R. § 484.18(a). This authorization and direction is effectuated by written individualized plans of care for each patient and signed by the physician. Therefore, a skilled nurse can only provide services as ordered by the physician and cannot operate outside the boundaries of the plan of care. Techota's own written policies echo the regulatory requirements and home health industry standards of care. The policy for patient plans of care indicate that any patient services by Techota must be under medical supervision requiring a plan of care, signed by the patient's physician, which is developed by the HHA upon admission and which is reviewed and revised as needed but at least every 60 days. The policy further states that all interim verbal orders from a physician must be confirmed in writing and signed by the physician and that all interventions and treatments provided by the HHA are to be consistent with the patient's plan of care. See CMS Ex. 8, at 6-7.

The surveyors then determined that Petitioner failed to meet another standard, Tag G165, under the condition of participation, when Petitioner administered an injection of Lovenox, a blood thinner, to a patient on two occasions without an order by the physician and without indication in the plan of care that this was an ordered medication, treatment or intervention. 42 C.F.R. § 484.18(c).

Patient Medical Record (MR) 4

Patient MR4 was a 52-year-old woman whose physician admitted her to Petitioner's agency on August 27, 2007. CMS Ex. 3, at 4. The plan of care stated at Section 21 that Patient MR4 was to receive skilled nursing services twice a week for 21 days and then once a week for 39 days. She was also to receive the services of a home health aide twice a week for 60 days. CMS Ex. 3, at 4; P. Ex. 12, at 41; Tr. 36. Also, under the section titled, Orders for Discipline and Treatments, it indicates on an addendum page "wound" and "assess wound for healing," "assess circumference, depth, character and presence or absence of infection," "change dressings." The plan of care also indicates in Section 22, Goals/Rehabilitation Potential/Discharge Plans, that the primary goal of the HHA services to be rendered to Patient MR4 is "to promote the healing of skin tears @ sacrum/gluteal folds." *Id.*

The surveyor found that the HHA did not provide the twice weekly frequency for skilled nursing care for the first 21 days as ordered by the physician and as set forth in the patient's plan of care. The surveyor examined the medical record for this patient and noted the date of each nurse's note in the record. The surveyor found that the patient was provided skilled nursing care twice during the first week but thereafter skilled nursing services were provided only once a week for week two and week three (up to September 16, the 21st day).[5] CMS Ex. 1, at 3; Tr. 37-38. Petitioner does not dispute that the requisite skilled nursing visits were not made during week two, but contends that Petitioner provided skilled nursing visits three times (twice on September 12 and once on September 14) during week three.[6] P. Br. at 7. I find no basis for Petitioner's contention. I examined the records. The records indicate a nurse's note for September 12 (P. Ex. 12, at 102-06) and the same RN also filled out a form assessing, in a supervisory capacity, the care given to the patient by the home health aide (P. Ex. 12, at 102). Thus, the record does not establish that there were two skilled nursing visits made on the same day. As for the assertion that a skilled nursing visit was made on September 14, 2007, there is no nurse's note for that date in the record. Petitioner contends that its computerized log indicated an RN routine visit on September 14, 2007. However, upon closer examination, Petitioner agreed that indeed there was a discrepancy in the computerized calender-log. While the calendar indicated an RN visit, the same form indicated below on the billing information that the visit was actually made by the home health aide. P. Ex. 12, at 2; Tr. 191-92; CMS Reply Br. at 4-5; Petitioner's Br. at 7. There is no indication from the patient's medical record that there was any skilled nursing care rendered to the patient on September 14.

Petitioner nevertheless would have me believe that this is a minor issue; it contends that while skilled nursing services may not have been rendered as scheduled, a home health aide still provided services to the patient twice a week during this time so that someone was in the patient's home "checking on her." P. Br. at 7. This does not lessen the deficiency or lead me to find that Petitioner still met the relevant condition of participation. Here, Petitioner's RN made a complete assessment of the patient and determined that based on the patient's condition, the patient needed skilled nursing

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[5] CMS determined that Petitioner provided skilled nursing services on the following dates only during the first 21 days: August 27, August 31, September 4, and September 12, 2007. CMS Br. at 7-8; CMS Ex. 3, at 33, 40, 42, 44; Tr. 38.

[6] Petitioner also argued that an additional skilled nursing visit was made during week one on August 28. P. Br. at 7. However, the medical records reveal that no such skilled nursing visit was made to the patient on that date; rather, the RN called the patient's physician. P. Ex. 12, at 81, 84. This is not considered a skilled nursing visit under the plan of care.

services at least twice a week for 21 days **in addition to** twice weekly home health aide services. If the RN believed the patient needed skilled care for less than that, the plan of care would have so stated. Also, the patient's physician signed the plan of care. In doing so, the physician is ordering that skilled nursing services be rendered to the patient twice a week. Failure to provide those services amounts to a failure to follow the physician's specified order. But, more importantly, failure to follow the plan of care is breach of the regulatory requirement. 42 C.F.R. § 484.18(a). The condition of participation here has as one of its primary standards that each patient must have a plan of care that covers, among other things, all pertinent diagnoses, types of services and equipment required, frequency of visits, and medication and treatment appropriate for the specific patient. Failure to provide the frequency of the visits prescribed for rendering skilled nursing care is indeed a significant deficiency and a failure to meet the required standard. Also, as CMS pointed out, failure to provide this patient with the required twice weekly skilled nursing services was significant because she had a "wound" that needed to be assessed, cleansed, and dressed, and there is no indication from the plan of care that there was anyone in the household who was capable of providing, or was taught by the RN to provide, the necessary wound care. Tr. 39.

Petitioner also failed to properly develop the plan of care for Patient MR4. An HHA provides services and treatments to a patient in their home and the same nurse may not be providing the services each time. Therefore, the plan of care must be complete and comprehensible. It must indicate all the diagnoses and specify the treatments in such a way that the provider of the services knows what treatment to provide. The plan of care also should specify what supplies will be needed to provide the services in the plan of care, so that when the RN provides the requisite services she brings with her the supplies necessary to perform those services.[7] Tr. 43-44. Here, although this patient's "wound" was of primary concern to her physician, and treatment of the wound is listed as a treatment order, there is no diagnosis listed regarding the wound nor are there any supplies listed for cleansing and dressing the wound. *See* P. Ex. 12, at 82-83; Tr. 41-42. As the surveyor pointed out in her testimony, the plan of care lacks the necessary specificity. The only mention of the location on the wound is in Section 22, Goals. The plan of care, at the very least, should have indicated where the wound was, and described the condition of the wound, its dimensions and depth, and any other pertinent information which would be useful in assessing and staging the wound. There is no specificity in the plan of care as to how this wound should be treated; should it be cleansed with soap and

[7] Under section 14 of the plan of care form, all medical supplies and equipment necessary for the patient are supposed to be listed.

water or is saline necessary, should a transparent dressing be used or another kind of dressing be used? The orders for wound care should have specified these matters, and if the patient's physician did not so specify, the nurse should have contacted the physician for specific orders.[8]

As the surveyor pointed out, however, the RN did perform a comprehensive start of care assessment and the form filled out during that assessment has certain information that then was expected to be placed in the plan of care.[9] *See* CMS Ex. 3, at 6-32. For example, any question in the assessment that is noted by several stars also states the specific section in the HCFA Form 485, the plan of care, where this information should be input. Here the assessment form indicated that in Section 13, under medical supplies, the plan of care should have included the following: 4x4 gauze, alcohol prep, gloves, saline, Tegaderm, and wound cleanser. CMS Ex. 3, at 30. Yet none of these supplies were included on the plan of care (HCFA Form 485); in fact, no supplies for any kind of wound or pressure sore care was included.[10] P. Ex. 12, at 82; Tr. 45-46. Clearly, this too demonstrates the lack of necessary specificity in the plan of care. As CMS pointed out, this lack of required specificity in the plan of care means that Petitioner never had a complete written order for treatment of the patient's wound which was signed by her physician. CMS Br. at 8-9 and Reply at 5.

Therefore, I find significant failures with respect to the plan of care for Patient MR4 and that these failures clearly impacted the treatment provided to Patient MR4. Indeed, the failures with respect to this patient's wound care had the potential for causing harm to this patient, including the possibility of infection or sepsis. I also find it significant that since this was an initial certification survey to determine if Petitioner met the conditions

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[8] Apparently, the RN contacted the doctor for clarification, but the plan of care does not include any supplemental treatment order nor does the medical record contain any signed physician order as required by the HHA's own policy. CMS Ex. 8, at 1; Tr. 54-55.

[9] Petitioner's RN also filled out a Wound Assessment form at the time that the Start of Care Assessment was performed. However, this information included in this form was not inputted into the Plan of Care. *See* CMS Ex. 3, at 33-38; Tr. at 48.

[10] I find this puzzling considering that the Wound Assessment Form indicates "current treatments" for the patient's wound care, including that the wound had been cleansed with soap and tap water with "Duoderm" dressing, yet nothing of this specificity is included in the plan of care, and the start of care assessment form suggested very different cleaning methods and dressing type. P. Ex. 12, at 77, *compared with* 67; Tr. 48-50.

of participation, these kinds of failures, for even one patient, when Petitioner is only treating 10 patients, demonstrated that Petitioner was not qualified to participate in Medicare at the time of the survey.

Patient MR5

Patient MR5 was a 79-year-old man admitted to Petitioner's agency on August 8, 2007. CMS Ex. 5, at 4. The statement of deficiency indicated that Petitioner's Nurses Notes for visits to this patient on August 16, 2007, documented that the RN administered Lovenox by injection to Patient MR5 on two visits. CMS Ex. 5, at 4-5, 15. There were no notes as to the amount of the drug administered. The plan of care for Patient MR5 did not list this drug as one of the medications for this patient nor did it indicate that the RN should administer or "teach" the patient's spouse caregiver how to administer the injection. CMS Ex. 5, at 4-5. Lovenox is a blood thinner. Petitioner's administration of this medication was cited as a deficiency under both the Tag F159 - Plan of Care, and Tag F165 - Conformance with Physician Orders.

Petitioner does not dispute that this medication is not listed on the patient's plan of care. Petitioner contends that it was not on the plan dated August 8 for two reasons: one, because the patient received the medications in pre-filled syringes from Critical Care Systems ,who referred Patient MR5 to Petitioner; and, two, because the medication was not ordered by the physician until August 15. P. Br. at 10-11. Petitioner also contends that the RN only administered the injections on two occasions in order to provide a reminder demonstration to the patient's spouse, who had been instructed on how to administer the medication at the hospital. P. Br. at 11.

Neither reason excuses the error or changes the fact that the medication was administered without the plan of care indicating that Patient MR5 was prescribed this medication, and the physician had not ordered the HHA nurse to administer the injection or teach the patient's spouse how to administer the medication. Petitioner's own policy manual specifically provides that orders for medication and its administration by the HHA can only be taken from the physician and that orders for medications will be given only on written or phone orders by the physician to a RN or LPN. CMS Ex. 8, at 1. The medication policy further provides that when a new medication is ordered it is added to the patient's medication profile along with any appropriate information. CMS Ex. 8, at 2-5. For any injection, however, the medication policy specifically provides that for the RN to administer an injection and to provide teaching to the family to administer the injection requires specific written and signed orders by the patient's physician. CMS Ex. 8, at 3. Finally, Petitioner's own policies provide that all interventions and treatments provided by Petitioner's staff must be consistent with the plan of care and conform to the physician's orders and any interim verbal orders from the physician must be promptly

confirmed in writing and signed by the physician. CMS Ex. 8, at 6. Contrary to Petitioner's contentions, it has wholly failed to rebut CMS's prima facie case of Petitioner's noncompliance with respect to Patient MR5 with Tag G159 in providing care in accordance with the patient's plan of care, and under Tag G165, that requires that drugs and treatments are administered by agency staff only as ordered by the physician. If it had met this standard it would have been easy to prove its compliance by showing the conforming plan of care and the necessary written signed order by Patient MR5's physician. Petitioner did not do so.

Petitioner's failure to meet two out of the three standards under the condition of participation is significant. Petitioner's failures indicate to me a lack of capacity to furnish adequate care that had the potential to adversely affect the health and safety of Petitioner's patients. I find by a preponderance of the evidence that Petitioner failed to meet the condition of participation at 42 C.F.R. § 484.18.

III. Conclusion

Based on the above findings and analysis, I sustain CMS's determination that Techota, a prospective provider, was not in substantial compliance with the Medicare conditions of participation necessary to be certified as an HHA provider. In so finding, I determined that Petitioner's deficiencies would substantially limit its capacity to furnish adequate care or would adversely affect the health and safety of patients.

/s/
Alfonso J. Montano
Administrative Law Judge