Department of Health and Human Services

DEPARTMENTAL APPEALS BOARD

Civil Remedies Division

In the Case of:	)	
	)	
Progressive Home Care Services, Inc.,	)	Date: July 28, 2008
	)	
Petitioner,	)	
	)	
- v. -	)	Docket No. C-07-724
	)	Decision No. CR1822
Centers for Medicare & Medicaid Services.	)	
	)	

DECISION

Petitioner, Progressive Home Care Services, Inc. (Petitioner or Progressive), is a home health agency (HHA) based in Livonia, Michigan, that, until its August 2007 termination, was certified to participate in the Medicare program as a provider of services. Following surveys completed October 6, 2006, March 2, 2007, and August 17, 2007, the Centers for Medicare & Medicaid Services (CMS) terminated Progressive's Medicare participation because, according to CMS, the HHA failed to maintain substantial compliance with conditions of participation, specifically, 42 C.F.R. § 484.30 (Skilled Nursing Services). Petitioner here challenges its termination.

In a letter dated March 12, 2008, Petitioner confirmed that it waived its right to an in-person hearing and asked that the matter be resolved based on the written record.

For the reasons set forth below, I find that Progressive was not in substantial compliance with all Medicare conditions of participation. Although afforded ample opportunity to correct its deficiencies, it had not achieved or maintained substantial compliance by the time of the August 2007 survey. CMS was therefore authorized to terminate Progressive's Medicare provider agreement.

I. Background

An HHA is a public agency or private organization that provides skilled nursing and other health care services to patients in their homes. Social Security Act (Act), § 1861(o). It may participate in the Medicare program as a provider of services if it meets the statutory

definition and complies with certain requirements, called Conditions of Participation. Act, §§ 1861(o), 1891; 42 C.F.R. Part 484; 42 C.F.R. § 488.3. On the other hand, CMS, acting on behalf of the Secretary of Health and Human Services, may terminate a provider agreement based on failure to comply with provisions of section 1861. Act, § 1866(b)(2).

A "condition of participation" represents a broad category of home health services. Each condition is contained in a single regulation, which is divided into subparts called standards. 42 C.F.R. Part 484. Compliance with a condition of participation is determined by the manner and degree to which the provider satisfies the standards within the condition. 42 C.F.R. § 488.26(b). If deficiencies are of such character as to "substantially limit the provider's . . . capacity to furnish adequate care or which adversely affect the health and safety of patients," the provider is not in compliance with conditions of participation. 42 C.F.R. § 488.24(b).

CMS must determine whether a Medicare provider (including an HHA) complies substantially with Medicare's statutory and regulatory requirements. Act, § 1866(b)(2). To monitor compliance, CMS contracts with state agencies that conduct periodic surveys. Act, § 1864(a); 42 C.F.R. § 488.20. The regulations generally require that each provider be surveyed once every twelve months, and more often, if necessary, to ensure that identified deficiencies are corrected. Act, § 1819(g)(2)(A); 42 C.F.R. § 488.20. In lieu of an annual state survey, however, an HHA may be "deemed" to meet Medicare requirements based on its accreditation by an approved national accreditation program. 42 C.F.R. § 488.6. A "deemed" HHA is subject to a validation survey, conducted by the state survey agency, either as part of a representative sample (to validate the integrity of the accreditation process), or in response to substantial allegations of noncompliance. 42 C.F.R. § 488.7.

Petitioner here was deemed to be Medicare-compliant based on its accreditation by the Joint Commission on the Accreditation of Healthcare Organizations (JCAHO). Responding to a complaint, the Michigan Department of Health (State Agency) completed a validation survey on October 6, 2006. Based on the survey findings, CMS determined that Progressive was not in substantial compliance with two conditions: 42 C.F.R. § 484.10 (Patient Rights) and 42 C.F.R. § 484.30 (Skilled Nursing Services). As a result, Progressive lost its deemed status, and was subject to survey by the State Agency. CMS Ex. 1; P. Ex. 1. Loss of deemed status is not a reviewable determination. 42 C.F.R. § 498.3(d)(9).[1]

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[1] I consider irrelevant Petitioner's charge that a disgruntled former employee lodged the complaint that ultimately led to the loss of Progressive's deemed status. Petitioner's Pre-hearing Brief (P. Br.) at 3. A "deemed" HHA is subject to a validation survey at any time, and the State Agency's reasons for conducting that survey are not subject to review.

Months later – on March 2, 2007 – the State Agency surveyed Progressive, and, based on those survey findings, CMS determined that Progressive had not achieved substantial compliance. In a letter dated June 20, 2007, CMS warned that it would terminate Progressive's Medicare provider agreement on August 3, 2007. However, if Progressive submitted a credible allegation that it had achieved compliance, CMS would authorize a resurvey. CMS Ex. 3; P. Ex. 3. Petitioner has not appealed the March survey findings. Instead, alleging that it corrected its deficiencies, it asked for a resurvey. CMS Exs. 4, 5; P. Exs. 4, 5.

After completing a revisit survey on August 17, 2007, State Agency surveyors determined that Progressive had not brought itself into substantial compliance, finding one condition-level deficiency, 42 C.F.R. § 484.30 (Skilled Nursing Services), as well as multiple standard-level deficiencies. CMS Ex. 8; P. Ex. 8.

In a notice letter dated August 29, 2007, CMS advised Progressive that its follow-up survey showed that it was not in substantial compliance with the Skilled Nursing Services Condition, so its provider agreement terminated on August 3, 2007. CMS included with the letter a copy of the survey report form (CMS-2567), which contains a list of all the deficiencies cited. The letter reminded Petitioner that its appeal rights had been explained in the June 20, 2007 letter. CMS Ex. 9; P. Ex. 7.

By letter dated September 7, 2007, Petitioner appealed its termination, and the matter has been assigned to me.

The parties agree that this matter may be decided based on the written submissions, without an in-person hearing. Order (March 13, 2008); Petitioner's Correspondence (March 12, 2008). CMS has submitted 23 exhibits (CMS Exs. 1-23), and Petitioner has submitted 29 exhibits (P. Exs. 1-29), which I have admitted into evidence. Order (March 13, 2008).[2]

II. Issue

The sole issue before me is whether, based on the August 17, 2007 survey findings, CMS was authorized to terminate Petitioner's Medicare provider agreement.

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[2] With its closing brief Petitioner proffered two additional exhibits, but did not show good cause for their untimely submission, as required by my prehearing order. Order ¶ 3 (October 5, 2007). I therefore decline to admit them.

III. Discussion

Because Progressive failed to maintain substantial compliance with all Medicare Conditions of Participation, CMS may terminate its program participation.[3]

The regulations require that an HHA furnish skilled nursing services by or under the supervision of a registered nurse (RN) and in accordance with a patient's plan of care. 42 C.F.R. § 484.30.

Unless a patient's needs are limited to rehabilitation therapy, an *RN* must initially assess the patient to determine his/her immediate care and support needs. 42 C.F.R. § 484.55(a).[4] Within five days of the patient's start-of-care date, the nurse must complete a patient-specific comprehensive assessment that accurately reflects the patient's health status and can be used to demonstrate the patient's progress toward achieving desired outcomes. This assessment must incorporate Outcome and Assessment Information Set (OASIS) items. 42 C.F.R. § 484.55(b)(1).[5] Based on the comprehensive assessment, the HHA develops a plan of care.

The assessment and care plan are "the most important parts of the home care clinical record." All other information flows from the needs identified in the assessment and the services ordered in the care plan. The documents "must be complete"; their content "must be clear." They can have no gaps. Marrelli, T.M., *Handbook of Home Health Standards & Documentation Guidelines for Reimbursement*, 4th ed., Box 2-2 (CMS Ex. 23, at 7); *see* CMS Ex. 13, at 2 (English Decl. ¶ 7). Progressive uses an 18-page assessment form that incorporates the required data, and, according to Progressive's policy: "All assessment database fields must be completed/answered." CMS Ex. 22, at 51; *see*, *e.g.*, P. Exs. 15-24.

Petitioner's witnesses – Toms Mathew, PT (physical therapist and Progressive's president and sometime administrator), Janett Mitchell, RN (Director of Clinical Services), and Zinius Joseph, RN (Quality Assurance Nurse) – agree that the Marrelli handbook is a "helpful reference tool," but each claims that "neither federal nor state regulations

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[3] I make this one finding of fact/conclusion of law.

[4] If the patient's needs are limited to rehabilitation therapy services, an appropriate rehabilitation professional may conduct the initial assessment visit. 42 C.F.R. § 484.55(a)(2).

[5] Use of the CMS-developed OASIS allows for the electronic collection and transmission of data. *See* 42 C.F.R. § 484.20; 64 Fed. Reg. 3748 *et seq*. (January 25, 1999).

mandate that home health care services be documented according to this specific handbook." P. Ex. 26, at 2 (Mathew Decl. ¶ 5); P. Ex. 27, at 2 (Mitchell Decl. ¶ 5); P. Ex. 28, at 2 (Joseph Decl. ¶ 5). Of course, the importance of the assessment and care plan are reflected in the regulations themselves. 42 C.F.R. §§ 484.18, 484.30, 484.55. With respect to documentation, Progressive's own policies mandate that it be complete and accurate. *See, e.g.,* CMS Ex. 22, at 51; P. Ex. 25, at 22, 23, 25, 31-32, 36 ("Skilled care rendered shall be documented on the Nursing Note for each visit provided" and "shall be documented on the Nursing Note during or immediately following each patient visit."); P. Ex. 25, at 38, 41, 43, 51 ("OASIS/Admission paperwork must be completed and accurate. . ."). CMS may reasonably rely on the provider's policies as "evidence of the standard of care the facility expect[s] its staff to provide" as well as evidence of the professional standards of care. *The Laurels at Forest Glen*, DAB No. 2182, at 18 (2008); *Oxford Manor*, DAB No. 2167, at 5-6 (2008); *see also*, 42 C.F.R. § 484.48 (maintain clinical records "in accordance with accepted professional standards . . . ."). And even though Petitioner's witnesses seem to minimize the importance of documentation with respect to the specific inadequacies of Progressive's own practices, they at least tacitly recognize its importance: "Progressive strives to ensure that its nurses appropriately document the services rendered; in fact Progressive educates the nursing staff regarding appropriate documentation at the time of hire." P. Ex. 26, at 2 (Mathew Decl. ¶ 6); P. Ex. 27, at 2 (Mitchell Decl. ¶ 6); P. Ex. 28, at 2 (Joseph Decl. ¶ 6).

The RN must also regularly re-evaluate the patient's nursing needs. Those services that require substantial and specialized nursing skill must be provided by the RN. The RN must initiate "appropriate preventive and rehabilitative nursing procedures;" (s)he is also responsible for coordinating services and for informing the physician and other personnel of changes in the patient's condition and needs. 42 C.F.R. § 484.30(a).

March Survey

Progressive apparently has had long-standing difficulties complying with requirements for skilled nursing services. During the March 2007 survey, surveyors found that staff failed to ensure that nursing services were furnished in accordance with patients' plans of care. Among other problems, nurses failed to record patients' vital signs as required; they failed to notify physicians when vital signs fell outside the parameters designated in their care plans; an RN did not always re-evaluate a patient's nursing needs as required. Progressive was not visiting patients as frequently as called for in their care plans nor notifying physicians of missed visits. In its plan of correction, Progressive agreed that "clinicians must follow the care plan as set forth," and that "vitals must be checked on each visit, even if the patient's care giver and/or assisted living facility staff are also monitoring the patient's vital signs." It promised that "physicians will be notified immediately of vital signs that are outside of normal parameters for that patient as reflected on their care plan." Further, it promised that any missed visits would be documented and the referring physician notified. CMS Ex. 5, at 36-38, 45.

August Survey

But Progressive did not successfully implement these corrections. As the following discussion shows, by the August survey, HHA staff were still not following care plans; they were not consistently monitoring vital signs as called for in the care plans; they were not notifying physicians of aberrant findings; they were not making the ordered number of visits; they were not consistently notifying the referring physicians of missed visits. And nurses still failed to re-evaluate patient needs as required. Among their specific findings:

Patient 2 began receiving care from Progressive on July 16, 2007, following surgery to remove plaque from his carotid artery. He was also diagnosed with non-insulin dependent diabetes mellitus. CMS Ex. 16, at 1, 11, 16; P. Ex. 16, at 1, 11, 24, 25. Among other treatments, his care plan called for blood glucose monitoring as needed, RN monitoring for signs and symptoms of hypo/hyperglycemia, as well as wound care for his surgical site. The plan instructs staff to notify Patient 2's physician of blood sugar readings lower than 70 mg/dl or greater than 160 mg/dl. CMS Ex. 16, at 1, 11; P. Ex. 16, at 11.

Failure to monitor blood glucose levels. Notwithstanding the physician order for blood glucose monitoring, at the time of Patient 2's initial comprehensive assessment, the RN failed to record his glucose levels. Indeed, the HHA was apparently not even capable of measuring his blood glucose because neither the agency nurse nor the patient possessed a glucometer (the medical device used to determine the concentration of glucose in the blood). So, rather than recording a baseline blood glucose level, the RN wrote that Patient 2 "needs glucometer." CMS Ex. 16, at 28; P. Ex. 16, at 28.

Nor did the registered nurse record Patient 2's glucose levels at the time of his first regular skilled nursing visit on July 19, 2007. In the space for recording blood sugar (under vital signs), she simply wrote "awaiting glucometer." CMS Ex. 16, at 22; P. Ex. 16, at 22.

On July 27, the HHA finally recorded Patient 2's blood glucose reading, which, as the RN noted, was an elevated 181. CMS Ex. 16, at 20; P. Ex. 16, at 20.[6] The parties quibble about whether the nurse measured Patient 2's blood glucose with an agency glucometer or with the patient's own. CMS points to the nursing record, which says that the patient had a physician's order for a glucometer, and, in response to the "progress to goals," she writes that he "will get glucometer," and that she offered suggestions regarding the types

[6] The report does not reflect physician notification, even though 181 is outside the acceptable parameters for this resident. CMS Ex. 16, at 11, 20; P. Ex. 16, at 11, 20 ("Notify physician for vital signs outside . . . BS 70 – 160 mg/dl."). CMS, however, has not relied on this apparent omission, and neither do I.

available. CMS Ex. 16, at 20; P. Ex. 16, at 20. Petitioner, on the other hand, flatly denies issuing glucometers to its nurses, and cites a note indicating that the patient received his glucometer on July 24. I consider this dispute of little consequence. More important is the undisputable fact that the HHA was, for the first 8 to 11 days of providing care, incapable of measuring the blood glucose level of this diabetic patient, which means that it lacked the capacity to furnish adequate care to Patient 2. *See* 42 C.F.R. § 488.24(b).

Petitioner points out that the regulations do not explicitly require that the HHA issue glucometers to its nurses. While the regulations may not explicitly require the issuance of glucometers – or any other medical device – if, as here, a patient's care plan calls for monitoring blood sugar levels, the HHA must have the capacity to do so.[7] Here, Progressive admits that it did not, and that it did not take even a baseline measurement until the patient's third visit from an RN, 11 days after his care started.

Petitioner offers a number of justifications for its failure to measure Patient 2's blood glucose levels. First, while conceding that Patient 2's diabetes is "relevant," Petitioner nevertheless points out that diabetes was not the primary reason for his receiving home health services, apparently suggesting some lesser standard of care for secondary diagnoses. The Departmental Appeals Board recently rejected such reasoning, finding it "not reasonable" to focus on the nursing home resident's recent injuries, which necessitated his placement, "to the exclusion of addressing [his] diabetes, his . . . hypoglycemia, and the consequent need to monitor [his] blood sugar levels . . . ." *The Laurels,* DAB No. 2182, at 17.

Petitioner also argues that, unless the patient presented a specific indication of "need," the HHA was not required to monitor blood sugar levels, since the care plan required blood glucose monitoring PRN (as needed). Neither the care plan nor Petitioner suggests what indication would trigger taking a blood glucose level, nor how, without a glucometer, the HHA proposed to measure blood glucose if the patient presented with significant symptoms of abnormal blood glucose levels.

At a minimum, the HHA is charged with measuring a diabetic patient's blood glucose levels as part of his assessment. The OASIS form calls for it, and I do not consider an adequate response the question mark that the RN filled in here. P. Ex. 16, at 28; *see* CMS Ex. 22, at 51 ("All assessment data base fields must be completed/answered."). Further, as Surveyor Mariole English explains, a diabetic patient's blood glucose level must be checked and recorded during the comprehensive assessment to establish monitoring parameters in the patient care plan. CMS Ex. 13, at 4 (English Decl. ¶ 14).

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[7] Nor do the regulations specifically mandate that the HHA provide thermometers or watches with second hands, but lacking such equipment does not excuse HHA nurses from taking temperatures or pulse rates called for in patient care plans.

I note also the significant risk a provider takes if it limits blood glucose testing to situations where the patient presents with significant symptoms of hyper or hypoglycemia. *See, e.g., The Laurels,* DAB No. 2182, at 27 ("Some people have no symptoms of hypoglycemia . . . and may lose consciousness without ever knowing their blood sugar levels were dropping.") Indeed, when finally measured on July 27, Patient 2's blood sugar was elevated, even though the nursing record does not describe any particular symptoms or complaints related to abnormal blood sugar levels. P. Ex. 16, at 20.

Citing 42 C.F.R. § 484.18(b), Petitioner next argues that, by notifying his physician that Patient 2 needed a glucometer, it effectively and acceptably altered the care plan. 42 C.F.R. § 484.18(b) requires the attending physician and HHA personnel to review the care plan at least every 60 days and more often if necessary; the HHA's professional staff must also "promptly alert" the physician of any changes that suggest a need to alter the care plan. This is a far cry from the HHA's retroactively declaring a care plan "altered" after the provider staff have failed to follow it.

Moreover, asking the physician to order a glucometer for Patient 2 is not the same as telling him that the HHA cannot and will not measure the patient's blood glucose. Measuring blood glucose levels is such a basic and routine part of caring for a patient with diabetes that it seems unfathomable that a health care professional treating a patient with diabetes would not be capable of doing it, whether or not the patient had his own glucometer. In the absence of evidence that the physician explicitly determined that blood glucose levels not be monitored, I find it unreasonable to infer that he changed the care plan in this regard. Certainly, nothing in the record suggests that any health professional intended to alter Patient 2's care plan to eliminate blood glucose testing. In fact, the opposite is true. As reflected in their reports, HHA staff recognized that they were supposed to be recording glucose levels among Patient 2's vital signs. CMS Ex. 16, at 28; P. Ex. 16, at 28. Indeed, in her July 19 report, the RN not only records the need for a glucometer, under "Plan for Next Visit," she writes "[vital signs] glucose monitor." CMS Ex. 16, at 22.

Deficiencies regarding wound care. CMS also cites deficiencies with respect to Patient 2's wound care.

Patient 2's care plan called for "wound care: surgical site right neck, teach wound dressing, cleanse with NSS (saline) and apply 4X4 dressing, secure with tape daily until healed." CMS Ex. 16, at 11. During the assessment, the RN apparently showed Patient 2's wife how to provide wound care, checking "yes" to "satisfactory return demo." CMS Ex. 16, at 31. Of course, this did not mean that Patient 2's wife was proficient in wound care, hence the transfer order directed staff to assess the wife's dressing change and the care plan directed them to "teach wound dressing." CMS Ex. 16, at 23, 11.

No documentation suggests that, during the July 19 visit, the RN either assessed the wife's dressing change or taught wound dressing. CMS Ex. 16, at 22. Petitioner, however, points to an entry in the nursing visit record indicating no signs or symptoms of infection. P. Ex. 16, at 22. But skilled observation of the wound was a requirement separate from the requirements of assessing the dressing change and teaching wound care. It seems that the nurse followed some of the care plan's instructions, but not others. The RN was required to follow them all.

Petitioner then characterizes the absence of wound care/education documentation as "an isolated, and non-recurring event." P. Pre-hearing Brief at 17. But where, as here, the record is replete with examples of staff failure to provide services in accordance with patients' care plans, the deficiencies are no longer "isolated" and "non-recurring," but instead evidence a systemic failure that justifies termination.

Patient 8 began care with Progressive on July 13, 2007. He was an 86-year-old man suffering from congestive heart failure (CHF), venous embolism and thrombosis, as well as dementia and other maladies. Among other orders, his care plan called for skilled observation of his cardiovascular status and evaluation of his cardiopulmonary status, with the goal of stabilizing his cardiovascular pulmonary condition by September 13, 2007. CMS Ex. 21, at 9, 20; P. Ex. 22, at 9, 20.

According to Surveyors English and Theresa Jacobs, evaluating cardiopulmonary status necessarily includes monitoring edema and the patient's weight. CMS Ex. 12, at 9 (Jacobs Decl. ¶ 33); CMS Ex. 13, at 8 (English Decl. ¶ 33) (Monitoring weight and measuring edema "are completely basic . . . necessary to accurately evaluate cardiopulmonary status for a CHF patient."). For a CHF patient, a weight gain of 2 pounds within 24 hours or 5 pounds in a week could indicate cardiac failure. CMS Ex. 12, at 9 (Jacobs Decl. ¶ 35).

Petitioner claims that Patient 8 weighed 165 pounds at the time of his initial assessment, and maintained that weight. But the record does not indicate that HHA staff ever weighed Patient 8. At the time of his assessment, the nurse recorded his "reported" weight at 165, but she did not actually weigh him. P. Ex. 22, at 28. Petitioner offers no support for its claim that Patient 8 weighed 165 pounds at the time of his discharge.

For a patient with deep vein thrombosis, measuring lower extremity edema is also standard. CMS Ex. 13, at 8-9 (English Decl. ¶ 33). Nurses measure edema by one of two methods: by using a tape measure to measure the affected area (*e.g.,* in monitoring the lower extremity, the nurse would measure the ankle, calf, and arch of the foot), or by pressing down on the swollen area to see the amount of indentation (pitting) that results, and expressing that pitting on a numerical scale that goes up to a maximum of "4+," which reflects severe edema. According to CMS, both measures should be taken in monitoring edema. CMS Ex. 12, at 8 (Jacobs Decl. ¶ 31).

Yet, even though the nurse consistently – on July 17, 20, 24, 27, and August 3, 2007 – observed lower extremity edema in Patient 8, she did not consistently measure his extremities; she did not weigh him at all. CMS Ex. 21, at 18, 19.

Further, Patient 8 had a deep vein thrombosis in his left leg. CMS Ex. 21, at 20, 22. He initially had edema in his lower left leg, but his right leg was not affected. CMS Ex. 21, at 28. On July 17 and 20, the nurses reported edema in his left leg. CMS Ex. 21, at 18, 19. For the first time, on July 27, the nurse reported *bilateral* edema. CMS Ex. 21, at 16. On August 3, the nurse again reported that Patient 8 had edema in both legs. CMS Ex. 21, at 15. Yet nothing suggests that the nurse notified Patient 8's attending physician of edema in the previously unaffected leg.

Patient 8's care plan also called for recording his vital signs, including his temperature to insure that it fell within set parameters of 95.8 to 101 degrees Fahrenheit. CMS Ex. 21, at 9; P. Ex. 22, at 9. Yet, during patient visits on July 17, July 24, and August 3, 2007, Patient 8's temperature was not recorded. CMS Ex. 21, at 15, 17, 19; P. Ex. 22, at 15, 17, 19.

Patient 3 was a sixty-five-year-old man, suffering from Type II diabetes, who began care with Progressive on July 6, 2007. CMS Ex. 17, at 22.

Patient 3's assessment is incomplete. Although it indicates previous hospitalizations, it does not include the reasons for those hospitalizations. CMS Ex. 17, at 44. Nor did the nurse report his weight. CMS Ex. 17, at 49.

His care plan calls for skilled observation of his vital signs, and requires physician notification of vital signs outside certain parameters, including blood sugar levels lower than 60 or higher than 200 mg/dl. CMS Ex. 17, at 22; P. Ex. 17, at 22. But the July 20 nursing visit record shows that his blood sugar then measured 306 mg/dl, without any indication that the physician was notified. Spaces on the record form for designation of the date, time, and content of physician notification are left blank. CMS Ex. 17, at 33; P. Ex. 17, at 33. On July 27, Patient 3's blood sugar levels are recorded as 123, 114, and 213, which the RN characterized as "unstable." Again, nothing on the form suggests that the nurse notified the physician of the high (213) reading; the physician notification spaces are left blank. CMS Ex. 17, at 32; P. Ex. 17, at 32.

Also the care plan called for physician notification of a pulse rate above 100 or below 60. CMS Ex. 17, at 22; P. Ex. 17, at 22. On July 20, Patient 3's pulse rate was 108, but the physician contact information is left blank. CMS Ex. 17, at 33; P. Ex. 17, at 33.

With regard to the aberrant vital signs from the July 20 visit, Petitioner seems to acknowledge the absence of any nurse's note, but points to notes generated by the nursing supervisor who purportedly spoke to the nurse. A note dated July 21 says that the RN

"stated she had indeed notified the physician regarding the [patient's blood glucose level and pulse]." P. Ex. 17, at 19. In a second note, dated July 23, the nursing supervisor again says that the nurse "indicated that she had indeed notified physician regarding the blood sugar," and that the physician was "aware of pulse . . . ." P. Ex. 17, at 18. The notes are silent as to the date, time, and specific content of the physician notification.

I do not find this evidence particularly reliable and it is certainly not an acceptable practice to report, second or third-hand, a nurse's consultation with the physician. The nurse herself is charged with documenting her own consultations. As explained by Surveyor English:

> It is the standard of care to document physician notification when it happens. Also it is not proper to document care provided by someone else. Rather, the nurse who visited the patient and said she consulted with the physician would be responsible for making a late entry in the clinical record.

CMS Ex. 13, at 5-6 (English Decl. ¶ 20); *accord*, CMS Ex. 23, at 5. Progressive's policies also require that "all documentation is to be completed on the day the service is rendered . . . ." CMS Ex. 22, at 36.

No evidence suggests that the physician was advised of the unstable blood sugar levels found on July 27.

Patient 4 was a 68-year-old man suffering from Type II diabetes, chronic renal failure, and multiple other problems. He had muscle weakness and an abnormal gait. He started care with Progressive on July 5, 2007. His care plan called for a variety of interventions, including skilled observation, teaching diabetic care, teaching compliance with medication and diet, and therapeutic exercises. CMS Ex. 18, at 6.

Inadequate assessment/care plan. Patient 4 was taking insulin (Humulin); his caregiver reported that his blood sugar ranged from 32 to 270. CMS Ex. 18, at 41. Yet, the RN who conducted his initial assessment apparently did not take a baseline blood glucose level. And, although she suggested parameters for physician notification with respect to other vital signs that were incorporated into the care plan, she did not include suggested parameters for blood glucose levels, and the plan contains none. CMS Ex. 18, at 6, 52.

According to his initial assessment, Patient 4's medications included Ambien, a sedative used to treat insomnia, as needed. The assessment notes that the Ambien causes him nightmares and confusion at times. CMS Ex. 18, at 51, 52. Yet, the Ambien is not listed

among his medications on Patient 4's care plan.[8]

Not making required visits. Patient 4's care plan says this about frequency and duration of visits: 1WK1, 1-3WK8 + 3 PRN visits. CMS Ex. 18, at 6. According to CMS, this means that Patient 4 was to receive one visit the first week (in addition to the assessment visit), followed by 3 visits per week, reducible to 1 if medically indicated and justified. The HHA could also provide up to 3 additional visits as needed "for metabolic instability." CMS Ex. 18, at 6.

The parties dispute the significance of these instructions. According to Surveyor English,

> When the plan of care has a range (rather than a fixed number) for the visit frequency, it is understood that the patient is to start at the top of the range, and if the frequency is adjusted downward within the range, there is to be documentation as to why. Normally it is expected an HHA patient's need for visits will go down. If frequency is adjusted back up, that would indicate a worsening of the patient's condition that should be reported to the physician.

CMS Ex. 13, at 6 (English Decl. ¶ 23).

Similarly, Surveyor Jacobs testified that "[t]he HHA is not simply free to give any amount of weekly visits within the range without a medical justification. The frequency should be based on the needs of the patients, not staffing issues." CMS Ex. 12, at 5 (Jacobs Decl. ¶ 16).

According to Progressive's Transfer of Responsibility form, Patient 4 was to receive visits 2 to 3 times a week for 8 weeks, which seems to buttress the surveyor explanation of the care plan. CMS Ex. 18, at 19.

Petitioner's witnesses agree that "1 wk 1, 1-3 wk 8" means that "the physician determined that anywhere in the range from one visit to three visits would be appropriate for the eight weeks following the initial week of care," but they claim "there is no requirement" that a nurse "must provide one visit on the first week and then three visits for the next eight weeks (unless there is documentation of why fewer visits were performed)." P. Ex. 26, at 3 (Mathew Decl. ¶ 12); P. Ex. 27, at 3 (Mitchell Decl. ¶ 13); P. Ex. 28, at 3 (Joseph Decl. ¶ 12). This opinion is inconsistent with instructions given at Progressive's June 20, 2007 staff meeting (and subsequently supplied to CMS). When a care plan called for "ranging visits" staff were then instructed to "begin high and gradually decrease frequency

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[8] CMS also says that the care plan also omits mention of the anti-anxiety drug, Xanax, but, in fact, the care plan lists it as "Alprazolam (Xanax)." CMS Ex. 18, at 6.

according to patient[']s needs," which is consistent with the surveyors' testimony. CMS Ex. 5, at 84.

Moreover, Petitioner's witnesses leave unanswered the question of who decides whether to provide one, two, or three visits in a given week, and how that decision is reached. I do not believe that HHA staff are simply free to make that call for reasons independent of the patient needs. More reasonable is the view that the physician has afforded the HHA the flexibility to make the determination based on the patient's needs. But this means that HHA staff should make a conscious and reasoned decision as to the appropriate number of visits within the ordered range. Petitioner offers no evidence that any such decision was made here.

Even if I accepted that the HHA was required only to visit once a week (which I do not), the HHA plainly failed to make the ordered visits and failed to notify Patient 4's attending physician that it was not making the visits. In the first week, the nurse visited Patient 4 three times, on July 10, July 12, and July 13. CMS Ex. 18, at 22-27. The nurse next visited on July 18, reporting that the patient had fallen, suffering a head scratch and bruising. He had a headache and left leg edema. CMS Ex. 18, at 21. A nurse did not visit again until more than two weeks later, on August 4, 2007. CMS Ex. 18, at 20.

The record contains little explanation for the gap between visits. It appears that, on the morning of July 27 (more than a week after his last visit), the nurse called, attempting to schedule a visit that same day, but the patient was not available, and an appointment was scheduled for the following week, presumably, August 4. CMS Ex. 18, at 18. I do not consider acceptable practice the HHA's waiting until the last possible minute before attempting to schedule a same-day visit.

The failure to visit is particularly troublesome considering Patient 4's recent fall and head injury.

Failure to notify the attending physician. Obviously, the HHA's failure to visit for 17 days violated Patient 4's care plan. According to Progressive's policies, the physician must be notified whenever ordered visits are not provided. The HHA should either obtain a verbal order for missed visits or incorporate into the patient's medical record documentation of the physician notification. If the requisite visits are not made because the client, family, or caregiver cancels, the HHA must notify the physician and document in the medical record that the physician is aware of the change. CMS Ex. 22, at 31-32 (Progressive Policy # C-480), 51.

While it appears that the physical therapist communicated with the physician, no evidence shows that anyone advised him of the missed nursing visits.

CMS cites other instances of HHA staff's failure to notify the physician as necessary. At the August 4 visit, the nurse reported that Patient 4 was in significant pain – marked 5 on a 0-to-10 scale – because of an inguinal hernia. CMS Ex. 18, at 20. During the prior visit, he had a headache (pain level of 2) but nothing suggests that he then complained of hernia pain. CMS Ex. 18, at 21. According to CMS, the August 4 pain findings should have sparked physician notification, so the physician could have considered additional pain relief measures. CMS Ex. 12, at 5 (Jacobs Decl. ¶ 19). The HHA's policies afford patients "the right to management of their pain." CMS Ex. 22, at 27 (Policy # C-380). Pain is to be assessed on every home visit and documented on a pain or symptom flow sheet, and staff determine whether a referral is necessary. CMS Ex. 22, at 43-44 (Policy # C-980).

According to Petitioner, Patient 4 had that level of pain from his hernia at the time of his assessment so this did not represent a change that would trigger physician notification. P. Ex. 18, at 41. But, as CMS points out, he had been *pain free* on July 10, 12, and 13. CMS Ex. 18, at 23, 25, 27. On July 18, his pain was from a headache, not his hernia, and registered at a relatively low level 2. CMS Ex. 18, at 21. Unfortunately, nurses did not visit him again until August 4, so we do not know his pain levels – if any – for the intervening weeks, but it appears that his previously well-controlled hernia pain was no longer under control. This is a change that merited consultation with his physician.

At the next visit, almost a week later, on August 10, 2007, the nurse notes pain from Patient 4's inguinal hernia, but does not document the pain level nor the effectiveness of pain management, if any. CMS Ex. 18, at 17.

On August 10, Patient 4 also had edema to both legs and a low blood sugar level (65). (Normal 70-110). CMS Ex. 12, at 6 (Jacobs Decl. ¶ 21). Nothing suggests that the physician was notified about any of these problems. The space for indicating physician contact was left blank.

Failure to re-assess. Also troublesome is the absence of evidence that an RN re-evaluated Patient 4 following his fall and resulting head injury. Progressive dismisses this as inconsequential since Patient 4 had been identified as at risk for falls. But there may be a big difference between the patient who is merely "at risk" for falls and the patient who has actually started to experience falls. Without a skilled reassessment, the HHA simply cannot determine the significance of the change.

Finally, no RN re-evaluated when Patient 4 experienced increased hernia pain, nor when he presented with edema and low blood sugar. The RN did not even measure his edema.

Patient 6 was a 93-year-old man suffering from chronic airway obstruction, asbestosis, and lumbago. He had difficulty walking, generalized weakness, and hypertension. His start of care date was July 5, 2007. A cardiac diet had been prescribed for him, but his

nutritional screen assessment indicates that he was non-compliant with the prescribed diet. CMS Ex. 19, at 18. Among other instructions, his care plan directed the HHA staff to teach him diet, home safety/falls prevention, and medication. CMS Ex. 19, at 12; P. Ex. 20, at 40. According to CMS, none of the home visit records nor his discharge summary show any teaching on these topics. CMS Ex. 19, at 42, 43, 47, 62.

Petitioner points to a nurse's note that she instructed him "regarding ambulation, pacing and endurance" on July 20, which arguably might address home safety/falls prevention (P. Ex. 20, at 43), and on July 18, a note mentions "compliance with medication taking," which, though ambiguous, arguably suggest that she taught him compliance with taking medication. P. Ex. 20, at 42. But nothing suggests that she provided education regarding his diet. Petitioner points to changes in his diet, but that does not address the problem of teaching him to be compliant.

The care plan also called for skilled evaluation of Patient 6's cardiopulmonary status. CMS Ex. 19, at 12. Yet, when the RN noted edema in both his ankles during a July 27 visit, the record shows no evaluation. No measurements were taken. Nor is there any indication that the physician was contacted. CMS Ex. 19, at 62.

No nursing visits were documented after July 27, and Patient 6 was discharged on August 9 because he refused nursing visits. CMS Ex. 19, at 8. He did not, however, refuse physical therapy visits. Therapy progress notes indicate PT visits on July 31 and August 3. CMS Ex. 19, at 31-34. It seems that no one inquired as to why he refused nursing, but not PT visits. Nor does any documentation establish that, prior to the time of the discharge, staff notified the physician of his refusals, notwithstanding Progressive's policy that "[i]f fewer visits are provided than ordered, the physician is to be notified . . . ." CMS Ex. 22, at 31.

Patient 7 was an 89-year-old man who began his care with Progressive on July 17, 2007. He suffered from prostate cancer, as well as congestive heart failure and dementia. He had difficulty walking and retained urine. CMS Ex. 20, at 47; P. Ex. 21, at 35. His initial assessment reflected bilateral edema in his lower extremities. "Hemodynamic monitoring" was listed among the primary reasons for his receiving home health services. CMS Ex. 20, at 19; P. Ex. 21, at 19.

His care plan called for "2WK1-3WK8 (may decrease as medically indicted and discharge service as appropriate.)." CMS Ex. 20, at 47. His care plan called for skilled observation of his vital signs and his edema, evaluation of his cardiopulmonary status, and nutrition/hydration/elimination, as well as monitoring for urinary retention. CMS Ex. 20, at 47.

But the HHA visited only once a week, July 20, July 26, August 2, August 9. No reason for the decreased frequency is documented. CMS Ex. 20, at 7-10. I reject Petitioner's claim that the care plan required only one visit per week through eight weeks of care, an argument even weaker here than it was with respect to Patient 4's care plan. Here, on its face, the plan calls for three visits per week starting the second week, *unless* "medically indicated." This plainly places the onus on the HHA to justify any decrease in the number of visits.

On July 20, the visiting nurse measured the edema in Patient 7's feet as "+4 bilaterally," reflecting severe edema. CMS Ex. 20, at 7. On July 26, however, his nursing visit record does not reflect that the RN measured his edema, with the space for recording the result left blank. CMS Ex. 20, at 8. On August 3, the nurse recorded "trace" edema. CMS Ex. 20, at 9. On August 9, the nurse recorded "hard legs." CMS Ex. 20, at 10. According to CMS, while "hard legs" is not considered standard terminology, it reflects severe swelling that has stretched the skin very tight. CMS Ex. 12, at 8 (Jacobs Decl. ¶ 31).

Nothing in Patient 7's record suggests that the nurse notified Patient 7's physician of his severe edema. Petitioner dismisses this as inconsequential because Patient 7 had edema at the time of his assessment, so edema did not constitute a change in condition. CMS Ex. 20, at 24. But Patient 7's physician was plainly concerned about his edema, and specifically ordered the visits for hemodynamic (blood circulation) monitoring, which includes monitoring for edema. The edema seemed to improve, but then went from "trace" to "hard legs" – a level arguably even beyond the +4 previously reported. This represents a significant change which merits a physician consultation.

It was also critically important the patient be weighed since, as noted above, a weight gain of as little as 2 pounds in a patient suffering from CHF could indicate cardiac failure. CMS Ex. 12, at 9 (Jacobs Decl. ¶ 35). I see no record of Patient 7's weight.

IV. Conclusion

Review of these patient records thus establishes the HHA's ongoing failure to provide the level of skilled nursing services called for in the regulations. The problems were widespread, evidencing systemic problems. I find that the these deficiencies limited Progressive's capacity to furnish adequate care. Petitioner was therefore not in

substantial compliance with the skilled nursing services condition of participation, 42 C.F.R. § 484.30.[9] CMS is therefore authorized to terminate its provider agreement.

/s/
Carolyn Cozad Hughes
Administrative Law Judge

[9] While I agree that Progressive's uncorrected standard-level deficiencies may also justify termination, the HHA is ordinarily given 60 days from the date of notice in which to correct standard-level deficiencies. 42 C.F.R. § 488.28. Here, Petitioner claims that it did not receive notice of the March survey findings until July. Although Progressive certainly knew of its deficiencies following the October survey, whether the results of a validation survey can trigger termination based on failure to correct standard-level deficiencies is a question that I need not address.

Petitioner has also argued that termination should not be sustained because it was again accredited by JCAHO based on a survey conducted in September 2007. Where, as here, the provider has lost its deemed status, I am bound to review the results of the State Agency survey upon which CMS relies, and not the JCAHO determination. 42 C.F.R. § 488.7. Moreover, I note that the Joint Commission apparently still found uncorrected standard-level deficiencies, which would itself justify termination.