

Department of Health and Human Services

DEPARTMENTAL APPEALS BOARD

Civil Remedies Division

In the Case of:)
)
Aspen Grove Home Health,) Date: January 7, 2009
(CCN: 13-7104),)
)
Petitioner,)
) Docket No. C-07-186
- v. -) Decision No. CR1878
)
Centers for Medicare & Medicaid)
Services.)
)

DECISION

Petitioner, Aspen Grove Home Health, was not in substantial compliance with Medicare conditions of participation for home health agencies and there was a basis for termination of its provider agreement effective November 28, 2006.

I. Background

Petitioner, located in Twin Falls, Idaho, was a home health agency (HHA) authorized to provide home health services to Medicare eligible beneficiaries and to receive reimbursement for those services from Medicare. The Idaho Bureau of Facility Standards (the state agency) completed a recertification survey of Petitioner on August 30, 2006, and determined that Petitioner was not in substantial compliance with nine conditions of participation. Joint Stipulation (Jt. Stip.); Centers for Medicare & Medicaid Services (CMS) Exhibit (CMS Ex.) 38. On October 5, 2006, Petitioner submitted a plan of correction and allegation of compliance to the state agency, which were rejected by the state agency on October 10, 2006. Jt. Stip.; CMS Exs. 1, 39. On November 3, 2006, CMS notified Petitioner that based on the findings of noncompliance, Petitioner's provider agreement would be terminated effective November 28, 2006. Jt. Stip.; CMS Ex. 1. CMS notified Petitioner by letter dated November 15, 2006, that Petitioner's plan of correction dated November 12, 2006 and its allegation of compliance dated November

13, 2006, were accepted and that an unannounced revisit survey would be conducted before the proposed termination date. Jt. Stip.; CMS Ex. 2. From November 20 through 22, 2006, CMS and state agency surveyors conducted a revisit survey and concluded that Petitioner was not in substantial compliance based upon violation of three conditions of participation. Jt. Stip.; CMS Exs. 3, 4. On December 7, 2006, CMS notified Petitioner of its decision to continue the termination process originally described in its November 3, 2006 termination notice to Petitioner and that termination would occur effective November 28, 2006. Jt. Stip.; CMS Ex. 3.

By letter dated January 3, 2007, Petitioner requested review by an administrative law judge (ALJ) and the matter was assigned to me. The parties stipulated that only the survey completed on November 22, 2006, and the deficiencies cited therein are at issue before me. Jt. Stip.; Tr. 15-21. I convened a hearing in Boise, Idaho, September 5 through 7, 2007. CMS offered 48 exhibits, CMS Exs. 1 through 46 were admitted with the exception of the following pages of CMS Ex. 46: pages 72-135, 162-168, 172-208, 215-220, 262-268 and 271-297.¹ Tr. 30-33. Petitioner offered 18 exhibits. Petitioner Exhibits (P. Exs.) 2, 3, 4, 6, 12, 16, 17, and 18 were admitted in their entirety. P. Ex. 1 and P. Ex 15 were not admitted; P. Ex. 5, pp. 3-107 were admitted; P. Ex. 7, pp. 7-19 were admitted; P. Ex. 8, pp. 2-49 were admitted; P. Ex. 9, pp. 2-57 were admitted; P. Ex. 10, pp. 2-12 were admitted; P. Ex. 11, pp. 3-9 were admitted; P. Ex. 13, pp. 2-3 were admitted; and P. Ex. 14, pp. 1-20 were admitted. Tr. 557-69, 678, 733. The parties submitted post-hearing briefs and post-hearing reply briefs.²

II. Discussion

A. Issue

Whether there was a basis for termination of Petitioner's Medicare provider agreement.

B. Applicable Law

The Social Security Act (Act) sets forth requirements for home health agencies participating in the Medicare and Medicaid programs, and authorizes the Secretary of

¹ CMS withdrew CMS Exs. 47 and 48 and they were not admitted or considered.

² CMS moved to strike all or at least pages 31-56 of Petitioner's response (Petitioner's post-hearing reply brief) to CMS's post-hearing brief because Petitioner's brief exceeded the page limit set for post-hearing briefs. I deny the CMS motion.

Health and Human Services to promulgate regulations implementing the statutory provisions. Act, §§ 1861(m) & (o), and 1891 (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 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 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 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)(2). Furthermore, deficiencies that might not amount to a violation of a condition of participation if considered individually, 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. 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. The Departmental Appeals Board (the Board) has interpreted 42 C.F.R. § 488.28 to permit CMS to terminate a provider where there are repeated standard-level violations, none of which rises to a condition-level violation either singly or collectively, if the provider does not timely submit a plan of correction acceptable to CMS and implement the accepted plan within a reasonable period. *CSM Home Health Services*, DAB No. 1622, at 19.

A provider terminated for noncompliance by CMS has a right to have the determination reviewed in accordance with the procedures of 42 C.F.R. Part 498. 42 C.F.R. §§ 488.24, 489.53(3), 498.3(b)(8). The ALJ reviewing the termination may review the characterization of deficiencies as condition or standard-level violations. The ALJ may also determine whether termination was appropriate given the deficiencies found on review. *CSM Home Health Services*, DAB No. 1622, at 6-7.

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 terminate the petitioner's provider agreement. In order for a petitioner to prevail, the petitioner must prove by a preponderance of the evidence that it was in substantial compliance with the relevant statutory and regulatory provisions. *Hillman Rehabilitation Center*, DAB No. 1611, at 8 (1997), *aff'd Hillman Rehabilitation Center v. U.S. Dept. of Health and Human Services*, No. 98-3789 (GEB) (D.N.J. May 13, 1999).

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

My conclusions of law are in bold followed by factual findings and analysis.

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 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 and termination must occur. 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. CMS argues in this case that there were condition-level deficiencies and that Petitioner failed to correct standard-level deficiencies and return to substantial

compliance. However, 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. Therefore, it is not necessary for me to consider all the conditions of participation or repeated standard-level deficiencies cited by CMS as a basis for termination.

- 1. Petitioner violated the condition of participation at 42 C.F.R. § 484.30 (Tag G168).**
- 2. Petitioner's violation of 42 C.F.R. § 484.30(a) adversely affected the health and safety of patients.**
- 3. Petitioner's violation of 42 C.F.R. § 484.30(a) shows that Petitioner's capacity to furnish adequate care was substantially limited.**
- 4. There was a basis for termination of Petitioner's provider agreement effective November 28, 2006.**

A HHA must meet the condition of participation that requires an HHA to furnish skilled nursing services by or under the supervision of a registered nurse (R.N.) and in accordance with a patient's plan of care. The two standards set forth under this condition of participation establish the specific duties of a registered nurse and a licensed practical nurse (L.P.N.). 42 C.F.R. § 484.30.

The surveyors who conducted the survey that ended on November 22, 2006, the results of which are reported in a Statement of Deficiencies (SOD) bearing that date, concluded that Petitioner violated 42 C.F.R. § 484.30 (Tag G168).³ CMS Ex. 4, at 24-61. The SOM lists 15 separate Tags, G168 through G183, under the condition of participation Tag G168. In this case, the surveyors concluded that Petitioner violated both standards of participation citing the violations under Tags G169, G170, G172 through G177, and G180. The surveyors concluded that the violation of the standards amounted to a condition-level violation of 42 C.F.R. § 484.30 (Tag G168). I conclude that the deficiencies cited by the surveyors under Tags G172 through G174 amply demonstrate the standard-level violation

³ The Tag designation is a reference to the applicable part of the guidance to surveyors found in the State Operations Manual (SOM), App. B (Rev. 11, Aug. 12, 2005). Although the SOM is not promulgated as a regulation and is not binding as law, it reflects the CMS interpretation of the survey regulations and conditions and standards of participation in the Act and regulations, which are enforceable.

of 42 C.F.R. § 484.30(a). Furthermore, the three deficiencies I discuss are deficiencies “which adversely affect the health and safety of patients” and they amount to a condition-level violation of 42 C.F.R. § 484.30. I also conclude that the three deficiencies discussed amply demonstrate that Petitioner’s capacity to furnish adequate care was substantially limited by the failures of its R.N. staff, supporting my conclusion that there was a condition-level violation of 42 C.F.R. § 484.30. Accordingly, I conclude it unnecessary to discuss other alleged standard or condition-level deficiencies cited by the survey that concluded on November 22, 2006.

(a) Tag G172

The standard at 42 C.F.R. § 484.30(a) requires that a R.N. regularly re-evaluate the nursing needs of the patients. The surveyors found that Petitioner failed to ensure that a R.N. regularly re-evaluated the nursing needs of seven of the patients whose clinical records were fully reviewed. CMS. Ex. 4, at 31. CMS presented medical evidence for all seven residents (CMS Exs. 24-28, 31-32), but I find it sufficient to discuss only the cases of Patients 4, 9, and 14.

Patient 4 was 94 years old and lived in an assisted living facility. She began receiving care from Aspen Grove Home Health on October 27, 2006. Her “Home Health Certification and Plan of Care” (Plan of Care) for the period October 27, 2006 through December 25, 2006, indicated that she was admitted for home health services for management of a wound and hematoma on her right knee and monitoring for congestive heart failure (CHF). CMS Ex. 4, at 34; CMS Ex. 25, at 7-8, 10-11. Her physician ordered skilled nursing services 1 to 2 times a week for 60 days with an authorization for three additional visits as necessary. The order directed that the skilled nurse cleanse the area with sterile water, apply DuoDerm with skin prep and cover with tape. The dressing was to be changed as needed and the nurse was to monitor for signs and symptoms of infection. CMS Ex. 25, at 27.

The surveyors state in the SOD that a home visit note for November 13, 2006 documented that the dressing for the knee wound was in place and that there was no increase in swelling or pain, but the document did not reflect that the wound was examined or the dressing changed. The surveyors also state that the home visit note for November 17, 2006 documented that the dressing was changed, there were no signs or symptoms of infection, a tracing of the wound was done, but there was no documentation of the actual status of the wound, such as wound bed, the presence or absence of drainage or odor, the condition of surrounding skin, the presence of pain or increased temperature, or comparison of the wound size to previous measurements. A surveyor visited the patient with a R.N. on November 20, 2006. The surveyor noted a foul odor and dark red

drainage from the wound outside the dressing. The R.N. indicated that she would change the dressing the next day, but the surveyor asked that the dressing be changed immediately. When the dressing was removed there was a large amount of odorous sanguineous drainage and the wound bed was covered with slough. The R.N. replaced the dressing but did not measure the wound, touch the surrounding skin, or ask the patient about local pain or tenderness. CMS Ex. 4, at 34-35. The surveyors' allegations in the SOD are consistent with Petitioner's clinical record for Patient 4. CMS Ex. 25, at 9, 12, 14-16, and 18-19. The surveyors concluded that the R.N. had not regularly reevaluated the patient's nursing needs.

I conclude that the evidence is consistent with the conclusion that the R.N. did not regularly reevaluate Patient 4's nursing needs. Patient 4 was receiving home health services from Petitioner because the assisted living facility contacted this patient's doctor to obtain assistance dressing Patient 4's right knee wound. CMS Ex. 25, at 28. With a person of Patient 4's age, it was of particular concern that someone be able to cleanse the wound and properly apply a new dressing as well as monitor the wound for signs and symptoms of infection, as neither Patient 4 nor the assisted living facility was able to do the necessary treatment and monitoring.

The R.N. notes from the skilled nursing visits do not demonstrate that physician ordered services, which required the R.N. to properly evaluate and assess Patient 4's wound each visit and cleanse and redress it as necessary, were in fact being done. CMS Ex. 25; P Ex. 13. The documentation from the November 11 and November 17, 2006 visits does not reflect a thorough evaluation of the wound. The record for the November 13, 2006 visit indicates that the DuoDerm dressing was not changed, yet the R.N. reported that she assessed the wound to the right knee. CMS Ex. 25, at 18. It would be impossible to thoroughly assess the wound without removing and changing the dressing, as the DuoDerm dressing is not transparent. Moreover, the record of the November 13, 2006 home visit to Patient 4 does not contain, contrary to Petitioner's argument, complete evaluation of Patient 4's wound. There is no wound assessment indicating the stage of the wound, its length and width, its depth, whether it was open, whether there was drainage and in what amount, nor was there a record of other similar types of assessments that would ordinarily be done when assessing a serious wound in an elderly patient. CMS Ex. 25, at 17-19. Petitioner argues that it provided the requisite care to Patient 4 on November 17, 2006 because the R.N. checked off on the home visit form that she changed the dressing and that there were no signs or symptoms of infection. CMS Ex. 25, at 13-15; Tr. 390-91. While the documentation of the home visit for November 17 includes a Wound Measuring Guide with a sketch of the wound's size, there is no indication of the staging of the wound, its color, its depth, its drainage, the drainage type, whether there is an odor, erythema, eschar, undermining and/or tunneling—the kinds of

assessments that, at the very least, should be made when assessing a wound. CMS Ex. 25, at 16. I also note that a comparison of the rough sketch done by the R.N. on November 17, 2006 with the tracing of the wound made on November 9, 2006 indicates that the open area of the wound had become bigger.⁴ CMS Ex. 25, at 16 and 29. The increased open area should have triggered a comment in the home visit documentation or perhaps a consult with Patient 4's physician, but there is no comment in the documents and there was no consultation.⁵ Just three days later, the surveyor accompanied the R.N. to visit Patient 4. The surveyor immediately noticed dark red stains showing through the non-transparent DuoDerm dressing and the surveyor detected an odor emanating from Patient 4's leg. CMS Ex. 25, at 22; Tr. 342-43. When the surveyor alerted the R.N. to her observations, the R.N. indicated that she need not change the dressing or look at the wound, but that it would be done the next day. It was only at the surveyor's insistence that the R.N. proceeded to change the dressing and look at the wound. When the old dressing was removed, a large amount of sanguineous fluid drained from the wound and the wound was covered with slough.⁶ CMS Ex. 25, at 23; Tr. 344. The surveyor was concerned that the wound may not have been adequately cleansed because it was done so quickly she did not see it done. She was particularly concerned because the R.N. did not examine the wound. The R.N. did not palpate the area to find out the status of the surrounding skin, whether other materials came loose from the wound, whether there was undermining indicating extension of the wound, and whether the local area of the wound was warm, which might indicate inflammation or perhaps infection. Tr. 345.

⁴ The R.N. wrote a "Patient Update" on November 21, 2006 after the unscheduled visit with the surveyor to see Patient 4. The update was sent to Patient 4's physician and states that there was a decrease in the size of the wound since Patient 4 was first admitted for HHA care on October 27 and that the change in the wound discovered on the November 20 visit was a big change in Patient 4's condition. However, a visual comparison of the the Ez Graph wound assessment tracings done on November 1 to the ones done on November 9 and November 17, 2006 do not indicate that the size of the open wound was smaller and it appears that just the opposite was true. Compare CMS Ex. 25, at 26 with CMS Ex. 25, at 16 and 29.

⁵ Arguably, one purpose of skilled nursing home health care services for the home bound patient is to provide reliable information for the treating physician so that proper care planning can be done and interventions implemented if necessary.

⁶ "Slough" was described as dead adherent tissue which can occur when there is infection and it shows there is inflammation to the wound due to dead white blood cells. Tr. at 344.

I conclude that Petitioner failed to ensure that its R.N. properly reevaluated Patient 4's nursing needs each visit. There was an adverse effect upon the health of Patient 4.

Patient 9 was a 61-year-old male, admitted for home health services on October 8, 2006 with a primary diagnosis of inoperable lung cancer. He also had a diagnosis of chronic obstructive pulmonary disease (COPD) for which he required continuous oxygen. He had a poor prognosis with a life expectancy of six months or less. His plan of care for the October 8 through December 6, 2006 certification period included an order for skilled nursing to assess his pain level every visit and to teach him and his care-givers about taking his pain medications when his pain exceeded a level four on a scale of one to ten (ten being the highest level of pain) before his pain became too severe. The skilled nurse was to notify his doctor if there were any concerns with this. CMS Ex. 28, at 49, 138, 142. The goal was to try to keep Patient 9's pain level at a moderate but bearable level (less than a level five on a scale of one to ten). CMS Ex. 28, at 50, 139, 142, 161.

The surveyors concluded that Petitioner's nursing staff did not follow Petitioner's policy for assessment of pain. CMS Ex. 4, at 38. Petitioner's pain assessment policy, revised October 1, 2006 and effective November 7, 2006, requires that a comprehensive assessment of a patient's pain be done that includes the following elements: intensity, location, frequency, character, current therapy, effectiveness of therapy, and influence of pain on movement and activity. CMS Ex. 20. The surveyors concluded that assessment of Patient 9's medical and nursing needs related to pain was insufficient, consistent with their conclusion that the R.N. had not regularly reevaluated Patient 9's needs regarding pain control. CMS Ex. 4, at 30, 38.

I conclude that the surveyors' evaluation was correct. When Patient 9 was admitted for home health services on October 8, 2006, he reported constant intractable pain at least daily that affected his sleep, appetite, physical or emotional energy, concentration, personal relationships, emotions, and physical activity. CMS Ex. 28, at 155. He complained of a burning pain in his right upper chest at an intensity of eight on a scale of one to ten with ten being the worst pain. CMS Ex. 28, at 142, 161. No other location for pain was identified in his intake assessments. The certification and plan of care for the period October 8 to December 6, 2006, did not identify locations for pain, but directed skilled nursing to assess pain level every visit, to instruct the patient and care-giver on taking pain medication before pain became severe with the goal of keeping the intensity of pain less than five on a ten point scale, and the nurse was to contact Patient 9's physician with any concerns. CMS Ex. 28, at 138-39.

On November 5, 2006, the R.N. noted that Patient 9 reported no pain, he had pain

medication to take as necessary, but the R.N. also noted that Patient 9 complained of pain daily but not constantly. There is no indication that the R.N. assessed the location of the pain when it occurred daily or the effectiveness of Patient 9's pain medication in relieving the pain. The nurse noted that Patient 9 had a new pressure ulcer over the coccyx but does not indicate if Patient 9 complained of pain associated with the ulcer. The R.N. noted that she did teaching on dressing the ulcer, but no indication that she did teaching on managing pain. CMS Ex. 28, at 107-12.

On November 7, 2006, a L.P.N. visited Patient 9. She recorded that she assessed Patient 9's pain level, but she made no entries indicating whether or not he had any pain nor did she note any of the other assessment criteria specified in Petitioner's pain policy that became effective that day. The L.P.N. also indicated that pain management training was done. CMS Ex. 28, at 102-06.

On November 14, 2006, Patient 9 was admitted to the hospital because he was more short of breath than usual and his intravenous line had come out. He reported no chest or abdominal pain and specifically no pain related to his lung cancer. He was diagnosed with left-sided pneumonia and started on an antibiotic. CMS Ex. 28, at 92-93.

On November 15, 2006, Patient 9 received a resumption of care assessment by Petitioner's R.N., who noted that he complained of pain at level eight all the time, that the pain affected sleep, appetite, physical or emotional energy, concentration, personal relationships, emotions, and physical activity. CMS Ex. 28, at 56-57, 76-77. The R.N. recorded that Patient 9's "main pain is in the coccyx at 8." CMS Ex. 28, at 65; CMS Ex. 28, at 61. The R.N. did not indicate that she assessed whether Patient 9 had pain in other locations associated with his lung cancer or pneumonia or whether his present medication was effective to keep his pain at an intensity level of less than five. CMS Ex. 28, at 64-68, 73-85, 55-60. The R.N. circled the word "Done" on the list of interventions at the end of the line that requires the nurse to assess pain and do teaching on pain control every visit and to notify the M.D. if there are concerns. However, the evidence does not include a document reflecting consultation with the physician or a physician's order on November 15. A physician's order dated November 17, 2006 does not address pain. CMS Ex. 28, at 120.

On November 16, 2006, Patient 9 was readmitted to the hospital with complaints of shortness of breath. He was assessed as suffering pneumonia and anxiety, in addition to terminal lung cancer and end-stage COPD. CMS Ex. 28, at 43-48. On November 17, 2006, someone allegedly broke into his house and stole approximately 40 pills of his oxycodone, a powerful pain reliever. CMS Ex. 28, at 38, 115-17. On November 20, 2006, Petitioner's R.N. did a resumption of care assessment. The R.N. noted Patient 9

complained of intractable pain at an intensity of ten, that was constant, not easily relieved, and affected all functional areas. The R.N. did not specify the location of the pain or the effectiveness of pain medication but, she did note that Patient 9's oxycodone had been stolen. CMS Ex. 28, at 16, 30-34

The records of the home visits by L.P.N.s on October 31, November 3, November 10, and November 13, 2006, provide no better assessments than those already described.

Although Patient 9 was terminal, management of his pain, whether from his lung cancer or coccyx wound, was clearly an important part of his plan of care. The skilled nurses, L.P.N.s and R.N.s, did not perform assessments as prescribed by Petitioner's policy. Petitioner has presented no evidence that, if Patient 9's complaint of severe coccyx pain was ever reported to his physician, that the physician responded. Petitioner has presented no evidence that any action was taken to replace the stolen oxycodone, although the record indicates that Patient 9 did have other pain medication that he used. I conclude that Petitioner's R.N.s did not regularly reevaluate Patient 9's nursing needs with respect to pain control. The health of Patient 9 was adversely affected.

Patient 14 was an 81-year-old female whose start of care with Petitioner was April 6, 2006. Her diagnoses included a history of urinary tract infection, diabetes with a history of hypoglycemia, and malaise and fatigue. Her blood glucose levels were documented as chronically high, with the lowest level at 171 and the highest level at 585 for the period between November 8 and November 15, 2006. She also had two blood glucose readings in the 400's and three in the 300's. CMS Ex. 4, at 32; CMS Ex. 31, at 18-25, 105.

The R.N. visited Patient 14 on October 23, 2006. She noted that Patient 14's son, who was her care-giver, refused to get-up to give Patient 14 insulin so the nurse did. She also noted that Patient 14 had been sitting in urine. CMS Ex. 31, 62-65. On November 8, 2006, the R.N. called Adult Protection. CMS Ex. 31, at 54. On November 8, 2006, a home aide reported to the R.N. that Patient 14's blood sugar was high twice and, the second time, the care-giver refused to get up and give Patient 14 insulin. The R.N. noted she was concerned about medical management and she called the social worker and the two decided to call Adult Protection again. CMS Ex. 31, at 55. The R.N. noted on November 13, 2006 that Patient 14's main care-giver was incarcerated for six months and the patient's granddaughter was going to move the patient to her home and care for her. The R.N. noted that she would notify Medicaid, the physician, and Adult Protection. The R.N. noted she spoke with the granddaughter and arranged for her to meet with the social worker, but there was no mention of the R.N. visiting. CMS Ex. 31, at 56, 113. The R.N. notified the physician on November 14, 2006 indicating the social worker would visit with the granddaughter and Patient 14, but no mention of the R.N. visiting. CMS Ex. 31,

at 43. The R.N. updated the doctor on November 17, 2006, indicating that she spoke with the granddaughter, the new primary care-giver for Patient 14, and she requested education about diabetes and appropriate diet, and the R.N. coordinated with the dietician. The R.N. also reported that Patient 14 was having difficulty adjusting to the granddaughter's young children and had pushed the young son, that Patient 14 refused to permit the granddaughter to help with care, and that Patient 14 was causing disharmony in the home. The R.N. suggested a meeting with her, the social worker, and others, but no schedule for the meeting was set. CMS Ex. 31, at 41. The record documents that a L.P.N. visited Patient 14 twice a week for the period of October 25 through November 20, 2006. The record does show that the R.N. reviewed the L.P.N.'s reports of the home visits and also made a joint visit on November 3, 2006 for the purpose of assessing by direct observation the performance of the L.P.N. However, there is no record of any further visits by the R.N. at which the R.N. could have or did evaluate or reevaluate Patient 14 after the visit made by the R.N. on October 23, 2006. CMS Ex. 31, at 61-62; CMS Ex. 31, at 66-101; P Ex. 8.

The surveyors concluded that the R.N. had not reevaluated Patient 14's nursing needs between October 23, 2006 and November 22, 2006, the last day of the survey. The surveyors also concluded that the R.N. had not evaluated Patient 14's current environment and the new care-giver's ability to meet Patient 14's needs, particularly her diet. CMS Ex. 4, at 33-34. Petitioner argues that the note by the R.N. dated November 7, 2006 indicates that teaching was done regarding diabetic issues; that if an R.N. visited every two weeks the next visit would have been November 21; that there is evidence the new care-giver received training from the L.P.N. regarding diet and diabetes; and that blood glucose levels were better. P. Brief, Ex. A, at 19-20. However, Petitioner points to no evidence that the R.N. actually reevaluated Patient 14's nursing needs between October 23 and November 22, 2006.

The L.P.N. visits are well documented and it is clear that Patient 14 was receiving nursing services. However, the standard of participation requires that all assessments and evaluations and reevaluations of a patient's nursing needs be performed by the R.N. Contrary to the suggestion of Petitioner, there is no 14-day period for reevaluation specified by the regulation. Rather, the regulation specifies that reevaluation by the R.N. is to be done regularly, without specifying frequency. However, in the case of Patient 14 I concur with the surveyors' evaluation that a reevaluation of Patient 14 was required, but not done. The need for the reevaluation was obvious based on the following: the care-giver son had demonstrated his unreliability to get out of bed, to keep Patient 14 clean and dry, and to administer insulin when needed; Patient 14's blood glucose levels were clearly out of control; the care-giver became the granddaughter upon incarceration of the son; Patient 14 had to be moved to the new environment in the home of the care-giver who

had small children; and the care-giver specifically requested training in how to care for Patient 14. To be sure, the R.N. did react to the circumstances of Patient 14 by calling and notifying Adult Protection, the physician, the social worker, and the new care-giver. But there is no explanation for why the R.N. did not go see for herself and reevaluate the needs of Patient 14, despite the obvious signs that reevaluation was necessary. Petitioner 14's uncontrolled blood glucose levels and the neglect of her care-giver son posed significant potential for harm.

Based upon the examples of the three patients, I conclude that Petitioner violated 42 C.F.R. § 484.30(a) because it did not ensure that the needs of its patients were being regularly reevaluated by an R.N. For each of the patients discussed, the failure of the R.N. to regularly reevaluate adversely affected the health and safety of each patient and either harmed or had the potential for harm to each patient. Petitioner's failure to ensure that its R.N. regularly reevaluated these patients' needs also limited Petitioner's capacity to furnish adequate care.

(b) Tag G173

The regulation requires that a R.N. initiate the plan of care for each patient and any necessary revisions to that plan based on the changing needs or changing condition of the patient. 42 C.F.R. § 484.30(a). The surveyors cite the example of Patient 9 as the basis for their conclusion that Petitioner violated the standard. The surveyors found that Patient 9 was hospitalized on November 1, 2006, suffering fecal impaction for which he was given a potent sedative and manually disimpacted. However, despite the emergency room visit for fecal impaction, Petitioner did not revise Patient 9's plan of care related to bowel management. CMS Ex. 4, at 41-45; Tr. 395-96.

The case of Patient 9 was discussed under Tag G172. In addition to his terminal lung cancer and end-stage COPD, he had problems with constipation. His plan of care provided for skilled nursing services one to three times a week for the 60-day certification period October 8 through December 6, 2006, required that skilled nursing was to teach Patient 9 and his care-giver regarding bowel routine, medication, and diet; to assess bowel movements and concerns regarding constipation; and to notify the physician with any concerns. CMS Ex. 28, at 140. Constipation was a significant issue for this patient and his plan of care listed constipation as a secondary diagnosis. CMS Ex. 28, at 140. The surveyors observed that Patient 9 was on two opiate analgesics, oxycodone and morphine sulphate, which are known to cause constipation. CMS Ex. 4, at 42. The R.N. reported to the physician on October 10, 2006, that Patient 9 had not had a bowel movement in four to five days, he refused an enema by the R.N., the wife gave the enema and reported no results, the nurse instructed the wife to give Patient 9 warm prune juice

and milk of magnesia, and the R.N. advised the doctor that she may need an order for magnesium citrate. CMS Ex. 28, at 142. The physician issued an order for magnesium citrate and sorbitol on October 13, 2006. CMS Ex. 28, at 137. Patient 9 was hospitalized on November 1, 2006, for fecal impaction. At the time of his hospitalization he indicated he had not had a bowel movement in a week. P. Ex. 5, at 26; CMS Ex. 28, at 123. The emergency room physician, upon Patient 9's release after manual extraction, indicated that Patient 9 should continue with laxatives and stool softeners and follow-up with his physician or in the emergency room for further evaluation and treatment. P. Ex. 5, at 25; CMS Ex. 28, at 124. On November 5, 2006, Patient 9 reported that he had several bowel movements. CMS Ex. 28, at 107, 110. He also reported having a bowel movement on November 7, 2006. CMS Ex. 28, at 104. On November 7, 2006, Petitioner's R.N. mentioned in a report to Patient 9's physician that Patient 9 had been to the emergency room for emergency disimpaction because he was uncomfortable due to severe constipation and the Veterans Administration hospital⁷ had recommended that he go to the emergency room. The R.N. did not recommend or request further orders to treat Patient 9's constipation. CMS Ex. 28, at 113. A L.P.N. noted on November 10 that Patient 9 had not had a bowel movement in three days and he refused an enema. P. Ex. 5, at 95. A report by the R.N. documenting a home visit with Patient 9 on November 15, 2006, shows he reported not having a bowel movement since November 13, 2006, but he refused an enema. The report also indicates bowel sounds active and that if he needed an enema later in the day his wife could do it. CMS Ex. 28, at 64-66.

Petitioner argues that Patient 9's physician was aware and that there was nothing more that could be done about Patient 9's problem constipation. P. Brief, Ex. A at 35-36. Petitioner misses the point. The requirement is that the R.N. initiate the plan of care and any necessary revisions. The emergency room manual disimpaction on November 1, 2006, Patient 9's refusal to have enemas administered by nursing staff, the reported ineffectiveness of enemas administered by the wife, and repeated episodes of constipation, all indicated that the R.N. needed to evaluate whether revision of the care plan was necessary. However, after the emergency room procedure on November 1, the evidence reflects that the R.N. did not communicate with the physician about the event for several days. Further, there is no evidence that the R.N. considered, with the physician or on her own, whether different interventions might be appropriate revisions to the plan of care. A plan of care signed by the R.N. on November 19 and the physician on November 20, does not include new interventions for Patient 9's constipation. CMS Ex.

⁷ Patient 9 received his medical care through the Veterans' Administration hospital. However, when he required emergency care he was seen at the regional medical center hospital emergency room. CMS Ex. 28, at 123.

28, at 49-53. Further, contrary to Petitioner's argument that nothing more could be done, on November 24, 2006, Petitioner's R.N. and physician implemented new interventions for Patient 9's constipation, including changing medication and implementing a bowel routine that required warm prune juice if Patient 9 had no bowel movement for two days, use of milk of magnesia if no movement on the third day, enema on the fourth day if no results, and contacting skilled nursing if the enema was ineffective. P. Ex. 5, at 77. Prior to the new interventions on November 24, the evidence does not show that the R.N. suggested or considered adjusting Patient 9's plan of care subsequent to his emergency disimpaction on November 1. I conclude that Petitioner's R.N. failed to revise Patient 9's care plan as necessary, with adverse impact upon his health.

(c) Tag G174

The regulation requires that a R.N. furnish those services requiring substantial and specialized nursing skill. 42 C.F.R. § 484.30(a). The surveyors concluded that Petitioner's R.N. failed to deliver services requiring substantial and specialized nursing skills in the case of Patient 4, as discussed under Tag G172. CMS Ex. 4, at 45-49. Patient 4 was referred for home health services because the assisted living facility where Patient 4 lived could not provide the skilled nursing services needed for Patient 4's knee wound. CMS Ex. 25, at 28. Based upon the facts already discussed regarding Patient 4's knee wound, I find that Petitioner's R.N. failed to deliver substantial and specialized skilled nursing care. I find Petitioner's arguments to the contrary to be meritless. P. Brief, Ex. A at 9-10. The fact that the surveyor had to direct the R.N. to change the dressing immediately, rather than the next day as the R.N. proposed, is a good example of how the R.N. failed to provide the specialized nursing care required. I conclude that Petitioner violated 42 C.F.R. § 484.30(a) with adverse impact upon Patient 4's health.

III. Conclusion

There was a condition-level violation of 42 C.F.R. § 484.30 and, therefore, a basis for termination of Petitioner's provider agreement and participation in Medicare effective November 28, 2006.

/s/

Keith W. Sickendick
Administrative Law Judge