Department of Health and Human Services

DEPARTMENTAL APPEALS BOARD

Civil Remedies Division

In the Case of:	)	
	)	
Access Home Care,	)	Date: April 15, 1998
	)	
Petitioner,	)	
	)	
- v. -	)	Docket No. C-97-351
	)	Decision No. CR528
Health Care Financing Administration.	)	
	)	

DECISION

For the reasons stated below, I conclude that Access Home Care, Petitioner was in substantial compliance with Medicare conditions of participation (COP) governing home health agencies. Accordingly, the Health Care Financing Administration (HCFA) was not authorized to terminate Petitioner's Medicare participation agreement.

I. Procedural history

Petitioner is a home health agency (Agency or HHA) located in Lakewood, California. On February 13 through 21, 1997, the Los Angeles County Department of Health Services (LACDHS) performed a follow-up Medicare certification survey at the Agency, pursuant to 42 C.F.R. § 488.10, to determine the Agency's eligibility to continue participation in the Medicare program.[1] During the

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During a survey of the Agency from December 16, 1996 through December 26, 1996, LACDHS found numerous deficiencies relating to the furnishing of care and services to patients. During an exit conference on December 26, 1996, LACDHS informed the Agency that it was out of compliance with a number of conditions required for its continued participation in the Medicare program. In a letter to Petitioner dated January 29, 1997, LACDHS specifically identified those conditions. P. Ex. 6.

follow-up survey, LACDHS determined that the COP for skilled nursing services, 42 C.F.R. § 484.30, remained uncorrected. LACDHS recommended that HCFA terminate Petitioner's Medicare provider agreement. See HCFA Ex. 1, 2. Based on the follow-up survey findings and LACDHS recommendation, HCFA terminated Petitioner's participation in Medicare, effective April 25, 1997. By letter dated April 3, 1997, HCFA notified Petitioner of its determination. HCFA Ex. 3; P. Ex. 10.

I held a hearing in this case on August 6, 1997 through August 8, 1997. Following the hearing, both parties submitted posthearing briefs and reply briefs. HCFA and Petitioner also submitted proposed findings of facts and conclusions of law.

II. Applicable law

A. Generally

The applicable law for providers, including HHAs, whose participation in the Medicare program has been terminated has been set forth in numerous decisions, including Prescribed Care, Inc., DAB CR492 (1997) and CSM Home Health Services, Inc., DAB CR440 (1996), aff'd, DAB No. 1622 (1997). Much of my discussion below reflects the applicable law stated in those decisions.

Section 1861(m) of the Social Security Act (Act) describes the covered services that HHAs provide under the Medicare program. The statutory requirements for HHAs, including COP, are described in section 1861(o) of the Act.

The Secretary of the United States Department of Health and Human Services (Secretary) has issued regulations which govern the participation of HHAs in the Medicare program. These regulations are contained in 42 C.F.R. Part 484. Specifically, the provisions contained in 42 C.F.R. §§ 484.10-484.52 set forth the Secretary's requirements for Medicare participation of HHAs and establish COP for these entities. The regulations express these COP as broadly stated participation criteria. For example, the provisions of 42 C.F.R. § 484.30, the COP for skilled nursing services, states that "[t]he HHA furnishes skilled nursing services by or under the supervision of a registered nurse and in accordance with the plan of care."

The regulations also state standards of participation as subsidiary components of the COP. As an example, the standard for the duties of the registered nurse, contained in 42 C.F.R. § 484.30(a), includes but is not limited to: regular reevaluation of the patient's nursing needs; coordination of services;

preparation of clinical and progress notes and informing the physician and other personnel of changes in the patient's condition and needs; and counseling the patient and family in meeting nursing and related needs.

The Secretary is required to determine whether a Medicare provider of services, including a HHA, is complying substantially with the Medicare participation requirements established by the Act and regulations. Act, section 1866(b)(2). The Secretary may terminate the participation in Medicare of a provider which the Secretary finds not to be complying substantially with participation requirements. Act, section 1866(b)(2)(A).

The process and criteria for determining whether a provider is complying substantially with Medicare participation requirements are established by regulations contained in 42 C.F.R. Part 488. The Secretary, through HCFA, has entered into agreements with State survey agencies, pursuant to the Act and regulations, to conduct periodic surveys of providers, including HHAs, in order to ascertain whether the providers are complying with Medicare participation requirements. Act, section 1864(a); 42 C.F.R. §§ 488.10, 488.11, 488.20.

State survey agencies conduct surveys of HHAs and make recommendations to HCFA as to whether such facilities meet federal participation requirements for the Medicare program. Id. HCFA considers survey results from the State survey agencies as the bases for its determinations regarding the initial or continued participation of a HHA in the Medicare program.

In determining whether a provider is compliant with a particular COP, the State survey agency evaluates the manner and degree of the provider's satisfaction of the various standards within each condition. 42 C.F.R. § 488.26(b). The State survey agency documents its findings on HCFA Form 2567, which the provider receives after the survey is completed. The State survey agency also makes a recommendation to HCFA as to whether there is a basis for termination. HCFA may accept or reject the recommendation after reviewing the survey findings.

HCFA may terminate participation in Medicare when it determines, either on its own initiative or based on a State survey agency report, that a provider is not complying with one or more Medicare COP. See 42 C.F.R. §§ 488.20, 488.24, 488.26. Failure to comply with a COP occurs where deficiencies, either individually or in combination, 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).

Where HCFA determines that there is a deficiency, but that the deficiency is not so severe as to constitute a condition-level deficiency, then HCFA may not terminate the provider's

participation in the Medicare program without first affording the provider the opportunity to correct the deficiency. 42 C.F.R. § 488.28.

> Termination of participation is a remedy intended to protect the health and safety of program beneficiaries and not a punishment. Termination of participation should be invoked in the circumstances where a provider's deficiencies establish that the provider is substantially incapable of providing care consistent with Medicare participation requirements. Termination should not be invoked unless the evidence proving a provider's failure to comply with participation requirements established that the provider cannot provide care consistent with that which is required by the Act and regulations.

CSM Home Health Services, Inc., DAB CR440 (1996), at 3.

B. Burden of proof

The burden of proof in this case is governed by the decision of an appellate panel of the Departmental Appeals Board in Hillman Rehabilitation Center, DAB No. 1611 (1997). Under Hillman, HCFA bears the burden of coming forward with evidence sufficient to establish a prima facie case that Petitioner failed to comply with participation requirements. Petitioner has the burden of proving, by a preponderance of the evidence, that it complied substantially with participation requirements. Hillman, at 3-8.

In determining whether HCFA has met its burden of establishing a prima facie case, I may consider rebuttal evidence offered by Petitioner that HCFA's evidence is neither credible or relevant to the issue of Petitioner's compliance with participation requirements or that the weight of the evidence establishes that the regulatory deficiency alleged by HCFA did not occur. If I conclude that the preponderance of the evidence establishes that such circumstances exist, then I will find that HCFA has not met its burden of establishing a prima facie case (but rather, that its case is based on unsubstantiated allegations) and Petitioner will not be obligated to prove that it was substantially complying with participation requirements.[2]

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[2] An appellate panel of the Departmental Appeals Board, in a recent decision, reiterated that the burden of persuasion set forth in Hillman applies only where the evidence proffered by both sides is "in equipoise." Oak Lawn Pavilion, Inc., DAB No. 1638 (1997), at 16-17. In such cases, the burden of persuasion

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would be on Petitioner.

III. Discussion

A. Basis for evaluation of deficiencies

I base my decision in this case on the governing law, the evidence I received at hearing, and the parties' arguments as expressed in their posthearing briefs, reply briefs and proposed findings.[3] Below, I evaluate each of the deficiencies identified by LACDHS and adopted by HCFA. In my analysis of each deficiency, I must determine whether, for each deficiency, HCFA has established a prima facie case that a deficiency existed. If HCFA has put forward this prima facie case, I then must determine whether Petitioner has successfully rebutted HCFA's prima facie case and proved, by a preponderance of the evidence, that no deficiencies existed which caused it to be out of substantial compliance with participation requirements. Finally, if, after evaluating all the evidence, I find that one or more deficiencies existed, I must determine whether such deficiency or deficiencies rise to the level of a COP which would support termination of Petitioner's participation in Medicare.

I use the following format for my decision. The paragraphs set out in boldface, and any subheadings thereunder, are my findings of fact and conclusions of law (Finding(s)). The descriptive text under each heading is my rationale for such determinations.

1. G Tag 172: HCFA has failed to present a prima facie case that Petitioner's registered nurse failed to regularly reevaluate the patient's nursing needs with respect to Patients 3, 5, and 7, three patients out of seven patients sampled; or, alternatively, Petitioner has established by the preponderance of the evidence that it is in compliance with the regulatory requirements pertaining to these patients.

The regulation containing the COP for skilled nursing services states that "[t]he HHA furnishes skilled nursing services by or under the supervision of a registered nurse and in accordance with a plan of care." 42 C.F.R. § 484.30. As a subsidiary component of that COP, the standard for duties of the registered nurse is set forth and states, in relevant part, that "[t]he registered nurse . . . regularly

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[3] I have evaluated carefully all arguments made by the parties in their briefs. If I do not refer specifically to such argument in my decision, I have rejected it.

re-evaluates the patient's nursing needs . . . ." 42 C.F.R. § 484.30(a); see HCFA Ex. 1 at 9.

a. Patient 3

At the time LACDHS conducted its follow-up survey of Petitioner in February 1997, Patient 3 was an 84-year-old female. The certification period for Patient 3 was January 15, 1997 through March 15, 1997; and, she was within her initial 60-day period of home health certification (certification period). HCFA Ex. 7 at 1. The principal diagnosis contained in the Home Health Care Certification and Plan of Care (plan of care) for Patient 3 was hypertension (January 14, 1997). Id. Other pertinent diagnoses for this patient included angina pectoris (October 1, 1996), gout (October 1, 1996), and osteoarthritis (October 1, 1996). Id.

The skilled nursing orders contained in the plan of care for Patient 3 included: (1) assessing blood pressure, signs and symptoms of hypertension, and hypertension crisis; (2) assisting the patient in identifying precipitating factors for chest pain; and (3) assessing the effectiveness of medications such as nitroglycerin (NTG). Id. For chest pain, her physician prescribed NTG (0.6 mg, one tablet as necessary), which dosage could be repeated up to three times sublingual (SL), that is, under the tongue. Id. at 2. For Patient 3, the plan of care goals included stabilization of her blood pressure with a systolic range of 100-140 and diastolic range of 70-90, four to six weeks after beginning home care. Id. at 1.

The State agency surveyor, Ms. Evelyn Bruce, reviewed nursing notes for Patient 3 dated January 17, 20, 22, 24, and 27, 1997 and February 7, 1997, respectively, which reflected the existence of chest pain.[4] Additionally, Patient 3's blood pressure readings ranged from 104-142 systolic to 60-82 diastolic. Based on these findings, as set forth in HCFA Form 2567, Ms. Bruce concluded that the registered nurse failed to reevaluate the nursing needs of the patient. HCFA Ex. 1 at 10.

Ms. Bruce admitted that the blood pressure readings found in the nursing notes were within normal ranges. Tr. 98. However, she criticized Petitioner's skilled nursing staff for failing to inform the physician that the discharge goal for Patient 3, that

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[4] The skilled nursing note documentation for five visits to Patient 3, on January 17, 20, 22, and 27, 1997 and February 7, 1997, respectively, contain observations of chest pain. Ms. Bruce admitted during the hearing that the HCFA Form 2567 referred, erroneously, to six occasions of chest pain, and that her reference to a notation for January 24, 1997 was incorrect. Transcript (Tr.) 198. See also, HCFA's Opening Posthearing Memorandum (HCFA PHBr.), at 16, n.10; HCFA Ex. 7 at 21.

is, to stabilize and maintain her blood pressure, had been met early. Tr. 96-100. In essence, Ms. Bruce concluded that the staff's failure to inform the physician led to the patient receiving nursing services which were no longer necessary. Id. Such a conclusion is not supported by the record.

For Patient 3, the plan of care goal with regard to her blood pressure was to stabilize and maintain normal blood pressure four to six weeks after home care began on January 15, 1997. The readings at issue were all within this initial four-week to six-week period. The documentation from the skilled nursing visits reflected that the patient was able to maintain normal blood pressure during the period January 17, 1997 through February 7, 1997. The plan of care, however, included this evaluation period to ensure that the patient's blood pressure could be maintained at normal levels. The Agency achieved its plan of care goal for this patient. There is no basis to conclude that, prior to the end of the four-week period, the skilled nurse should have informed the physician that the blood pressure was normal and to end the evaluation. Rather, the goal was to stabilize and maintain the blood pressure over a four-week to six-week period. By definition, some period of time must elapse in order to determine that the blood pressure is stabilized and maintained at the desired level, including a period of skilled nursing visits. This four-week to six-week period had not ended by February 7, 1997. So, contrary to Ms. Bruce's observation, it would have been premature to end the services before the goal observation period had been completed.

Next, Ms. Bruce expressed concern about the chest pain Patient 3 experienced on five occasions between January 17, 1997 and February 7, 1997. See HCFA Ex. 1 at 10; HCFA Ex. 7 at 18-20, 22, 26. As indicated in the plan of care, Patient 3 also had a non-principal diagnosis of angina pectoris,[5] and was prescribed NTG to control the chest pain.[6] Ms. Bruce expressed her belief that the patient's frequent complaints of chest pain during the

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[5] **The typed version of the plan of care listed hypertension as the principal diagnosis but the start of care work sheet for this patient is somewhat ambiguous because both angina pectoris and hypertension appear to be noted as principal diagnoses. HCFA Ex. 7 at 2, 8.**

[6] The record also is ambiguous as to the exact medication dosage the patient was taking for her chest pain. The typed version of the plan of care referenced NTG 0.6 mg, as compared to the work sheet for the care plan, which referenced NTG 0.4 mg. HCFA Ex. 7 at 2, 8.

skilled nursing visits reflected a change in the patient's nursing needs, thereby necessitating a communication to the physician about the possibility of a need to change the plan of care. Tr. 94-95, 98, 373-74.

According to Ms. Bruce, the nursing notes did not indicate any communication with the physician. Id. She stated specifically that there was no notation in the nursing notes assessing the efficacy of the patient's NTG as required in the care plan. Tr. 373-75. Even though a patient with angina pectoris would be expected to have chest pain, Ms. Bruce opined that the physician still should have been notified because the nurse is in regular contact with the physician and is responsible for evaluating the patient's condition. Tr. 94-95, 108-09, 375-76. Ms. Bruce also was concerned that, since the principal diagnosis was hypertension (which she admits was controlled during the certification period), the frequent complaints of chest pain reflected a change in nursing needs which should have been brought to the attention of the patient's physician.[7] She also indicated that there was potential harm to the patient because the patient's complaints about chest pain could have been signs of a heart attack. Tr. 124.

I agree with Ms. Bruce's interpretation as to the purpose of the applicable regulation, that is, to provide information to the physician, who then considers this information in deciding whether to alter the care plan. Tr. 94-95. The issue in this case, however, is whether the notations of pain were of such significance that they should have been brought to the physician's attention, or, a normal consequence of the underlying diagnosis of angina pectoris, with the medication accomplishing its purpose of relieving the pain.[8]

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[7] I note with interest that Ms. Bruce further opined that if the diagnoses were reversed, that is, had the principal diagnosis for Patient 3 been angina pectoris instead of hypertension, then physician notification would not have been necessary in these circumstances. Tr. 375-76. I do not agree with the significance that Ms. Bruce attributes to the principal diagnosis. This patient, like many elderly individuals, had multiple medical problems. Whether a diagnosis is labeled "principal" or "pertinent" is not of particular importance and should not alter the treatment of the patient.

[8] HCFA attempts to supplement its prima facie case by submitting, as Attachment B to its Opening Posthearing Memorandum, an excerpt from a treatise on medical-surgical nursing. HCFA was apprised of the schedule for submitting

A closer examination of the nursing notes suggest that the notations of pain were not significant. At issue are the contents of Petitioner's "Nurse Progress Notes." The "Nurse Progress Note" is a form that the registered nurse completed when conducting a home visit. The form provided five indicia to record the presence of pain, on which the nurse indicated: (1) whether a patient was experiencing pain, by recording yes or no; (2) what level of pain intensity the patient experienced, by using an intensity index numbered from 1-5, with 5 representing the most severe pain; (3) where the pain was located, by recording observations in the blank space provided; (4) whether the pain was controlled, by recording yes or no; and, (5) what means were used to control the pain, by recording observations in the blank space provided. See HCFA Ex. 7 at 18-27.

For Patient 3, these notations indicate that when she experienced chest pain, the prescribed medication controlled it adequately. See HCFA Ex. 7 at 18-20, 22, 26. In three of the five instances where chest pain is noted, the pain is recorded at level 2 intensity (out of 5) and in two instances the pain is recorded at level 1 (out of 5); the pain is located in the left chest and it is relieved, either separately or in combination, by rest and medication (NTG 0.4 mg SL). Id. On four visits during the period until February 15, 1997, that is, on January 24 and 29, 1997, February 5, 1997 and February 15, 1997, the documentation contained no notes on chest pain. See HCFA Ex. 7 at 21, 23-25.

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exhibits in my Prehearing Order dated July 3, 1997. When given the opportunity at the hearing to submit rebuttal evidence, HCFA chose not to do so. Having failed to offer the evidence at the proper time during the hearing, it is patently unfair to Petitioner to allow HCFA to offer new exhibits at this late date, when there is no opportunity to have witnesses discuss their testimony in light of these exhibits. Due to the obvious breach of due process, this untimely exhibit is rejected and will not be considered. Additionally, all other documents attached to HCFA's Posthearing Memorandum, Attachments A, and C-F, respectively, are rejected as untimely exhibits.

Similarly, Petitioner attempts to supplement its case by attaching two documents to its posthearing Response Brief (P. PHRep.). These documents are a one-page excerpt from the Physicians' Desk Reference (Schedule A) and a three-page description of diabetes from the National Institutes of Health Internet web page (Schedule C). For the same reasons stated above, I am rejecting these documents as untimely exhibits.

I find credible the testimony of Ms. Dorothy Ausman, who appeared as an expert witness for Petitioner.[9] Ms. Ausman has many years of nursing experience, including 23 years as an acute care nurse. She is now a home health administrator. She testified that chest pain intensity at level 1-2 is not indicative of mild heart attack but of continued chest pain for which the patient was receiving adequate treatment of NTG to control the pain. Tr. 253-54.

That Patient 3 would experience chest pain was not unexpected. The plan of care for this patient specifically addressed the assessment of NTG for pain management, as part of the nursing orders. The goals contained in Patient 3's plan of care did not include elimination of chest pain, as the patient was likely to experience mild chest pain. Rather, the goal for this patient was to manage her pain with medication. The nursing notes demonstrate that, in instances of chest pain, the prescribed medication (NTG) achieved the appropriate result of controlling the pain. Notes of skilled nursing visits for this patient indicate the chest pain symptoms observed were within the parameters of the plan of care; therefore, the physician need not be notified in order to consider altering the plan. Moreover, there is nothing in the record to show that Patient 3's cardiac status was compromised during any of the nursing visits that would necessitate a communication with her physician or a reevaluation of her nursing needs.

Based on the review of the record pertaining to this patient, HCFA has failed to establish a prima facie case that Petitioner's actions regarding this patient violated the cited standard. In the alternative, I find that Petitioner has presented persuasive

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HCFA takes issue with the lack of experience of this witness regarding the State survey process, including her inability to understand the difference between standard and condition level deficiencies. HCFA also questioned the value of Ms. Ausman's testimony, in light of her admission that she had not reviewed any of the patient medical records prior to her testimony. HCFA PHBr. at 6. I disagree that these factors reduce the credibility or reliability of her testimony. Ms. Ausman was not called as an expert on the survey process, but rather, on skilled nursing practices, with which she has extensive experience. I do note that HCFA did not raise any objection to her testimony as an expert at the hearing. As to her failure to review the patient records, this circumstance is not controlling, as she did sit through the testimony of Ms. Bruce, and, apparently was aware of the factual issues relied on by HCFA in supporting the deficiencies cited in HCFA Form 2567.

evidence that the Agency's care of Patient 3, contrary to the deficiency cited on HCFA Form 2567, was in substantial compliance with the applicable standard.

b. Patient 5

At the time LACDHS conducted its follow-up survey, Patient 5 was a 71-year-old male, living alone, who was within his initial 60-day certification period (December 28, 1996 to February 28, 1997). The plan of care listed his principal diagnosis as insulin dependent diabetes mellitus (IDDM) (December 28, 1996). Other pertinent diagnoses were hypertension (December 28, 1996) and asthma (December 28, 1996). HCFA Ex. 9 at 1. The skilled nursing orders contained in the plan of care included an evaluation by a medical social worker (MSW) for an "able, willing and available caregiver." Id. at 2. Discharge planning for this patient included "ongoing SN [skilled nursing] visits for Insulin preparation and administration until a skilled caregiver will be (sic) available." Id.

The goals contained in the plan of care for Patient 5 included the performance of activities of daily living and self-care by three to four weeks, ability to verbalize signs and symptoms of acute complications with appropriate actions by six to eight weeks. Another goal for this patient was that he have the ability to verbalize disease process, long-term complications and preventable measures in six to eight weeks. HCFA Ex. 9 at 1-2. According to statements contained in the discharge planning section of the plan of care, Patient 5 was considered to have fair potential to demonstrate compliance with the diabetes regimen (that is, to demonstrate the ability to care for himself on a daily basis) in four to six weeks. The plan of care also contained statements that clearly anticipated that Patient 5 would require skilled nursing visits for insulin preparation and administration until a skilled caregiver became available. Id. at 2.

With the start of care, the patient, for the most part, received skilled nursing services twice a day for insulin injections and blood glucose monitoring. Tr. 103. The progress notes for this patient reflect that he refused to self-inject his insulin and to monitor his blood sugar throughout the skilled nursing visits. HCFA Ex. 9 at 44, 47, 49, 57-58, 68, 87, 93, 102-105, 113; HCFA Ex. 18 at 8. In a case conference note dated February 10, 1997, the nursing staff reported that Patient 5 continued to refuse to manage insulin injection and blood sugar testing and would continue to need skilled nursing services twice per day until the MSW found an alternative care giver to provide the insulin and do the blood sugar monitoring. HCFA Ex. 9 at 13. When the MSW

consulted with the patient on February 10, 1997, he refused to accept in-home support services and requested that arrangements be made for him to apply for Section 8 housing.[10] HCFA Ex. 9 at 31. The next scheduled MSW visit was to occur in two to three weeks. Id.

Ms. Bruce met with Patient 5 and his nurse on a home visit on February 19, 1997. During this visit, the patient informed Ms. Bruce that he had taken insulin for 10 years and that he knew how to give himself insulin injections and monitor his own blood sugar levels. The patient also stated, however, that he was afraid of overdosing himself on insulin, since that had occurred on one occasion. Tr. 104-06; HCFA Ex. 18 at 7. Ms. Bruce opined that the registered nurses failed to reevaluate the patient's nursing needs, because his reluctance to administer insulin and monitor his blood sugar was due to his "fear," rather than an inability to perform the home care. Tr. 106. She argued that, rather than focusing their efforts on an alternative caregiver, the nurses should have directed their attention to the patient's fears and notified his physician about these fears. Tr. 388-89. Ms. Bruce testified that there was nothing in the patient's record to suggest that the patient's fear was addressed even though he reported such fear to the skilled nurses on several occasions. HCFA Ex. 9 at 93, 102, 104; Tr. 106, 108, 385-89.

HCFA contended that the plan of care should have been amended to address the patient's fear and how this fear may have influenced the patient's refusal to accept an alternative care giver. HCFA PHBr. at 21. HCFA concludes, based on the opinion of Ms. Patience,[11] that Petitioner's failure to reevaluate Patient 5's

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[10] Petitioner's counsel argues that Patient 5 did not refuse in-house support services, but, in fact, was referred for such services. P. PHRep. at 3. While the writing in the telephone contact report from the MSW is difficult to read, I accept HCFA's contention that the word used is "refused" rather than "referral." See HCFA Ex. 9 at 31. Such an interpretation is supported by the MSW's evaluation report dated February 11, 1997, where she has checked off that the "[patient/care giver] is aware & declined the following CRs: IHSS [in-home support services] . . . ." HCFA Ex. 9 at 11.

HCFA refers to Ms. Ruth Patience, who is employed by HCFA as a nurse consultant. In that position, she has surveyed health care providers seeking HCFA certification under the Medicare program. Further, she acts as a consultant to the California State survey agency in interpreting Medicare regulations relating to survey and certification issues. She has been a trainer and

nursing needs regarding the use of an alternative caregiver could compromise his mental and emotional well being. Id. at 21-22; HCFA Ex. 21. Moreover, HCFA concludes that Petitioner's failure to address Patient 5's fears, coupled with his unwillingness to accept an alternative skilled caregiver, meant that the only recourse available to Petitioner was to continue providing skilled nursing services twice per day, rather than have Patient 5 become self-sufficient and live independently, which was the desired outcome in his plan of care. HCFA PHBr. at 21-22; HCFA Ex. 21 at 3.

Petitioner responds to HCFA's arguments by contending that it acted appropriately, in reaction to Patient 5's unwillingness to inject insulin, by requesting the MSW to locate an alternative caregiver. Therefore, in Petitioner's view, its action alleviated the need to reevaluate the patient's nursing needs. P. PHRep. at 3. Petitioner argues further that the MSW was providing assistance in finding in-home support for Patient 5. P. PHRep. at 3. Moreover, Petitioner argues that the MSW "was ordered to address the patient's fear of giving his own insulin injection and a note in the intervention section of the chart documented that the MSW had provided a [sic] supportive emotional and cognitive behavioral counseling." Id. In conclusion, Petitioner argues that with regard to Patient 5: (1)"efforts were underway to locate a caregiver to further assist in fear reduction, help with injections and decrease dependence on nursing staff;" (2) his needs were addressed as expeditiously as possible with no excess skilled nursing services being rendered, as he was within his initial certification period; and (3) cessation of care for Patient 5 prematurely would have been tantamount to "abandonment" of the patient. Id.

At the outset, statements contained in the plan of care (starting December 28, 1996) make evident that, while there was some hope that Patient 5 could become self-sufficient, that is, be able to self-inject insulin and monitor his blood sugar after four to six weeks of skilled nursing training (that is, between January 26, 1997 and February 9, 1997), skilled nursing services would be necessary until an alternative skilled caregiver was in place. See HCFA Ex. 9 at 2. Although the plan of care makes reference to the MSW assisting in the identification of alternative skilled care, the physician's order for such a visit did not occur until January 27, 1997. HCFA Ex. 9 at 27. The MSW contacted the

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reviews HCFA Form 2567s to ensure that they meet HCFA guidelines. Lastly, she has experience as a State surveyor and previously was employed as a registered nurse. Ms. Patience submitted a declaration in lieu of testimony. HCFA Ex. 21; HCFA PHBr. at 5.

patient and they mutually agreed that the visit should occur on February 10, 1997. HCFA Ex. 9 at 10.

In a case conference note dated February 10, 1997, the registered nurse recorded Patient 5's refusal to manage home care by self-injecting insulin and monitoring his blood sugar and indicated a referral to the MSW to find an able, willing, and available caregiver. HCFA Ex. 9 at 13. The MSW, in a February 10, 1997 home visit with the patient, could not get him to agree to in-home support services. During that same visit, an application for Section 8 housing was initiated and a follow-up visit was anticipated in two to three weeks. HCFA Ex. 9 at 31.

Considering the varied reasons Patient 5 cited for refusing to care for himself at home--such as, poor vision, fear of needles and blood sugar monitoring machines, and his refusal to use in-home support service when offered on February 10, 1997, I find that Petitioner's skilled nursing staff acted reasonably in dealing with a clearly difficult patient. The registered nurses made numerous efforts to train Patient 5 in self-care despite his resistance.[12] Nor does the record indicate that any delay by Petitioner, in reevaluating the nursing needs of Patient 5 regarding the use of an alternative caregiver, led to the provision of an excessive amount of skilled nursing services as alleged by HCFA.

The physician authorized continued skilled nursing visits for Patient 5 as early as January 10, 1997, for the purpose of administering insulin injections and monitoring blood sugar, due to the lack of a willing and available caregiver. HCFA Ex. 9 at 26. The physician reevaluated the patient's care as of the end of January 1997, approximately four weeks after the start of care, when it was determined that a MSW should assist in obtaining an alternative caregiver. The patient, if unwilling, could not be forced to administer the injections and monitor his blood. Nor could skilled nursing care be stopped absent an alternative caregiver. Moreover, there is nothing in the record to suggest that Petitioner did not aggressively seek an alternative skilled caregiver.

HCFA places much emphasis on Patient 5's fear of overdosing as the basis for his reluctance to care for himself. As HCFA points out, the record contains some indication that Patient 5 articulated fear relating to self-injecting insulin prior to the in-home visit by Ms. Bruce on February 19, 1997. A careful examination of the record, however, fails to demonstrate that the

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[12] See P. PHRep., Schedule G.

sole fear the patient expressed related to overdosing. The record reflects a number of instances when Patient 5 expressed fear, such as: January 7, 1997: "fear of needle;" January 3, 1997: "[u]nwilling to do self-injection of insulin due to fear of needle;" and, January 2, 1997:"[p]t. was resistive of using One Touch, stated [illegible] scared to use that machine." HCFA Ex. 9 at 93, 102, 104, respectively. In addition to the complaints of "fear," the nurse progress notes are replete with references to Patient 5's unwillingness or reluctance to self-inject insulin and do blood sugar monitoring. See HCFA Ex. 9 at 44, 47, 49, 57-58, 68, 87, 93, 102-105, 113; HCFA Ex. 18 at 8. This patient gave various reasons, ranging from poor vision, fear of needles, and unwillingness to use the blood glucose machine, in refusing to exercise home care. The progress notes of record end with the visit on February 8, 1997. HCFA Ex. 9 at 34. The only indication of the fear of overdosing was from the home visit on February 19, 1997; the only record of that visit is Ms. Bruce's work sheet. HCFA Exhibit 18 at 7.

As to whether Petitioner adequately addressed Patient 5's fear, the record reflects attempts to counsel the patient regarding his fears. As pointed out by Petitioner, the MSW in her visit with the patient on February 10, 1997 addressed "released stress," "learning coping skills," "expressed/ventilated thoughts, feelings, concerns, frustrations."[13] In reviewing the record of this visit, it would appear that the MSW discussed with Patient 5 many of his concerns or fears regarding self-administration of insulin and blood glucose monitoring. Petitioner cannot be faulted for failing to counsel him on the fear of overdosing since that particular fear was not raised until the home visit on February 19, 1997. I agree with Petitioner that, in repeated skilled nursing home visits to Patient 5, the registered nurses addressed techniques for administering injections and blood sugar monitoring. In fact, it was during these demonstrations that Patient 5 expressed his fear of needles and the blood glucose machine. No additional skilled nursing reevaluation was necessary to address such fears. While it may have been helpful to raise the issue of Patient 5's fears with his physician, his reference to "fears" (as opposed to unwillingness or inability to care for himself) in the skilled nursing visits was sporadic and limited, and no mention of the "fear" of overdosing occurred prior to February 19, 1997. I have no information of record as to what action if any that was taken by Petitioner based on that

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P. PHRep., Attachment A at 4-5; Schedule B-1.

home visit.[14] That the registered nurse failed to notify the physician in such circumstances does not support the conclusion that Petitioner did not properly reevaluate Patient 5's skilled nursing needs.

Consequently, I must conclude that HCFA has failed to establish that any circumstances arose which would necessitate a reevaluation of Patient 5's skilled nursing needs other than the reevaluation reflected in the record. I do not find that Patient 5's emotional and mental well-being was compromised by any action taken by Petitioner. Nor do I find that Petitioner took any action that caused any unnecessary delay in Patient 5 achieving independent living.

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[14] The survey of Petitioner by Ms. Bruce was completed on February 21, 1997. HCFA Ex. 1.

Based on review of the record pertaining to this patient, HCFA has failed to establish a prima facie case that Petitioner's actions regarding this patient violate the cited standard. In the alternative, I find that Petitioner has presented persuasive evidence that the care of Patient 5, contrary to the HCFA Form 2567 cited deficiency, was in substantial compliance with the applicable standard.

c. Patient 7

At the time LACDHS conducted its follow-up survey, Patient 7 was a 53-year-old female. The Agency began to provide home health care services to Patient 7 on December 6, 1995. There are two certification periods in issue with respect to Patient 7. The first certification period is from December 6, 1996 to February 6, 1997; the second certification period is from February 6, 1997 to April 6, 1997. The principal diagnosis for Patient 7, as set forth in the plan of care for the first of the certification periods at issue, was stage IV wound of the left breast. HCFA Ex. 11 at 1. The other pertinent diagnosis for this patient was cancer of the left breast, which she apparently developed in November 1992. Id. In the first plan of care, the physician ordered skilled nursing care for Patient 7 twice a week. In the second plan of care, the frequency of skilled nursing care for Patient 7 increased to three times a week. For each plan of care, the goals for Patient 7 were to minimize the wound infection and to teach the patient wound care and ways to minimize infection. HCFA Ex. 11 at 1-9.

In a 60-day summary report dated December 3, 1996, the registered nurse wrote that Patient 7 "is very anxious & nervous about possible active bleeding. Pt [patient] refused to change dressing by herself." HCFA Ex. 11 at 20. A case conference note on the same date stated that the "pt [patient] refused to change her dressing daily due to possible active bleeding." HCFA Ex. 11 at 21.

Ms. Bruce testified that she concluded the care for this patient was deficient, because the summary report and case conference notes reflected a change in the patient's nursing needs with respect to the patient being willing to be taught to change her wound dressings. In Ms. Bruce's view, it was apparent throughout the two certification periods that Patient 7 had refused to change her dressings and was unwilling to do so. See HCFA Ex. 1 at 11-12. That the second plan of care dated February 6, 1997, failed to address the patient's unwillingness to treat her wound,

led Ms. Bruce to cite this circumstance as a deficiency in the HCFA Form 2567. Tr. 112-13.[15]

HCFA contends that Patient 7's refusal to perform her own wound care, coupled with Petitioner's failure to change the patient's plan of care from one certification period to the next, were particularly significant due to: (1) the wound being infected and the patient's failure or refusal to do the daily dressing changes as expected; (2) lack of nursing care to change the dressings on a daily basis (or twice-weekly basis as indicated in the first plan of care) because the nursing staff had missed numerous visits or only saw the patient on an irregular basis; and (3) the likelihood that her wound dressings were not changed between skilled nursing visits, a situation that became exacerbated due to the Agency's inability or failure to provide the patient with skilled nursing care visits on a frequently scheduled basis as ordered. HCFA PHBr. at 23-24. Thus, based on Petitioner's failure to reassess Patient 7's skilled nursing needs, particularly her fears regarding wound care, HCFA concludes that the patient's health (mental and emotional well-being) or safety was adversely affected. Id. at 24-25.

Initially, Petitioner attacks HCFA's contentions by arguing that the alleged deficiency is beyond the scope of the survey because the 60-day summary and the case conference notes were dated December 3, 1996. As support for its position, Petitioner cites to the testimony of Mr. Wayne Moon, HCFA's Director, Hospital and Community Care Operations, Division of Health Standards and Quality. Mr. Moon testified that the follow-up survey of Petitioner ending February 21, 1997 was to address deficiencies which occurred after December 26, 1996, the date the initial recertification survey was completed. P. PHBr., Summary GTAG 172 at 8.[16] Second, Petitioner argues that its skilled nursing staff

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[15] Fully assessing this deficiency is difficult because the record does not include the plan of care for the certification period prior to December 6, 1996. I am, therefore, unable to determine whether the 60-day summary and case conference notes of December 3, 1996 indicate a change in circumstances. What is clear is that a physician order on the same date, regarding the certification period starting December 6, 1996 and ending February 6, 1997, did indicate that the skilled nurses should encourage the patient to change her dressings. HCFA Ex. 11 at 17. For some reason, that specific order was not contained in the plan of care for that period. See HCFA Ex. 11 at 1-2.

The information contained in "Summary GTAG 172" is part of an attachment to Petitioner's posthearing brief.

changed the dressings despite Patient 7's refusal to do it herself. Id. Third, Petitioner contends that despite the physician's order to encourage the patient to change her dressings, the plan of care had the registered nurses doing the change of dressings and did not reference the need to encourage the patient. Petitioner's alleged rationale for such a treatment plan was to relieve the patient's fear as the size of the wound decreased and thereby facilitate the transition of the patient to self-management. P. PHRep. at 4.

In evaluating this deficiency, that is, whether the skilled nursing needs of Patient 7 had to be reevaluated, I will look at the care Patient 7 received subsequent to December 26, 1996. But, in determining the appropriate level of skilled nursing services, the patient's refusal to engage in her own wound care prior to December 26, 1996 is material as to whether Petitioner should have reevaluated her nursing needs subsequent to that date. Therefore, Petitioner's argument that the deficiency is beyond the scope of the second survey is without merit.

Under the first plan of care, the registered nurses were to "perform and instruct wound care" on a twice-weekly basis, with the goal that Patient 7 would "demonstrate compliance with the wound care regimen" and "demonstrate wound care as instructed" by nine weeks. HCFA Ex. 11 at 1. At the time of the second plan of care, the frequency of skilled nursing visits was increased to three times per week, with the goal that the patient would implement measures to minimize wound infection in two to four weeks.[17] HCFA Ex. 11 at 7-8. The patient's rehabilitation potential to demonstrate the prescribed wound care management was noted to be only "fair." Id. at 8. From reading the nursing notes of record (January 13, 1997 to February 12, 1997), Patient 7 had a large wound in her left breast which apparently was difficult to treat and had increased in size. The patient also suffered significant pain associated with the wound, with severe yellow or bloody drainage and foul odor. HCFA Ex. 11 at 22-28, 31-33.

The essence of HCFA's cited deficiency is that Petitioner did not alter Patient 7's skilled nursing care after she expressed unwillingness to treat the left breast wound herself. HCFA's counsel contends that other measures should have been considered such as training an alternate caregiver, having the patient

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[17] The increase of skilled nursing visits to three times a week for skilled care was ordered by the physician on January 20, 1997, prior to the second certification period. HCFA Ex. 11 at 16.

evaluated by a social worker or other health professional to deal with her fears, or "perhaps even scheduling more frequent nursing visits." HCFA PHBr. at 24.

I find HCFA's arguments regarding the need to reevaluate skilled nursing of this patient to be unpersuasive. First, contrary to HCFA's assertions, the skilled nursing frequency was increased from two to three times per week prior to the second plan of care, that is, during the week commencing January 26, 1997. While no specific reason is stated in the treating records for this change, it is quite possible that the severity of the patient's wound, despite treatment, coupled with the patient's reluctance to treat herself, led to an increase in skilled nursing. For HCFA to suggest that alternate caregivers or psychological or psychiatric intervention would have resulted in greater wound care is pure speculation.

Considering the nature of the wound and associated pain, I agree with Petitioner's counsel that an increase in the frequency of skilled nursing visits would hopefully result in enough improvement in the condition of the wound that the patient could treat it properly. At the time Petitioner implemented the second plan of care, her potential to do so was deemed only "fair." I agree with HCFA that missed skilled nursing visits likely would further compromise the care of this severe breast wound and make recovery more difficult. During week seven of the first certification period, Petitioner apparently did not provide a skilled nursing visit, but the impact on patient care from one missed visit is unclear.[18] HCFA Ex. 20 at 4. My review of the nursing notes after February 6, 1997, the beginning of the certification period for the second plan of care, does not reveal any missed skilled nursing visits. HCFA offered no proof as to what impact such missed visit(s) had on the wound, and consequently, I am unable to make any specific findings related to the impact on Patient 7 from such missed visit(s).

Having determined that Petitioner's registered nurses did not fail to reevaluate the skilled nursing needs of this patient based on her unwillingness to treat her stage IV decubitus left breast wound herself, there are no adverse health or safety issues to consider. The evidence of adverse consequences offered by HCFA cannot be supported by the record and is pure speculation and based on an erroneous assumption that the care was deficient.

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[18] Ms. Bruce noted a missed visit during week five, the week commencing January 19, 1997, as well. Two visits were noted that week. I am unable to determine whether the change in frequency of visits from two to three times per week was to commence with week five or week six. See HCFA Ex. 20 at 4; HCFA Ex. 11 at 1, 16.

Based on review of the record pertaining to Patient 7, HCFA has failed to establish a prima facie case that Petitioner's actions regarding this patient violated the cited standard. In the alternative, I find that Petitioner has presented persuasive evidence that the care of Patient 7, contrary to the deficiency cited in HCFA Form 2567, was in substantial compliance with the applicable standard.

2. G Tag 176: HCFA has provided credible evidence in its prima facie case and Petitioner has failed to provide evidence that it is in substantial compliance with the requirement that its registered nurses prepare progress notes, coordinate services, and inform the physician and other personnel of changes in the patients' conditions and needs with respect to Patients 2, 3, 5, and 7, four patients of seven patients sampled.

a. Patient 2

At the time LACDHS conducted its follow-up survey, Patient 2 was an 85-year-old man whose certification period was from January 15, 1997 to March 15, 1997. Patient 2's plan of care noted the principal diagnosis as hypertension. Other pertinent diagnoses were angina pectoris and osteoarthritis. HCFA Ex. 6 at 1. The skilled nursing orders included an assessment of the "amount, frequency, sites of chest pain and report to MD as indicated" and a requirement that the physician be notified "of any significant clinical finding." Id. at 1-2. Moreover, Petitioner had a policy establishing criteria for physician notification which included "any adverse changes in the patient's condition" such as an "increase in severity of the patient's illness." HCFA Ex. 13 at 1.

The HCFA Form 2567 contains the State surveyor's findings that despite "nurses notes dated 01/20/97, and 01/29/97, [which] revealed the patient was complaining of chest pain . . . [t]here was no documented evidence to indicate the registered nurse had informed the physician of the patient's chest pain." HCFA Ex. 1 at 12.[19]

In reviewing the record, the "Nurse Progress Note" for January 29, 1997 indicates that Patient 2 suffered left chest pain at an

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[19] HCFA counsel has acknowledged that the reference to chest pain in the January 20, 1997 progress note in the HCFA Form 2567 was in error. HCFA PHBr. at 28; Tr. 182-83.

intensity level of 2 on a scale of 1-5, with the number 5 representing the most severe pain. HCFA Ex. 6 at 24. The note also indicated that Patient 2's chest pain was controlled with medication (NTG, 0.4 mg SL, as needed). Id. In addition to administering the medication, the registered nurse instructed the patient to "get plenty of rest and avoid physical and emotional stress . . . Educated on S/S [signs and symptoms] of angina pectoris such as tightness in chest, squeezing, aching pain radiating to neck, shoulder, [left] arm, indigestion, dizziness, sweating and weakness." Id. Finally, the notes also indicate that the chest pain was relieved in 20 minutes. Id. None of the additional signs and symptoms of angina pectoris, with the exception of chest pain, described by the registered nurse are set forth as clinical findings in the "Nurse Progress Note." Id. The record is unclear as to the basis for administering NTG to Patient 2 for chest pain because the patient's physician had not prescribed such medication for him.[20] The patient's list of medications did not include NTG, nor did the list of medications noted in the plan of care include NTG.[21] HCFA Ex. 6 at 1, 34-35. HCFA contends that the presence of chest pain on January 29, 1997 is a significant clinical finding, in light of the patient's past history of angina pectoris, and should have been reported to the patient's physician. HCFA PHBr. at 28. HCFA further argues that the presence of chest pain is one of the "significant clinical findings" that the registered nurses were ordered in the plan of care to report to the physician. Id.; HCFA Ex. 6 at 2. HCFA also relies on the testimony of Ms. Bruce, who pointed out that the patient's primary diagnosis was hypertension--not angina. HCFA PHBr. at 28. Ms. Bruce testified that the patient had a past history of angina, with no current symptoms of angina present at the start of care. Tr. 445-47. She referred to the plan of care, which required the nurse to assess the amount, frequency, and sites of chest pain and report such findings to the physician. Tr. 121; HCFA PHBr. at 28-29; HCFA Ex. 6 at 1, 28-29. Lastly, HCFA contends that the failure to notify the physician of the presence of chest pain adversely affected the

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However, while this issue might be a basis for a separate deficiency under the cited regulation, the findings contained in HCFA Form 2567 did not address it, and therefore, I am not considering it.

The record reflects a written notation of NTG on the plan of care, but it appears that such notation was placed on the document by Ms. Bruce. Tr. 192-93. Patient 2 might have taken medication that had been prescribed for Patient 3, who also had a diagnosis of angina pectoris and was married to and living with Patient 2. See HCFA Ex. 6 at 1; HCFA Ex. 7 at 1-2.

health and safety of the patient, given the "potential of the patient having a heart attack" or that the chest pain could be an indication of some other disease process. HCFA PHBr. at 29-30; Tr. 120.

In response, Petitioner argues that since the chest pain was controlled by the "prescribed" NTG, the physician need not be contacted and there was no resulting harm to the patient. P. PHBr. at 9. Petitioner further argues that the NTG "was inadvertently not listed" in the plan of care but it was prescribed by the patient's physician as Ms. Bruce determined in her home visit of this patient. Id. Lastly, Petitioner contends that the patient was prescribed Isordil (10 mg. 3 times per day), which proves he had "chronic angina symptoms." Petitioner asserts further that any "mild" chest pain is adequately addressed by the NTG, and although the patient visited his physician on January 10, 1997 and February 10, 1997, there was no change in his medication, thereby indicating that the physician felt the chest pain was being treated adequately. Id.

My analysis of the cited deficiency begins with the issue of whether a single report of chest pain on January 29, 1997 could be a basis for a deficiency under the cited regulation. No pattern of chest pain need be shown for the regulation to be violated. If the chest pain appears cardiac related and there is ongoing treatment for such pain, such an incident, even if it happens only once, should be reported to the physician to determine the appropriate response.

In this instance, a major factual issue is whether the patient's physician had prescribed the medication (NTG) that the registered nurse administered on January 29, 1997 to treat mild chest pain. If so, we could infer that the physician was aware of the existence of ongoing pain and prescribed medication to treat it. I raised this issue at the hearing and indicated then that the record contained nothing to support any contention that the patient's physician had prescribed this medication. Tr. 191-92, 194.

Petitioner's counsel continues to contend that the medication (NTG) was prescribed. P. PHRep. at 5. Petitioner also contends that Ms. Bruce observed such medication on her home visit. I have checked the home visit record for this patient and find that Ms. Bruce made one reference to the patient having been administered NTG. HCFA Ex. 15 at 7. The fact that Ms. Bruce observed the administration of NTG is insufficient, however, to support Petitioner's position that the physician had prescribed NTG for Patient 2. The plan of care for this patient noted angina pectoris as a pertinent diagnosis (December 1, 1996).

HCFA Ex. 6 at 1. Despite setting forth this diagnosis, the plan of care does not indicate that NTG was being prescribed to treat chest pain. Id. Indeed, the registered nurse's initial assessment of this patient, on January 15, 1997, noted only a history of angina. HCFA Ex. 6 at 28.

I note that the plan of care for Patient 2 does list the medication Isordil, 10 mgs, three times per day. HCFA Ex. 6 at 1, 33-35. This drug is described as an anti-anginal medication that relaxes and dilates coronary vessels. Id. at 33-34. While no specific expert testimony was offered regarding this drug, I must conclude that the physician prescribed this drug to control further angina symptoms rather than to treat a specific instance of angina. My conclusion is based on the record evidence, as reflected in the plan of care, that the patient was treated in the past for angina pectoris.

My review of the record leaves no doubt that the physician was concerned about the potential for active angina pectoris. In the plan of care, the registered nurse was ordered to assess any chest pain if it occurred and report the "amount, frequency, [and] sites" to the physician. HCFA Ex. 6 at 1. The potential for future chest pain was present even with the use of Isordil. Both the plan of care and Petitioner's own policy regarding physician notification indicated that its staff should report significant clinical findings, including an increase in the severity of the patient's illness. Id.; HCFA Ex. 13.

I find, based on the record, that the patient had no reported chest pain from the start of care on January 15, 1997 until January 29, 1997, nor was the physician aware of ongoing chest pain. The skilled nursing visit notes for January 29, 1997 reflect a new incidence of chest pain, albeit mild, with the provision of NTG by the registered nurse to control the pain. HCFA Ex. 6 at 20. Petitioner's treatment records for this patient do not indicate that anyone reported this information to the physician. Petitioner's counsel does not dispute this point. Rather, he argues that there was no need to make such notification. I disagree.

There is no evidence of ongoing angina, such as repeated instances of chest pain. Nor does the record show that the physician was aware of such pain, or had directed medical intervention to treat such pain. I conclude from the record that the physician was concerned about the possibility of future chest pain. He directed Petitioner's nurses to report any new incidence of such pain. Patient 2 suffered an incidence of chest pain but the physician was not notified.

While I am unable to determine the precise significance of the chest pain that Patient 2 encountered on January 29, 1997, it is more likely than not that the patient was not suffering a heart attack. Whether Patient 2 exhibited the signs and symptoms of a heart attack is not dispositive, however, of whether a violation of the regulation occurred. The regulation requires notification whenever there is a change in the patient's condition that might impact on the care of the patient.

In this instance, Patient 2 had a change in his condition. The change is significant because Patient 2 suffered chest pain and had a prior history of chest pain. I need not find that the reported chest pain was an indication of a heart attack. The physician is responsible for assessing the significance of the change. The registered nurse is responsible, under the cited regulation and, more specifically, under the plan of care, for notifying the physician of the circumstances of the change in the patient's clinical findings. Based on such notification, the physician then is in a position to decide whether the nursing needs of the patient should be altered, including a modification of the patient's treatment to specifically address the presence of chest pain.[22] Petitioner's failure to notify the physician of the changed circumstance deprived the physician of information that was germane to the treatment of the patient and potentially delayed implementation of changes in treatment necessary for the health of the patient.

Based on my review of the record pertaining to Patient 2, I find that HCFA has established a prima facie case that Petitioner's actions regarding this patient violate the cited standard. In the alternative, I find that Petitioner has not presented persuasive evidence that the care of Patient 2 was in substantial compliance with the applicable standard.

b. Patient 3

Detailed information about Patient 3, who suffered from chest pain, was set forth in the section of this decision relating to the first deficiency cited under G Tag 172. See HCFA Ex. 1 at 10. The standards contained in G Tag 172 and G Tag 176 have a similar nursing responsibility, that is, that a change in the

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Interventions a physician is likely to consider include: change the patient's medications to control angina; use of a medication, such as NTG, to ameliorate any chest pain that occurs; or, order cardiac diagnostic tests for the patient to determine whether there has been a deterioration in his cardiac status.

patient's condition triggers an obligation on the skilled nurses to reevaluate the nursing needs and bring such change to the attention of the patient's physician. The physician, in turn, is in a position to alter the plan of care, if necessary, in response to such change. My analysis under G Tag 172 is applicable here. I incorporate that analysis herein and find that this patient's complaints of chest pain are not clinically significant and do not trigger a need to contact the patient's physician.

HCFA also alleged that Petitioner had a policy to inform the physician when the patient had a weight gain of three or more pounds in one work week. HCFA Ex. 13. With regard to Patient 3, HCFA specifically alleged that she gained more than three pounds in one work week. On January 29, 1997, Patient 3 weighed 101 pounds; on February 5, 1997, she weighed 106 pounds (a gain of five pounds).[23] Lastly, it is alleged that there was no documentation that Petitioner's registered nurse informed Patient 3's physician of the weight gain. HCFA Ex. 1 at 13.

Petitioner does not dispute that Patient 3 gained five pounds. Instead, Petitioner directs its arguments to the definition of work week. P. PHBr. at 13. Petitioner's applicable policy states that physician notification will occur when there is a "[w]eight gain: 2 pounds or more in 24 hours, 3 pounds or more in a work week." HCFA Ex. 13. The term "work week" is not defined in the policy.

Ms. Bruce testified that Petitioner's work week was Sunday through Saturday. Tr. 216-17, 381. Based on that definition, she observed that since the weight gain occurred from Wednesday, January 29, 1997 through Wednesday, February 5, 1997 (which period constituted a work week), the five-pound gain should have been reported. Tr. 382-83. She further testified that she discussed her conclusions with a member of Petitioner's staff who

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[23] I have reviewed all the "Nurse Progress Notes" for this patient for the period January 15, 1997 through February 7, 1997. The patient's weight was not recorded on each skilled nursing visit. For example, no weight is recorded on January 24, 1997, February 1, 1997, and February 7, 1997. Patient 3's weight ranged from 110 pounds on January 15, 1997 to 106 pounds on February 5, 1997. Her weight dropped from 110 pounds on January 15, 1997 to 105 pounds on January 27, 1997 and then to 101 pounds on January 29, 1997. Petitioner's policy did not require physician notification for weight loss. Assessing weight gain over a three-week period is difficult, given the variations in the weight of Patient 3.

did not contradict such interpretation. Tr. 383-84. HCFA's counsel points out that Ms. Bruce discussed this finding at the exit conference and, neither Mr. Rey G. Santos, Petitioner's counsel and administrator, or Mr. Nemy Marcelo, Petitioner's assistant administrator, objected to the finding. HCFA maintains that the lack of objection from Petitioner's staff established the validity of Ms. Bruce's interpretation of work week. HCFA PHBr. at 33.[24] Absent any contrary interpretation of the work week policy, HCFA contends that Ms. Bruce's interpretation must be accorded deference. Id.; see 42 C.F.R. § 488.26.

Petitioner contends, with regard to the exit conference, that contrary to Ms. Bruce's assertions regarding her findings and interpretations of the work week, Ms. Bruce informed Petitioner that there were no deficiencies pertaining to skilled nursing. P. PHRep., Attachment A at 10-11. Petitioner did not indicate, in its posthearing reply brief why it offered no evidence supporting a different interpretation of work week at the hearing.

I find that HCFA's position on the proper interpretation of "work week" is reasonable absent clear evidence to the contrary. Petitioner was providing services to its patients seven days a week; therefore, a reasonable conclusion is that a work week for this Agency was similar to a calendar week.

The larger issue is how to interpret Petitioner's policy on weight gain when the gain occurs midweek. I find that work week must be interpreted in a way that is consistent with the intent of Petitioner's policy. Under that policy, a weight gain of three or more pounds is significant. If the stated weight gain occurs in any seven-day period, irrespective of when it occurs in the work week, the physician should be notified. The physician should decide the relative significance of the weight gain, based on the patient's underlying condition(s) and other clinical findings.

HCFA has presented a prima facie case that Petitioner's policy for reporting a weight gain has not been met in this case. Petitioner made no such report. Petitioner has not presented any credible evidence to rebut HCFA's case or to show by the

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[24] HCFA also points out the Petitioner had the opportunity to present testimony from one of its personnel of a different interpretation of work week but offered no such testimony. HCFA PHBr. at 33.

preponderance of evidence that it is in compliance with the cited nursing standard. As the five-pound weight gain, based on Petitioner's own policy, was considered a basis to trigger physician notification, I must conclude that the failure to notify the physician under such circumstances has the potential to adversely affect the health of the patient.

c. Patient 5

Detailed information about Patient 5, who was diagnosed with IDDM, was set forth in the section of this decision relating to the first deficiency cited under G Tag 172. See HCFA Ex. 1 at 10-11. The standards contained in G Tag 172 and G Tag 176 relate to a similar nursing responsibility, that is, that a change in the patient's condition triggers an obligation on the skilled nurses to reevaluate the nursing needs and bring such change to the attention of the patient's physician. The physician, in turn, is in a position to alter the plan of care, if necessary, in response to such change. My analysis under G Tag 172 is applicable here. I incorporate that analysis herein and find that this patient's fluctuating blood glucose levels were clinically significant and triggered a need for Petitioner's staff to contact the patient's physician.

With respect to this standard, the State surveyor cited Petitioner for a deficiency, in the HCFA Form 2567, due to lack of "documented evidence that the registered nurse had informed the physician of the patient's blood glucose levels." HCFA Ex. 1 at 13. In support of its allegation related to lack of physician notification, HCFA referred to the plan of care for Patient 5, in which the registered nurses were required to observe "patient's response to treatment and medications," assess blood sugar results, and to notify the physician of "any significant clinical findings." HCFA PHBr. at 34; HCFA Ex. 9 at 1-2. Ms. Bruce testified that the patient's blood glucose levels should have been reported to the physician as a significant finding, particularly in view of his fluctuating and often elevated glucose levels. Tr. 131, 393; HCFA PHBr. at 36. In Ms. Bruce's view, the elevated glucose levels were due either to the medication failing to work or the patient failing to adhere to his diet. Tr. 230; HCFA PHBr. at 36. Accordingly, the physician should have been notified, so that he could assess the need to revise the patient's plan of care, especially with regard to medication. Tr. 393; HCFA PHRep. at 36.

An important issue for me is whether I can conclude from the record that the physician was aware of the unstable blood sugar, wanted monitoring by the skilled nurses, and wanted them to report any complications from that situation. Unfortunately, I

cannot determine what the physician's intent was from the record.

The plan of care for Patient 5 did not instruct skilled nurses to do either a fasting blood sugar (fbs) or random blood sugar (rbs) test. The plan of care stated that the skilled nurses should assess "BS results" and signs and symptoms of "hypoglycemia/hyperglycemia." HCFA Ex. 9 at 1. The plan of care also contained the standard requirement of reporting significant clinical findings to the physician. But the S.O.C. [start of care] work sheet does indicate, as skilled nursing orders, that "all body systems, espec. diabetic status, FBS √ [check] & RBS √ [check]" should be assessed. HCFA Ex. 9 at 14. The skilled nursing orders contained in the S.O.C. conform to skilled nursing orders contained in the physician order dated January 10, 1997 for that certification period. HCFA Ex. 9 at 30. The S.O.C. further indicated that this patient had an increased blood sugar level and he was "non-compliant with diabetic regimen." HCFA Ex. 9 at 14.

But, none of the records reflecting the physician's orders indicate the amount, timing, and frequency of fbs or rbs or provide any guidance as to parameters on acceptable range of blood sugars for Patient 5. In the case conference report for Patient 5 dated February 10, 1997, a wide range of blood sugars was recorded and the blood sugar was noted as unstable. HCFA Ex. 9 at 13.

The records for skilled nursing visits during the period in issue are confusing. The progress notes contain a place to indicate after the glucose reading whether the reading was random or fasting but that space on the form is usually not completed. There are references contained in the progress notes to "fbs" on both morning and afternoon visits. Yet, it is highly unlikely that the patient would be instructed to fast until 4:00 P.M. to 5:00 P.M. in the afternoon for a fbs, particularly where his nutritional status was a concern. What "fbs" meant, therefore, becomes an issue--that is, whether "fbs" meant fasting or finger blood sugar readings. What is clear is that the registered nurses checked at each visit to see that the patient had no apparent complications for his elevated blood sugars. HCFA Ex. 9 at 33-49, 51-113.[25] Petitioner does not dispute that the patient's blood sugar was elevated and ranged from 112 to 378 as HCFA alleged in HCFA Form 2567. HCFA Ex. 1 at 13. Ms. Ausman

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See n.9, supra. As indicated therein, I will not consider the exhibits, offered by the parties as attachments to their briefs, relating to diabetes.

testified that normal blood sugar readings range from 80 to 100 on laboratory based blood sugars after fasting. Tr. 298.

The record does not indicate that the nurses notified the physician of the wide range of blood sugar readings. As is evident from many of the readings, the patient's blood sugar was demonstrated to be excessively high. Contacting the physician in such circumstances would seem warranted to determine whether the doctor wanted to alter the treatment to better control the blood sugar. Complications could arise from out of control blood sugar, but the nurses monitored the patient's blood sugar levels and no actual harm resulted. I do note that the patient was scheduled to visit the physician only once during this certification period. I agree with HCFA that the plan of care placed responsibility on the registered nurses to monitor and assess the patient's blood sugar results. The nurses had an even greater responsibility to notify the physician of their assessment in these circumstances, given that the blood sugar was still not under adequate control.

With regard to Patient 5, the Petitioner had the ability to establish for the record what the physician knew about the unstable blood sugar. He could have offered into evidence an affidavit to clarify the knowledge of the physician as to the blood sugar instability and whether additional contact was needed. Also, he could have offered a 60-day summary report for this patient, which should have contained information about the unstable blood sugar readings and which the surveyor tells me would be provided to the physician by the Agency. See, e.g., HCFA Ex. 11 at 20. Absent such evidence from Petitioner, I must conclude that the physician was not fully aware of the range of readings and should have been notified. Moreover, I conclude that such failure had the potential to adversely impact the health of the patient.

Based on review of the record pertaining to Patient 5, HCFA has established a prima facie case that Petitioner's actions regarding this patient violate the cited standard. In the alternative, I find that Petitioner has not presented persuasive evidence that the care of Patient 5 was in substantial compliance with the applicable standard.

d. Patient 7

Detailed information about Patient 7, a 53-year-old female, was set forth in the section of this decision relating to the first deficiency cited under G Tag 172. The diagnoses for Patient 7 were Stage IV wound of the left breast and cancer of the left breast. HCFA Ex. 11 at 1.

In examining the standard for the registered nurse contained at G Tag 172 with respect to Patient 7, I focused on the obligations of the nurse to regularly reevaluate the patient's nursing needs. Under the standard for the duties of the registered nurse contained in G Tag 176, the nurse also was responsible for preparing clinical notes and progress notes for this patient. HCFA alleges that Petitioner failed to meet one of the requirements for G Tag 176 with respect to Patient 7 because the registered nurse did not prepare progress notes for her, as evidenced by the absence of documentation in the clinical record. HCFA Ex. 1 at 13-14; HCFA PHBr. at 39. Ms. Bruce, in citing this deficiency, also alleged that her finding had been substantiated by an interview with the administrative staff of the Agency. HCFA Ex. 1 at 13-14.

The definition of "progress note" in the regulations is somewhat vague--"a written notation, signed and dated by a member of the health team, that summarizes facts about care furnished and the patient's response during a given period of time." 42 C.F.R. § 484.2. In examining the alleged deficiency, a question arises as to what types of reports HHAs are required to maintain with regard to its patients. The key issue is whether Petitioner's failure to maintain progress notes for Patient 7, if true, constitutes a deficiency so serious that the absence of such documentation affected the Agency's capacity to furnish adequate care to Patient 7 or adversely affected her health and safety.

In testimony related to this deficiency, Ms. Bruce stated that she found that Petitioner had no progress notes for Patient 7. Tr. 134; HCFA PHBr. at 39-40. Ms. Bruce found the absence of these notes significant because Petitioner had indicated in its plan of correction that it would prepare written progress notes for all patients. Tr. 134. Ms. Bruce testified that she expected to see progress notes for Patient 7 in particular, because the patient had received services from Petitioner for more than one year (that is, since December 6, 1995), and Petitioner had stated, in its plan of correction, that the deficiency would be corrected by January 27, 1997. Id.

Generally, HHAs are responsible for preparing three types of patient reports. As noted above, the registered nurse is responsible for preparing clinical and progress notes with respect to a patient. See 42 C.F.R. § 484.30(a). The HHA is responsible for preparing summary reports, which compile relevant information from a patient's clinical notes and progress notes and are submitted to that patient's physician approximately every 60 days. See 42 C.F.R. § 484.14(g).

The terms "clinical note," "progress note," and "summary report" are defined by regulation at 42 C.F.R. § 484.2. A "clinical note" is defined as a "notation of a contact with a patient that is written and dated by a member of the health team, and that describes signs and symptoms, treatment and drugs administered and the patient's reaction, and any changes in physical or emotional condition." A "progress note" is defined as "a written notation, signed and dated by a member of the health team, that summarizes facts about care furnished and the patient's response during a given period of time." A "summary report" is defined as "the compilation of the pertinent factors of a patient's clinical notes and progress notes that is submitted to the patient's physician."

The "Nurse Progress Note" is an example of the type of record Petitioner maintained with respect to Patient 7. The "Nurse Progress Notes" for Patient 7 showed 10 skilled nursing visits covering the period January 13, 1997 through February 10, 1997. An example of the information contained in these "Notes" for Patient 7 is a skilled nursing visit to Patient 7 on January 16, 1997. During that visit, the registered nurse noted vital signs and symptoms, such as, blood pressure and pulse, existence of pain and its intensity, drugs administered (on this visit, morphine), and care provided for the patient's wound. HCFA Ex. 11 at 23. Other "Nurse Progress Notes" included in the record for Patient 7 contain similar information. HCFA Ex. 11 at 22-28, 30-33. The nurses prepared all of these "Nurse Progress Notes" on the same date as their visits to Patient 7.

Other documents in the record pertaining to Patient 7 include a 60-day summary report, dated December 3, 1996. The 60-day summary report also noted that the patient's "wound size . . . gradually getting smaller." HCFA Ex. 11 at 20. The report also contained statements that the patient "is very anxious & nervous about possible active bleeding . . . . Pt [patient] refused to change dressing by herself." Id. A case conference note of the same date reflected the same failure of the patient to change her own dressings due to fear of active bleeding. HCFA Ex. 11 at 21.

According to Ms. Bruce, a clinical note is "a note that the nurse prepare (sic) on the date they provide services." Tr. 136. A progress note, by contrast, "summarized facts about the care furnished during a given period of time." Id. In Ms. Bruce's opinion, the registered nurses' "Nurse Progress Notes" did not meet the regulatory definition for "progress note," but rather, were "clinical notes" prepared on the date they provided skilled nursing services. HCFA Ex. 11 at 23; Tr. at 136-37.

Ms. Bruce also testified that the agency chooses the period to be covered by the summary and differentiated this note from the other notes the agency prepares. See Tr. 134-40. In the plan of correction that Petitioner submitted in response to the December survey, it indicated [in response to G Tag 176] "Progress note form was re-instituted to summarize facts about care furnished and patient response during the period of 60 days." P. Ex. 7 at 4. Petitioner argues that the actions in the Plan of Correction were to be effective as of January 26, 1997, which is based on the testimony of Mr. Moon from HCFA. P. PHBr., Summary GTAG 176 at 16.[26] He further stated that "our plan of correction indicate [sic] that a progress note will be prepared every 30 days starting January 27, 1997 (emphasis added)." Id. This interpretation by Petitioner is invalid.

The letter from LACDHS indicates that Petitioner had to be in compliance within 30 days of the exit conference for the December 1996 survey. The exit conference occurred on December 26, 1996. The State agency and HCFA construe compliance, as contemplated in the plan of correction, will be achieved at the end of the 30-day period from the exit conference, not that compliance will begin at that date. See Tr. 42, 50, 134; HCFA PHRep. at 29-31. Thus, Petitioner was obligated by his plan of correction to be in full compliance, including having created monthly progress notes for each patient by January 26, 1997. P. Ex. 6.

The "Nurse Progress Notes" for Patient 7 contained in the record do not satisfy this requirement. Ms. Bruce's testimony on the distinction between clinical note and progress note is credible. Tr. 134-40. When reviewing the contents of the "Nurse Progress Notes" in the record, the documents more closely fit the definition of "clinical notes" rather than "progress notes." Registered nurses prepared "Nurse Progress Notes" contemporaneously with their visits to Patient 7 and recorded information such as her vitals signs, symptoms, and medications administered. Therefore, the record contains no progress notes for Patient 7 which would evidence compliance with the plan of correction by January 26, 1997.

By contrast, the record does contain at least one "progress note" for Patient 5. HCFA Ex. 9 at 44. That document is styled "Progress Notes." Just below the heading is a parenthetical phrase which reads: "[d]ue at month end and at least every thirty days." Id. The "Progress Notes" also contain space to provide a "[s]ummary of facts about care furnished" and "[p]atient

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[26] The information contained in Petitioner's "Summary GTAG 176" is part of an attachment to Petitioner's posthearing brief.

response." Id. Thus, I can reasonably infer that, based upon the existence in the record of a progress report for Patient 5, dated January 31, 1997, Petitioner recognized the requirement to prepare three types of reports--that is, clinical notes, progress notes and summary reports and Petitioner also understood that these documents or reports were distinguishable in some way.

Ms. Bruce testified that there were no monthly progress notes generated for this patient as of January 26, 1997 and Petitioner does not contradict this. As noted above, the record indicates that at least one such report was generated but the date of that report also supports HCFA's allegation that Petitioner failed to demonstrate compliance with the plan of correction by January 27, 1997. When viewed, however, in light of the numerous other reports generated on Patient 7, such as, 60-day reports, case conference notes, and clinical notes, I conclude that the impact on patient care appears to be minimal. HCFA has made no showing of harm or even potential harm in light of the existence of the other reports of record.

A second issue relating to Patient 7 pertains to a weight loss of 16 pounds[27] between January 13, 1997 and February 7, 1997 (approximately a one-month period) and the failure of Petitioner's registered nurses to notify the physician of the change in her condition. See HCFA Ex. 1 at 14. HCFA's counsel acknowledges the various calls by the nurses to Patient 7's physician during the January 13, 1997 to February 7, 1997 period but emphasizes the lack of a specific reference in such communications to the patient's weight loss. HCFA PHBr. at 41-42.

The record contains significant information about Patient 7's weight, nutritional status, and overall condition during this period. The plans of care for this patient contained skilled nursing orders to "[a]ssess appetite," and "[a]ssess adequacy or diet." HCFA Ex. 11 at 1, 7. The skilled nursing care plan included an instruction to observe "weight change." Id. at 9. The record also contains a physician's order, dated December 3, 1996 (signed on December 24, 1996), for the period December 6, 1996 to February 6, 1997, noting Patient 7's weight as 98 pounds and indicating the patient's diet should include "Ensure" (a dietary supplement). Id. at 17. The physician also ordered that the patient's nutritional status, among other things, be assessed by the registered nurses. Id. Additionally, on December 3,

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[27] The HCFA Form 2567 erroneously refers to this weight loss as being 18 pounds. HCFA Ex. 1 at 14.

1996, the registered nurse instructed the patient on the need for "balanced & enough caloric diet (sic) . . . ." Id. at 18-19.

As for the weight loss during the period at issue, the "Nurse Progress Note" dated January 13, 1997 indicated Patient 7's weight as 104 pounds. HCFA Ex. 11 at 22. On the same date, Patient 7 also reported nausea and vomiting (probably attributable to the effects of taking morphine) and no bowel movements for three days. Id. Due to the apparent severity of her complaints, the registered nurse called the patient's physician regarding her increased pain, lack of bowel movements, and vomiting. Id. On January 16, 1997, the registered nurse recorded Patient 7's weight as 102 pounds. The "Nurse Progress Note" for that date also indicated the patient was suffering from nausea, was anorexic, and had experienced no bowel movements for six days. Id. at 23. The nurse instructed Patient 7 to take her medicine with food to avoid gastrointestinal upset. Id. at 23. On January 22, 1997, Patient 7's weight was 98 pounds. The nurse again noted that the patient's oral intake was poor and that she was experiencing nausea and vomiting. The nurse administered fluids through an intravenous (I.V.) tube and noted that an I.V. should be administered again on the next visit for hydration. Id. at 24. Patient 7's weight was recorded as 99 pounds on January 24, 1997 and her food intake again was noted to be poor. Id. at 25. On January 27, 1997, her weight was unrecorded and nutritional intake was rated as fair, as opposed to the repeated findings from earlier visits of poor nutritional intake. Id. at 26. On January 29, 1997, the patient's weight is recorded as 100 pounds and her nutritional intake has deteriorated from fair to poor. The patient reported that her vomiting and nausea had increased and the nurse noted decreased body weight and dry skin. On this occasion, the nurse called the patient's physician and the case manager about Patient 7's severe pain, nausea, and vomiting. Id. at 27. The record contains no weight for Patient 7 on January 31, 1997 but did reflect that she suffered from nausea and vomiting. Again, as on January 29, 1997, the nurse called the physician about the patient's refusal of I.V. fluid. The physician did not issue an order that the patient be given I.V. fluid. Id. at 28.

The next visit date is February 7, 1997 where Patient 7's weight was recorded as 88 pounds; and, again, poor nutritional intake was noted. Id. at 31. The record listed her weight to be 88 pounds on February 10, 1997, in addition to noting nausea and vomiting, no bowel movements for nine days, and the patient's refusal to use a fleet enema. The record contains a reference to a telephone call to the patient's physician about the absence of bowel movements and the physician ordered a fleet enema if the

patient could tolerate it. Id. at 32. On February 12, 1997, Patient 7's weight was noted to be 86 pounds. Id. at 33.

Based upon review of the record, there is no doubt that the Patient 7's nutritional status was severely compromised. She was taking morphine by I.V., which caused her to suffer extensive nausea and vomiting. At times, her bowel movements were excessively delayed, which was another indication of nutritional compromise. Her weight during the period fluctuated; nevertheless, she lost 16 pounds between January 13, 1997 and February 7, 1997. My concern is whether Patient 7's physician, when notified three times during this period by the registered nurse about factors affecting Patient 7's nutritional status, such as nausea, vomiting, bowel movements, and lack of I.V. fluid intake should also have been informed specifically about Patient 7's weight fluctuation and loss. The record showed that the physician was aware of his patient's weight of 98 pounds on December 3, 1996.

While it is a close question, since the physician was notified three times concerning issues regarding nutrition, I must conclude that Patient 7's weight loss of 16 pounds is significant as a separate clinical finding and should have been independently reported to the physician. The physician was not advised of a key point that might have affected his treatment of the patient. The question of harm may be minimal, since he received other calls during which he was provided with information that strongly suggested nutritional compromise and a loss of weight would be an expected consequence. But the physician should have been apprised of the patient's weight loss, so he could consider that information, along with the other information he received, in order to decide what action to take.

Moreover, even Petitioner's expert witness, Ms. Ausman, recognized that the physician should have been called in view of the circumstances of this case. See HCFA PHBr. at 43-44; Tr. 270-71. Petitioner's counsel points to the physician order for multivitamins by I.V. for dehydration dated January 21, 1997 as an indication that the physician was aware of Patient 7's nutritional status, and, by implication, the loss of weight. See P. PHBr., Summary GTAG 176 at 17;[28] HCFA Ex. 11 at 15. I cannot tell from the record what generated this order. A second telephone order related to the administration of an I.V. for hydration, dated February 7, 1997, is most likely based on the registered nurse visit of January 31, 1997, when Patient 7 refused her I.V. fluid. See HCFA Ex. 11 at 28. In sum,

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See n.27, supra.

Petitioner wants me to infer, or take constructive notice, from the physician's I.V. order and the registered nurses' communications in the record, that the physician is aware of the weight loss. See P. PHRep., Attachment A at 14. I cannot agree.

Petitioner has an obligation, based on the appropriate regulations and case law, to show that it is in substantial compliance with the standard. To make such a showing requires more than a presumption of what the physician knew. Petitioner had the opportunity to have the matter clarified by having the physician submit an affidavit or testify as to his knowledge. Petitioner offered no such evidence of this type. Lastly, I conclude that Petitioner's failure to notify Patient 7's physician about her 16-pound weight loss could impose a potential for a negative impact on the patient's care. Certainly, the physician was deprived of vital information he could have used in determining the correct course of treatment for Patient 7.

Accordingly, based on my review of the record pertaining to Patient 7, I conclude that HCFA has established a prima facie case that Petitioner's actions regarding this patient violate the cited standard. In the alternative, I find that Petitioner has not presented persuasive evidence that the care of Patient 7 was in substantial compliance with the applicable standard.

3. G Tag 177: HCFA has failed to present credible evidence in its prima facie case, or, in the alternative, Petitioner has shown by the preponderance of the evidence that its registered nurses counseled Patients 2, 3, and 5 and their families in meeting nursing and related needs. HCFA did present credible evidence in its prima facie case and Petitioner has failed to present by the preponderance of the evidence that the registered nurses adequately counseled Patient 4 in meeting nursing and related needs. Petitioner failed to meet the requirements of this standard for one patient out of the seven patients surveyed.

a. Patient 2

Detailed information about Patient 2, who suffered from hypertension, angina pectoris, and osteoarthritis, was set forth in the section of this decision relating to the second deficiency cited under G Tag 176. The plan of care for this patient contained orders for the registered nurses, among other things, to assess pain management and control, teach the patient activity restrictions/modifications, and teach pain management and energy conservation techniques. HCFA Ex. 6 at 1-2. As more

specifically indicated in the skilled nursing instructions, the nurse was to instruct Patient 7 in two areas: non-invasive pain management techniques, including: distraction and heat; and, comfort measures, including: skin care, massage, positioning, and medication administration. HCFA Ex. 6 at 7.

Under the relevant regulation, the registered nurses are required to counsel the patient and family in meeting nursing and related needs. See 42 C.F.R. § 484.30(a). To determine whether Petitioner complied with this regulatory standard, an analysis of the wording of the regulation must be undertaken. More specifically, I must determine what the term "nursing and related needs" means, for it is undefined in the regulation. What is clear in the regulations is that any care provided to the patient, including skilled nursing care, must follow a written plan of care established and reviewed by the patient's physician. Therefore, to determine the appropriate level of skilled nursing services, the physician's written order and the subsequent plan of care incorporating that order is the controlling document for purposes of determining the appropriateness of the care provided. 42 C.F.R. § 484.18.

In reviewing the deficiency cited in the HCFA Form 2567, it is apparent that the State surveyor, Ms. Bruce, merged the obligations placed on the registered nurses in the plan of care with the nursing instructions indicated in the Agency's nursing care plan. The deficiency is based upon the failure of Petitioner to instruct Patient 2 in "pain management, non-invasive pain management technique, including distraction, heat, massage, skin care and positioning." Exhibit 1 at 15. The pain management techniques cited are contained in the nursing care plan, whereas the only reference in the plan of care is to a general instruction on "pain management."

In elaborating upon her position as to Petitioner's obligations under this standard, Ms. Bruce indicated that it was her interpretation of the regulatory standard that Petitioner's registered nurses had to provide instruction on each and every item checked off in the nursing care plan relating to pain management, including comforting measures. Tr. 159-60. In further testimony, she implied that every item listed for pain management in the nursing care plan had to be covered on each skilled nursing visit with the patient. Id. Ms. Bruce later testified that if a patient reported a problem during a skilled nursing visit, she would give the agency credit for satisfying the regulation if she saw some documented indication of patient instruction on pain management during that visit. Tr. 170. When I questioned Ms. Bruce on her interpretation, she clarified her

interpretation so that any documentation of the instruction during the coverage period would satisfy the regulation. Id.

Even with this clarification, I do not agree with LACDHS' interpretation of this regulation. The contents of the nursing care plan are not controlling for the purpose of determining compliance by the HHA. Rather, the authorized treatment and services contained in the plan of care approved by the patient's physician are controlling for this purpose.[29] To determine whether there has been compliance, we look to what the physician authorized as relates to this patient, that is, with regard to instruction on pain management, and a review of the clinical notes, to ascertain what areas of pain the patient has identified to the registered nurse.

The HCFA Form 2567 identifies complaints for Patient 2 pertaining to "bilateral knee pain," "chest pain," and "lower back pain." HCFA Ex. 1 at 15. HCFA contends that no instruction was provided, even during times when the patient indicated pain in the presence of the registered nurse. Id. As support for its position, HCFA also cites to the testimony of Ms. Bruce. Tr. 146, 148-52. As to knee pain, Ms. Bruce cited the skilled nursing visit to Patient 2 on January 20, 1997 as being indicative of a lack of documentation on pain management techniques. Tr. 147; HCFA Ex. 6 at 24. Ms. Bruce also identified February 7, 1997 as a date when the patient complained of knee pain. Tr. 148. In response to a question from HCFA counsel as to whether instruction given the patient to "rest in bed due to risk of falls and taught signs and symptoms of osteoarthritis" was an example of instruction in pain management techniques, she replied that the nurse's instruction appeared to relate to the disease process, rather than pain management. Tr. 148-49.

In its brief, HCFA cited a portion of Ms. Bruce's testimony, in which she attempted to make a distinction between instruction in pain management and comfort and energy conservation. HCFA PHBr. at 49-50; Tr. 195-98. Specifically, HCFA states that Ms. Bruce testified that the January 20, 1997 instruction to Patient 2 to "rest joints and ambulate only when necessary to help [decrease] pain" did not constitute proper pain management instruction. HCFA PHBr. at 49-50; Tr. 195-96. HCFA also cited to Ms. Bruce's

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I note that the physician reviews and approves, in writing, the plan of care, whereas he does not review and approve the nursing care plan. The Agency prepares the nursing care plan independently as its means of implementing the physician's authorized treatment contained in the plan of care.

testimony that the February 7, 1997 instruction to the patient to "rest in bed due to risk of falls . . . [t]aught S/S of osteoarthritis including joint pain, motion limitation, joint tenderness, stiffness and fatigue, [decreased] exercise tolerance," as not constituting proper instruction in pain management. HCFA PHBr. at 49-50, citing to HCFA Ex. 6 at 17; Tr. 196. Finally, the HCFA brief refers to Ms. Bruce's example of the February 5, 1997 instruction to Patient 2 to "rest and ambulate only when necessary, to have frequently used items close by to avoid getting up . . . and to avoid situations that may produce feeling of anxiety," as not being indicative of proper instruction in pain management. HCFA PHBr. at 49-50, citing HCFA Ex. 6 at 18; Tr. 196-97.

Petitioner, in its briefs, offered examples of the complete instructions Patient 2 received on specific dates in support of its contention that Patient 2 received proper instruction on pain management. In one example, on January 29, 1997, the nurse instructed the patient "to get plenty of rest and avoid physical and emotional stress (emphasis added)." P. PHBr., GTAG 177 at 21;[30] HCFA Ex. 6 at 20. In another example, on February 5, 1997, Patient 2 received instructions "to rest and ambulate only when necessary, to have frequently used items close by to avoid getting up, to do activities seating (sic) if possible, and to avoid situations that may produce feeling of anxiety (emphasis added)." P. PHBr., GTAG 177 at 20-21; HCFA Ex. 6 at 18. Petitioner also cited to other skilled nursing visits for Patient 2, during which visits he received pain management instruction. See generally, P. PHRep., Schedule D.

In reviewing the record, I noted that the instructions Patient 2 received were based upon the type and severity of pain he reported to the registered nurse on a visit. For example, on January 20, 1997, Patient 2 reported pain in both knees at level 1 intensity. The nurse reported controlling his pain by rest and medication (Tylenol, 500 mg); the nurse also advised the patient "to rest joints and ambulate only when necessary to help ↓ [decrease] pain." HCFA Ex. 6 at 24. On January 29, 1997, Patient 2 reported chest pain at level 2 intensity. In this instance, the nurse controlled the pain by medication (NTG, 0.4 mg) and advised the patient to "get plenty of rest and avoid physical and emotional stress." Id. at 20. Similarly, during a visit to Patient 2 on February 5, 1997, the nurse indicated that the patient reported lower back pain at level 1 intensity (on a scale of 1-5, with 1 indicating lowest level of pain intensity).

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[30] The information contained in Petitioner's "GTAG 177" is part of an attachment to Petitioner's posthearing brief.

Id. at 18. Again, the patient's pain was treated by rest and medication and he was advised to limit his movements, to keep items he used frequently close to where he sat, and to avoid situations that might cause feelings of anxiety. Id. Finally, on February 7, 1997, the patient reported pain in both knees at level 1 (or the lowest level of pain) intensity. Id. at 17. The nurse indicated again that the patient's pain was controlled by rest and medication (Tylenol, 500 mg). Id. These instructions are, on their face, related to pain.

Ms. Ausman, who testified on behalf of Petitioner, stated that the purpose of pain management instruction is really to educate and instruct patients on how to care for themselves with the pain they have. Tr. 251. She further testified that such instruction should include the signs and symptoms of the underlying disease process or injury causing the pain. In essence, Ms. Ausman testified that patients should be provided with information that can be used to avoid situations that might bring on pain or increase existing pain. Id. In contrast, Ms. Bruce, when describing proper pain management instruction, seemed to be guided by the specific items delineated in the nursing care plan. Tr. 146-60.

HCFA acknowledges Ms. Bruce's testimony that she would have credited Petitioner for "documented instruction to a patient in any of the areas listed in the patient's plan of care at any time during the patient's certification period," and not cited Petitioner for a deficiency. HCFA PHRep. at 34. HCFA maintains, however, that Petitioner provided no such documented instruction. I find HCFA's contention, as well as Ms. Bruce's testimony, and the affidavit of Ms. Patience as to the type of instruction provided and the alleged adverse impact on the patient, to be unpersuasive and contrary to the evidence of record.

Clearly, my review of the record, including the registered nurses' notes, shows that the nurses did not instruct the patient on each of the subjects stated in the nursing care plan. HCFA Ex. 6 at 7. However, the nurses provided instruction that, in a cumulative sense, was sufficient to meet the physician's order that the patient be trained in pain management. Failure to cover each and every subheading of pain management delineated in the nursing care plan is not required by this regulation. The subheadings listed in the nursing care plan were intended to be used as an internal guide for Agency personnel and described the type of instruction to give. A reasonable description of pain management techniques, as Petitioner's nurses did here, coupled with a description of the disease process, meets the regulatory requirement. There is nothing in the cited regulation that compels the registered nurse to cover each and every item listed

in the nursing care plan.[31] The latter statement is important, because as Petitioner correctly noted, nearly one month of the certification period remained when the survey concluded. Petitioner still had time to complete other areas of instruction. The principal instruction or counseling that Petitioner was mandated to provide here relates to pain management, which it did. I do not find the absence of training on distraction, heat, skin care, or massage to be material in light of the training provided.

HCFA has failed to present a credible prima facie case that Petitioner violated this standard as relates to Patient 2. In the alternative, Petitioner has shown by preponderance of the evidence that it was in substantial compliance with the standard.

b. Patient 3

Detailed information about Patient 3 was set forth in the section of this decision relating to the first deficiency cited under G Tag 172. As previously indicated in this decision, Patient 3's plan of care indicated pertinent diagnoses of hypertension, angina pectoris, gout, and osteoarthritis. The skilled nursing orders included instructing the patient in pain management. HCFA Ex. 7 at 1-2. The nursing care plan referred to instruction in: (1) non-invasive pain management techniques, including distraction, cold, and heat; and (2) comfort measures such as skin care, positioning, and medication administration. Id. at 6.

The nurse's note for January 24, 1997 indicated that Patient 3 complained of arthritic pain in his right hip and shoulder and that he had a knowledge deficit in the signs and symptoms of osteoarthritis. HCFA Ex. 7 at 21. In response, the registered nurse instructed Patient 3 to rest and avoid activity to help decrease his pain. The nurse also instructed Patient 3 on the signs and symptoms of osteoarthritis, including joint pain. Id. The nurse indicated that the patient was able to understand instruction given regarding his pain in his hip and shoulder, which was relieved by resting for 50 minutes. Id.

There were other notes in the record indicating that Patient 3 received instruction in pain management. These notes indicate

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[31] Arguably, failure to provide instruction on each and every item listed in the plan of care may violate 42 C.F.R. § 484.18--"[c]are follows a written plan of care established and periodically reviewed by a doctor . . ." However, the items that were challenged were contained in the nursing care plan, which is not part of the plan of care.

that Patient 3 received instruction on a number of points, including: taking NTG for chest pain; learning what caused angina pain; doing chores while seated; avoiding activities with hands above head; relieving chest pain by rest; limiting activity, in order to reduce pain in right hip and shoulder; using pain medication if pain becomes unbearable; and, calling the physician, registered nurse, or an ambulance if instances of angina pain occurred more frequently or increased in severity. See HCFA Ex. 7 at 18-25; see also, P. PHRep., Schedule E.

HCFA describes the instruction provided as relating to "energy consumption" and not pain management. HCFA PHBr. at 50. I find such a distinction to be artificial and not supported by the record. HCFA concludes that the absence of all of the specific instructions tracking the pain management techniques and comfort measures in the nursing care plan, specifically, distraction, cold and heat, skin care, positioning, and medication administration, constitute a violation of the cited standard. I disagree.

The instruction provided should be considered in the context of the physician's order and the plan of care. The physician's written order only refers to the provision of "instruction" without specifying the type of instruction to be provided. HCFA Ex. 7 at 4. Similarly, the plan of care refers only to instruction on "pain management." Id. at 2. The plan of care does not describe further the types of pain management techniques to be included in such instruction. The nursing care plan, which is not signed or approved by the physician, contained the instructions that HCFA contends were not provided. See HCFA Ex. 7 at 6. I have previously found that the nursing care plan document is an internal home health agency guideline for its registered nurses and does not have specific regulatory significance under the applicable regulations covering the COP.

As I stated with regard to Patient 2, the determination of whether the registered nurses provided the requisite counseling in meeting nursing and related needs should be based on adequacy and completeness of the instruction provided and not whether the patient received instruction on all the points of instruction itemized in the nursing care plan. The controlling point is the description of the type of instruction stated by the physician in the written order and later more fully described in the plan of care. Based on my review of the these documents and the notes related to the skilled nursing visits, I conclude that the Agency's nurses gave Patient 3 adequate instruction on pain management.

Patient 3 received instruction to include: a description of the signs and systems of the underlying condition causing the pain; the appropriate use of medications to relieve the pain; and, measures to be taken to avoid situations where the pain might occur. While arguably, Patient 3 could have received instruction on comforting measures to alleviate his pain, such as distraction, heat and cold, the absence of these measures does not render the information provided as inadequate or insufficient under the cited regulatory standard. Moreover, in the instant case, the registered nurses did provide instruction on positioning and medication administration, as mandated in the nursing care plan. The failure of the nurses to comply more fully with such plan is an internal matter for the HHA to deal with, if it chooses to, and not a matter of regulatory significance, since the nurses provided adequate instruction on pain management to the patient.

HCFA has failed to present a credible prima facie case that Petitioner violated this standard as it relates to Patient 3, or, in the alternative, Petitioner has shown by preponderance of the evidence that it was in substantial compliance.

c. Patient 4

Patient 4 was a 79-year-old male at the time of the follow-up survey by LACDHS. The certification period for Patient 4 was January 9, 1997 through March 9, 1997. The plan of care for this patient stated his principal diagnosis as hypertension and a pertinent diagnosis of cerebral vascular accident (CVA). HCFA Ex. 8 at 1-2. The plan of care contained skilled nursing orders for the registered nurse to instruct Patient 4 on numerous subjects, including: (1) the disease process for hypertension and CVA; (2) low salt diet; (3) safe use of oxygen at two liters per minute when short of breath; (4) self-monitoring his blood pressure and pulse; (5) care of incontinency and anti-constipation diet; (6) safety precautions; and, (7) exercise and rest activity. Id.

HCFA alleges that there was no documented evidence that the registered nurse counseled the patient on any of these subjects. HCFA Ex. 1 at 15. The State surveyor, Ms. Bruce, testified that her review of the nurses' notes indicated that the registered nurse provided no instruction in any of the areas enumerated in the plan of care. Tr. 161.

In response to my questioning of Ms. Bruce at the hearing, she clarified the nature and extent of the deficiency, indicating that Petitioner's registered nurses failed to instruct the patient on the disease process relating to CVA, while

acknowledging that there was instruction relating to hypertension. HCFA PHBr. at 52-53; Tr. 165-66.[32] When specifically requested to differentiate instruction on hypertension from CVA, Ms. Bruce was able to give an example of the types of instruction on the CVA disease process that were not given, on subjects such as blurred vision and numbness on one side of the body. Tr. 166.

My review of the record indicates that the bulk of the instructions the registered nurse provided related to problems Patient 4 had with constipation. The nurse provided the patient with instruction on diet and medication that would reduce the effects of his constipation. See HCFA Ex. 8 at 24, 28-33; P. PHRep., Schedule F. The nurse also offered some general instructions on signs and symptoms of hypertension and side effects of Procardia, a medication taken to treat this condition. HCFA Ex. 8 at 33, 36, 38. I cannot find any instructions relating to the signs and symptoms of CVA. Nor can I find any instructions related to the other items referenced in the deficiency.

From my review of the record, it is clear that the only instruction related to CVA would be the instruction relating to the signs and symptoms of hypertension and the information about Procardia, a medication for hypertension. Elevated blood pressure can cause complications, one of which is CVA. The registered nurse instructed Patient 4 on hypertension but did not discuss numbness and one-sided weakness. I concur that these two signs can be associated with a CVA and no instruction was provided. Therefore, the instruction on CVA was incomplete and deficient.

The plan of care also included other instructions relating to hypertension, such as diet, blood pressure monitoring, and pulse monitoring, which the nurse failed to address. Consequently, I find that such instruction was incomplete as well. The absence of instruction on these subjects was particularly meaningful, because the records for Patient 4 indicate that he had high blood pressure which was difficult to control. See HCFA Ex. 8 at 23-

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[32] In citing the deficiency, the State surveyor did not mention hypertension as a disease process, although it was referred to in the plan of care. See HCFA Ex. 1 at 15. I must conclude that its absence was based on the State surveyor's conclusion that Petitioner had provided adequate instruction on hypertension.

44, 28-33, 35-38.[33] Obviously, misuse of the portable oxygen, which was available for the patient's use when short of breath, also could have endangered the patient's health and safety. I concur with the evidence offered by HCFA that the registered nurse's failure to provide the missing areas of instruction could potentially adversely affect the health and safety of this patient. Tr. 162.

Petitioner argues that the certification period ended on March 9, 1997 and that additional time was available to relate the missing instructions, such as the safe use of oxygen. P. PHRep., GTAG 177 at 20.[34] Petitioner's position is misguided. Petitioner is correct when stating that it has to provide the mandated instruction only one time during the certification period. However, the determination as to whether this standard has been met will depend on whether the instruction provided during the period surveyed demonstrates that Petitioner's skilled nurses were making a reasonable and responsible effort to provide the instruction mandated by the plan of care. A reasonable person would not expect the patient and other caregivers to receive all of the necessary instruction(s) at one time, since the receipt of such a voluminous amount of information would likely result in the inability of these persons to retain the information.

With respect to Patient 4, however, the record fails to demonstrate that the registered nurses made a reasonable and timely effort to ensure that all the instructional areas contained in the plan of care would be covered during the certification period. The nurses failed to provide instruction on too many of the mandated areas at the time of the follow-up survey. The nurses should have commenced such instruction at the beginning of the certification period and continued on a regular basis throughout such period. The record fails to demonstrate that the nurses acted in this manner. Moreover, at the conclusion of the follow-up survey, over two-thirds of the certification period already had elapsed. Petitioner had insufficient time remaining in the certification period for the nurses to have provided all the missing information in a manner that Patient 4 or his caregivers would have understood.

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[33] The same clinic records suggest that although the Patient 4's blood pressure was elevated, he was otherwise asymptomatic--that is, he suffered no clear side effects from the hypertension.

The information contained in "GTAG 177" is part of an attachment to Petitioner's posthearing brief.

HCFA has presented credible evidence in its prima facie case that Petitioner violated this standard as relates to Patient 4 and Petitioner has failed to show by a preponderance of the evidence that it was in substantial compliance with this standard. Such failure by Petitioner could have had the potential to adversely affect the health or safety of the patient.

d. Patient 5

Detailed information about Patient 5, who suffered from IDDM, hypertension, and asthma, was set forth in the sections of this decision relating to the first deficiency cited under G Tag 172, as well as the second deficiency cited under G Tag 176. See HCFA Ex. 9 at 1; HCFA Ex. 1 at 10-11. The plan of care for Patient 5 ordered skilled nursing instruction on a number of subjects, including: blood sugar monitoring; insulin self-injection; skin care; signs and symptoms of hypoglycemia and hyperglycemia, and actions to take; and exercises for range of motion, strengthening, and breathing. HCFA Ex. 9 at 1-2. The physician's orders also generally directed skilled nursing teaching and instruction. HCFA Ex. 9 at 30. The Agency's nursing care plan included instruction for Patient 5 on such subjects as: the disease process; emergency procedures; diet; nutritional status; skin care; range of motion; weekly weights; and, anxiety control. HCFA Ex. 9 at 3-6.

In citing Petitioner for a deficiency under G Tag 177, the State surveyor, Ms. Bruce, referred to the plan of care as well as the Agency's nursing care plan as requiring the nurses to provide instruction on skin care, range of motion, strengthening exercises, breathing exercises, weekly weights, and anxiety control. HCFA Ex. 1 at 16; see also, HCFA Ex. 9 at 3-6. She also concluded that no documentation existed to demonstrate that the registered nurses instructed Patient 5 in any of the identified areas. Tr. 168. Again, as in previous instances cited earlier in the decision, Ms. Bruce testified that if Petitioner had documented instruction to Patient 5 in any of the identified areas at any time during the certification period she would have given Petitioner credit for such instruction and not found a deficiency. Tr. 170.

I must initially disregard the references in the HCFA Form 2567 to lack of documentation of instruction in anxiety and weekly weights, as these references are not part of the plan of care,

but are contained in the nursing care plan. As indicated previously, I give little weight to the nursing care plan.[35]

I note that the physician reviews and approves, in writing, the plan of care, whereas he does not review and approve the nursing care plan. The Agency prepares the nursing care plan independently as its means of implementing the physician's authorized treatment contained in the plan of care.[36] While the nursing care plan is important as a guide to nurses on how to administer the plan of care, the registered nurses must follow the plan of care in providing treatment and services to patients. Thus, in this instance, where the nursing care plan embellishes the plan of care and requires more instruction than authorized by the physician, even if it arguably would benefit the patient, failure to provide such instruction does not violate this standard.

With regard to Patient 5, my review of the record indicates that Petitioner did not meet the standard under G Tag 177 because the registered nurses failed to cover a number of instructional areas the physician identified in the plan of care. The record shows that most of the instruction the nurse provided to Patient 5 related to his diabetes and hypertension, which were the principal areas of concern during the skilled nursing visits.[37] The nurse also provided Patient 5 with instruction on skin care and the need for exercise, as well as general instruction on the risk factors relating to asthma. See P. PHRep., Schedule G; HCFA Ex. 9 at 106. The nurse did not provide instruction on breathing exercises or range of motion. In this instance, the registered nurse did not provide all the instruction set forth in the plan of care. I find, however, that the missing instruction did not appear crucial to Patient 5's diagnoses or place him in jeopardy, with the possible exception of failing to instruct Patient 5 in breathing exercises. In fact, the standard for G Tag 177 is general and does not require any specific type of instruction or counseling. A determination as to whether the standard has been

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[35] As I indicated earlier in my discussion under G Tag 177 with regard to Patients 2 and 3, the contents of the nursing care plan are not controlling for the purpose of determining compliance by the HHA. Rather, the authorized treatment and services contained in the plan of care approved by the patient's physician are controlling for this purpose.

[37] I note that the State surveyor did not cite Petitioner, under G Tag 177, for failure to provide Patient 5 with instruction relating to hypertension and diabetes.

met in a particular case is dependent on a review of the nature of the instruction or counseling provided. Failure to provide instruction in every identified area should not be a basis for a deficiency, unless the identified areas are meaningful and their absence would place the patient in jeopardy. In short, unless the registered nurse's counseling was deficient in a crucial area needed for patient care, there is no basis for a deficiency.

HCFA has failed to present a credible prima facie case that Petitioner violated this standard as relates to Patient 5, or, in the alternative, Petitioner has shown by a preponderance of the evidence that it was in substantial compliance with this standard. HCFA did not provide an adequate basis for its conclusion that Petitioner's failure to provide such instruction had the potential to adversely affect the health or safety of Patient 5 relating to diabetes and asthma. See Tr. 168; HCFA Ex. 21, ¶¶ 15-16. As to diabetes, the registered nurse made numerous efforts to educate the patient on diabetic issues, particularly with regard to monitoring his blood sugar, skin care and the need for exercise. Though the nurse did not instruct Patient 5 in range of motion exercises or breathing exercises, she did provide him with general instruction on asthma, which was not a significant problem in the certification period.[38]

IV. Summary

In determining whether there has been compliance with the COP for Skilled Nursing Services, 42 C.F.R. § 488.30, I must evaluate the manner and degree of the provider's compliance with the various standards cited in the HCFA Form 2567 as being deficient. My decision reflects my review of the record as to each of the deficiencies cited by the State survey agency and adopted by HCFA as supporting the basis for concluding that Petitioner did not satisfy the condition.

A provider of home health services, such as Petitioner, will be deemed as failing to comply with a COP where the deficiencies found to exist, either individually or in combination, are of such character as to substantially limit the provider's capacity to furnish adequate care, or adversely affect the health and

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[38] Arguably, Petitioner's failure to provide instruction in all of the subjects delineated in the plan of care violates the general requirement of the COP set forth at 42 C.F.R. § 484.18. That COP states, in relevant part, that "[c]are follows a written plan of care established and periodically reviewed by a doctor of medicine, osteopathy, or podiatric medicine." Id. But, while HCFA cited Petitioner for deficiencies at the standard level under that COP, it did not find that the deficiencies rose to the condition level. See HCFA Ex. 1 at 5-8.

safety of patients. 42 C.F.R. § 488.24(b). The fact that deficiencies exist does not necessarily support a conclusion that a provider is failing to met a COP. In such circumstances, the remedy is submission of a plan of correction and not termination. 42 C.F.R. § 488.28.

My analysis of the deficiencies is based upon the regulatory framework set forth above. I also concur with Judge Kessel's finding in CSM Home Health Services.[39] That finding, which I set forth in that part of my decision addressing applicable law, states in relevant part: "[t]ermination should not be invoked unless the evidence proving a provider's failure to comply with participation requirements established that the provider cannot provide care consistent with that which is required by the Act and regulations."[40]

In this case, I found, in examining the alleged deficient standards HCFA cited with regard to COP for skilled nursing services, that Petitioner was: (1) not deficient with regard to any of the patients cited under G Tag 172,[41] the standard requiring the registered nurse to regularly reevaluate the patient's nursing needs; (2) deficient regarding one patient out of four patients[42] cited under G Tag 177, the standard requiring Petitioner's registered nurses to counsel patients and their families in meeting nursing and related needs; and, (3) deficient with respect to all four patients cited[43] under G Tag 176, the standard relating to the obligation that the registered nurse inform the physician of significant changes in the patient's condition. Though I found that Petitioner had not met the standard with respect to G Tag 176, and did not satisfy the standard under G Tag 177 with respect to Patient 4, I cannot conclude, without more, that these deficiencies rose to the level of failing to meet the COP for skilled nursing services.

Under G Tag 176, the registered nurse is required to inform the physician of changes in the patient's condition and needs. I

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[39] CSM Home Health Services, Inc., DAB CR440 (1996), at 3.

[40] Id.

[41] LACDHS found that Petitioner was deficient with respect to three patients out of the seven patients surveyed.

[42] LACDHS found that Petitioner was deficient with respect to four patients out of the seven patients surveyed.

[43] LACDHS found that Petitioner was deficient with respect to four patients out of the seven patients surveyed.

found that the record supported HCFA's finding of a deficiency under this standard with respect to Patients 2, 3, 5, and 7, four patients out of seven patients surveyed. Yet, I often found it difficult to discern from the record what information the physician had. Moreover, there were instances where the physician was notified but it was difficult to ascertain from the record the precise nature of the communication. Other cited deficiencies were either isolated, that is, not showing a pattern of circumstances that would suggest a systemic failure within the Agency, or did not demonstrate that Petitioner was substantially incapable of providing care that met the COP for HHAs. I also found it difficult to assess the potential for harm to the patients or the extent of provider culpability resulting from the deficient conduct.

For example, the State surveyor, Ms. Bruce, cited Petitioner for a deficiency under G Tag 176 with respect to Patient 2. Her decision to cite the deficiency appears based, in large part, on a single instance of reported chest pain involving a patient with known diagnoses of hypertension and angina. HCFA argued that its finding of a deficiency was justified given the "potential of the patient having a heart attack." HCFA PHBr. at 29-30; Tr. 120. HCFA also argued that the patient's chest pain could be indicative of some other disease process. Id. But HCFA did not, either through testimony presented at hearing, or in its briefs and exhibits, offer any convincing evidence as to how the failure of the registered nurse to notify the physician of the presence of chest pain in a patient with known heart problems including angina pectoris, adversely affected the health and safety of the patient. Nor did HCFA convincingly demonstrate that such an isolated situation rendered Petitioner substantially incapable of providing care that meets the COP for HHAs.

In another example, HCFA cited Petitioner for a deficiency under G Tag 176 relating to its failure to report Patient 3's significant weight gain over a one-week period. I found that the registered nurse should have reported Patient 3's weight gain to the physician as a significant clinical finding and in accordance with Petitioner's internal policy guidance. However, my review of the record also showed that the registered nurse made several calls to the physician about the patient's overall nutritional status during the certification period, but that the physician did not order a change to the plan of care. Additionally, the HCFA Form 2567 containing the finding of a deficiency states that "nurse's notes throughout the plan of care from 12/06/96 through 02/06/97, made reference to the patient's poor appetite and decreased body weight," thereby acknowledging that Petitioner had assessed Patient 3's appetite as required in the plan of care. HCFA Ex. 1 at 14.

As additional support for the position that Petitioner was obliged to report the patient's weight gain to her physician, HCFA relied upon, in its posthearing brief, Petitioner's definition of "work week" contained in its internal physician notification policy. See HCFA PHBr. at 32-33; HCFA Ex. 13. Although I concluded that HCFA met its prima facie case with respect to Patient 3, its very reliance on the definition of Petitioner's "work week" contained in its physician notification policy, rather than a showing of potential or actual harm to Patient 3 or a limitation on the Petitioner's capacity to furnish adequate care, illustrates the largely technical nature of the deficiency when considered with all of the other evidence in the record.

As to Patient 5, an insulin-dependent diabetic, I found that HCFA failed to establish a prima facie case that Petitioner's actions violated the cited standard at G Tag 176. In this instance, the patient's blood sugar levels remained unstable for a period of time--a circumstance that the registered nurse should have reported to the physician. Yet, my review of the record also showed that the registered nurses checked Patient 5 at each visit to see that the patient had no apparent complications for his elevated blood sugars. HCFA Ex. 9 at 33-49, 51-113. Clearly, Patient 5 could have suffered complications arising from out of control blood sugar, but the record also shows that the nurses continually monitored the patient's blood sugar levels and no actual harm resulted.[44]

Finally, with respect to Patient 7, who suffered from an infected stage IV wound associated with treatment for breast cancer, I concluded that HCFA established a prima facie case that Petitioner's actions regarding this patient violate the cited standard. The cited deficiency involved Petitioner's failure to prepare progress notes for Patient 7 and to inform the physician (or other Agency personnel) of changes in the patient's condition and needs.

I reviewed the record for the purpose of determining whether Patient 7's physician, when notified three times during this period by the registered nurse about factors affecting Patient 7's nutritional status, such as nausea, vomiting, bowel movements, and lack of I.V. fluid intake, should also have been

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[44] A finding of the potential for harm, which I found, is all that is necessary to establish violation of the standard. A determination as to the degree of harm, however, is necessary in determining whether a COP is "out" based on the regulatory requirements of 42 C.F.R. § 484.24(b).

informed specifically about Patient 7's weight fluctuations and weight loss. I found, with respect to the deficiency related to failure to inform the physician of changes in the patient's conditions and needs, that Patient 7's nutritional status was severely compromised. I concluded that while a close question, Patient 7's weight loss of 16 pounds was significant as a separate clinical finding, and should have been independently reported to the physician. Clearly, the physician was deprived of vital information that he could have used in determining the correct course of treatment of Patient 7. But I also found that the question of harm might be minimal, since the registered nurse called the physician several times during the certification period about Patient 7, during which calls she provided the physician with information that strongly suggested nutritional compromise, with loss of weight an expected consequence.

With respect to the cited deficiency related to the Petitioner's failure to prepare progress notes for Patient 7, I reviewed the record in an attempt to answer the question as to what types of reports HHAs are required to maintain with regard to its patients. I identified the key issue as whether Petitioner's failure to maintain progress notes for Patient 7, if true, was a deficiency so serious that the absence of that documentation affected the Agency's capacity to furnish adequate care to Patient 7 or adversely affected her health and safety. I found that Petitioner did not maintain progress notes, as defined by regulation, for this patient. I also concluded, however, that in light of the numerous other reports generated on Patient 7, such as, 60-day reports, case conference notes, and clinical notes, that Petitioner's failure to prepare progress notes for Patient 7 had a minimal impact on her care. HCFA made no showing of harm or even potential harm in light of the existence of the other reports of record.

Without more, I cannot find that HCFA has demonstrated that these deficiencies cited under G Tag 176 rise to the level of violating the COP for skilled nursing services. 42 C.F.R. § 484.30. Nor has HCFA shown that the deficiencies were part of a pattern or practice that rendered Petitioner substantially incapable of providing adequate care or adversely affected the health and safety of the Agency's patients, as set forth in 42 C.F.R. § 488.24(b).

In citing deficiencies under G Tag 177, HCFA alleged that Petitioner failed to satisfy the standard which required the registered nurse to counsel the patient and family in meeting nursing and related needs with respect to four patients of seven patients surveyed. Yet I found, based upon my review of the record, that Petitioner had met the standard with respect to

three patients out of the four patients cited in the HCFA Form 2567, namely, Patients 2, 3, and 5. I found that the record supported HCFA's finding of a deficiency under this standard with respect to Patient 4. But, without more, I cannot find that HCFA has demonstrated that the deficiency under this standard rose to the level of violating the COP for skilled nursing services. 42 C.F.R. § 484.30. Nor did HCFA demonstrate that the deficiency, with respect to Patient 4, was part of a pattern or practice that rendered Petitioner substantially incapable of providing adequate care or adversely affected the health and safety of the Agency's patients, as set forth in 42 C.F.R. § 488.24(b).

In citing Petitioner for deficiencies under G Tag 177, the State surveyor, Ms. Bruce, appeared to require a rote adherence to each and every item of instruction included in the plan of care the physician approved. I found the standard for counseling under the regulation to be more general, that is, the standard does not require any specific type of instruction or counseling. A determination as to whether the standard has been met in a particular case is dependent on a review of the nature of the instruction or counseling provided. Failure to provide instruction in every identified area should not be a basis for a deficiency, unless the identified areas are meaningful and their absence would place the patient in jeopardy. In short, unless the registered nurse's counseling was deficient in a crucial area needed for patient care, I would find that there was no deficiency.

The State surveyor also relied upon Petitioner's internal guidelines--specifically, the nursing care plan, as part of her basis for citing Petitioner for deficiencies under G Tag 177. In my review of the deficiency as cited in the HCFA Form 2567, I noted that the State surveyor, Ms. Bruce, had merged the obligations placed on the registered nurses in the plan of care with the nursing instructions indicated in the Agency's nursing care plan. I also stated that the contents of the nursing care plan were not controlling for the purpose of determining compliance by the HHA. Rather, the authorized treatment and services contained in the plan of care approved by the patient's physician would be controlling for this purpose. I also found that, in instances where the nursing care plan embellished the plan of care and required more instruction than authorized by the physician, even if it arguably would have benefitted the patient, failure to provide such instruction would not violate this standard

My review of the record revealed that the registered nurse had instructed Patient 4 on a variety of issues related to his condition including issues related to his diagnosis of

hypertension, but not with regard to another pertinent diagnosis, CVA. I found the nurse's failure to provide such instruction deficient under the relevant standard. I also found that the registered nurse had failed to provide other instruction set forth in the plan of care. Finally, I found that HCFA had demonstrated the potential for harm to this patient. But HCFA did not show that the deficiency with respect to Patient 4 was part of a pattern or practice that rendered Petitioner substantially incapable of providing adequate care or adversely affected the health and safety of the Agency's patients, as set forth in 42 C.F.R. § 488.24(b).

The questions presented were close ones, and usually showed technical violations without much evidence of harm. I did not find the instances in which Petitioner did not comply with standards, contained in 42 C.F.R. § 484.30, sufficient to show a pattern of failures such as to violate the COP for skilled nursing services. Nor did HCFA demonstrate that the deficiencies shown were part of a pattern or practice that rendered Petitioner substantially incapable of providing adequate care or adversely affected the health and safety of the Agency's patients, as set forth in 42 C.F.R. § 488.24(b). The limited violations of the standards I found did not give rise to a conclusion that termination was warranted under the test set forth above.

V. Conclusion

I am persuaded that the record establishes that Petitioner's conduct relating to the condition of participation at 42 C.F.R. § 484.30, Skilled Nursing Services, was in substantial compliance with the Medicare requirements. Consequently, I conclude that HCFA did not have a basis to terminate Petitioner's participation in Medicare.

/s/

Edward D. Steinman
Administrative Law Judge