Department of Health and Human Services

DEPARTMENTAL APPEALS BOARD

Civil Remedies Division

In the Case of:	)	
	)	
Freedom Home Care, Inc.,	)	Date: March 24, 2009
	)	
Petitioner,	)	
	)	
- v. -	)	Docket No. C-09-65
	)	Decision No. CR1930
Centers for Medicare & Medicaid Services.	)	
	)	

DECISION

I grant summary judgment to the Centers for Medicare & Medicaid Services (CMS) sustaining its determination to terminate Petitioner, Freedom Home Care, Inc.'s, provider agreement.

I. Background

Petitioner, located in Rancho Cucamonga, California, was certified by Medicare as a home health agency (HHA). On August 11, 2008, the California Department of Public Health (DPH) completed a recertification survey of Petitioner. CMS determined that the survey documented deficiencies that Petitioner failed to meet four conditions of participation ― 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 patients, plan of care, and medical supervision; and 42 C.F.R. § 484.30 Skilled nursing services ― and that some of the deficiencies under the condition of participation at section 484.18 posed immediate jeopardy to the health and safety of Petitioner's patients. CMS further determined that those documented deficiencies either individually or in combination substantially limited Petitioner's capacity to render adequate care or adversely affected patient health and safety. Consequently, because Petitioner was not in compliance with all conditions of participation, CMS, by notice dated October 8, 2008, determined to terminate Petitioner's provider agreement effective October 31, 2008.

Petitioner timely requested review and this matter was assigned to me. Pursuant to my initial order, CMS filed a Motion for Dismissal and/or Summary Disposition with a brief (CMS Br.) together with CMS Exhibit (Ex.) 1. Petitioner responded to CMS's motion (P. Br.) and submitted Petitioner's Exhibits (P. Exs.) 1-12. CMS filed a Request for Leave to Reply (CMS Reply), which I granted, together with CMS Ex. 2. Neither party objected to the other's exhibits, and they are admitted.

II. Issue, applicable law, and findings of fact and conclusions of law

A. Issue

In its motion, CMS raises two issues. First, it contends that Petitioner's hearing request is on its face inadequate to respond to the allegations of noncompliance made by CMS. It urges that I dismiss the hearing request for the reason that it fails to comply with the requirements of 42 C.F.R. § 498.40(b) that a hearing request identify the specific findings of fact and conclusions of law with which the affected party disagrees and specify the basis for contending that the findings and conclusions are incorrect. Alternatively, CMS urges that I grant it summary disposition, contending that Petitioner has not contested allegations of fact which are, on their face, sufficient to establish that Petitioner has contravened HHA participation conditions.

I find it unnecessary to address CMS's motion to dismiss. In this decision I address CMS's alternative argument that summary disposition is appropriate.

B. Applicable law.

The Social Security Act (Act) sets forth requirements for HHAs participating in the Medicare and Medicaid programs, and authorizes the Secretary of Health and Human Services to promulgate regulations implementing the statutory provisions. Act, sections 1861(m) and (o), and 1891 (42 U.S.C. §§ 1395x(m) and (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 its services a HHA must be in compliance with all applicable "conditions" as specified in 42 C.F.R. Part 484. 42 C.F.R. § 488.3(a)(2). Periodic review of compliance with the conditions of participation is required and such reviews or surveys are generally conducted by the state agency. Based upon its survey, the state agency either certifies compliance or noncompliance of the surveyed provider. 42 C.F.R. §§ 488.20, 488.24, 488.26.

The state agency certifies that a HHA is not in compliance 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); *CSM Home Health Services*, DAB No. 1622, at 6-7 (1997). 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)(2).

CMS is authorized to terminate a provider agreement when the provider no longer meets the requirements of the Act or fails to meet the conditions of participation, among other grounds listed in the regulation. 42 C.F.R. § 489.53.

C. Findings of fact and conclusions of law

I make findings of fact and conclusions of law (Findings) to support my decision in this case. I set forth each Finding below as a separate heading.

1. Summary judgment is appropriate where there are no disputed issues of material fact.

2. The undisputed material facts alleged by CMS support a finding that Petitioner failed to comply with a condition of participation.

The regulations governing hearings at 42 C.F.R. Part 498 do not explicitly provide for summary judgment as a means of deciding cases. But these regulations have been interpreted consistently in this forum and by the Departmental Appeals Board (Board) to allow for summary judgment in circumstances that are analogous to those for which summary judgment is appropriate under FED. R. CIV. P. 56.

Rule 56 permits summary judgment where there is no dispute as to the material facts of a case. A fact is "material" where it is necessary to deciding a case's outcome. Summary judgment may be granted when a moving party alleges facts which, if not disputed, would be sufficient to establish a basis for that party to prevail on the merits.

Allegations of facts which if undisputed establish a basis for a judgment favorable to the moving party impose a burden on the party opposing summary judgment to allege facts which create a genuine dispute. A party opposing a motion for summary judgment need not prove that the weight of the evidence in the case supports its position in order to prevail on the motion. But, at a minimum, it must allege facts and claim inferences which, if ultimately proven, would create a genuine controversy as to the facts of a case. The Board's most recent discussion of the evaluation of facts and inferences in the context

of summary disposition appears in *Brightview Care Center*, DAB No. 2132 (2007), and I have followed the principles set out in that case here.

CMS's allegations of condition-level noncompliance by Petitioner are based on a compliance survey. That survey determined that Petitioner failed to comply with four conditions of participation for a HHA as stated in the following regulations:

- 42 C.F.R. § 484.14 (Organization, services & administration);
- 42 C.F.R. § 484.16 (Group of professional personnel);
- 42 C.F.R. § 484.18 (Acceptance of patients, plan of care, & medical supervision); and
- 42 C.F.R. § 484.30 (Skilled nursing services).

CMS Ex. 1; CMS Notice Letter dated October 8, 2008.

In its motion for summary disposition, CMS argued that Petitioner had admitted facts sufficient to warrant summary judgment in CMS's favor with respect to at least three of the conditions. CMS pointed out that each of the admitted deficiencies involved a serious breach by Petitioner's professional staff concerning the care given or, in some instances, not given to Petitioner's patients. In its response to the motion, Petitioner failed to respond to many of CMS's arguments, failed to dispute certain facts and findings or failed to present credible evidence to establish the existence of a genuine issue of material fact in a number of instances which were critical to ruling against CMS's motion.

In deciding this case, it is unnecessary that I find that Petitioner failed to comply with all four of the conditions that were cited by CMS. As I discuss below, failure by Petitioner to comply with even one of these conditions gives CMS grounds to terminate its participation in Medicare. Thus, viewing the evidence in the light most favorable to Petitioner, and drawing every inference in Petitioner's favor that can reasonably be supported by that evidence, the undisputed facts establish that Petitioner was not in substantial compliance with all the conditions of participation and summary judgment is therefore appropriate.

3. CMS is authorized to terminate Petitioner's provider agreement when Petitioner no longer meets the requirements of the Act for participation as a HHA.

The regulations at 42 C.F.R. Part 484 establish the conditions of participation and standards by which HHA compliance with the Medicare program is determined. The standards set forth in the regulations are essentially the yardsticks by which surveyors

measure the level of compliance of the HHA. If a HHA's performance does not measure up to the regulatory standard, a deficiency exists. If a deficiency exists, 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 and termination may be appropriate. If no condition-level deficiency exists, CMS may still consider whether one or more standard-level deficiencies are repeated on survey and resurvey and, if no correction has occurred, CMS may declare the provider agreement terminated on that basis. If I determine that Petitioner failed to meet even one condition of participation, I may conclude that there is a basis for termination of Petitioner's provider agreement. 42 C.F.R. § 489.53(a) (CMS may terminate a HHA's provider agreement if it no longer meets the appropriate conditions of participation.)

4. Petitioner did not meet the condition of participation at 42 C.F.R. § 484.14 (Organization, services & administration) because it failed to meet certain standards of the condition of participation and these deficiencies both alone and in combination with each other substantially limited Petitioner's capacity to furnish adequate care or adversely affected the health and safety of the patients.

The surveyors determined that Petitioner failed to meet four standards under this condition of participation. I address two standards here and find they are sufficient to support CMS's finding that Petitioner did not meet the condition of participation. Thus, I need not discuss the other two standards found deficient under this condition because even if Petitioner established that it was in compliance with the other standards, it still would not be in substantial compliance with the condition of participation.

a. G 134[1] (42 C.F.R. § 484.14(c) Administrator)

This standard requires that an administrator employ qualified personnel. The survey found that the Petitioner's Administrator failed this standard when she hired a licensed vocational nurse (LVN) who did not have one year of professional nursing experience as required by California state law. California state law requires that a LVN who provides services in a patient's temporary or permanent place of residence through a home health agency must have one year of prior professional nursing experience. CAL. CODE REGS.,

[1] This is the prefix tag reference for the applicable standards and conditions of participation as indicated on the Statement of Deficiencies. Each tag represents a particular regulatory provision.

tit. 22 § 74707; CMS Ex. 2. The survey found that according to Petitioner's personnel records, the LVN was hired on July 29, 2008 and, after the surveyors uncovered her lack of experience, the LVN was terminated on August 11, 2008. Petitioner does not dispute that this LVN was hired without the requisite experience required by state law. Instead, Petitioner contends that the LVN in question was hired mistakenly but there was no problem because the LVN had no visits to patients scheduled nor were any patients yet assigned to her. CMS Ex. 1, at 7.

I conclude that the undisputed evidence is that Petitioner's Administrator failed to ensure that the HHA employed only qualified personnel. It is only fortuitous that the unqualified LVN had not yet been assigned any patients or had any visits to patients scheduled when the survey disclosed that the LVN did not have the requisite experience. That does not diminish the fact that an unqualified LVN was hired. I conclude that CMS found a clear violation of this standard. Besides being a violation of state licensing requirements, Petitioner's failure to hire qualified staff also adversely affects the health and safety of the patients. Accordingly, I find that Petitioner failed to meet the standard at G 134.

b. G 143 (42 C.F.R. § 484.14(g) Coordination of patient services)

This standard requires that all personnel furnishing services maintain liaison to ensure that their efforts are coordinated effectively and support the objectives outlined in the plan of care. The clinical record should establish that effective interchange, reporting, and coordination of patient care does occur.

The survey determined that this standard was not met with respect to two patients, Patient 1 and Patient 9, when there was no documentation in the patients' clinical records to indicate that the HHA nursing staff notified the patients' physicians of significant changes in the patient's condition or notified the other HHA staff to ensure that care was coordinated effectively. Petitioner did not dispute the findings with respect to Patient 1. As for the findings with respect to Patient 9, Petitioner disputed one small aspect of the findings but failed to dispute the material aspects of the surveyor's findings.

Patient 1's plan of care showed he had diagnoses which included diabetes mellitus type 2 insulin dependent and peripheral vascular disease. His physician ordered the HHA to provide skilled nursing services twice a week for 60 days. CMS Ex. 1. The surveyor accompanied the skilled nurse (SN) to her visit with Patient 1. The surveyor observed that Patient 1 had a 3 ½ inch by 4 inch open wound on the shin of his left leg. The SN told the surveyor that she had observed the open wound the day before but that she had not notified the physician. The SN claimed that the patient would not let her do anything about the wound but when the SN asked the patient in the surveyor's presence if he wanted her to call the doctor, the patient stated, "Sure." The surveyor later spoke with the Administrator and the Director of Patient Care Services about the open wound and they informed the surveyor that the SN had not notified the agency about the wound. The

surveyor's review of the clinical record indicated that the SN had not documented the open wound nor did she document that she contacted Patient 1's doctor. CMS Ex. 1. Petitioner failed to respond to this deficiency anywhere in its pleadings before me.

Any observation of such a wound should have triggered a comment in the home visit documentation of the patient's clinical record, a consultation with the patient's physician, and an immediate notification to the HHA Administrator and Director of Patient Care Services. The important purpose of skilled nursing home health care services for the home-bound patient is to be the "eyes" of the treating physician; the SN provides reliable information about the patient, especially any new or perceived changes in the patient's condition, so that the physician can properly assess whether changes to the plan of care are necessary and whether new interventions should be implemented. Manifestly, the appearance of a large, open wound for a patient with diabetes is significant and should have been documented in the clinical record. It also required the skilled nurse to either consult personally with the treating physician or to contact the HHA Administrator and Director of Patient Care Services to notify them to consult with the physician. This is an obvious failure to meet the required standard and, more importantly, the failure adversely affected the health and safety of this patient.

Patient 9 began receiving home health care from Petitioner on June 23, 2008. Her plan of care, dated June 23 to August 21, 2008, revealed diagnoses which included traumatic fracture of the hip, status post surgical repair with an open reduction internal fixation of the femur. Her physician ordered skilled nursing services twice a week for the first week, and once a week thereafter for the next eight weeks. The physician also ordered the HHA to report to him any significant changes in Patient 9's condition.

The surveyor reviewed the clinical record of the patient. The review of a home visit note indicated that on June 27, 2008, Patient 9 complained of urinary frequency three to four times a night and burning with urination. The note further indicated that the HHA office was contacted regarding the patient's condition. There was no documentation showing that the physician was contacted regarding the change in the patient's condition and her complaint. The nursing note from the home visit on July 3, 2008, indicated that Patient 9 continued to complain about the urinary burning and frequency and that this was reported to the on-call nurse. However, the records revealed that the physician was not contacted regarding Patient 9's urinary complaints until July 7, 2008. The physician ordered a urinalysis and a culture and sensitivity test. The nurse's notes of the home visit on July 8, 2008, indicated that Patient 9 was still complaining of burning. The results of the test were not received until some three days later and showed a significant bacterial infection. On July 15, 2008, the physician ordered the agency to administer the prescribed antibiotic but on that same date Patient 9's family requested to discontinue the HHA's services. CMS Ex. 1.

Petitioner does not dispute its failure to notify Patient 9's physician of her urinary complaints until 10 days after she first brought it to the nurse's attention. Nor do they dispute that while the nurse reported the information to the Administrator, neither the nurse, the Administrator or the Director of Patient Care Services notified and consulted with the physician in a timely manner so that the physician could order new interventions for her condition. Rather, the only argument or dispute that Petitioner makes in response to CMS's motion for summary judgment is to single out the surveyor finding that there was no documentation showing that the SN monitored the patient while she was on antibiotic therapy. Petitioner contends that it could not do so since the physician did not order the antibiotics until July 15, 2008, and the family requested that HHA services be discontinued that same date. P. Br. at 3. Even accepting Petitioner's contention as true, it does not rebut the finding that the HHA staff from the SN who provided the actual services to Patient 9 to the Administrator and Director of Patient Care Services failed to coordinate and maintain effective liaison so that Patient 9's physician was contacted and consulted in a timely manner. Clearly, after Patient 9 complained again of urinary burning and frequency during the July 3, 2008 home visit, the SN should have contacted both HHA staff as well as the physician to ensure that new interventions were planned by the physician. The fact that the physician was not notified for over 10 days after the patient first complained of this condition is unconscionable and certainly fails to meet the requisite standard. I further find that Petitioner's failure under this standard adversely affected the health and safety of Patient 9. I also conclude that Petitioner's failures under this standard (G 143) as well as its failures under the previous standard (G 134) demonstrate that Petitioner's ability to furnish adequate care was substantially limited by the failures of both the skilled nursing staff as well as the administrative staff, supporting my conclusion that there was a condition-level violation of 42 C.F.R. § 484.14.

> ***5. Petitioner did not meet the condition of participation at 42 C.F.R. § 484.18 (Acceptance of patients, plan of care, and medical supervision) because it failed to meet certain standards of the condition of participation and these deficiencies both alone and in combination with each other substantially limited Petitioner's capacity to furnish adequate care or adversely affected the health and safety of the patients.***

The surveyors found Petitioner violated two of the standards under this condition and that the cumulative effects resulted in the failure of Petitioner to meet the condition of participation.

I address the standards here and find that Petitioner's failures adversely affected the health and safety of several of its patients and that these failures demonstrate a significant systemic problem which shows that Petitioner's capacity to furnish adequate care was

substantially limited. I find and conclude that these failures support the ultimate conclusion that Petitioner was not in compliance with the condition of participation.

a. G 164 (42 C.F.R. § 484.18(b) Periodic review of plan of care)

Under this standard, the HHA professional staff must promptly alert the physician to any changes in a patient's condition that suggest a need to alter the plan of care. The surveyor found that this standard was not met because the HHA failed promptly to alert the physician about a large open wound on the leg of a diabetic patient, Patient 1, and failed to inform the physician that Patient 9 complained of urinary burning and urgency. The failures under this standard are based on the same undisputed facts as discussed under Tag G 143 and I need not repeat them here. Again, Petitioner did not respond with respect to CMS's motion for summary judgment with respect to this finding nor did it dispute the facts except for one aspect with respect to Patient 9 noted above which does not materially affect the other more serious failures for this patient which Petitioner did not dispute.

The failure of the HHA's nurses to notify the patients' physicians in any timely fashion about these significant changes in their condition was indeed a violation of this standard. Moreover, the HHA's failures under this standard adversely affected the health and safety of Patient 1 and Patient 9 and demonstrated that Petitioner's capacity to furnish adequate care was substantially limited.

b. G 165 (42 C.F.R. § 484.18(c) Conformance with physician orders)

This standard requires that drugs and treatments are administered by agency staff only as ordered by the physician. The survey determined that Petitioner failed to meet this standard with respect to four out of 11 of the patients reviewed.

The Survey findings 1. A-H with respect to Patient 1. Patient 1 was an insulin-dependent diabetic. The physician ordered skilled nursing services for this patient twice a day for 60 days. The order required the nurse to administer both Humulin N insulin, 12 units in the morning, and 10 units every evening, subcutaneously, as well as Humulin R insulin two times a day, the amount of which, if any, was based on a sliding scale determined by the patient's blood sugar reading at the time. The orders also required that if the patient's blood sugar was more than 400 mg/dl, the physician was to be called. CMS Ex. 1, at 27. The survey report detailed eight different deficiencies (1. A-H) in the administration of the patient's insulin.

Petitioner alleges certain facts with alleged supporting evidence which, if ultimately proven, would create a genuine controversy as to the facts of this case with respect to findings 1. A, B, C, D, and E.[2], [3] For purposes of summary judgment, I accept these assertions, both factual and inferential, in the light most favorable to Petitioner. However, Petitioner presents no facts or arguments in response to the deficiency findings set forth at 1. F, G, and H. The deficiency findings at 1. F and H indicated two instances when Patient 1 was administered four units of Humulin R insulin rather than two units as ordered under the sliding scale for the patient's blood sugar level.[4] In both instances, Petitioner does not dispute that the wrong amount of insulin was given to the patient. Rather, the only response Petitioner makes is to argue whether the failure to give the requisite amount of insulin to this patient in two separate instances constituted immediate

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[2] Petitioner presented the Diabetic Flow Sheet for Patient 1 for the month of June 2008, which it contends shows the correct amount of Insulin N and R given to the patient as opposed to the Nursing Notes for Home Visit Records for the dates in question. P. Ex. 8. No Diabetic Flow Sheet was presented, however, for July 2008.

[3] Petitioner contends that the surveyors only reviewed the home visit notes and not the Diabetic Flow Sheet. Petitioner admits these documents were in conflict but argues that they were not deficient under the standard for conformance with Physician Orders but were deficient under the standard for clinical records, for which they were not cited. I need not address these contentions here since Petitioner's overall undisputed deficiencies are sufficient to support the termination. However, even if I accept Petitioner's contentions that for findings A-E, their failures were the result of bad record keeping and not failures to give the requisite amount of medication, their failures to have accurate and non-contradictory records of the amount of insulin being given to a diabetic patient is particularly egregious. The purpose of the home visit records is to provide an accurate description of all aspects of a patient's condition and care so that any practitioner caring for that homebound patient can ascertain from reviewing the clinical records just what actions have been taken with respect to that patient. But even accepting Petitioner's claim as true that the Diabetic Flow Sheet accurately represented the amount of insulin given, it is clear — and Petitioner does not dispute — that the Home Visit Notes and documentation, which include the nurse's notes which should be contemporaneous notes from the home visit, are inconsistent with the Diabetic Flow Sheets.

[4] The nursing record indicates that on June 29, 2008, Patient 1's blood sugar level was 186 and she was administered four units of Humulin R insulin. The physician sliding scale indicates that for blood sugar levels of 151 to 200 mg/dl, the patient should be given two units of Humulin R. Survey Finding 1. F, CMS Ex. 1, at 30. The nursing record indicates that on July 12, 2008, Patient 1's blood sugar was 165 and the nurse administered four units of Humulin R when Patient 1 should only have received two units. Survey Finding 1. H, CMS Ex. 1, at 31.

jeopardy because there was no crisis situation, and there was no *actual* serious injury, harm, impairment or death of the resident. Petitioner did not respond to the deficiency finding at G that on July 7, 2008, it gave Patient 1, eight units of Humulin R based on his blood sugar level of 367 when the patient should have received 10 units. These undisputed deficiencies plainly show egregious failures by Petitioner's staff to accurately and correctly follow and conform its provision of care to the physician's orders. Despite Petitioner's argument, these undisputed failures created a very clear, palpably real possibility of serious injury to Patient 1 and unanswerably show that Petitioner's capacity to furnish adequate care was substantially limited. Therefore, I find that Petitioner's egregious failure under this standard, G 165, was sufficient in and of itself, let alone in combination with the violation of the standard for periodic review of the plan of care, G 164, to support a determination that Petitioner failed to meet the condition of participation at 42 C.F.R. § 484.18 (Acceptance of patients, plan of care, and medical supervision).[5]

6. Petitioner's violation of even one condition of participation is sufficient to sustain CMS's termination.

The undisputed facts support a determination that Petitioner did not meet at least two conditions of participation. A finding of a violation of even one condition is sufficient to sustain the termination. Here, I find and conclude that Petitioner violated at least two conditions of participation and these violations were sufficient to sustain CMS's termination of Petitioner.[6]

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[5] Petitioner did not dispute the findings under this condition with respect to certain deficiencies with respect to the care of Patient 3 (failure to take fasting blood sugar as ordered; failure to notify physician of medications not being taken or to notify pharmacy of prescription change; administering medications not included in physician's order), Patient 13, and Patient 14. For example, the surveyors found that Patient 13 was taking Coumadin and because this medication requires careful laboratory monitoring to ensure a balance between excessive bleeding and blood clots, her physician ordered that certain blood tests be drawn on July 28, 2008. The records indicate that no lab test was obtained as ordered. As for Patient 14, her physician ordered the SN to administer a certain antibiotic via a peripherally inserted central catheter but the order also indicated that prior to the administration of this drug, a lab test for a Vancomycin trough (to determine the amount of the Vancomycin medication presently in the blood stream as well as to determine other levels) be done and reported to the physician prior to any infusion. Instead, the nurse infused the patient before the lab test was performed. This was in direct conflict with the physician's order.

[6] I did not discuss whether Petitioner violated the conditions of participation at 42 C.F.R. § 484.16 (Group of professional personnel) and 42 C.F.R. § 484.30 (Skilled nursing services), since the other violations were more than sufficient to sustain CMS's termination action here. I do note, however, that many of the deficiencies cited under the

(…continued)

III. Conclusion

Based on the above findings and analysis, I sustain CMS's determination that there was a condition-level violation of the Medicare conditions of participation and, therefore, a basis for termination of Petitioner's provider agreement and participation in Medicare effective October 31, 2008.

/s/
Richard J. Smith
Administrative Law Judge

[6](continued…)

condition at section 484.18 were cited also as deficiencies under the condition at section 484.30 with respect to skilled nursing services.