Department of Health and Human Services

DEPARTMENTAL APPEALS BOARD

Civil Remedies Division

In the Case of:	)	
	)	
Pacific Coast Home Health,	)	DATE: June 1, 1998
	)	
Petitioner,	)	
	)	
- v. -	)	Docket No. C-97-151
	)	Decision No. CR534
Health Care Financing Administration.	)	
	)	

DECISION

I decide that the Health Care Financing Administration (HCFA) correctly determined to terminate the participation in the Medicare program of Petitioner, Pacific Coast Home Health. In this case, HCFA asserted that Petitioner failed to comply with two conditions of participation in the Medicare program. I find that the preponderance of the evidence is that Petitioner did in fact fail to comply with these two conditions of participation.

I. Background

A. Applicable law and regulations

Petitioner is a home health agency that participated in the Medicare program. The services provided by home health agencies that are covered by the Medicare program are described in section 1861(m) of the Social Security Act (Act). The statutory requirements of participation for a home health agency are described in section 1861(o) of the Act.

The Secretary of the United States Department of Health and Human Services (Secretary) has published regulations which govern the participation in the Medicare program of home health agencies. These are contained in 42 C.F.R. Part 484. The regulations which define the Secretary's requirements for Medicare participation of home health agencies establish conditions of participation for these agencies. 42 C.F.R. §§ 484.10 - 484.52. The regulations express these conditions of participation as broadly stated

participation criteria. For example, 42 C.F.R. § 484.18 states as a part of the condition of participation contained in that regulation that care provided to patients by a home health agency must follow a written plan of care that is established and periodically reviewed by a physician.

The regulations also state standards of participation as subsidiary components of the conditions of participation. For example, in 42 C.F.R. § 484.18, there are specific standards governing: what a plan of care must contain (42 C.F.R. § 484.18(a)); who must review a plan of care (42 C.F.R. § 484.18(b)); and how a physician's orders, prepared pursuant to a plan of care are to be made, issued, and carried out (42 C.F.R. § 484.18(c)).

The Secretary is required to determine whether a Medicare participant, including a home health agency, is complying substantially with the Medicare participation requirements established by the Act and the regulations. Section 1866(b)(2) of the Act. The Secretary may terminate a provider's participation in the Medicare program if the Secretary finds the provider is not complying substantially with participation requirements. Section 1866(b)(2)(A) of the Act.

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.

Pursuant to the Act and regulations, the Secretary has entered into agreements with State survey agencies to conduct periodic surveys of Medicare providers, including home health agencies, in order to ascertain whether these providers are complying with Medicare participation requirements. Section 1864(a) of the Act; 42 C.F.R. §§ 488.10, 488.11, 488.20.

In determining whether there has been compliance with a particular condition of participation, 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 in a HCFA Form 2567 which is given to the provider after completion of the survey. The State survey agency makes a recommendation to HCFA as to whether there is a basis for termination, which HCFA may accept or reject after reviewing the findings of the survey.

HCFA may terminate a provider's participation in the Medicare program if HCFA determines, either on its own initiative or based on a survey report from a State survey agency, that the provider is not complying with one or more Medicare conditions of participation. Failure to comply with a condition of participation 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, DAB CR440, at 3 (1996).

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. 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 nor 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. Hillman Rehabilitation Center, DAB CR500, at 3 - 8 (1997). 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 its case is based on unsubstantiated allegations) and Petitioner will not be obligated

to prove that it was substantially complying with participation requirements.[1]

C. History of this case

Petitioner operated a home health agency in Seal Beach, California. Two surveyors from the California Department of Health Services, the State survey agency, completed a recertification survey of Petitioner on September 18, 1996. HCFA Ex. 1, at 1. The revisit survey was a follow-up to an earlier recertification survey completed May 9, 1996. The surveyors completed a Statement of Deficiencies (HCFA Form 2567) which was forwarded to the HCFA Regional Office where it was reviewed by a HCFA nurse surveyor. HCFA Ex. 2.

In a December 2, 1996 letter, HCFA notified Petitioner that HCFA had determined that Petitioner was out of compliance with the following two conditions:

> 1. 42 C.F.R. § 484.18 (Acceptance of Patients, Plan of Care, and Medical Supervision); and
>
> 2. 42 C.F.R. § 484.30 (Skilled Nursing Services). HCFA Ex. 1.[2]

HCFA then informed Petitioner that its Medicare agreement would be terminated on December 20, 1996. Id. at 2.

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[1] When Petitioner establishes by the preponderance of the evidence that the factual basis for the deficiency set forth by HCFA in the HCFA Form 2567 either did not occur as alleged or did not violate any of the participation requirements, it is also tantamount to demonstrating that it is in substantial compliance with participation requirements. It demonstrates such compliance by challenging the validity of the evidence offered by HCFA rather than by affirmative evidence that, despite HCFA's prima facie case, it was in substantial compliance with program requirements.

[2] At the exit conference with Petitioner's staff, the State surveyors informed Petitioner that it was out of compliance with only one condition of participation, 42 C.F.R. § 484.30 (Skilled Nursing Services). Transcript (Tr.) at 36. The surveyors then sent a Certification and Transmittal Form to the HCFA Regional Office with a recommendation that Petitioner's certification not be continued because of a failure to comply with 42 C.F.R. § 484.30. HCFA Ex. 3. In reviewing the surveyors' report, HCFA determined, however, that Petitioner was also out of compliance with 42 C.F.R. § 484.18 (Acceptance of Patients, Plan of Care, and Medical Supervision). Tr. at 37, 484.

Petitioner timely requested a hearing, and the case was assigned to me for a hearing and a decision. The hearing was held in Santa Ana, California, on April 21 - 25, 1997, with additional testimony taken by telephone on May 1, 1997. The parties then submitted posthearing briefs and reply briefs. I base my decision in this case on the governing law, the evidence I received at hearing, and on the parties' arguments as expressed in their briefs.[3]

D. Basis for evaluation of deficiencies

Below, I evaluate each of the deficiencies identified by the California Department of Health Services 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 must then 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 a level of a condition of participation which would support termination of Petitioner's participation in the Medicare program.

I use the following format for my Decision. The conditions and standards at issue, as set forth in the HCFA Form 2567, are set forth in boldface. The numbered paragraphs set out in italics, 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.

In the interests of efficiency and simplicity, the parties at the hearing addressed the alleged deficiencies in the order, with several minor exceptions to accommodate the schedules of witnesses, that the deficiencies appeared on the HCFA Form 2567. In their briefing, the parties continued to follow this same order. Accordingly, I will address each alleged deficiency in the order that the deficiencies appeared on the HCFA Form 2567. Each of the statements describing the alleged deficiencies are taken verbatim from the HCFA Form 2567 completed by the State surveyors. I am taking this approach as the HCFA Form 2567, along with HCFA's December 2, 1996 termination notice, provide the only formal notice, as set forth in Hillman, of the deficiencies Petitioner could contest at the hearing.

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

During the hearing HCFA attempted to elicit testimony from the surveyors concerning the standard level of deficiencies set forth in the first seven pages of the HCFA Form 2567. HCFA explained that, while these deficiencies were not cited as condition level deficiencies, HCFA takes such standard level deficiencies into account in establishing a pattern of problems at a facility. Tr. at 646. I denied testimony on these standard level deficiencies since they were not relied upon and cited by HCFA in its December 2, 1996 notice terminating Petitioner. Tr. at 646 - 47. HCFA thus failed to give timely notice, as required by Hillman, to Petitioner that the alleged standard level deficiencies would be raised by HCFA at the hearing. Another basis for not considering these cited deficiencies is that since they were not cited as condition level deficiencies, HCFA could not terminate the provider's participation in Medicare without first affording the provider the opportunity to correct the deficiency. CSM Home Health Services, DAB No. 1622, at 10, n.7 (1997); 42 C.F.R. § 498.28.

II. The alleged deficiencies

Part One of my discussion concerns Petitioner's alleged failure to meet the condition set forth at 42 C.F.R. § 484.18; Part Two concerns Petitioner's alleged failure to meet the condition set forth at 42 C.F.R. § 484.30.

Part One

The State surveyors summarized Petitioner's failure to comply with the condition set forth at 42 C.F.R. § 484.18 as follows:

G 156 484.18 CONDITION: ACCEPTANCE OF PATIENTS, PLAN OF CARE, AND MEDICAL SUPERVISION

> **The Agency failed to accept patients for treatment on the basis of a reasonable expectation that the patient's medical, nursing and social needs could be met adequately by the agency in the place of residence (G157); render care that followed a written plan of care established and periodically reviewed by a doctor of medicine (G158); develop a plan of care in consultation with the agency staff that covered the mental status of patients, the functional limitations; prognosis and activities permitted and included instructions for timely discharge or referral (G159); and alert the physician to any changes that suggested a need to alter the plan of care (G164).**

HCFA Ex. 2, at 7 - 8.

Under this condition-level deficiency, the surveyors then proceeded to list the alleged four standard-level deficiencies.

G 157 484.18 Standard: Patients are accepted for treatment on the basis of a reasonable expectation that the patient's medical, nursing and social needs could be met adequately by the agency in the place of residence.

Based on a review of nine open clinical records, the surveyors determined Petitioner failed to accept three patients (Patients 5, 7, and 8) for treatment in a timely manner.

1. For Patients 5 and 8, Petitioner has shown by a preponderance of the evidence that its services were provided in a timely manner and/or that any delay was not Petitioner's responsibility and did not result in any actual or potential harm to the patients. For Patient 7, Petitioner has failed to establish by a preponderance of the evidence that it provided services in a timely manner, and such failure had the potential to cause more than minimal harm, with a possible adverse affect on the patient's health and safety.

Patient 5

The surveyors made the following assertions concerning the care Petitioner gave to Patient 5:

> A plan of care for Patient #5 dated 8/10/96 cited that the patient would receive physical therapy services two times for one week. However, the physical therapy service was not started until 8/19/96. There was no documentation in the clinical record explaining why the service was delayed.

HCFA Ex. 2, at 8 - 9.

Patient 5 had an incisional wound on her thigh following heart surgery and was referred to home health care for wound care. HCFA Ex. 9, at 9.

At the hearing, the State surveyor, Josefina Sabino, testified that this patient's plan of care (POC) called for the patient to receive physical therapy twice a week for the following purposes: evaluation, strengthening, therapeutic exercises, transfer training on all surfaces, establishment and instruction of a home exercise program, instruction in transfers and home safety, and gait training on level surfaces. Tr. at 42; HCFA Ex. 9, at 11. The surveyor testified that the skilled nurse's assessment of the patient noted that the patient had symptoms of weakness and was at a high risk for falls. Tr. at 44; HCFA Ex. 9, at 16. The surveyor questioned why the patient did not begin to receive physical therapy until August 19, nine days after the writing of the POC and stated that "there was no documented evidence or documentation explaining why the service was delayed." Tr. at 44. The surveyor testified that, under HCFA guidelines which the State surveyors follow, physical therapy should have been

provided within 48 to 72 hours from either the patient's referral or the date of the physician's order. Id. Petitioner's delay in providing the physical therapy was the basis for the deficiency cited for this patient. Id.

HCFA's Nurse Consultant, Ruth Patience, testified that she trained California State Agency surveyors and reviewed the statement of deficiencies prepared by the State surveyors at issue here. Tr. at 481 - 82. Ms. Patience stated that there was a deficiency in regard to this patient because "[i]t's HCFA's expectation that when a Home Health Agency accepts a patient for treatment that services are going to be provided as soon as possible, and a timely a fashion as possible." Tr. at 486. Ms. Patience further testified that HCFA has no standard as to the number of days in which a service must be provided, but that most home health agencies have their own policy as to when services must be delivered, and that policy is usually 72 hours. Tr. at 488 - 89. Ms. Patience added that in the absence of any agency policy, HCFA would question why there was a delay in providing an ordered service, if a delay went beyond four or five days. Tr. at 490.

HCFA argued that there is no evidence that Patient 5's physician was contacted regarding any extenuating circumstances that might have warranted a delay in executing the order stated in the POC. HCFA contended that, in regard to this patient, Petitioner failed to accept the patient for treatment on the basis of a reasonable expectation that the patient's need for a physical therapy evaluation and physical therapy treatment could be adequately met by Petitioner, because it delayed this service for a period of nine days following the start of care.

In response, Petitioner made the following general arguments with respect to Patient 5 (and with respect to Patients 7 and 8, to be discussed below also under Tag G 157): 1) HCFA failed to meet its burden of coming forward with evidence to establish a prima facie violation of this standard, since it did not demonstrate that the patient's medical, nursing, and social needs were not met by Petitioner; 2) the "delay" in services alleged does not, in and of itself, constitute a violation of the standard; 3) HCFA failed to articulate and publish for providers any interpretation of the required timeliness for the provision of services; 4) HCFA's own witnesses could not agree on the unwritten and unpublished standard to be used for timeliness and, therefore, none of these arbitrary standards may be enforced to find a deficiency here; and 5) Petitioner demonstrated that the services were in fact provided in a timely manner to ensure that the patient's needs were met.

As to the specific details concerning this patient, Petitioner asserted that only skilled nursing services, not physical therapy services, were ordered for this patient at the time of referral,

with only skilled nurse services ordered. HCFA Ex. 9, at 9; Tr. at 709 - 10. Petitioner argued that it was the skilled nurse, during the evaluation visit on August 10, 1996, who determined that the patient might benefit from a physical therapy evaluation. HCFA Ex. 9, at 16. According to Petitioner, because August 10, the start of care (SOC) date for this patient, was a Saturday, the skilled nurse did not call the physician's office until Monday, August 12, whereupon she left a message concerning the patient's need for a physician's order for a physical therapy evaluation. P. Ex. 1, at 1; HCFA Ex. 9, at 32; Tr. at 708. Petitioner claimed that the physician did not return the call until August 15, 1996, when a verbal order for a physical therapy evaluation was given. P. Ex. 1, at 1 and 2. According to Petitioner, a skilled nurse is required to date a verbal order from a physician on the date it is actually confirmed by the physician, and verbal physician orders are effective only on the date they are verbally confirmed by the physician and may not be implemented earlier. Petitioner argued that since it did not receive any orders to perform a physical therapy evaluation until August 15, 1996, that is the date that must be used to determine the timeliness of the provision of physical therapy services, rather than the SOC date of August 10, 1996. Tr. at 694 - 95. Petitioner contended that when the physical therapy evaluation was performed on August 19, that was only two working days and four calendar days from the date it received the physician's orders. Petitioner claimed that this met both the standard enunciated by Ms. Patience (four-five days) and its own policy of performing services within two working days. P. Ex. 11, at 2.

Petitioner further asserted that it met this patient's needs as evidenced by the following: its skilled nurse determined that the patient might benefit from physical therapy evaluation and treatment; the evaluation was promptly performed once the physician ordered a physical therapy evaluation; and its staff met the physical therapy goals by performing three visits within eight days after the commencement of physical therapy, with the patient able to ambulate 150 feet, using a cane rather than a walker, and independent with her home exercise program (on her admission to Petitioner, the patient was unable to ambulate more than 100 feet before resting, was too weak to stand unassisted, and ambulated with a walker). P. Ex. 1, at 3 and 11; HCFA Ex. 9, at 16. Additionally, Petitioner asserted that, even if there could be considered a deficiency regarding the timeliness of services, there was no potential or actual harm to the patient. Petitioner pointed out that the patient had a 24-hour care giver at the time of her admission to Petitioner, and Petitioner's skilled nurse visited the patient on nearly a daily basis from the SOC date of August 10 until the patient's discharge on September 10, with 29 visits in a one-month period. P. Ex 1, at 3; HCFA Ex. 9, at 8.

In assessing the parties' arguments, I begin by agreeing with Petitioner that 42 C.F.R. § 484.18 does not specifically impose a timeliness requirement as to the start of care. The regulation, however, can reasonably be construed to mean that care to be provided in a patient's residence, rather than at another location, will be done within a period of time that will not jeopardize the patient's care. When a physician writes an order for a home health agency to perform services, it reasonably can be inferred that the physician expects the home health agency to provide those services in an expeditious manner. Thus, any argument that focuses on the lack of consistency in the testimony of the State surveyor Ms. Sabino and Ms. Patience, as to the exact period of time that the provision of services should commence, begs the question that a home health agency in the business of providing home care should know that the care has to be started timely in order that the patient's health and safety not be compromised. I do not find that there is a specific need for HCFA to publish such a standard on timeliness.

The issues, then, in the absence of any published interpretation of timeliness by HCFA are whether it reasonably can be inferred from 42 C.F.R. § 484.18 that a home health agency must provide services timely after the SOC date, and whether that timeliness can be measured by either a standard in the industry or the home health agency's own policies.

HCFA has failed to provide any cogent argument as to what standard I should apply in determining whether the service was timely. HCFA does not state what the standard is in the industry (assuming that there is such a standard in the industry). Petitioner argued that neither of the timeliness standards advanced by HCFA's witnesses reflected standards within the home health agency industry. Petitioner failed, however, to state what that standard is (unless I assume that Petitioner's own policy is reflective of the industry standard).

As discussed above, HCFA's witness, Ruth Patience, stated that most home health agencies have policies requiring that services be provided within 72 hours after being ordered. Tr. at 489. (Although Ms. Patience also stated that HCFA would question the timeliness of services provided beyond four to five days after a physician's orders. Tr. at 490.) That statement alone, however, does not establish a standard in the industry. Rather, HCFA falls back on Petitioner's own policy of providing services within 48 hours and HCFA's interpretation of that policy to mean calendar days rather than work days.

Petitioner's policy, as dated October 10, 1990 and December 1993, states the action to be taken in response to all referrals as:

> If ordered, visit patient for initial evaluation within twenty four (24) hours (RN, PT) forty-eight (48) hours (SLP) of referral or discharge (if inpatient) or the following Monday, if patient discharged on a weekend. . . .

P. Ex. 11, at 2.

Thus, physical therapy services were to be provided within 48 hours, but this document is not clear on its face whether the 48-hour period refers to calendar days or working days. At the hearing, however, Petitioner's Director of Nurses, Colleen Collar, testified that the policy referred to working days. Tr. at 710. In the absence of any evidence to the contrary from HCFA, I accept Petitioner's declaration that its policy referred to working days.

I conclude that a fair reading of the regulation is that care must be rendered timely after it is ordered, but determining what is timely depends on the nature of the care ordered and the status of the patient. I accept Petitioner's version of events regarding this patient, i.e., the date from which the timeliness of the physical therapy evaluation should be measured is not the SOC date of August 10, but the August 15 date when the physician ordered the physical therapy evaluation. The regulation at 42 C.F.R. § 484.18(c) provides that " . . . treatments are administered by agency staff only as ordered by the physician." Since the physical therapy evaluation was not ordered by a physician until August 15, HCFA's position that the services were provided nine days late (on August 19) is baseless. In the absence of a physician's order, the physical therapy evaluation could not have been performed any earlier than August 15. The question then is whether the provision of the physical therapy evaluation four days after the physician's order violates the timeliness implied in 42 C.F.R. § 484.18. August 15, 1996, was a Thursday. Thus, under Petitioner's policy that services be provided within 48 hours and Petitioner's unrebutted declaration that the 48 hours referred to working days and not calendar days, the physical therapy evaluation for this patient should have been performed no later than the following Monday, August 19, 1996, the date on which the parties agree that the service was indeed rendered. Thus, under <u>either</u> Petitioner's own policy or HCFA's position, as stated by Ms. Patience, that services provided beyond four to five days after an order would raise a question of timeliness, the physical therapy evaluation for this patient was not untimely.

In any event, I do not find that a delay, if there was one in this case, was meaningful with regard to this patient. There is no showing by HCFA that suggests either a potential for or actual

harm to this patient. The patient was seen by the skilled nurse on the SOC date, the need for a physical therapy evaluation was determined, the physician was contacted on the next working day, there was a three-day delay caused by the physician not calling Petitioner back, with the service not being given until August 19. The patient then received physical therapy on August 22 and 27, and no further physical therapy visits were needed.

Consequently, for this patient, I cannot find that proof of a delay, if there was one in this case, establishes that Petitioner's capacity to furnish adequate care has been substantially diminished or that such a delay demonstrated an adverse affect on the health and safety of this patient.

Patient 7

The surveyors made the following assertions concerning the care Petitioner gave to Patient 7:

> Patient #7 had a start of care dated 8/21/96 with post total hip replacement. The plan of care cited that the patient would receive home health aid services; however, the patient did not receive home health aid services until 8/26/96. There was no documentation in the clinical record explaining why the service was delayed.

HCFA Ex. 2, at 9.

Patient 7 had a total hip replacement on July 20, 1996, and further surgery to close a dislocated hip on July 29, 1996. HCFA Ex. 11, at 8.

At the hearing, State surveyor Sabino testified that this patient's POC, dated August 21, 1996, indicated that the patient would receive home health services two times a week for four weeks to perform the following services: complete bed bath, personal care, oral hygiene, shampoo, foot care, assist with ambulation and front wheel walker, assist with transfers, and report to the nursing supervisor any decreased mobility, skin breakdown, and increases in pain. HCFA Ex. 11, at 9; Tr. at 77 - 78. Ms. Sabino testified that these certified home health aide (CHHA) services were to begin within 48 to 72 hours from August 21 POC, but did not actually start until August 26, 1996. Tr. at 78; HCFA Ex. 11, at 24. Petitioner's delay in providing CHHA services was the basis for the deficiency cited for this patient.

In addition to the same general legal arguments it made in regard to Patient 5 concerning the timeliness of services, discussed above, Petitioner argued that it provided the CHHA services in a timely fashion. Petitioner noted that with the CHHA services provided on August 26, five days from the SOC date, it met the standard enunciated by Ms. Patience that services should be

provided within four-to-five days. Petitioner further alleged that under 42 C.F.R. § 484.30 a skilled service professional such as a registered nurse or a physical therapist must first open a case before unskilled service providers such as CHHA services may visit a patient.

Petitioner's Director of Nurses, Ms. Collar, described the process for procuring CHHA services, with the skilled service professional who opened the case completing the CHHA POC, also known as the CHHA Plan/485 Worksheet. Tr. at 682 - 83.

Petitioner asserted that the following sequence of events occurred with this patient: on August 21 (a Wednesday) a physical therapist evaluated the patient, with the patient scheduled to see a physician on August 22 (P. Ex. 2, at 4; Tr. at 745); on August 23 the physical therapist again saw the patient (P. Ex. 2, at 5) and the skilled nurse completed the CHHA Plan/485 Worksheet and assigned a CHHA to the case (P. Ex. 2, at 15; Tr. at 1308); and, on August 24, an occupational therapist performed an evaluation visit (P. Ex. 2, at 12 - 13; Tr. at 747). Petitioner argued that on August 26 (a Monday) the CHHA visited the patient as soon as practicable, given the number of skilled services visiting and evaluating the patient (P. Ex. 2, at 16; Tr. at 746).

Furthermore, Petitioner contended that there was no dispute that it met the patient's needs here. Recovering from hip surgery, the patient primarily required physical and occupational therapy, with the physical therapy goals met by September 12 and the occupational therapy requiring only one visit. P. Ex. 2, at 11 and 12 - 13. Additionally, Petitioner argued that, even if there could be considered a delay in the provision of CHHA services, as the patient had a spouse assisting her at home and could perform basic grooming tasks for herself, there was no evidence of actual harm or a potential for harm because the CHHA visits were not begun until August 26.

Once again, as with Patient 5 discussed above, I have no evidence as to what the industry standard is for the timeliness of CHHA services. The only evidence I have before me is Petitioner's own policy which states, in regard to CHHA services, that the home health aide is to "visit patient within forty-eight (48) hours of referral, unless otherwise specified." P. Ex. 11, at 2.

Here, the 485 Worksheet calling for CHHA services was not completed by the skilled nurse until August 23, a Friday. The rendering of the CHHA services on the following Monday would therefore appear to place the services within the 48 working hours set forth in Petitioner's policy. Yet there has been testimony here that the physical therapist who opens a case has the authority to complete a 485 Worksheet. Tr. at 682 - 83.

Petitioner's physical therapist visited this patient on August 21. If the physical therapist had completed the 485 Worksheet, CHHA services should have been provided under Petitioner's policy no later than August 23. Petitioner provided no explanation why its physical therapist failed to perform this responsibility.

On this point, I find the testimony of Petitioner's Director of Nurses particularly relevant. In response to my questions at the hearing, Ms. Collar, in reviewing the physical therapist's August 21 evaluation of the patient (P. Ex. 2, at 4), stated that there was no mention that the physical therapist made a determination of the need for CHHA services. Tr. at 764. Yet on the August 19, 1996 physician's referral of this patient to Petitioner, there were explicit orders for home health aide services. HCFA Ex. 11, at 6. Ms. Collar agreed that when the physical therapist evaluated the patient on August 21, the therapist was aware of the fact that the patient needed CHHA services. Tr. at 766. Ms. Collar could offer no explanation why the 485 Worksheet was not prepared until August 23. Id. She agreed that there was a delay and that the preparation of the 485 Worksheet should have been done on August 21. Tr. at 766 - 67. Ms. Collar testified that the other visits the patient was receiving were extenuating circumstances that justified the delay. Tr. at 767. Ms. Collar admitted, however, that there was no documentation in the record for the delay, even though Petitioner's policy called for some type of written communication to explain a delay. Id. Furthermore, I do not accept any inference that the CHHA could not deliver services while other employees of Petitioner were delivering skilled services. There is no basis for this conclusion. Skilled and unskilled services could be delivered on the same day, unless there is an indication in the clinical record demonstrating that the delivery of two or more services in one day might be injurious to the patient. Ms. Collar testified that there was nothing in Petitioner's procedures that prevented a CHHA from visiting a patient on the same day another service was scheduled. Tr. at 760 - 61.

I therefore find that Petitioner has failed to prove by a preponderance of the evidence that there is justification for the delay of CHHA services from August 23 to August 26. Petitioner did not follow its own policy for the delivery of services within 48 hours, and there is no contemporaneous documentation justifying delay. Ms. Collar's testimony to justify the delay on the basis that the patient was receiving other services is a post-event rationale that does warrant any weight, especially in light of Ms. Collar's earlier testimony that different services could be performed on the same day. Furthermore, given that the August 19 physician's order explicitly called for home health aide services ("bath aid"), there was the potential for harm for this patient if she attempted to bathe without assistance. Moreover, the patient's physician issued the order for CHHA service with the expectation that it would be delivered timely.

Petitioner's failure to adhere to its own policy on the delivering of care places some doubt as to whether the physician's orders can be properly carried out and creates question as to its ability to provide adequate care to its patients.

Accordingly, I sustain HCFA's determination of a deficiency here regarding the delay in the provision of CHHA services to Patient 7.

Patient 8

The surveyors made the following assertions concerning the care Petitioner gave to Patient 8:

> Patient #8's clinical record contained a supplemental physician's order on 8/1/96 for medical social work services to evaluate the patient's safety and need for hired care in the home. However, the patient was not visited by a medical social worker until 8/9/96. There was no documentation in the clinical record explaining why the service was delayed.

HCFA Ex. 2, at 9.

At the hearing, State surveyor Sabino testified from her notes that there was a supplemental physician's order dated August 1, 1996, for medical social work (MSW) services to evaluate the patient's safety and the need for hired care in the home. Tr. at 191; HCFA Ex. 12, at 3. Ms. Sabino testified that the patient's nursing assessment indicated that the patient was forgetful and non-compliant in taking her medication, necessitating a MSW evaluation. Tr. at 192; HCFA Ex. 12, at 12. The MSW services, however, were not provided until August 9, 1996. HCFA Ex. 12, at 19. Ms. Sabino again testified that this constituted a delay in the provision of MSW services, because the services were not rendered within 48 to 72 hours, and that this was the basis for the deficiency citation for this patient. Tr. at 193.

In addition to the general arguments Petitioner made with regard to patient 5 concerning the timeliness of services, discussed above, Petitioner contended here that the MSW services were provided on a timely basis and met the patient's needs. Petitioner argued that its skilled nurse had determined that this patient needed assistance with her medications and that the skilled nurse had been assisting the patient in the use of a medication box.[4] P. Ex. 3, at 4, 5, 6, 6a and 9; Tr. at 776. Petitioner further explained that a friend of the patient was helping the patient with her medications and the fact that this

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[4] The medication box organizes the medications to be taken by day and hour.

friend was going to be leaving town prompted the skilled nurse to seek a MSW evaluation. P. Ex. 3, at 5 and 6a; Tr. at 776. The request for a MSW order was made on August 1. P. Ex. 3, at 15. According to Petitioner, the skilled nurse did not consider this a problem in which the patient was in any real danger, because the nurse noted on August 2 that the patient was not in need of adult protective services. P. Ex. 3, at 10; Tr. at 777. Additionally, the patient previously had negative experiences with MSW services. Tr. at 795. Petitioner argued that these factors led the skilled nurse to believe that there was no need to expedite the MSW services any faster than Petitioner's own policy of a social worker visiting a patient within a week of an order.

Janet Derderian, a licensed clinical social worker, provided social services for this patient as an independent contractor for Petitioner. At the hearing, Ms. Derderian testified that a telefacsimile of a physician's order directing a MSW evaluation of this patient was received in her office at 3:55 p.m. on August 7, 1996. Tr. at 790. Ms. Derderian testified that she called the patient on the following day, August 8, and that she was prepared to visit the patient on that day. Tr. at 791, 793 - 94. Ms. Derderian testified that the patient told her that it would be inconvenient for Ms. Derderian to make a site visit that day as the patient's attorney was coming to the patient's house. Tr. at 791, 794; P. Ex. 3, at 17. Ms. Derderian testified that she then scheduled a visit for the afternoon of the next day, August 9. Tr. at 791. Ms. Derderian further testified that she believed that the patient had the right to decline to accept the MSW intervention on August 8. Tr. at 796 - 97. Ms. Derderian testified that it was common for home health patients to refuse a visit on a date that Ms. Derderian wanted to schedule it, and that she would always document this. Tr. at 809 - 10.

Additionally, Petitioner argued that, even if there was a technical deficiency in the timeliness of the provision of MSW services, this deficiency did not cause any potential or actual harm to the patient. Petitioner noted that the patient was discharged on September 13, with the goal of "Medication Schedule/Purpose" successfully met. P. Ex. 3, at 13.

Again, in the absence of any evidence concerning standards of timeliness in the home health care industry, I am evaluating this alleged deficiency by Petitioner's own policy. Petitioner's policy directs that social services should "[v]isit patient within one (1) week of referral unless otherwise specified." P. Ex. 11, at 2. It is apparent that the one week refers to seven calendar days and not seven working days. Ms. Derderian testified that it was her understanding that she was required to see a patient within five working days and to make contact with a patient within 48 hours of a referral. Tr. at 793.

Arguably then, the MSW services should have been provided no later than August 8, seven days after the physician's supplemental order. I have in this particular case, however, a patient who, in effect, denied Petitioner the ability to comply with its own policy. Ms. Derderian testified persuasively that she attempted to visit the patient on August 8, but was rebuffed by the patient because of the patient's prior commitment to meet with her attorney that day. There has been no explanation as to why Petitioner's staff did not send the MSW referral to Ms. Derderian until August 7, but the fact remains that Petitioner's policy on timeliness would have been met save for the patient's objection to receiving Ms. Derderian on August 8.

I therefore find that while there was a one-day delay in providing MSW services to Patient 8, the delay in the provision of services was due to the patient rather than to Petitioner. Moreover, there has been no showing of actual or potential harm to the patient resulting from the delay or any showing that the patient's needs were not met. The frequent visits by the skilled nurse and the patient's friend were efforts to ensure that the patient was taking her medications properly.

Consequently, for this patient, I cannot find that proof of a delay establishes that Petitioner's capacity to furnish adequate care is substantially diminished or that such a delay demonstrates any adverse affect on the health and safety of this patient.

G 158 484.18 Standard: Care follows a written plan of care established and periodically reviewed by a doctor of medicine, osteopathy, or podiatric medicine.

Based on a clinical record review, the surveyors determined that for six of nine sampled patients (Patients 1, 3, 5, 6, 7, and 8), Petitioner failed to ensure that care followed the written plan of care. HCFA argued that this established a pattern of noncompliance which demonstrates that the requirements of section 488.24(b) have been met, thus establishing that this condition is out of compliance.

2. For Patients 3, 5, 6, and 8, Petitioner has failed to show by a preponderance of the evidence that the services which were provided were in accord with the written plan of care and authorized by the patients' physicians. Such failures had the potential to cause an adverse affect on the health and safety of these patients. For Patient 1, Petitioner has failed to show by a preponderance of the evidence that the use of a Combiderm dressing on the patient's wound was authorized by the patient's physician. Also, for Patient 1, Petitioner has shown by a preponderance of the evidence that the use of Comfeel powder on the patient's wound was a one-time inadvertent occurrence that did not have the potential to cause any harm to the patient. For

Patient 7, Petitioner has established by a preponderance of the evidence that the care provided was in accord with the plan of care and authorized by the patient's physician. To the extent that there was any error, it was a harmless documentation error, but the "foot care" was provided as contemplated in the plan of care.

Patient 1

The surveyors made the following assertions concerning the care Petitioner gave to Patient 1:[5]

> b. On 6/28/96, a supplemental physician's order was written to cover the wound of Patient #1 with "comfeel" dressing. Review of the skilled nurse's notes dated 7/5/96 revealed that the wound was covered with "combiderm" instead of the ordered "comfeel" dressing. There was no documentation that the physician had changed the treatment order.
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> c. On 8/2/96, a supplemental physician's order was written to continue using "comfeel paste" to patient's decubitus. Review of the skilled nurse's notes dated 8/7/96 revealed that "comfeel powder" was used instead of "comfeel paste". There was no documentation that the physician had changed the treatment order.

HCFA Ex. 2, at 10.

b. Patient 1 had a decubitus ulcer on her coccyx. A supplemental order dated June 28, 1996, directed that this would be covered with "comfeel" dressing. The skilled nurse, however, on a July 5, 1996 visit, changed the cover dressing to "combiderm" which, according to the nurse's notes, "is more absorbent" and "may be able to reduce dressing changes to 2x/wk if [the dressing] stays in place well." HCFA Ex. 5, at 49. The State surveyor testified that there was no indication in the record that there was a physician's order to change the type of dressing. Tr. at 212 - 13.

Petitioner admitted that its Enterostomal Therapy[6] (ET) nurse initiated a one-time trial of Combiderm in place of Comfeel and failed to obtain a physician's order for the change. P. Br. at 35. Petitioner alleged, however, that there was no potential or actual harmful effect on the patient's wound healing from this

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[5] Another alleged deficiency involving Patient 1 appearing on the HCFA Form 2567, cited as 1.a. under Tag G 158, was withdrawn by HCFA at the hearing held in this case. Tr. at 212.

[6] An Enterostomal Therapy nurse specializes in ostomy care, wound care, and incontinence care. Tr. at 1437.

change. Petitioner bases this claim on the fact that the active ingredient in the two dressings is the same, both being hydrocolloid dressings. P. Ex. 17. The ET nurse testified that both dressings provide the same type of healing environment, with the only difference being that Combiderm was a newer product with an added absorbent pad. Tr. at 1448 - 49. The ET nurse added that the names of the dressings are different because they are brand names to different companies' versions of hydrocolloid dressing. Tr. at 1450. The ET nurse testified that she applied a Combiderm dressing to the patient once to see if the Combiderm dressing was more efficient in absorbing wound drainage. Tr. at 1451 - 52. The ET nurse testified that the Combiderm dressing had absorbed the drainage better, but that the dressing lifted along the edges, so that the dressing was changed back to Comfeel. Tr. at 1453. The ET nurse testified that there was no impact on the patient from the one-time change of dressing, with no potential for harm to the patient. Tr. at 1459 - 60. The ET nurse further testified that it was common practice among ET nurses to make changes in wound treatment that they considered necessary and then to contact a physician to obtain a signed order. Tr. at 1461 - 63.

Petitioner concluded that this was merely an "inadvertent error" in failing to obtain a physician's order for the one-time trial of Combiderm that should not be used as a basis for a condition-level deficiency. P. Br. at 38.

The regulations governing home health agencies participation in the Medicare program specifically provide under conditions of participation that "[d]rugs and treatments are administered by agency staff only as ordered by the physician." 42 C.F.R. § 484.16(c). Here, the treatment ordered by a physician, which included the use of Comfeel dressing, was unilaterally changed by one of Petitioner's employees. Petitioner's argument that it was common practice among ET nurses to make such changes without first consulting a physician is refuted by the ET nurse's own admission that, "legally," there should have been a physician's order for the one-time use of Combiderm. Tr. at 1456. It is evident that the ET nurse changed the dressing on a trial basis without discussing the change with the physician. Thus, even if Petitioner is correct as to the standard among ET nurses, the ET nurse did not follow that here, as there is no documentation in the record that she ever discussed the change in dressing with the physician.

It is unclear from the record and the testimony at the hearing why the skilled nurse changed the dressing back to Comfeel; presumably, it was because the experiment with Combiderm was unsuccessful. A change in dressing or treatment by a nurse without getting authorization is a significant violation, not merely a technicality. The regulation is clear on its face and the ET nurse admitted that she violated it by not getting an

authorization for the change. No nurse, not even an ET nurse consultant, can initiate experimental treatment on a patient without authorization. There was no "inadvertent error" here, as alleged by Petitioner; rather, the ET nurse made a conscious decision to make the change in the dressing without getting authorization from the physician. There is an established procedure for initiating such a change, but the ET nurse did not follow that procedure here.

The purpose of such regulation is obvious. Provision of medical treatment by home health agency personnel without the authorization by the treating physician could potentially compromise the patient's health and safety. Agency staff can suggest treatment changes but cannot undertake them until authorized by the physician. The physician is charged with the care of the patient. Agency personnel only carry out the physician's directed treatment. To allow agency staff to initiate their own care would place patients in jeopardy. A strict standard of liability applies in such circumstances.

Thus, although I accept Petitioner's argument that there was no potential for harm in this case, I nevertheless find that the use of Combiderm on Patient 1's wound without authorization by a physician constituted a deficiency in Petitioner's provision of care to the patient, with a possible adverse affect on the health and safety of the patient.

c. This alleged deficiency again concerns the treatment of Patient 1's decubitus ulcer, with the nurse applying Comfeel powder to the patient's wound on August 7, 1996, when the physician's August 2, 1996 supplemental order directed that Comfeel paste continue to be used on the wound. The State surveyor testified that there was no physician's order for a change to Comfeel powder. Tr. at 224.

Petitioner maintained that the one-time use of powder instead of paste was an inadvertent error by the skilled nurse which had absolutely no potential or actual detrimental effect on the patient. The ET nurse testified that both the paste and the powder are wound fillers, with no medication in either product, the only difference being the ease of application of their use. Tr. at 1474 - 76. The ET nurse could give no explanation why the skilled nurse applied the powder, but stated that it did not harm the patient or delay the healing of the wound. Tr. at 1479 - 80.

Petitioner argued that when the skilled nurse on August 7, 1996, documented that she applied powder instead of paste, that was either a documentation error (applied paste, but wrote powder), or an inadvertent error in application of the compound (picked up the powder instead of the paste). P. Br. at 39 - 40. Petitioner noted that of the 48 visits to this patient reviewed by the surveyors, this was the only incident where an incorrect Comfeel

compound was used. Petitioner maintained that its processes were not at fault in this incident and that, therefore, there is no basis for using this deficiency as the basis for a condition-level deficiency.

Unlike the use of the Combiderm dressing, I am more willing to accept Petitioner's explanation for the one-time use of the powder on the patient's wound. Here there does not appear to have been any conscious effort on the part of Petitioner's staff to change a physician's order, as there was in the use of the Combiderm dressing. The one-time use of Comfeel powder rather than paste appears to have been an isolated, inadvertent event. Moreover, HCFA has failed to provide any credible evidence that use of the Comfeel powder rather than the paste placed the patient's health and safety in jeopardy, either actually or potentially.

Consequently, I reject HCFA's argument that the use of the Comfeel powder should be considered the same type of violation as the Combiderm dressing. The latter was a deliberate experimentation, while the former was a one-time inadvertent use. I therefore find that the one-time use of Comfeel powder on Patient 1's wound should not be considered a factor in whether a condition-level deficiency existed.

Patient 3

The surveyors made the following assertions concerning the care Petitioner gave to Patient 3:

> a. Patient #3 had a start of care dated 6/29/96. During the initial evaluation on 6/29/96, the skilled nurse documented that instruction was given regarding use of upper extremity splint and sling. On 7/3/96, the skilled nurse documented that the patient was instructed to wear splint/sling to support the right arm/hand. However, review of the plan of care dated 6/29/96 revealed no physician's order for the use of a splint or sling.
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> b. On 8/5/96, a supplemental physician's order was written that physical therapy services would be continued two times per week for four weeks. On the week of 8/11 to 8/17/96, the patient received three physical therapy visits instead of the two visits. There was no documentation that the physician had changed the order.

HCFA Ex. 2, at 10 - 11.

a. Patient 3 had suffered multiple strokes in 1995 and had paralysis of the right arm and weakness of the right leg. Tr. at 1275. During the initial visit by Petitioner's skilled nurse on June 29, 1996, the nurse gave the patient instructions on the use

of an upper extremity splint and sling. HCFA Ex. 7, at 15. On July 3, 1996, the skilled nurse visited the patient and instructed the patient to "wear splint/sling to support [right] arm/hand." P. Ex. 5, at 12. The POC dated June 29, 1996, had no mention of a sling or a splint. HCFA Ex. 7, at 12.

The State surveyor, Lily Martinez, testified that there was "no guidance from the physician" in the POC about the sling/splint, what it was for, how long the patient was to wear it, or whether it could be removed. Tr. at 310. The surveyor testified that her concern was that the nurse, without guidance from a physician, might be providing inappropriate instructions to the patient. Tr. at 310 and 313. Ms. Martinez stated that the basis for this deficiency was the nurse's failure to follow the POC. Tr. at 313.

HCFA's Nurse Consultant, Ruth Patience, testified that anything a home health agency is going to provide instructions for must be based on a physician's order. Tr. at 506. Ms. Patience testified that a splint or a sling is a device intended to immobilize, and a nurse would need to know how a physician wanted a patient to wear such a device and for what period of time. Id.

Petitioner made the following arguments in response: 1) instructions were only provided to the patient on the use of a canvas arm sling, not a splint; 2) since instructions regarding the sling for the patient fall within the nursing scope of practice, no specific physician's order is required, and, therefore, there is no violation of the standard; 3) such instructions fall within the general physician's orders to assess and instruct the patient in home safety; and 4) such instructions are beneficial to the patient and do not constitute a basis for a condition-level deficiency, because there is no actual or potential harm to the patient.

The patient's physician, Dr. Jeffrey Punim, testified that he had been treating the patient since 1994. Tr. at 1190. Dr. Punim testified that this patient, after her second stroke, had no use whatsoever of her right arm, that the arm would hang limply at her side if it were not supported, and that the patient would use her left hand to support her right arm. Tr. at 1194. Dr. Punim testified that the arm sling was used to free up the patient's left hand for other activities. Id. Dr. Punim testified that the patient had no control over her right arm and that it would swing and bang into objects as she walked. Tr. at 1195. Dr. Punim further testified that the purpose of the sling was to prevent injury to the patient and to prevent bleeding when the arm struck objects (the patient was taking the medication Coumadin, an anticoagulant). Tr. at 1195 - 96. Dr. Punim also testified that he had seen the patient wearing the sling and that it was his understanding that the patient was instructed in the use of the sling while she was hospitalized in 1995. Tr. at

1196. Dr. Punim testified that he had no knowledge about the patient wearing a splint, and that he never ordered a sling or a splint for the patient and never authorized anyone to provide instruction on a sling or a splint to the patient. Tr. at 1197 and 1213. Dr. Punim further testified that teaching a patient on the use of a sling was within the scope of the practice of nursing. Tr. at 1201. Dr. Punim stated that he would not have expected a nurse to telephone him for an order for a sling. Id.

The nurse who attended this patient, Janet Smith-Scott, testified that the patient had right-sided paralysis of the right upper extremity such that the patient had no purposeful movement or sensation in her arm. Tr. at 1275. Ms. Smith-Scott testified that when she visited the patient on June 29, the patient had an arm sling to support her right upper extremity. Tr. at 1278. Ms. Smith-Scott stated that the patient was not wearing the sling when she visited, but rather the sling was on a chair. Tr. 1281 - 82. The nurse further testified that she assumed the patient got the sling at a rehabilitation facility following the patient's stroke. Tr. 1278 - 79. The nurse stated that the patient did not have a splint, but only a sling which acted as a splint, in that it kept the patient's upper arm from bending and moving. Tr. at 1279 - 80. Ms. Smith-Scott testified that the purpose of the instructions she gave the patient was to reinforce what the patient had been taught at the rehabilitation facility. Tr. at 1281. The nurse further testified that she believed her instructions on the use of the sling were included in the physician's order to provide basic instruction in home safety, but that Dr. Punim did not give any specific orders to give instructions about the sling. Tr. at 1287 and 1290. Ms. Smith-Scott stated that, as the sling was a piece of equipment the patient received in her rehabilitation stay, a new order from the physician was not necessary. Tr. at 1296.

It is clear that the device used by this patient was more than a simple canvas sling. As this device was used to immobilize the patient's right upper extremity, the use of the term splint to help describe the device was appropriate. I do not find the testimony of the physician or the nurse to be particularly credible, as both have a motive to justify their own actions. The device worn by this patient should have been included in the POC and no instructions on its use should have been given without authorization. When the nurse first noticed the patient wearing the sling, the prudent course would have been for her to check with Dr. Punim to see if the use of the sling was appropriate and, if so, what instructions should be given to the patient about the use of the sling. Instead, the nurse relied on the supposition that the patient had received the device at a rehabilitation facility. The nurse had no independent knowledge of the circumstances under which the patient was to wear the device.

While no actual harm has been shown, the potential for harm existed here. More importantly, this deficiency raises a serious question about Petitioner's ability to provide adequate care to its patients since this circumstance provides another indicia of its personnel to provide care not authorized by the physician. Patients cannot be adequately treated when care givers substitute their judgment for that of the patient's physician.

I therefore find that the instructions provided by Petitioner's nurse on the use of a splint/sling that was not mentioned in the POC constituted a deficiency in Petitioner's provision of care to this patient because there was a potential adverse affect on the patient's health and safety.

b. The June 26, 1996 POC for Patient 3 called for the patient to receive physical therapy three times a week for four weeks. P. Ex. 5, at 1. On August 5, 1996, a supplemental physician's order directed that physical therapy services were to be continued for four weeks, with two visits per week. HCFA Ex. 7, at 6. During the week of August 11 to August 17, 1996, however, the patient received three physical therapy visits: August 12 (P. Ex. 5, at 5); August 14 (P. Ex. 5, at 6); and August 16 (P. Ex. 5, at 7).

According to the State surveyor, only the physician can decide whether a patient should have more physical therapy, there being the danger that the patient may be over-worked by additional physical therapy sessions. Tr. at 319. The surveyor testified that, even if Patient 3 had in fact fallen, it was still necessary for the therapist to obtain a physician's order for an additional visit. Tr. at 322.

Petitioner argued that the extra visit caused no potential or actual harm to the patient and actually benefitted the patient. The physical therapist explained that on the morning of August 12, a regularly scheduled visit, he learned that the patient had fallen the night before. Tr. at 1167. The physical therapist stated that he scheduled a third visit on August 16, because he believed that the patient needed reinforcement of safety skills, strength, and balance. Tr. at 1169. The physical therapist testified that there was no danger to the patient from the extra visit, as the patient had previously tolerated a regimen of three physical therapy sessions a week. Tr. at 1179 - 80.

Furthermore, Petitioner stated that it did not bill the patient or Medicare for the additional visit, recognizing that it was provided without a physician's order, so that neither Petitioner nor the physical therapist benefitted from the extra visit, only the patient. Petitioner concluded that since HCFA failed to present any evidence that there was actual or potential harm to the patient as a result of the extra visit, this alleged deficiency should not be used as a basis for a condition-level deficiency.

The issue of treatment authorization should be construed strictly. The clear intent of the regulations is that care be given only under the orders of a physician. There is no provision in the regulations for non-physician care givers to provide unauthorized care or services. Even though in this particular case for this patient, there may have been good intentions on the part of the physical therapist and a favorable outcome, there was still the potential for an adverse effect on the patient. The patient's physician should have been consulted before the third visit was undertaken.

The physical therapist himself admitted at the hearing that, in retrospect, he should have gotten a physician's order for the third visit. Tr. at 1172. Moreover, in response to general questions about the need for a home health agency to provide all the visits ordered by a physician in a plan of care, Petitioner's Director of Nursing agreed that if a skilled nurse or physical therapist felt that a patient needed an extra visit, that person needed to get an order for that visit from a physician, and that a physical therapist is not authorized to schedule and perform a visit on his own initiative without a physician's order. Tr. at 673.

It is of no consequence to this deficiency that Petitioner did not charge for the unauthorized visit. If anything, the fact that there was no charge for the unauthorized visit indicates that Petitioner was aware of the questionable nature of its provision.

I therefore find that the provision of an unauthorized physical therapy visit to Patient 3 was not in accord with the patient's plan of care and was, therefore, a deficiency.

Patient 5

The surveyors made the following assertions concerning the care Petitioner gave to Patient 5:[7]

> a. The plan of care for Patient #5 dated 8/10/96 cited that the skilled nurse would perform wound care to the patient's left leg by cleansing with hydrogen peroxide 3%, dry, apply dry sterile dressing, then tape. Review of the skilled nurse's notes on 8/14/96, revealed documentation that "wound care with H2O2/NS (hydrogen peroxide/normal saline) covered with NS gauze W-D (wet to dry)" was provided. There was no documentation that the physician had changed the treatment order.

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[7] Another alleged deficiency involving Patient 5 appearing on HCFA Form 2567, cited as 3.b. under Tag G 158, was withdrawn by HCFA at the hearing held in this case. Tr. at 242.

> On 8/15/96, a supplemental physician's order was written to irrigate the wound with hydrogen peroxide solution, pack with nugauze, and cover with dry sterile dressing. On 8/21/96, the skilled nurse documented that the wound was irrigated with hydrogen peroxide and normal saline (½ and ½). On 8/22/96, the skilled nurse documented that the wound was irrigated with hydrogen peroxide and normal saline mix. There was no documentation that the physician had changed the treatment order.

HCFA Ex. 2, at 11 - 12.

Patient 5 had an incisional wound on her thigh following heart surgery and was referred to home health care for wound care. HCFA Ex. 9, at 9. An August 10, 1996 POC directed that the wound be cleaned with a three percent solution of hydrogen peroxide and be covered with a dry dressing. HCFA Ex. 9, at 11. A supplemental physician's order on August 15, 1996, directed that the wound be cleaned with a hydrogen peroxide solution. Upon reviewing the nursing progress notes for this patient, the State surveyor determined that on three occasions Petitioner's skilled nurses did not follow the physician's orders for the treatment of the wound: on August 14, the skilled nurse cleansed the wound with hydrogen peroxide and normal saline and covered the wound with a wet-to-dry dressing rather than a dry dressing (HCFA Ex. 9, at 27); on August 21, the skilled nurse irrigated the wound with hydrogen peroxide and normal saline (HCFA Ex. 9, at 21); and on August 22, again the skilled nurse used hydrogen peroxide and normal saline to irrigate the wound (HCFA Ex. 9, at 20).

The State surveyor, Ms. Sabino, testified that the basis for the deficiency was that Petitioner was providing treatment to the patient not in accordance with the plan of care. Tr. at 238. The surveyor testified that the hydrogen peroxide solution ordered in the supplemental physician's order is the same as the three percent hydrogen peroxide solution ordered in the original physician's order. Tr. at 236. The surveyor further testified that hydrogen peroxide with normal saline is a dilution of the hydrogen peroxide solution. Id.

Petitioner admitted that on three occasions the skilled nurses diluted the hydrogen peroxide with some amount of normal saline. P. Br. at 52 - 53. Petitioner argued, however, that, although the wound care provided by the skilled nurse deviated slightly from the physician's orders, these were inadvertent errors by individual skilled nurses and that there was no potential or actual harm to the patient due to these errors. Petitioner offered the testimony of a physician who stated that there would be no delay in the cleansing of the wound by using hydrogen peroxide with normal saline and that using a wet-to-dry dressing would have no different effect on the wound than a dry gauze dressing. Tr. at 866, 870. The ET nurse confirmed that the

dilution of hydrogen peroxide with normal saline and the change in dressing would have no detrimental effect on the wound. Tr. at 1495 - 96. Petitioner maintained that these harmless inadvertent errors should not be used as a basis for a condition-level deficiency.

As discussed above in regard to Patient 3, the issue of treatment authorization should be construed strictly because of the clear potential for harm where care givers apply treatment not authorized by a physician. The fact that in this instance there was no actual harm, or arguably no potential harm arising from the use of a different solution of hydrogen peroxide or different type of dressing, does not diminish the overall concern that unauthorized care can be potentially and actually harmful to a patient. The regulations at 42 C.F.R. § 484.16 are clear in stating that treatments are to be administered by home health agency staff "only as ordered by the physician." There is no exception in the regulations giving a non-physician the discretion to alter the treatment if such a change will not result in actual harm to the patient. Petitioner's arguments that the patient suffered no harm from the unauthorized changes in treatment is an after-the-fact justification that ignores the clear import of the regulations, that communication with the physician is required concerning the change in treatment before the altered care is provided. A physician must be involved in any decision to alter the care and treatment of a patient unless, such alteration is of no meaningful significance. I am not willing to conclude that the dilution of the solution of the hydrogen peroxide ordered by the physician to irrigate and cleanse the patient's wound, or the change in the type of dressing, were insignificant alterations to the treatment ordered by the physician.

I therefore find that the use by Petitioner's skilled nurses of a different solution of hydrogen peroxide and of a different type of dressing than that specified in the patient's POC constituted a deficiency in Petitioner's provision of care to this patient, with a possible adverse affect on the patient's health and safety.

Patient 6

The surveyors made the following assertions concerning the care Petitioner gave to Patient 6:

> Patient #6 had a start of care dated 8/31/96. The plan of care indicated that the patient was on regular diet with fluid restriction 1500-2000 ml. in 24 hrs. The plan of care cited that the skilled nurse would instruct patient/care giver regarding diet. Review of the skilled nurses notes revealed no documented evidence that the patient or care giver were instructed regarding the fluid restrictions.

> During the home visit on 9/13/96, the skilled nurse was observed instructing the patient/care giver that the patient should drink one glass of water every hour. When the patient's spouse was interviewed regarding the patient's fluid intake, he responded that the patient "can drink as much as she wants."

HCFA Ex. 2, at 12 - 13.

Upon admission to Petitioner, Patient 6 suffered from multiple myeloma (a form of cancer), aplastic anemia, poor nutrition, nausea, and a urinary tract infection.

The State surveyor, Ms. Sabino, testified that the basis for the deficiency was that Petitioner's skilled nurse failed to follow the POC, in that the POC indicated that the patient was on a fluid restriction and that instructions were to be provided to the patient and her care giver regarding the patient's hydration. Tr. at 247. The State surveyor testified that this patient's POC stated under the heading of nutritional requirement that the patient was on a fluid restriction of 1500 to 2000 ml. in 24 hours. Tr. at 243 - 44; HCFA Ex. 10, at 8. Ms. Sabino testified that the POC directed the skilled nurse to assess and monitor the patient's nutrition and hydration, but that there was no documented evidence that the skilled nurse had ever instructed the patient on the subject of fluid restriction. Tr. at 244; HCFA Ex. 10, at 9. To the contrary, Ms. Sabino further testified that when she made a home visit to this patient she observed the skilled nurse instruct the patient to drink a glass of water every hour and the patient's care giver stated that the patient could drink as much water as she desired. Tr. at 244. Ms. Sabino further testified that this patient had a history of congestive heart failure and that excessive fluids in the patient's system makes the heart work more, so that monitoring of fluid intake is important. Tr. at 245. Ms. Sabino testified that a normal fluid intake for a healthy adult consists of eight glasses of eight ounces per day, or 1920 ml. of liquid per day. Tr. at 248 - 49. Ms. Sabino also testified that if there is any ambiguity or confusion in a POC the skilled nurse has the obligation to consult with the physician to resolve the ambiguity. Tr. at 262.

Petitioner argued that the POC contained a typographical error stating "fluid restriction" and that the physician intended that the patient, rather than be placed on a fluid restriction, be encouraged to drink fluids up to the normal daily fluid intake of 1500-2000 ml in 24 hours, and more, if possible. Petitioner disputed HCFA's contention that the patient was being treated for congestive heart failure, a condition which calls for fluid restriction. Rather, according to Petitioner, the patient was undergoing chemotherapy treatment and had a urinary tract infection, conditions that called for the patient to have at

least a normal fluid intake, if not more. Petitioner argued that the medication Petitioner was taking indicates that the patient was not suffering from any condition that called for fluid restriction. P. Ex. 25, at 1. Petitioner maintained that the patient received the care intended and ordered by the physician, and that, therefore, there is no basis for this deficiency. Petitioner contended that the original 485 Worksheet, which reflected the initial discussions between the patient's physician and Petitioner's staff regarding the care to be given to the patient, had, under the heading "Nutritional Requirements," a line marked for "encourage fluids" with the handwritten notation of 1500 - 2000 ml., and no marking at the "fluid restriction" line. P. Ex. 25, at 4. Petitioner argued that a clerk apparently miskeyed information on the patient's need for fluids into the computer, typing in the code for "fluid restriction" and then entering the fluid amount, "1500-2000."

Dr. Prakash Narian, Petitioner's Medical Director in 1996, testified, after reviewing this patient's medical records, that the patient was not being treated for congestive heart failure. Tr. at 893. Dr. Narian testified that normal fluid intake is 1800 to 2000 ml., with a fluid restriction being 1000 to 1200 ml. Tr. at 894. Dr. Narian concluded that, on his review of the patient's records, the patient did not require a fluid restriction, but, because of the patient's nausea and bladder infection, the patient needed adequate fluids daily. Tr. at 895. Dr. Narian further testified that he did not consider the notation on the patient's POC "FLUID RESTRICTION 1500-2000 ML IN 24 HRS" to be a fluid restriction, and that it would be appropriate for the skilled nurse to direct the patient to drink at least one glass of water an hour. Tr. at 896 - 97. Dr. Narian additionally testified that, from the 485 Worksheet for this patient (P. Ex. 25, at 4), the basis for the POC, the physician intended the nurse to encourage the patient to take 1500 to 2000 ml. of fluid daily. Tr. at 899. Dr. Narian testified that there was no actual or potential harm from the nurse directing this patient to drink one glass of water every hour. Tr. at 901.

Petitioner's Director of Nursing, Ms. Collar, testified on the relationship between the 485 Worksheet and the POC. According to Ms. Collar, the Worksheet is a summary of what the nurse who opened this patient's case discussed with the physician during her telephone conversation with the physician. Tr. at 1011 - 12. This handwritten document is then given to clerks to type. Tr. at 1011. Ms. Collar testified that between the handwritten Worksheet and the POC, the document which more accurately reflects the physician's instructions is the 485 Worksheet since it is in the nurse's own handwriting made at the time of her conversation with the physician. Tr. at 1012. As to the discrepancy between the handwritten 485 Worksheet and the POC, Ms. Collar stated that she believed that the clerk made a keying

error which the nurse missed when she signed the POC. Tr. at 1013.

Accepting at face value Petitioner's claim that this patient's POC contained a typographical error, I agree that there was an ambiguity within this patient's records. The 485 Worksheet called for the encouragement of fluids, while the POC called for a fluid restriction, with the amount of recommended fluid intake, 1500 to 2000 ml., the same in both documents. Obviously, there is a significant difference between restricting fluids and encouraging the patient to drink as much fluid as desired. Even if I were to accept Petitioner's position that the patient's physician intended the encouragement of fluids up to 2000 ml. daily, however, I would find troubling the unrebutted indication, apparently based on instructions from the skilled nurse, that the patient's care giver believed that the patient had no restrictions on the amount of fluid she could intake. There is nothing in the record before me to support Petitioner's position that drinking fluids up to 1500 - 2000 ml. encourages unlimited intake of fluid. That interpretation defeats the clear meaning of the language in both the POC and the 485 Worksheet. The basis for this deficiency is that the patient was told to take an unlimited amount of fluid, arguably beyond the normal fluid intake of 1900 - 2000 ml. per day. The fact remains that the skilled nurse, in telling the patient and her care giver that the patient could have as much fluid as she wanted, was acting in contradiction to the instructions in the POC and the 485 Worksheet.

Confronted with this ambiguity in the patient's records, with her symptoms calling for the encouragement of fluids and the POC calling for fluids to be restricted, the prudent course of action would have been for the nurse to consult the physician to resolve the ambiguity. I note that both witnesses Petitioner presented on this patient, Dr. Narian and Ms. Collar, agreed that if there is any confusion on the part of the nurse as to whether there should be a fluid restriction, the nurse should contact the physician to clarify the instruction. Tr. at 906 and 1025. This was not done here. Furthermore, if the skilled nurse who regularly visited the patient was not available, another one of Petitioner's skilled nurses visiting the patient and reviewing the POC might direct the patient to restrict her fluid intake. This could easily result in confusion for the patient and her care giver on the proper amount of fluid to be taken, establishing all the more reason for the regular skilled nurse to have contacted the physician to resolve any ambiguity about the correct fluid intake. While there was no apparent harm to the patient here, the potential for harm existed.

Accordingly, I find that Petitioner's skilled nurse did not follow the POC for this patient regarding instructions on the intake of fluids and that this constituted a deficiency in Petitioner's provision of care to this patient.

Patient 7

The surveyors made the following assertions concerning the care Petitioner gave to Patient 7:[8]

> a. Patient #7's plan of care cited that the patient would receive home health aide services two times per week to provide personal care that included foot care. However, there was no documented evidence that foot care had been provided.

HCFA Ex. 2, at 13.

The August 21, 1996 POC for Patient 7 directed that the patient would receive home health aid services two times per week to "perform complete bed bath, personal care, oral hygiene, shampoo 1 x per week per pt request, foot care, assist w/ambulation . . ." HCFA Ex. 11, at 9. Petitioner's home health aide plan, CHHA Plan/485 Worksheet, repeated these directions. P. Ex. 2, at 15. The State surveyor, Ms. Sabino, testified, however, that a review of the home health documentation revealed that no foot care had been provided. Tr. at 269. The surveyor testified that foot care included such items as soaking the feet, cleaning between the toes, applying lotion, and drying the feet. Tr. at 270. The surveyor further testified that bathing a patient, including the patient's feet, does not constitute foot care. Tr. at 272.

HCFA's Nurse Consultant, Ms. Patience, who reviewed the surveyors' findings, similarly agreed that mere bathing of the feet would not encompass foot care, which would include the application of lotion, the attending to toe nails, and the observation of the condition of the feet. Tr. at 511.

Petitioner contended that the home health aide did in fact provide foot care when the aid provided personal care and bathing to the patient. Petitioner's RN supervisor, Wilma Austin, testified that she completed the 485 worksheet after talking with the physical therapist who opened this case. Tr. at 1308. Ms. Austin testified that she never talked with the patient's physician before completing the 485 and, therefore, had no specific instructions about foot care for the patient. Tr. at

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[8] Another alleged deficiency involving Patient 7 appearing on the HCFA Form 2567, cited as 5.b. under Tag G 158, was withdrawn by HCFA at the hearing held in this case. Tr. at 284.

1336. Ms. Austin further testified that there was no difference to her between a bed bath and foot care, as the former would include the latter. Tr. at 1313. Ms. Austin stated that she checked off the box next to foot care on the 485 worksheet to be all-inclusive and that she routinely checked it on instructions to home health aides in performing personal care. Tr. at 1332 - 33.

Petitioner argued that there is evidence that the patient did receive baths and nail care, which demonstrates that the patient also received foot care. Petitioner asserted that even if the home health aide did not separately list foot care as one of the tasks she performed, this was just a documentation error rather than a deficiency in the actual care provided to the patient. Petitioner attributed the confusion over the provision of the foot care to the fact that the CHHA Progress Note used by Petitioner does not exactly match the 485 worksheet, there being no specific listing for foot care on the Progress Notes.

I agree with Petitioner that this is a documentation error and not an error in the care that was provided. The physician's home health referral for this patient did not mention foot care at all. HCFA Ex. 11, at 6. I find persuasive the testimony of the RN supervisor that she included foot care in this patient's POC as a routine service, along with other components of personal care.

Furthermore, the testimony of HCFA's witnesses was not convincing as to whether foot care was indeed distinct from the services provided in the process of bathing the patient. The surveyor admitted that she did not understand what type of foot care was called for in the POC, but that the deficiency was based on the lack of documentation that foot care had been provided. Tr. at 280. The surveyor stated that, although there was no check-off box on the progress notes for foot care, she expected that the provision of foot care would have been noted in the "comments" section of the progress notes. Tr. at 281 - 82. The CHHA Progress Notes indicate, however, by a checkmark in a box, that the patient, under a section labeled "personal care," received either a chair bath or a bed bath on four occasions, with nail care twice. P. Ex. 2, at 16 - 19. As Petitioner argued, these Progress Notes do not contain a separate box for foot care. I do not agree with HCFA that foot care must be separately documented, even if the foot care is provided as part of the bathing of feet. HCFA failed to show that the foot care contemplated in the POC was not in fact delivered as part of the bathing of the patient.

Accordingly, I find that there was no deficiency in the foot care provided to Patient 7.

Patient 8

The surveyors made the following assertions concerning the care Petitioner gave to Patient 8:

> Review of the clinical record for Patient #8 revealed that on 7/17/96 a supplemental physician's order was written for an additional skilled nursing visit to reinforce use of medication box, use of compression stocking and follow up physician's visit of 7/18/96. Review of the skilled nurse's note dated 7/19/96 revealed no documented evidence that the skilled nurse had reinforced the use of the compression stocking. There was no documented evidence that the skilled nurse had followed up with the patient regarding instructions or changes made during the physician's visit on 7/18/96.

HCFA Ex. 2, at 13.

The State surveyor, Ms. Sabino, testified from the notes she took during the survey that a July 17, 1996 physician's order directed the skilled nurse to make an additional visit to the patient on July 19 to reinforce the use of the medication box and the use of a compression stocking. Tr. at 286; HCFA Ex. 12, at 3; P. Ex. 3, at 12. Ms. Sabino testified that the skilled nurse's daily visit record for July 19, while indicating that instructions were given regarding the use of the medication box, did not have any information that the skilled nurse reinforced the use of the compression stocking. Tr. at 287; HCFA Ex. 12, 17. Ms. Sabino explained that a compression stocking is a device to assist with the blood flow in the patient's lower extremity. Tr. at 287. Ms. Sabino stated that the basis for the deficiency for this patient was the skilled nurse's failure to follow the physician's instructions regarding the compression stocking.[9]

Petitioner, while admitting that there was no documentation that its skilled nurse discussed the use of the compression stocking with the patient during the July 19 visit, contended that the primary needs of the patient were met during the visit. Petitioner maintained that on earlier and subsequent visits the use of the compression stocking was reinforced. See, e.g., P. Ex 3, at 3 (July 15), 3a (July 16), 4 (July 17), and 10 (August 2). Petitioner further argued that the patient met the discharge

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[9] At the hearing, HCFA clarified that this alleged deficiency concerns only the failure of the nurse to follow up on the use of the compression stocking and not on the medication box or whether the skilled nurse failed to follow up on instructions or changes in the patient's POC made during a July 18 physician's visit. Tr. at 289 - 91.

goals regarding the use of the stocking in a timely manner, establishing that there was no potential or actual adverse effect on the patient. Petitioner argued that during the July 19 visit the skilled nurse must have determined that the instruction on the use of the compression stocking was secondary that day to the more critical situation involving the medications. Petitioner contended that at most this deficiency is a technical deficiency which would cause no potential or actual harm to the patient, and therefore should not be used as a basis for a condition-level deficiency.

It is uncontested that Petitioner's skilled nurse did not follow the physician's July 17 order reinforcing the use of the compression stocking during the July 19 visit. There is nothing in the record before me that indicates that the physician left it up to the skilled nurse whether the care prescribed should be delayed because of the discussion on the medications, which may have been the primary focus of the visit. Petitioner's argument, that the ultimate improvement in the patient's leg is evidence that the instructions on the compression stocking that were given were effective, is a post hoc rationalization that does not negate the fact that failure to provide the care that was ordered on the use of the stocking might have led to complications. As HCFA pointed out, the patient might have improved more quickly had the nurse followed the physician's orders. The fact that the skilled nurse reinforced the use of the compression stocking on August 2, when it was supposed to have been delivered on July 19, does not relieve Petitioner of its responsibility here, under 45 C.F.R. § 484.18, to follow the physician's orders as written.

I therefore find that the failure of Petitioner's skilled nurse to reinforce the use of the compression stocking during the July 19 visit constituted a deficiency in Petitioner's provision of care to this patient, resulting in a possible adverse affect on the patient's health and safety.

G 159 The plan of care developed in consultation with the agency staff covers all pertinent diagnoses, including mental status, types of services and equipment required, frequency of visits, prognosis, rehabilitation potential, functional limitations, activities permitted, nutritional requirements, medications and treatments, any safety measures to protect against injury, instructions for timely discharge or referral, and any other appropriate items.

Based on a clinical record review, the surveyors determined that, for two of nine sampled patients (Patients 7 and 3), Petitioner failed to ensure that the plan of care developed in consultation with Petitioner's staff covered all pertinent diagnoses, including treatments, and any other appropriate items.

3. For Patients 7 and 3, Petitioner has failed to show by a preponderance of the evidence that the plan of care it developed included all the information relevant to the treatment of these patients. Such failure had the potential to adversely affect the health and safety of these patients.

Patient 7

The surveyors made the following assertions concerning the care Petitioner gave to Patient 7:

> Patient #7 had a start of care dated 8/21/96 with a diagnosis of dislocated hip, with surgical procedures of total hip replacement (7/20/96) and closed hip reduction (7/29/96). The plan of care under #14 (DME and supplies) included left hip brace; and under #15 (Safety Measures) included total hip precautions. The plan of care also cited that the physical therapist would instruct proper donning/doffing of left hip brace. However, the plan of care did not address the use of the brace while other disciplines were providing care to the patient.

HCFA Ex. 2, at 14 - 15.

The State surveyor, Ms. Sabino, testified that the basis for this deficiency was that the POC did not specify when the brace would be removed, when it would be reapplied, the duration of time the patient should wear the brace, and whether the brace should be worn while the patient was sleeping or receiving personal care. Tr. at 298. Ms. Sabino testified that there should have been additional instructions regarding the brace in the POC, particularly for the home health aide in providing personal care to the patient. Tr. at 299. Ms. Sabino stated that neither the home health aide nor the occupational therapist is allowed to remove a hip brace without a physician's order. Tr. at 302 - 03. Ms. Sabino testified that her understanding of the POC was that only the patient herself was supposed to be taking the brace on and off. Tr. at 305. Ms. Sabino agreed that the only ambiguity in the POC was that the home health aide might need to bathe the patient or do some other type of personal care on the patient and the aide would not know what to do with the brace, and that was the basis for the deficiency. Tr. at 306.

Petitioner argued that this patient's POC was complete and that there was no need to provide further instructions regarding the hip brace, since, without specific orders, the other disciplines, including the home health aide and the occupational therapist, are not allowed to manipulate, put on, or take off the hip brace. Petitioner further contended that all its staff were instructed on the POC to provide total hip precautions to the patient, which would protect the patient's hip if the brace happened to be

removed by the patient. Therefore, according to Petitioner, no further instructions were needed in the POC.

Stanley Papek, Petitioner's physical therapist for this patient, testified that he wrote the order in the POC that the patient was to be instructed on the "proper donning/doffing of left hip brace." Tr. at 1101 - 02; P. Ex. 2, at 2. Mr. Papek testified that when he visited the patient for the first time the patient was already wearing the brace and the patient told him that the physician wanted her to keep the brace on all the time. Tr. at 1103 - 04. Mr. Papek testified that he discussed this with the physician and the physician confirmed that the brace was to be on all the time. Tr. at 1105. Mr. Papek further testified that the patient was aware of this and that on every visit with the patient he reinforced this instruction. Id. Mr. Papek testified that he discussed the hip brace with the home health aide on her first visit, August 26, and that he told her that the hip brace was to remain on at all times. Tr. at 1112 - 13.

On cross-examination, Mr. Papek admitted that the physician's order that the hip brace not be removed was given verbally and that he erroneously did not confirm the order in writing. Tr. at 1115 - 16. Mr. Papek further admitted that from the instruction in the POC, "[i]nstruct proper donning/doffing of left hip brace," it would not be possible for one of Petitioner's staff members to know that the patient was supposed to have the brace on at all times, and that he talked to the home health aide only on the one occasion of August 26. Tr. at 1117. Mr. Papek stated that he did not document his conversation with the home health aide. Tr. at 1119 - 20. Mr. Papek, in examining the home health aide care plan for this patient, stated that there was nothing in that worksheet that documented that the patient had to wear the brace at all times. Tr. at 1121; P. Ex. 2, at 15.

Petitioner's RN Supervisor, Ms. Austin, testified that she prepared the home health aide assignment sheet for this patient. Tr. at 1339. This CHHA Plan 485 Worksheet stated that the patient had a brace for support. P. Ex. 2, at 15. Ms. Austin testified that the physical therapist, Mr. Papek, told her that the patient was to wear the brace at all times and that she telephoned the home health aide and read her the assignment sheet. Tr. at 1339. Ms. Austin testified that she told the aide that the patient was to wear the brace and that it was not to be removed. Tr. at 1341. Ms. Austin further testified that she remembered that only one home health aide had been assigned to this patient. Tr. at 1342.

There is no documentation in the record before me to support the oral conversations that are at the heart of Petitioner's defense to this deficiency. Mr. Papek stated that he told the home health aide that the patient was to wear the brace at all times. He did not memorialize this conversation in writing. Ms. Austin

stated that she read the CHHA Worksheet to the aide over the telephone and told the aide that the brace was not to be removed. Once again, this conversation was not memorialized in writing. Petitioner's position is that the brace was to remain on the patient at all times. In the documentation for this patient in the record, however, there is no physician's order directing care givers or the patient herself not to remove the brace under any circumstances. To the contrary, the instructions in the POC related to the removal and reapplication of the brace. In other words, the opposite of what Petitioner is now contending. The POC was therefore deficient on how the brace was to be used. Since the POC is the basic document which communicates the physician's instructions to care givers, it is incumbent upon Petitioner to ensure that the POC is accurate and inclusive in covering all appropriate treatment contingencies.

While there was no actual harm to the patient in this situation, there clearly was the potential for harm. If the patient's regular home health aide had been unavailable one day, the replacement aide, without the benefit of the conversations with Mr. Papek and Ms. Austin, would not have been informed that the patient's brace was required to remain on at all times. There was nothing in either the POC or the 485 Worksheet to reflect this. Ms. Austin testified that it the responsibility of a replacement aide to come into the supervisor's office and review the 485 Worksheet for the patient. Tr. at 1350. Ms. Austin admitted that from the 485 Worksheet for this patient a replacement aide would have no way of knowing that the brace had to be worn at all times. Tr. at 1353 - 54. Clearly, if the patient had removed the brace before the arrival of the replacement aide, the patient could have incurred great harm when the aide attempted to bathe the patient, with an adverse affect on the patient's health and safety.

I therefore find that the POC developed by Petitioner for this patient was deficient in failing to state that the patient's hip brace had to be worn at all times, or, alternatively, was deficient in failing to direct how other disciplines caring for the patient, including home health aides, should treat the brace during the provision of their care.

Patient 3

The surveyors made the following assertions concerning the care Petitioner gave to Patient 3:

> Patient #3 had a start of care dated 6/29/96. During the initial evaluation on 6/29/96, the skilled nurse documented that instruction was given regarding use of upper extremity splint and sling. On 7/3/96, the skilled nurse documented that the patient was instructed to wear splint/sling to support the right arm/hand. However, review of the plan of

> care dated 6/29/96 revealed no physician's order for the use of an upper extremity splint or sling.

HCFA Ex. 2, at 15.

The fact situation for this deficiency is identical to that discussed above in the deficiency under Tag G 158 for this patient. The State surveyor, Ms. Martinez, testified that the basis for this deficiency under Tag G 159 is that the regulation, 42 C.F.R. § 484.18(a), requires that all pertinent information, including medical equipment, be included in the POC. Tr. at 324. Ms. Martinez explained that the deficiency for this patient under Tag G 158 was based on the skilled nurse's failure to follow the POC, while the deficiency under Tag G 159 was based on the POC itself, which failed to include any information about the splint and sling. Tr. at 325. Ms. Martinez testified that the POC must be developed by the physician in consultation with home health agency staff and that the skilled nurse should have consulted with the physician about the use of the splint and sling. Tr. at 327.

Petitioner argued that HCFA failed to demonstrate a violation of this standard, denying HCFA's contention that there was a deficiency, in that the patient's splint/sling was not discussed in the POC. Petitioner maintained that the POC was complete. Repeating the arguments it made concerning the deficiency in Tag G 158, Petitioner argued that: no splint was used by the patient; the patient had been using the sling for a long period of time prior to receiving care from Petitioner; and the general directive for "safety measures" in the POC covered the use of the sling. Petitioner again referred to the testimony of Dr. Punim, discussed above, and argued that the physician is ultimately in charge of the contents of a POC and that HCFA cannot dictate what particular instructions should be in the POC if the physician does not believe those instructions belong there.

I do not agree with Petitioner's principal contention that the physician can decide what matters in a POC. That determination has been decided by the issuance of the regulations. See 42 C.F.R. § 484.18. If there are services or treatment being provided that are not covered in the POC, it is incumbent on the home health agency staff to bring this to the attention of the physician for a supplemental order. The physician cannot avoid his or her responsibility to ensure that a complete and accurate POC is developed with the cooperation of the home health agency. If there is a refusal by the physician to issue a supplemental order after receiving essential information from the home health agency, e.g., the patient is wearing a sling, then the appropriate action is for the home health agency to document that in the record. Treatment in the POC is to be coordinated between the physician and the agency so that the POC is a complete recital of the authorized care to be delivered to the patient.

The regulation at 42 C.F.R. § 484.18(a) provides that the POC "covers . . . types of services and equipment required . . . [and] any safety measures to protect against injury . . ." Clearly, any use of a sling and/or a splint by a patient would be covered by this regulation. Moreover, the regulation specifically covers an instance such as the one present here, where the POC could not be completed until after an evaluation visit by a skilled service, with the physician to be "consulted to approve additions or modifications to the original plan." 42 C.F.R. § 484.18(a). A fair reading of this regulation supports my conclusion as to the obligations imposed on the physician and the home health agency. These obligations were not met by Petitioner here. While there has not been any showing that the patient was actually harmed by the omission in the POC regarding the splint/sling, there was the potential for harm here.

Accordingly, I find that the failure of this patient's POC to mention the splint/sling constituted a deficiency in Petitioner's provision of care to this patient, with a possible adverse affect on the health and safety of the patient.

G 164 Agency professional staff promptly alert the physician to any changes that suggest a need to alter the plan of care.

The surveyors determined that, based on a clinical record review, Petitioner's professional staff failed to meet this standard in regard to Patient 1.

4. For Patient 1, Petitioner has failed to show *by a preponderance of the evidence that its professional staff alerted the patient's physician to a significant increase in the patient's pulse rate. This failure had the potential to adversely affect the health and safety of this patient.*

Patient 1

The surveyors made the following assertions concerning the care Petitioner gave to Patient 1:

> Patient #1 had a start of care dated 6/3/96. The initial skilled nursing assessment dated 6/3/96 indicated that the patient's pulse rate was 88 beats per minute. The skilled nurse also documented that the patient was admitted to the hospital on 5/28/96 due to tachycardia.
>
> On 6/7/96, the skilled nurse documented that the patient's pulse rate was 92 beats per minute. On 6/10/96, the skilled nurse documented that the patient's radial pulse was 124 beats per minute with patient complaining of mild intermittent dizziness. There was no documentation that the physician was notified of the patient's elevated pulse rate.

HCFA Ex. 2, at 15 - 16.

This patient had been admitted to the hospital on May 28, 1996, for tachycardia, which is an excessive rapid heartbeat. HCFA's Nurse Consultant, Ms. Patience, testified that there were two occasions when Petitioner's skilled nurse observed this patient with a rapid heartbeat and failed to notify the physician: June 7, when the patient's pulse rate was 92 beats per minute, and June 10, when the pulse rate was 124 beats a minute with the patient complaining of dizziness. Tr. at 531. Ms. Patience stated that it was her understanding that this constituted two different errors by two different nurses. Tr. at 536. Ms. Patience further testified that, irrespective of whether Petitioner had a quality assurance program, she still considered there to be a deficiency with regard to the care provided to this patient. Tr. at 537.

Petitioner admitted that the skilled nurse should have notified the physician after the patient experienced the elevated pulse rate on June 10 and complained of dizziness. Petitioner argued that this was an isolated incident which it had already discovered and addressed with the skilled nurse prior to the survey through Petitioner's quality assurance program. Petitioner contended that since it demonstrated its ability to monitor for and detect such problem performance in its staff, this one incident cannot be used to demonstrate either a condition-level or standard-level deficiency. Petitioner strongly disputed Ms. Patience's assertions that there were two, or possibly three, incidents where Petitioner's skilled nurses failed to report this patient's elevated pulse rate, or that more than one nurse was responsible for failing to notify the patient's physician.

Petitioner declared that in the nine patient records reviewed by the State surveyors and HCFA, covering care rendered over a three-month period, the surveyors documented 189 visits by all disciplines, including 40 skilled nurse's visits for this one patient alone. Petitioner maintained that of all these visits, the State surveyors only noted one incident where the skilled nurse failed to inform the physician of a significant finding. Petitioner argued that, as even a rigorous quality assurance program cannot completely prevent human error and poor performance, it should not be penalized if only one staff member failed to report a significant finding on only one occasion.

Petitioner presented two witnesses to discuss its quality assurance program and how that program dealt with the June 10 incident. Cynthia Tew was employed by Petitioner as its Utilization Review and Quality Assurance Coordinator. Ms. Tew testified that it was her responsibility to track trends of problems that Petitioner's staff was having by auditing patients' charts and to educate the staff to better serve the patients.

Tr. at 1049 - 50. Ms. Tew explained that the existence of a quality assurance program does not ensure that nurses do not make mistakes or errors in judgment or procedures, but, rather, the program tries to detect errors and mistakes, track and trend them, and then proceed to educate, report, discipline, and supervise the nurses. Tr. at 1051. Ms. Tew testified that at the end of July 1996 she identified the specific problem with this patient, the nurse's failure to notify the physician after the increased heart rate. Tr. at 1061. Ms. Tew testified that the nurse supervisors had the responsibility for examining every visit record within 24 hours of the visit record being turned in, but the supervisors never noticed the June 10 incident. Tr. 1075. Ms. Tew testified that, as part of the quality assurance process, meetings were held in August 1996 with the skilled nurses, including the nurse at fault in regard to this patient, to discuss various items, including the need to notify the physician if a patient experienced an elevated heart rate. Tr. at 1068 - 69. Ms. Tew further testified that Petitioner continued to track the performance of this nurse and did a supervisory visit in the field to watch how the nurse performed her duties. Tr. at 1070. Ms. Tew stated that the skilled nurse was counseled about this incident with the patient as shown by an August 30, 1996 Employee Counseling Report. Tr. 1071 - 72; P. Ex. 15.

Petitioner's RN Supervisor, Ms. Austin, testified that at the time she began her employment with Petitioner in mid-July 1996, the nurse in question was being monitored by her supervisors as part of the quality assurance program, with a closer review of her notes and conversations with her supervisors regarding the care she was giving. Tr. at 1363. Ms. Austin testified that she verbally counseled the nurse in mid-August, but that there was nothing in writing that this counseling took place. Tr. at 1385. Ms. Austin stated that she went on a supervisory visit with the nurse at the end of August, after another incident of significant findings not being reported by the nurse. Tr. 1364. Ms. Austin stated that the nurse gave good care during that visit. Tr. at 1367. Ms. Austin testified that the monitoring of the nurse continued after the supervisory visit. Tr. at 1370.

At the outset, I agree with Petitioner, and not with HCFA (as expressed through the testimony of Ms. Patience), that only one incident, the failure to notify the physician of the elevated heartbeat rate on June 10, is the basis for this deficiency. In the initial nursing assessment for this patient on June 3, 1996, the patient had a pulse rate of 88. HCFA Ex. 15, at 24. The patient's pulse rate of 92 on June 7, cited by Ms. Patience as an occasion when the physician should have been notified, does not appear to have been so elevated, when compared to the patient's pulse rate recorded on other skilled nurse's visits, that notification of the physician was warranted. See HCFA Ex. 15, at 4 - 7. As to the June 10 visit where a rate of 124 was recorded,

Petitioner does not deny that this was an incident where the physician should have been notified, but contends that this was an isolated instance properly addressed through its quality assurance program prior to the September State survey.

I do not find Petitioner's arguments persuasive. Under the regulations, even an isolated incident (in this case, as asserted by Petitioner, one incident out of a total of 189 visits) can be so egregious as to warrant a finding of a condition-level or standard-level deficiency. I agree with Petitioner that a deficiency, or deficiencies, must be examined in terms of demonstrating that the home health agency has systemic problems affecting its provision of health care. A single significant violation of a standard, however, can raise the issue of the ability of a home health agency to furnish care to all its patients. Under 42 C.F.R. § 488.26(b), the question of compliance with a condition "depends upon the manner and degree" that a provider satisfies the standards within each condition. While this suggests that more than one incident may be required to find a provider out of compliance with a standard, 42 C.F.R. § 488.24(b) provides that a level of compliance, and a deficiency, may be 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." Here there was an incident where there was undeniable potential for harm to this patient.

Arguably, then, this is where the issue of a quality assurance program applies. If a home health agency is effectively able to deal with the circumstances that led up to an isolated incident on its own without HCFA involvement, then it would suggest there is no diminishment of the agency's capacity to render quality care. Even with an effective quality assurance program, however, a single instance of a flagrant violation of a standard could support a conclusion that the patients' health and safety are adversely affected. But the actual effectiveness of Petitioner's quality assurance program, as described in the hearing in regard to the June 10 incident, is open to question. The initial supervisory review of the nurse visit reports completely overlooked the patient's elevated heartbeat rate on June 10. It was not until the end of July that Ms. Tew, as the second line of defense in the quality assurance program, noticed the June 10 incident. Despite the recognition of the nurse's error in not notifying the physician of the elevated heartbeat rate, the nurse was not counseled about the incident until mid-August, approximately two months after the incident. Therefore, for these two months, this nurse was unaware of any shortcomings in her responsibility to report significant findings to the physician. Moreover, there was no written document establishing that this counseling actually took place. Furthermore, there was another incident of significant findings not being reported involving this same nurse. The Employee Counseling Report for

the nurse, submitted by Petitioner apparently as evidence of the effectiveness of its quality assurance program, does not even mention the June 10 incident; instead, the nurse is complimented for the care provided while being observed on the supervisory visit. P. Ex. 15, at 1. Finally, there is nothing in the record to indicate that Petitioner ever notified the physician of the elevated heartbeat rate on June 10.

In light of these problems that Petitioner's quality assurance program evidenced in dealing with the June 10 incident, along with the seriousness of the incident, in that the patient was placed at great risk, I find that a single incident of this type can support a deficiency, and does so here, and that deficiency places in serious doubt Petitioner's capacity to furnish care and protect its patients under 42 C.F.R. § 488.24(b). I do not need to conclude that it alone supports a finding of noncompliance with a condition, but it cannot be ignored when examining the other deficiencies within the condition set forth at 42 C.F.R. § 484.18.

Summary of deficiencies under the condition at 42 C.F.R. § 484.18

Generally, a determination as to whether a provider is not complying with a condition of participation depends on the extent to which the provider is found not to be complying with the standards that are components of the condition. 42 C.F.R. § 488.26(b). A provider may be found not to have complied with a condition of participation where it is shown that a provider has committed a pattern of failures to comply with the standards that comprise the condition. But, proof of a pattern of failures to comply with a standard or standards may not be the only basis to find that a provider has failed to comply with a condition of participation. The determinative issue in any case where noncompliance is demonstrated is whether the failure to comply is so egregious as to show that the provider is not capable of providing care consistent with that which is required by the Act and regulations.

5. The deficiencies found in the standards under the condition set forth at 42 C.F.R. § 484.18 are of such character as to substantially limit Petitioner's capacity to furnish adequate care or which adversely affect the health and safety of its patients.

In this case, I found, in examining the alleged deficient standards HCFA cited with regard to the condition for participation at 42 C.F.R. § 484.18 for Acceptance of Patients, Plan of Care, and Medical Supervision, that Petitioner was: 1) deficient regarding one patient out of three patients cited under Tag G 157, the standard requiring that patients be accepted for treatment on the basis of a reasonable expectation that the patient's needs could be met adequately by the home health agency

in the place of residence; 2) deficient regarding five out of six patients cited under Tag G 158, the standard requiring that care provided by the home health agency follow a written plan of care established and reviewed by a physician; 3) deficient regarding both patients cited under Tag G 159, the standard requiring that the plan of care be comprehensive in addressing the patient's diagnosis and treatment; and 4) deficient regarding one patient cited under Tag G 164, the standard requiring that the home health agency staff alert the physician of any changes that suggest a need to alter the plan of care.

Under Tag G 157, the duty to provide services to patients in a timely manner, I sustained only the deficiency for Patient 7. For Patients 5 and 8, I found that either Petitioner has proved by a preponderance of the evidence that the services were provided in a timely manner or that any delay was beyond the responsibility of Petitioner and did not result in any actual or potential harm to the patients. I find that the one instance involving Patient 7 does not establish a pattern of behavior on Petitioner's part that services were not provided in a timely manner. I therefore find that, in regard to this standard of 42 C.F.R. § 484.18, Petitioner was complying substantially with the Medicare requirements established by the Act and regulations and that therefore there is no basis for a termination of Petitioner's participation in the Medicare program under either of the elements of 42 C.F.R. § 488.24(b).

Under Tag G 158, however, upon review of HCFA's allegations of deficiencies regarding the six patients, I conclude that HCFA has established a pattern of practice where Petitioner provided care that was not authorized or failed to provide care that was ordered. I cannot overemphasize that in the situations discussed above in regard to these patients strict interpretation of the regulations is required. If there was any ambiguity in any case, as with the appropriate fluid intake of Patient 6, it was incumbent upon Petitioner to seek clarification from the physician. It is Petitioner's responsibility to provide the services ordered by the physician. Petitioner cannot fail to deliver those services if it wishes to avoid sanction. Petitioner cannot rely on post hoc rationalizations as to why the care was not provided as ordered, or claim inadvertent errors, or retreat behind the assertion that the patients suffered no harm. Failure to follow an expressed physician's order, without making any attempt to seek clarification from the physician if there is an ambiguity, poses a serious risk of potential harm to Petitioner's patients in general. More often than not in the patients discussed above, what Petitioner and its staff did, in direct contradiction to the specific requirements of the regulations, was to take on the responsibility of the physician by deciding on the appropriateness of the care given.

In a home health agency setting, it is contemplated that the home health care givers will follow the physician's orders. Unlike an in-patient setting, the physician cannot come to the patient's home to determine if the appropriate care is being given. The physician must rely on the home health agency. The physician is depending on the home health agency to implement the physician's medical judgment, not to exercise its own judgment as to what care is appropriate. A basic premise of home health care is to provide quality care in the patient's home rather than in the much more expensive environment of an in-patient setting. With the physician not being in attendance, all the more emphasis should be placed on the care giver following the explicit instructions of the physician. The fundamental concept of a home health agency depends on the agency bearing its responsibility to carry out the prescribed care and advise the physician if problems with that care arise. In no instance, should the home health agency be unilaterally substituting its judgment for that of the physician as to what the appropriate care for the patient should be.

I therefore find that, in regard to the standard set forth in 42 C.F.R. § 484.18 requiring a home health agency to follow a plan of care, HCFA has established the existence of deficiencies in Petitioner's care that justifies a certification of non-compliance as provided for in 42 C.F.R. § 488.24(b), in that said deficiencies are of such character as to substantially limit Petitioner's capacity to furnish adequate care and which deficiencies adversely affect the health and safety of patients.

Under Tag G 159, the duty to ensure that the POC covers all appropriate items, I sustained deficiencies for the two patients cited. I cannot overemphasize the duty of a home health agency to ensure that a POC be as comprehensive as possible. The POC serves as the roadmap for a patient's treatment for all the components of a home health agency. Where a patient is directed by a physician to wear a piece of equipment, a hip brace or a splint/sling for the patients at issue here, it is incumbent on the home health agency that instructions regarding the equipment are explicitly set forth in the POC. No ambiguity about the use of such equipment is to be permitted.

I therefore find that, in regard to the standard set forth in 42 C.F.R. § 484.18(a) requiring that a plan of care be comprehensive, HCFA has established the existence of deficiencies in Petitioner's care that justifies a certification of non-compliance as provided for in 42 C.F.R. § 488.24(b), in that said deficiencies are of such character as to substantially limit Petitioner's capacity to furnish adequate care and which deficiencies adversely affect the health and safety of patients.

Under Tag G 164, the duty to alert the physician of changes that suggest a need to alter the POC, I found that the single incident of the elevated pulse rate for Patient 1 was so serious, with the patient being placed at great risk, that a single incident of this type supported a deficiency.

I therefore find that, in regard to the standard set forth in 42 C.F.R. § 484.18(b) requiring a home health agency to alert the physician to any changes that suggest a need to alter the plan of care, HCFA has established the existence of a single deficiency in Petitioner's care which is so egregious that it justifies a certification of non-compliance as provided for in 42 C.F.R. § 488.24(b), in that said deficiency is of such character as to substantially limit Petitioner's capacity to furnish adequate care and which deficiency adversely affects the health and safety of patients.

At this point, I also find it necessary to address Petitioner's argument, made in its posthearing briefing, that HCFA failed to meet the requirement under Hillman to set forth the basis for this alleged condition-level deficiency in the HCFA Form 2567 with sufficient specificity for Petitioner to respond. Petitioner argued that HCFA failed to state the legal basis or standards for its findings under the various Tags under this condition, so that Petitioner, without this specific statement, was unable, prior to the hearing, to determine the standard used by HCFA to measure noncompliance and thus was unable to adequately prepare a response for the hearing. Petitioner further contended that HCFA failed to include a statement in the HCFA Form 2567 that described the "degree of hazard to health and safety, or the effect on quality of care" caused by the deficiencies listed under 42 C.F.R. § 484.18. Petitioner argued that the State surveyors made no claim in the HCFA Form 2567 that any of the deficiencies under 42 C.F.R. § 484.18 substantially limited Petitioner's capacity to furnish adequate care or adversely affected the health and safety of patients.

Petitioner's raising this issue in its posthearing briefing is troubling. Petitioner did not raise this argument at the hearing when it could have been corrected or clarified. Furthermore, in advance of the hearing, Petitioner was given, during the exhibit exchange, the surveyors' notes and worksheets for all the deficiencies. Moreover, the exhibits and testimony of the HCFA witnesses in its prima facie case provided additional clarification. Thus, I find no violation of the Hillman requirement, and, even if there were, Petitioner has waived it by not timely raising its objection prior to or during the hearing. Furthermore, I do not find that Petitioner was in any way prejudiced by any alleged failure by HCFA to give more specificity to the deficiencies, given that Petitioner was able to present a thorough case at the hearing, extensively cross-

examining HCFA's witnesses and presenting testimony from numerous witnesses of its own to rebut the alleged deficiencies.

Part Two

The State surveyors summarized Petitioner's failure to comply with the condition set forth at 42 C.F.R. § 484.30 as follows:

G 168 484.30 CONDITION: SKILLED NURSING SERVICES

> **The Agency failed to furnish skilled nursing services in accordance with the plan of care (G170); regularly re-evaluate the patient's nursing needs, make necessary revisions to the plan of care (G172 and G173); initiate appropriate preventive nursing services (G175); and prepare progress notes, coordinate services, inform the physician and other personnel of changes in the patient's condition and needs (G176). The cumulative effect of these systemic practices resulted in the failure of the Agency to deliver statutorily mandated compliance with providing skilled nursing services.**

HCFA Ex. 2, at 16 - 17.

Under this condition-level deficiency, the surveyors then proceeded to list the alleged five standard-level deficiencies.

G 170 484.30 Standard: The HHA furnishes skilled nursing services in accordance with the plan of care.

Based on a clinical record review, the surveyors determined that for five of nine sampled patients(Patients 1, 3, 5, 6, and 8), Petitioner failed to ensure that skilled nursing services were furnished in accordance with the plan of care.

6. For Patients 3, 5, 6, and 8, Petitioner has failed to show by a preponderance of the evidence that it furnished skilled nursing services in accordance with the plans of care for these patients. Such failures had the potential to affect the health and safety of these patients. For Patient 1, Petitioner has failed to show by a preponderance of the evidence that the use of a Combiderm dressing by its skilled nurse was in accordance with the plan of care for this patient. Also, for Patient 1, Petitioner has shown by a preponderance of the evidence that the one-time use of Comfeel powder on this patient's wound did not have the potential for harm for this patient.

The alleged deficiencies for these patients are put forth on pages 17 through 20 of the HCFA Form 2567. For the cited patients, the alleged deficiencies are, for all discussion relevant to this decision, identical to those deficiencies

previously listed under Tag G 158 discussed above.[10] The parties made the same arguments here as they did under Tag G 158.

The two cited regulatory provisions, 42 C.F.R. §§ 484.18 and 484.30, are complimentary, and violation of one means violation of the other. Accordingly, my findings and reasoning under Tag G 158 are applicable for each of the alleged deficiencies under Tag G 170. I therefore sustain the deficiencies for Patients 3, 5, 6, and 8. For Patient 1, I sustain the deficiency pertaining to the use of a Combiderm dressing, while reversing the deficiency for the use of Comfeel powder.

Six incidents involving five patients were cited by HCFA under this standard. I have sustained a finding of a deficiency in five of these incidents. This is more than sufficient to show a pattern of behavior by Petitioner and its staff. The regulations cannot be clearer in requiring a home health agency to follow the plan of care ordered by the physician. If there is any ambiguity about the plan of care, it is incumbent upon the home health agency to consult with the physician to clarify the plan of care. Here Petitioner's staff were making medical decisions for the physician (wound care), giving instructions where there was no specific order or the order was unclear (splint/sling, fluid intake), and disregarding specific orders (wound care, compression stockings). It is noteworthy that these incidents arose in a follow-up survey, after Petitioner indicated it would come into substantial compliance with the regulatory requirements. As a result of the initial survey in May 1996, Petitioner was placed on notice of the requirements that were previously found deficient. In spite of this notice, however, Petitioner continued to fail to comply with these regulatory requirements at the time of the September 1996 survey.

G 172 484.30(A) Standard: Duties of the Registered Nurse: The registered nurse regularly re-evaluates the patient's nursing needs.

Based on a clinical record review of nine patients, the surveyors determined that for four patients (Patients 9, 3, 8, and 4, in the order put forth in the HCFA Form 2567) Petitioner failed to

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[10] Patient 7 was cited under Tag G 158, but not under this tag. Also, while the surveyors cited two separate deficiencies for Patient 3 under Tag G 158, under this tag they cited only one deficiency, that concerning the use of a sling/splint by the patient, and not the other deficiency of an unauthorized third visit by a physical therapist. Apart from these differences, the alleged deficiencies in Tag 158 and Tag 172 are identical and repeated verbatim on the Form 2567.

ensure that the registered nurse regularly re-evaluated the patients' nursing needs.[11]

7. For Patient 9, HCFA has failed to establish a prima facie case that Petitioner's registered nurse failed to re-evaluate this patient's needs. For Patients 3 and 4, Petitioner has shown by a preponderance of the evidence that its registered nurse regularly re-evaluated the needs of these patients. For Patient *8, Petitioner failed to show by a preponderance of the evidence that its registered nurse re-evaluated the patient's needs in light of the patient's clearly apparent weight loss. Such failure had the potential to affect the health and safety of this patient.*

Patient 9

The surveyors made the following assertions concerning the care Petitioner gave to Patient 9:

> Patient #9's initial plan of care indicated that the patient had a condom catheter. On 8/27/96, the skilled nurse indicated that the rash on the patient's buttocks was decreased and not as red as previously noted. On 8/29/96, the physician ordered an indwelling catheter and on 9/3/96,

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[11] The introductory paragraph under Tag G 172 on the Form 2567 states that "for two (#3,9) of nine patients" Petitioner failed to ensure that its nurse regularly re-evaluated the patient's nursing needs. HCFA Ex. 2, at 20. The ensuing pages of the Form 2567, however, listed four examples, adding Patients 8 and 4, of this alleged failure by Petitioner's nurses. HCFA Ex. 2, at 20 - 23. Petitioner, citing Hillman, argued that the findings for Patients 8 and 4 should be dismissed, since there is no overall statement by HCFA on the Statement of Deficiencies that findings for these two patients are the basis for a violation of the standard.

HCFA disputed any notion that Petitioner did not have adequate notice of the alleged deficiencies involving Patients 8 and 4, noting that they were specifically discussed on the Form 2567. Moreover, HCFA continued, Petitioner brought to the hearing witnesses prepared to discuss all four deficiencies and had the opportunity to present evidence on all the examples and to cross-examine HCFA's witnesses.

I find that Petitioner was in no way prejudiced by the omissions in the introductory paragraph of this standard. Petitioner had adequate notice of the four alleged deficiencies under this standard, and was able to present a credible defense to all the alleged deficiencies under this standard.

> the physician ordered "OK to clamp Foley for up to four hours PRN (as needed)". There was no documentation to indicate that the registered nurse re-evaluated the patient's nursing needs regarding the Foley catheter.

HCFA Ex. 2, at 20 - 21.

Patient 9 had multiple sclerosis and a urinary tract infection, was bed bound, and was unable to perform any activities of daily living for himself. P. Ex. 7, at 1; HCFA Ex. 13, at 10; Tr. at 1226.

The State surveyor, Ms. Martinez, testified that this patient's POC, dated August 16, 1996, indicated that the patient had a condom catheter, and that there was no evidence that the condom catheter was not working. Tr. at 418; HCFA Ex. 13, at 10a. Ms. Martinez testified that there was no nursing evaluation of a need for an indwelling catheter.[12] Tr. at 418. Furthermore, according to Ms. Martinez, once there was an indwelling catheter in place, the physician ordered the catheter clamped for four hours without any evidence that the nurse provided an evaluation as to why this procedure was needed. Id. Ms. Martinez testified that the basis for the deficiency was the lack of evidence that the skilled nurse performed an evaluation of the need for the patient to have an indwelling catheter, when there was no evidence that the condom catheter was not working. Tr. at 417 - 18.

Ms. Martinez testified that she was concerned that the patient did not need to have an indwelling Foley catheter, which would subject the patient to a greater risk of a urinary tract infection from this invasive treatment. Tr. at 424. Ms. Martinez testified that at the start of his treatment the patient had a rash on his buttocks and his thighs, apparently from urine, but that the rash had improved by August 27, indicating that the condom catheter was working. Tr. at 424; HCFA Ex. 13, at 5. Ms. Martinez stated that if the condom catheter was not working she expected that the skilled nurse would have performed an evaluation to determine whether a Foley catheter was warranted. Tr. at 424.

Petitioner argued that HCFA failed to give sufficient notice of the basis of the deficiency in the HCFA Form 2567 to meet its burden under Hillman, and, therefore, this deficiency must be

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[12] A condom catheter is an external catheter, attached on the outside of the penis, so that it is not considered an invasive treatment. A Foley catheter is an indwelling catheter, meaning that it is inserted through the penis into the bladder and it remains there. It is considered an invasive procedure. Tr. at 422.

dismissed. Petitioner maintained that at the hearing the State surveyors stated they expected to find documentation of the justification for the changes from a condom catheter to a Foley catheter. According to Petitioner, this basis for the deficiency was not specifically stated in the HCFA Form 2567. As a result, Petitioner maintained that it had no notice of the specific basis for this deficiency, as required by Hillman, and this deficiency must therefore be overturned.

Petitioner also contended that HCFA did not substantiate the alleged violation of this standard. Petitioner produced two witnesses who testified that the use of a Foley catheter on this patient was appropriate. Dr. Narian, Petitioner's Medical Director in 1996, testified that the patient suffered from urinary retention, the inability to empty the bladder. Tr. at 917 - 18. Dr. Narian testified that this condition could lead to damage to the bladder and the kidneys, and also to increased risk of bladder infection. Tr. at 918. Dr. Narian testified that the use of a condom catheter is not the most appropriate treatment for this condition, as it does not address the urinary retention; rather, a treatment that empties the bladder is required. Tr. at 919. According to Dr. Narian, proper treatment would be the use of either an in-and-out catheter or a Foley catheter. Tr. at 920. Both of these treatments are invasive, but the Foley catheter remains in the bladder. Tr. at 927. Dr. Narian testified that in-and-out catherizations are done every four to six hours, but this patient's care giver, his wife, worked all day, so she was unable to perform the in-and-out catherizations. Tr. at 920 - 21.

Holly Robertson, a registered nurse employed by Petitioner in 1996, testified that she was the case manager for this patient and made home nursing visits, opening the patient's case on August 16, 1996. Tr. at 1225 - 26, 1251. Ms. Robertson testified that on admission to Petitioner the patient's wife was performing in-and-out catherizations on the patient. Tr. at 1227. Ms. Robertson testified that the wife worked 10 to 12 hours a days at the family business. Tr. at 1228. Ms. Robertson testified that on August 29 she called the physician's office to discuss having the patient fitted with a Foley catheter at the suggestion of the patient's wife. Tr. at 1242. Ms. Robertson testified that the wife said that she no longer wanted to do in-and-out catherizations and wanted an indwelling catheter. Tr. at 1243, 1258. Ms. Robertson stated that the order was received on August 29, with the Foley catheter inserted the next day. Tr. at 1244; P. Ex. 7, at 6.

I find that HCFA has failed to present a prima facie case that there was a deficiency here. HCFA's basis for a deficiency was the lack of any skilled nursing records showing the need for a Foley catheter as part of a re-evaluation of the patient's needs. HCFA argued that the skilled nurse had an independent duty under

42 C.F.R. § 484.30 to assess the medical need for the change in catheters and to convey that information to the physician. Generally, a nursing assessment of a medical need for a change in the type of catheter would be appropriate. If a patient's condition changes while under treatment, it is appropriate for the nurse to advise the physician and seek an alteration of the physician's orders for the patient.

Here, however, the motivation for the change in catheters was a non-medical need. It was done for the convenience of the patient's wife, at her suggestion. The physician agreed with the change to a Foley catheter. It thus appears that the physician was acting on his own initiative to assist the patient's wife, without any input from the nurse. There is nothing to suggest that the nurse had reason to question the physician's decision. What the State surveyors did here, in effect, was to second-guess the physician's order. The surveyors erroneously focused on the condom catheter without considering that the patient was undergoing in-and-out catherization by the wife. HCFA's arguments justifying the deficiency relate to medical judgments and not nursing needs. Evaluating the nursing needs of a patient does not give the nurse license to question the physician's medical judgment. Here the nurse is being faulted for not giving the physician an assessment of the nursing needs to support the physician's change of catheters. The skilled nurse provided in her notes the wife's dilemma in being present to help with the catherization.

The patient's wife asked the skilled nurse to relay to the physician that a different type of catheter should be used which was not as labor intensive for the wife. The skilled nurse did this and the physician switched to a Foley catheter. HCFA has not shown that the Foley catheter is more dangerous or harmful to the patient than the in-and-out catherization the patient was undergoing. Assuming that both devices work equally well, I find that there is no nursing assessment to be made in this situation. The decision to switch the catheters was not based on a medical decision and no nursing assessment was required. Consequently, Petitioner's nurse cannot be faulted for failing to provide a medical justification for the change in catheters since there was none. I concur with Petitioner that the nursing documentation was sufficient to document the reason for the change to the Foley catheter.

Accordingly, I find that there was no deficiency here.

Patient 3

The surveyors made the following assertions concerning the care Petitioner gave to Patient 3:

> Patient #3's clinical record contained skilled nurses notes dated 7/3/96 indicating that the patient's dentures "got lost by paramedics." There was no further documentation addressing the patient's lack of dentures. There was no documented evidence that the registered nurse re-evaluated the patient's potential nutritional problems in relation to the missing dentures.

HCFA Ex. 2, at 21.

The State surveyor, Ms. Martinez, testified that the basis for this deficiency was the failure of Petitioner's nurse to evaluate Patient 3's nutritional needs in light of the fact that the patient no longer had dentures. Tr. at 460. The surveyor noted that the patient's POC, dated June 29, 1996, had among its instructions that the skilled nurse assess the patient's "nutrition/hydration." P. Ex. 5, at 1. The surveyor testified that she understood this to mean that the skilled nurse was to make sure that "the patient had adequate nutritional intake without the use of dentures." Tr. at 461.

Petitioner denied that its skilled nurse was required to make a distinct evaluation of this patient's nutritional problems due to the patient's lack of dentures because this patient had at all times a set of replacement dentures. Petitioner referred to a June 29, 1996 nursing assessment that stated that the patient had replacement dentures. P. Ex. 5, at 10. That same assessment found all aspects of the patient's nutrition "normal." Id. at 11. Petitioner contended that when at the next skilled nursing visit on July 3, 1996, the patient reported that her "dentures got lost by the paramedics," the patient was referring to the previous loss of her dentures at the time of her stroke in 1995 and not to any new loss of her dentures.

At the hearing, the surveyor admitted, on a closer evaluation of this patient's records, that the skilled nurse did evaluate the patient's nutrition. Tr. at 464. The surveyor further admitted that she had not noticed that the patient had replacement dentures and that her opinion as to whether there was a deficiency here had changed. Tr. at 465 - 66, 475.

It is evident that the record is unclear as to whether the patient had lost her dentures as of July 3, had replacement dentures, or was wearing them. HCFA contends that it does not matter, as the skilled nurse should have re-evaluated the patient's nutritional needs in light of the denture problems. I find, however, that the skilled nurse did evaluate the patient's

nutritional needs. The June 29, 1996 nursing assessment notes the patient's nutrition as normal. P. Ex. 5, at 11. Furthermore, the record before me contains five "RN Daily Visit Records," covering a period between July 3 and July 26, 1996, on which the patient is recorded as denying any problems in the areas of nutrition/hydration. P. Ex. 5, at 12 - 16. I do not agree with HCFA that this is an insufficient assessment. If a problem is noted, then further elaboration is required. If, however, no problem is noted, no further elaboration is required by the skilled nurse.

Consequently, I find that there was no deficiency here.

Patient 8

The surveyors made the following assertions concerning the care Petitioner gave to Patient 8:

> Patient #8 had a start of care dated 7/15/96 with a physician's order for 2 Gm. sodium diet. Review of the clinical record revealed that the patient was forgetful, lived alone, and friends assisted her with errands.
>
> The initial skilled nurse's assessment documentation indicated that the patient's weight was 145 pounds. The registered nurse also documented that the patient had "Signif. (significant) wt. loss since last seen by this RN, 9 mos. ago (20#?)."
>
> Review of the skilled nurses notes revealed that from 7/15 through 9/20/96, the patient had intermittent bilateral pedal edema.
>
> Further review of the clinical record revealed no documented evidence that the patient's weight had been rechecked. There was no documentation that the skilled nurse re-evaluated the patient's nursing needs in relation to nutritional status.

HCFA Ex. 2, at 21 - 22.

The State surveyor, Ms. Sabino, testified that the basis for this deficiency was the failure of the nurse to re-evaluate the patient after the initial July 15 nursing assessment that the patient had lost a considerable amount of weight. Tr. at 371; HCFA Ex. 12, at 12a. Ms. Sabino testified that, given the initial assessment that the patient had lost significant weight, she would have expected to see in the notes of the skilled nurse some indication that the nurse was periodically checking the patient's weight and nutritional intake. Tr. at 353; HCFA Ex. 12, at 4 - 7. Ms. Sabino testified that a nurse can check a patient's weight without a physician's order. Tr. at 353. Ms.

Sabino further testified that the presence of an edema, as this patient had, could cause a patient to weigh more because of fluid retention. Tr. at 370. Ms. Sabino, on cross-examination, admitted that the nurse did re-evaluate in visits subsequent to the initial assessment the patient's dietary needs. Tr. at 368; P. Ex. 3, at 3a, 4 - 6, and 11 - 12. Ms. Sabino stated that she did not know of any standard in home health care that the patient's weight is taken on every visit by a nurse. Tr. at 372.

Petitioner made the following arguments: 1) there was no evidence in this case that the patient had any problems with her nutritional status which were not already being addressed by her POC; 2) there is no standard of nursing or home health practice that the skilled nurse recheck a patient's weight unless ordered to do by the physician, especially where there is no indication on initial or ongoing assessment of nutritional problems; and 3) the skilled nurse frequently did evaluate this patients's nutritional status on an ongoing basis.

Petitioner's Medical Director, Dr. Narian, testified that the patient's weight, 145 pounds, was normal for her 5'10" height, even taking into account the patient's edema in her leg. Tr. at 939; HCFA Ex. 12, at 12. Dr. Narian testified that an edema can add 10 pounds to a patient's weight, but that even if this patient's body weight was really 135 pounds, that was still an acceptable weight. Tr. at 940. Dr. Narian stated, in reviewing the patient's records, that there was nothing that would cause him to have significant concerns about the patient's nutritional status. Id. Dr. Narian further testified that it is not routine for a nurse to take a patient's weight on every visit, and that if a physician wants a patient to be weighed, a specific order is required. Tr. at 941. Dr. Narian testified that, from reading the nurse's reports of her visits, he believed that the nurse re-evaluated the patient's nutritional status on subsequent visits. Tr. at 944; P. Ex. 3, at 3a, 5, and 6. Dr. Narian further testified that a patient's weight is not generally monitored in a home setting, but rather in the physician's office. Tr. at 948. Dr. Narian noted that the patient visited her physician's office on July 18 and July 25, and he stated that the physician would, under the standards of the profession, weigh the patient on each visit. Tr. at 948 - 49; P. Ex. 3, at 4 and 5. Dr. Narian admitted on cross-examination, however, that a nurse could, without getting a specific physician's order, exercise nursing judgment in deciding to weigh a patient. Tr. at 956 - 57.

Petitioner maintained that, although the nurse documented a significant weight loss by the patient in the last nine months, the nurse also assessed the patient's abdominal girth as normal. P. Ex. 3, at 2a. Petitioner argued that the clear implication from this was that the patient had previously been overweight and had intentionally lost weight over the past nine months with a weight loss diet. Petitioner contended that there was nothing in

the record that demonstrated that the patient had significant nutritional problems, other than the documented low sodium diet for her medical condition. According to Petitioner, the skilled nurse therefore had no reason to monitor the patient's weight on an ongoing basis.

At the outset, I reject Petitioner's assertion that a skilled nurse cannot measure the weight of a patient without a physician's order. The regulation at 42 C.F.R. § 484.30(a) specifically directs the skilled nurse to inform the physician of changes in the patient's condition. The observation of an apparent significant weight gain or loss in a patient could reasonably be expected to lead a nurse to determine the actual weight of the patient and notify the physician of that determination. Moreover, Petitioner's own witness, Dr. Narian, stated that a nurse could weigh a patient without a physician's order. Tr. at 957.

I also find unpersuasive Petitioner's position that the weighing of the patient by the nurse was unnecessary because the physician would presumably weigh the patient on her weekly visits. The regulation places the responsibility on the skilled nurse to evaluate the patient's needs and report to the physician. To allow that responsibility to be shifted to the physician renders the regulation meaningless.

In evaluating the parties' position, I find it relevant that the skilled nurse was familiar with this patient. Apparently, the nurse had visited the patient nine months previously. The nurse was thus personally able to note a significant decline in the patient's weight. Petitioner failed to produce any factual support for its assertion that this patient had been overweight and had intentionally lost approximately 20 pounds on a diet. The patient was 85-years old in July 1996. P. Ex. 3, at 3b. I question the probability that such an elderly individual would consider or complete such a weight reducing diet.

There was, therefore, an unexplained reduction in the patient's weight. Furthermore, there is Dr. Narian's statement that the patient's weight might be overstated by 10 pounds due to her edema. Additionally, there were indications on the initial nursing assessment that the adequacy of the patient's diet was abnormal. HCFA Ex. 12, at 13. Under these circumstances, I find that it was incumbent under the regulation for the nurse to monitor the patient's weight during her visits to determine if the patient's nutritional needs were being met. While no actual harm to the patient was shown, a potential harm for this patient clearly existed.

Accordingly, I find that Petitioner's failure to re-evaluate this patient's nutritional needs by monitoring her weight constituted a deficiency in Petitioner's provision of care to this patient.

Patient 4

The surveyors made the following assertions concerning the care Petitioner gave to Patient 4:

> Patient #4's plans of care dated 4/11/96, 6/11/96 and 8/11/96 listed the primary diagnosis as decubitus ulcer. Documentation indicated that the patient was bed bound and 24 hour attendants that were relieved by family members on weekends. On 5/20/96, the skilled nurse documented "daughter is here from Nevada. She has hired PCG (patient care giver) because patient does not want to move." Documentation indicated that the care givers changed. For example, the regular attendant was relieved on weekends by either the patient's daughter or son and new personal attendants were hired. The patient was incontinent and dressings to the decubitus ulcer were often found wet with urine. For example, on 6/24/96, the skilled nurse documented "According to attendant, duoderm got wet with urine." The documentation indicated that the regular attendant was on duty and the patient's daughter had relieved the attendant over the weekend. On 7/15/96, the skilled nurse documented "Client refuse Foley catheter/according to attendant dressing ongoing gets wet with urine." The documentation further indicated "Regular attendant on duty. Has been changing dressing BID over coccyx ulcers. States due to dressing gets wet." The notes further indicated that the skilled nurse instructed wound care to attendant. On 7/29/96, the skilled nurse documented "Attendant to continue wound care BID." There was no documented evidence that the registered nurse re-evaluated the patient's nursing needs in relation to the patient's wound care.

HCFA Ex. 2, at 22 - 23.

State surveyor Martinez explained that since the patient was incontinent, the dressings were frequently wet with urine, requiring frequent dressing changes, with the attendants needing to learn how to make the dressing changes properly. Tr. at 605. Ms. Martinez testified that, in order for this standard to be met for this patient, she expected to see documentation that the skilled nurse instructed each of the care givers on wound treatment, supervising them on a regular basis to ensure that care appropriate to the current physician's order was being given. Id. Ms. Martinez noted that the patient's wound had become enlarged from June 17 to August 26, which should have, in Ms. Martinez's opinion, led the nurse to re-evaluate the patient's wound treatment. Tr. at 607 - 08; HCFA Ex. 8, at 34, 7. Ms. Martinez testified that the basis for this deficiency was that there was no documentation that the skilled nurse communicated with the patient's several care givers about the various changes in the treatment of the patient's wound and that

the nurse re-evaluated the care givers to ensure that the appropriate treatments were being provided. Tr. at 602 - 03. HCFA's Nurse Consultant, Ms. Patience, agreed that under this standard she expected to see some sort of notation from the skilled nurse as to how the attendants and family members were changing the dressing and providing wound care, with additional documentation as to the nurse's re-evaluation of the patient's needs. Tr. at 559 - 60.

Petitioner contended that the bases for this deficiency cited by HCFA's witnesses in their testimony, the lack of evidence that the patient's care givers were observed changing the dressing, or were instructed about wound care, and the increasing size of the patient's wound, do not appear anywhere in the HCFA Form 2567. Petitioner asserted that both Ms. Martinez and Ms. Patience acknowledged that there was no statement in the HCFA Form 2567 that describes these subjects as the surveyors' concerns. Tr. at 610 and 567. Petitioner therefore contended that it did not have the notice required by Hillman to allow it to adequately respond to this deficiency, and, consequently, the deficiency must be overturned. Furthermore, Petitioner alleged that there was evidence in the record that the skilled nurse frequently assessed the care givers' knowledge of wound care and instructed them in proper wound care.

Petitioner's Nurse Supervisor, Wilma Austin, testified that she frequently spoke with the skilled nurse about this patient. Tr. at 1506. Ms. Austin stated that the patient had a 24-hour care giver during the weekdays, with the patient's family taking over on the weekends. Tr. at 1518. Ms. Austin testified that from a series of communication notes and nursing records it appeared that the skilled nurse had educated the care givers in wound care. Tr. at 1508 - 11; P. Ex. 27, at 1 - 2.

I will first discuss Petitioner's argument that HCFA failed to give it adequate notice of the nature of this deficiency, as required by Hillman. I agree with Petitioner that at the hearing HCFA presented evidence which amplified the description of the deficiency in the HCFA Form 2567. I find, however, that HCFA gave Petitioner adequate notice on the HCFA Form 2567 as to the general nature of the conduct being found deficient: the patient's wound was being affected by wet dressings and the patient's care was complicated by the numerous care givers, attendants during the week and relatives on weekends. The deficiency is not invalid because HCFA did not indicate in the HCFA Form 2567 all the actions that the skilled nurse should have performed in re-evaluating the patient's nursing needs, including observing the care givers providing treatment to the wound or training the family members in providing treatment. I am troubled, however, by the fact that in its case HCFA often stressed a period of time in the care of this patient, from July 15 to August 8, which is not referenced in the HCFA Form 2567.

At the hearing, I instructed HCFA that it could not, at the hearing, reconstitute the deficiency by bringing documentation on matters that were not stated on the HCFA Form 2567. Tr. at 1531. I therefore will not consider any matters beyond the dates specified in the HCFA Form 2567. As to the general nature of this deficiency, I find that Petitioner did, though, have the opportunity at the hearing to present witnesses and evidence to rebut the deficiency as elaborated by HCFA's witnesses. Insomuch as I find below that Petitioner successfully met this standard and refuted the deficiency, I do not find that Petitioner was in any way prejudiced by any ambiguity in the HCFA Form 2567 or HCFA's elaboration of the specifics of the alleged deficiency at the hearing.

I find that the record supports a finding that the skilled nurse acted reasonably here, performing the necessary re-evaluations, contacting the physician for additional orders, and providing the appropriate instructions to the care givers. During the relevant time period, there appears only one time when someone other than the skilled nurse changed the patient's dressings; the patient's spouse, after being instructed by the nurse, changed the dressing on July 7. P. Ex. 27, at 1. On July 15, the nurse requested and received a physician's order changing the dressing, and on the same day instructed the attendant on wound care. P. Ex. 22, at 23; HCFA Ex. 8, at 31.

Additionally, I note that, while I restricted the relevant time frame for this deficiency to the dates stated in the Form 2567, the record contains documentation that the nurse discussed wound care with the attendant on August 5, 7, and 9. P. Ex. 27, at 3 - 5. On August 9, the nurse left written instructions for the patient's son on wound care, and on the next day observed the son performing wound care. P. Ex. 27, at 5 and 7. I consider these documents relevant only to the extent that they show that it appeared to be the skilled nurse's practice to instruct the patient's care givers in wound care. Furthermore, I do not agree with HCFA that personal observation by the nurse of the wound care provided by all the care givers is necessary or required. When the nurse visited the patient, the nurse could observe the performance of the care givers and the results of their efforts.

Accordingly, I find that there was no deficiency here.

G 173 484.30(A) Standard: Duties of the Registered Nurse: The registered nurse initiates the plan of care and necessary revisions.

Based on a clinical record review of nine patients, the surveyors determined that for two patients (Patients 4 and 3 in the order put forth on the HCFA Form 2567) Petitioner failed to ensure that the registered nurse initiated the plan of care and necessary revisions.

8. For Patients 4 and 3, Petitioner has failed to prove by a preponderance of the evidence that its registered nurse made necessary revisions to the plans of care for these patients. Such failure had the potential to adversely affect the health and safety of these patients.

Patient 4

The surveyors made the following assertions concerning the care Petitioner gave to Patient 4:

> Patient #4's clinical record contained skilled nurses notes dated 5/20/96 indicating "MD adjusting Coumadin. Lab comes to house per MD orders." There were no physician's orders for lab work. On 9/3/96, the registered nurse documented "SN notified her (physician's office nurse) of client's routine q month protime by lab due too hard to draw -- not done last month." There were no physician's orders for monthly lab draws. There was no documented evidence that the nurse initiated the appropriate revisions to the plan of care.

HCFA Ex. 2, at 23.

This patient was admitted to Petitioner on April 11, 1996, primarily for wound care for decubitus ulcers. HCFA Ex. 8, at 15. The patient also was taking Coumadin, an anti-coagulant medication, as treatment for a stroke she had experienced. The State surveyor, Ms. Martinez, testified that this patient's POC included "anticoagulant precautions" under Safety Measures and "anticoagulant therapy as ordered without complications" as one of the Goals of Petitioner's care for this patient. Tr. at 115; HCFA Ex. 8, at 10 - 11. Ms. Martinez testified that in her review of this patient's records, she came across a September 9 nurse's note that indicated that a laboratory was doing a monthly protime evaluation on the patient to measure the effectiveness of the Coumadin. Tr. 112 - 13; HCFA Ex. 8, at 24. This note indicated that the laboratory was not able to draw a sample of the patient's blood in the last month, and that the nurse notified the physician's office of this fact. HCFA Ex. 8, at 24. Ms. Martinez testified that she was concerned about how a nurse could ensure anticoagulant therapy without complications, as stated in the POC, unless there was a system in place to monitor the patient's use of Coumadin. Tr. at 115 - 16. Ms. Martinez expressed her concern that there did not appear to be a system in place to ensure that laboratory tests for protime levels were being conducted with the physician being notified of the results. Tr. at 113. Ms. Martinez stated that under 42 C.F.R. § 484.30(a) the nurse should have revised the POC to include documentation that a system was in place for monitoring the patient's use of Coumadin. Tr. at 116.

Petitioner argued that, contrary to HCFA's contentions on the Form 2567, there were physician's orders for the monthly protime levels performed, and the physician received the protime levels without Petitioner's intervention. Petitioner contended that since the physician's orders and protime results were maintained at the physician's office, there was no need to revise the POC to include such orders. The patient's physician, Thomas Denmark, testified that he treated the patient for seven or eight years. Tr. at 158. Dr. Denmark explained that the patient had sustained a major stroke in 1992 and was taking anti-coagulants. Tr. at 160. Dr. Denmark testified that he ordered protime laboratory levels for this patient, protime being the method to measure the clotting ability of blood and thus the effect of the blood thinning done by Coumadin. Tr. at 161 - 62. Dr. Denmark explained that Coumadin is a very effective blood thinner, but it must be controlled very exactly because if not enough is taken no protection results, while if too much is taken the patient can suffer bleeding. Tr. at 162. Dr. Denmark testified that a laboratory would visit the patient, draw her blood, and inform him of the results. Tr. at 163. Dr. Denmark testified that if the laboratory did not report the results, his nurse maintained a system to insure that the protimes were drawn. Id. Dr. Denmark stated that his office sent the protime laboratory orders directly to the laboratory, and not to Petitioner. Tr. at 165; P. Ex. 9. Dr. Denmark further stated that the laboratory results were sent to his office and not to Petitioner. Tr. at 165. Dr. Denmark testified that he did not intend for the protime orders to be a part of the home health agency POC because he found it more effective to have his office control the whole process. Id. Dr. Denmark stated that he did not expect home health nurses to get involved in the laboratory process. Tr. at 166. Dr. Denmark testified that the call on September 3 by the nurse to his office that the protime draw had not been done was unnecessary, as his office would have determined that and contacted the laboratory. Tr. at 168 - 69; HCFA Ex. 8, at 24. Dr. Denmark further stated that he did not intend for the laboratory draws to be included in this patient's POC. Tr. at 170; HCFA Ex. 8, at 10.

Dr. Narian, Petitioner's Medical Director, testified that in situations such as this, where a physician has a system in place where he orders a laboratory to draw blood and send the results to him, there is no need for a home health agency to intervene or coordinate those services. Tr. at 972. Dr. Narian testified that what Dr. Denmark had in place for this patient was a separate service that Dr. Denmark did not ask Petitioner to provide. Id. Dr. Narian did agree, however, that in an instance where a nurse observed that there was a missing laboratory draw, it would have been appropriate for the nurse to discuss with the physician possible changes to the POC to deal with this problem. Tr. at 988.

Petitioner further argued, that since the physician is responsible for establishing the POC and legally is responsible for revisions to the POC, it should not be penalized because the physician exercised his discretion to handle the lab work himself. Petitioner claimed that 42 C.F.R. § 484.30(a) does not require the skilled nurse to initiate changes in the physician's order. Petitioner referred to CSM Home Health Services, Inc., DAB CR440 (1996), arguing that the Administrative Law Judge there determined that this particular standard does not impose on a registered nurse the duty of writing a POC or of making revisions to a POC, but instead just means that a nurse must begin to implement and carry out all treatments that are ordered in the POC. CSM, DAB CR440, at 6. Petitioner maintained that this determination was upheld by the Appellate Division of the Departmental Appeals Board. CSM Home Health Services, Inc., DAB No. 1622, at 17 (1997).

I find that there was sufficient discussion of the need for Coumadin in the POC, with references to precautions and the need to avoid complications, that responsibility would accrue under 42 C.F.R. § 484.30(a) to the nurse to ensure that the monitoring of the Coumadin was being done properly. I am not persuaded by Dr. Denmark's testimony that he chose to monitor the protime levels outside the home health agency and that he did not expect the home health agency to have any input in this area. Coumadin was one of the principal medications the patient was taking and the nurse was charged with the responsibility of observing the patient's medication compliance. Furthermore, the POC signed by Dr. Denmark included under "Goals" that the patient "receive anticoagulant therapy as ordered w/out complications." HCFA Ex. 8, at 11.

Nor do I find convincing Dr. Narian's statement that from his experience home health agencies are not required to ensure that such monitoring is in place. Of importance here is the fact that Petitioner was informed that a problem in the monitoring occurred and action should have been taken at that point to ensure that an adequate monitoring system was in place. A record entry that the physician was notified and asked whether the POC should be amended to reflect the monitoring process probably would have been sufficient. Under these circumstances, I believe that the skilled nurse should have initiated an inquiry as to whether the POC needed to be changed.

As to Petitioner's argument that the holdings in the CSM decisions support its position that the skilled nurse is not required to initiate changes in the POC, I note that the Appellate Panel acknowledged that the physician establishes the POC, but does not necessarily write it, and, consequently, it would be appropriate for a home health agency, presumably through its skilled nurse, to prepare a POC for the physician's review and signature. CSM, DAB No. 1622, at 17 n.15. This conforms

with my understanding of what occurs in home health agencies and what happens in the creation of a POC. A skilled nurse prepares a POC worksheet; a clerk, using a computer, creates a POC; the POC is reviewed by a supervisor; and the POC is sent to the physician for signature. Here, the nurse had an obligation to bring the Coumadin monitoring issue to the attention of the physician and inquire whether the POC should be changed to reflect the process in place. The POC contained references to specific duties of the nurse regarding the Coumadin therapy. The fact that the monitoring may not have been working properly made it incumbent on the nurse to initiate action to determine whether adequate monitoring was being done and to ensure that the POC clearly differentiated the roles of the nurse and the physician concerning the lab work and the monitoring of the results.

Once the nurse learned of the problem with the blood collection and that the physician was adjusting the medication based on the lab results, the nurse should have made inquiries to the physician as to the process in place. The nurse then should have revised the POC to reflect the process the physician wanted to use. The nurse did not need to develop any particular monitoring plan, but the nurse was required to bring the situation to the attention of the physician and incorporate the physician's wishes in the POC so that it could be shown that the issue was considered and addressed. While this one particular nurse might have been apprised of the situation, a replacement nurse would be unaware of the process unless it were recorded in the POC.

I therefore find that the failure by the skilled nurse to revise the POC to indicate the system that was in place to monitor the patient's use of Coumadin constituted a deficiency in Petitioner's provision of care to this patient. It is incumbent that the home health agency and the patient coordinate their care of the patient. Whenever there is doubt about the type of care the physician ordered, the agency must obtain clarification. Failure to obtain such clarification could lead to confusion which could jeopardize the health of the patient.

Patient 3

The surveyors made the following assertions concerning the care Petitioner gave to Patient 3:

> Patient #3's initial skilled nursing evaluation dated 6/29/96 indicated that the patient was instructed on the use and purpose of an upper extremity splint and sling. The plan of care dated 6/29/96 did not address the use of a splint or a sling. There was no documented evidence that the registered nurse initiated the appropriate revision of the plan of care.

HCFA Ex. 2, at 23 - 24.

Once again, this is the same factual situation that was the basis for deficiencies under Tags G 158 and G 159, discussed above. State surveyor Martinez testified that the basis for this deficiency was the lack of any reference in the POC concerning the nurse instructing the patient on the use of the splint/sling. Tr. at 618.

Petitioner repeated its earlier argument that the physician was in charge of establishing this POC and determined that there was no reason to have a separate specific order for the device on the POC. Petitioner maintained that the POC was complete and there was no need for further orders regarding the device.

As I sustained HCFA's finding of a deficiency in this factual situation under Tags G 158 and G 159, I also find a deficiency here under Tag G 173. I have already concluded that instructions regarding the splint/sling should have been included in this patient's POC. The physician should have been notified concerning this device when the skilled nurse noticed the patient wearing it. Whatever instructions the physician may have wanted as to the use of the splint/sling should have been initiated by the skilled nurse. Since the skilled nurse prepares the POC for the physician's approval, the physician could have stated his opinion on the use of the splint/sling when reviewing the POC. If the physician did not want the patient to use the splint/sling, that should have been documented. That is what is called for under the regulation. Medical decisions are the physician's prerogative, but the skilled nurse has the responsibility to bring to the physician's attention issues for potential inclusion in the POC based on the nurse's evaluation of the patient. As stated previously, while no actual harm to the patient was shown, there was a potential for harm present under these circumstances.

I therefore find that the skilled nurse's failure to reference the patient's use of a splint/sling in the POC constituted a deficiency in Petitioner's provision of care to this patient.

G 175 484.30(A) Standard: Duties of the Registered Nurse: The registered nurse initiates appropriate preventive and rehabilitative nursing procedures.

Based on a clinical record review, observation, and interview, the surveyors determined that Petitioner failed to ensure that its registered nurse initiated appropriate preventive and rehabilitative nursing procedures for Patient 6.

9. For Patient 6, Petitioner has proved by a preponderance of the evidence that its registered nurse initiated the appropriate nursing procedures.

Patient 6

The surveyors made the following assertions concerning the care Petitioner gave to Patient 6:

> Patient #6 had a start of care dated 8/31/96. The plan of care indicated that the patient was on regular diet with fluid restriction 1500-2000 ml. in 24 hrs. The plan of care cited that the skilled nurse would instruct patient/care giver regarding diet. Review of the skilled nurses notes revealed no documented evidence that the patient or care giver were instructed regarding the fluid restrictions.
>
> During the home visit on 9/13/96, the skilled nurse was observed instructing the patient/care giver that the patient should drink one glass of water every hour. When the patient's spouse was interviewed regarding the patient's fluid intake, he responded that the patient "can drink as much as she wants."
>
> There was no documentation to indicate that the registered nurse had initiated appropriate preventive nursing procedures by assisting the patient and care giver to maintain the patient's fluid restrictions.

HCFA Ex. 2, at 24 - 25.

This is the same factual situation that was the basis for the deficiency under Tag G 158, discussed above.

HCFA's Nurse Coordinator, Ms. Patience, testified that the basis for the deficiency under this standard was the failure of the skilled nurse to initiate preventive procedures by not giving the proper instructions regarding fluid intake to the patient's care giver. Tr. at 592.

In response, Petitioner focused on the word "appropriate" in this standard. Petitioner maintained, as it did previously, that the physician actually ordered the nurse to encourage fluid intake. According to Petitioner, if the nurse thus did act in accordance with the physician's orders, the nurse did initiate the appropriate preventive and nursing procedures for this patient. Petitioner argued that, in recognition of the patient's medical conditions, it was appropriate for the nurse to instruct the patient and her care giver to have the patient drink as much fluid as possible and it would have been inappropriate to restrict fluids. Furthermore, Petitioner contended, there was no detrimental effect on the patient's care.

I agree with HCFA that there is no doubt in the record, and it is conceded by Petitioner, that the skilled nurse was encouraging unrestricted fluid consumption. If HCFA's interpretation of the

POC is correct, then the nurse needed to initiate preventive measures to ensure that the restriction was followed. The record indicates that this was not done. Above, I found that the POC was vague and clarification should have been sought by the nurse. If clarification had been sought by the nurse, preventive measures would have been in order if the patient and her care giver were now deemed to have been given incorrect instructions based on any revisions to the POC. But, since the record is not clear on what the physician intended, I am not prepared to conclude that the skilled nurse should have been required to initiate preventive measures under the circumstances presented here, particularly if the clarification would have led to a revision of the POC eliminating the "restriction" in fluid intake.

Accordingly, I find no deficiency here, and therefore no violation of this standard.

G 176 484.30(A) Standard: Duties of the Registered Nurse: The registered nurse prepares clinical and progress notes, coordinates services, informs the physician and other personnel of changes in the patient's condition and needs.

Based on a clinical review of nine patients, the surveyors determined that for two patients, Patients 4 and 8, Petitioner failed to ensure that its registered nurse coordinated services and informed the physician of changes in the patients' needs.[13]

10. For Patients 4 and 8, Petitioner has failed to show by a preponderance of the evidence that its registered nurse coordinated services for these patients and informed their physicians of changes in the patients' conditions and needs. Such failures had the potential to adversely affect the health and safety of these patients.

Patient 4

The surveyors made the following assertions concerning the care Petitioner gave to Patient 4:

> Patient #4's initial plan of care dated 4/11/96 listed decubitus ulcer as the primary diagnosis with no other pertinent diagnoses or surgical procedures identified. The

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[13] Although the introductory paragraph on the HCFA Form 2567 under this standard stated that Petitioner failed this standard in regard to an additional patient, Patient 1, the HCFA Form 2567 contained no further findings of a deficiency for Patient 1 and HCFA presented no evidence regarding this patient at the hearing. Consequently, only patients 4 and 8 are the basis for deficiencies under this standard.

plan of care dated 6/11/96 listed the primary diagnosis as decubitus ulcer and congestive heart failure and atrial fibrillation as secondary diagnoses. The plan of care dated 8/11/96 listed decubitus ulcer as the primary diagnosis with congestive heart failure, cachexia, and atrial fibrillation as secondary diagnoses.

Skilled nurses notes dated 6/17/96 indicated that the patient's oral intake consisted of four to five glasses of fluids per day and the "only nutritional intake creamed soups with milk." According to skilled nurses notes, the patient's nutritional intake remained poor. For example, on 7/29/96, the skilled nurse documented "Poor nutrition - multiple nutritional supplements provided - other foods offered." Documentation indicated that the skilled nurse provided instruction on nutrition and its importance and personal attendant offered food frequently.

On 8/13/96, a licensed enterostomal nurse documented that the patient's healing potential was guarded due to poor nutrition. There was no documented evidence that the physician was informed of the patient's nutritional state.

Skilled nurses notes dated 5/20/96 documented "M.D. adjusting Coumadin. Lab comes to house per M.D. orders." There were no protime results in the clinical record or evidence that the physician was notified of these lab results each month. On 9/3/96, the skilled nurse documented "SN notified her (physician's office nurse) of client routine q month protime by lab due too hard to draw - not done last month." There was no documented evidence in the record that the registered nurse had notified the physician of the missed lab work or that the registered nurse was coordinating the services to ensure that the lab tests were done.

HCFA Ex. 2, at 26 - 27.

Although not listed separately on the HCFA Form 2567, HCFA alleged two distinct deficiencies in regard to Petitioner's treatment of this patient, the first regarding the patient's nutrition, the second concerning another aspect of the previously discussed Coumadin issue (see Tag G 173 above).

a. State surveyor Martinez testified that the time frame that she considered in evaluating Petitioner's care for this patient was from June 11, 1996 to August 11, 1996. Tr. at 621 and 640. Ms. Martinez testified that good nutrition was very important to the successful healing of this patient's decubitus ulcer, with increased protein and vitamins needed for the healing of the patient's skin. Tr. at 619 and 623. Ms. Martinez stated that if nurses are documenting poor nutritional intake by a patient, she

expected that the nurses would notify the physician within several weeks. Tr. at 620. Ms. Martinez further testified that the patient's condition warranted aggressive treatment and that she did not see any evidence that Petitioner's nurses were keeping the physician informed until five or six weeks after the condition was first noted. Id. Ms. Martinez testified that she noted in her review of this patient's records numerous instances in June and July where the nurses commented on nutritional problems with this patient. Tr. at 621 - 22; HCFA Ex. 8, at 5 - 6. Ms. Martinez testified that the basis for this deficiency was that Petitioner's nurses were consistently documenting this patient's poor nutrition, but there was no documentation that the physician was being notified of the patient's condition. Tr. at 623.

Petitioner argued there was ample evidence that the physician was informed at appropriate intervals by the skilled nurse of the patient's poor oral intake and nutritional status and that the physician even ordered nutritional supplements for the patient. Petitioner contended that its skilled nurses took numerous measures throughout the period to address the patient's nutritional status.

Petitioner argued that there was no documentation prior to June 17, 1996, that this patient had any problems with oral intake or nutrition. Petitioner pointed out that the POC dated June 11, 1996, did not list any problems with the patient's nutritional status. According to Petitioner, a problem with the patient's nutrition, cachexia, a general wasting of the body during a chronic disease, first appeared as one of the patient's diagnoses on the August 11, 1996 POC, outside of the time frame Surveyor Martinez used to evaluate the care for the patient. HCFA Ex. 8, at 10. Petitioner further argued that the skilled nurse was aware that the patient was seen on a routine basis by the patient's primary physician, July 17 and September 17, at which times the physician would have noted any significant problems with the patient's nutritional status. P. Ex. 8, at 18 and 24. Petitioner further argued that Ms. Martinez agreed that a July 29, 1996 case conference, which noticed the patient's poor nutrition, was provided to the physician. Tr. at 625 - 26.

Petitioner stated that the patient had been placed on Ensure, a nutritional supplement, or an equivalent nutritional supplement, on May 31. P. Ex. 22, at 28. On June 29, according to Petitioner, the skilled nurse again instructed the patient to drink Ensure between meals to improve her caloric intake. HCFA Ex. 8, at 32. Petitioner argued that an August 5 communication note from the skilled nurse to the physician detailed the patient's nutritional problems. P. Ex. 8, at 21. Thus, according to Petitioner, the skilled nurse informed the physician on July 29 and August 5 about the patient's nutritional status.

The August 11 POC listed cachexia as one of the patient's diagnoses. HCFA Ex. 8, at 10. The physician signed this POC on August 15. Id. at 12. Petitioner argued that this is evidence that the physician was being notified of the patient's ongoing nutritional problem.

Petitioner concluded, relying on the testimony of Ms. Martinez, that there is no standard of practice that dictates that a physician be notified of the continuation of a chronic problem at any specific intervals, especially when the skilled nurse is taking other nursing measures to address the problems prior to notifying the physician. Tr. at 643. Petitioner noted that even after the physician was notified about the patient's nutritional status, the physician did not alter his treatment or the nutritional requirements for the patient.

I find Petitioner's arguments unpersuasive. First, Petitioner's assertion that this patient's poor nutritional status was a chronic condition is undermined by the fact that the June 11 POC makes no mention of any concerns about the patient's nutrition. Second, Petitioner's claim that the patient was seen routinely by the physician is not supported by its citation to only two visits, with only one in the period under review. Moreover, I am not persuaded by any suggestion that a visit by the patient to the physician relieves the skilled nurse of any responsibility to notify the physician of the patient's poor nutrition. Third, contrary to Petitioner's assertion that the skilled nurse's reminders to the patient to drink the nutritional supplement show that the patient's nutritional problems were being properly addressed, the efforts to have the patient drink the supplement only serve to emphasize the patient's poor nutritional status. While I do not agree with HCFA that the August 5 communication note was inadequate as it was not a direct communication with the physician, I nonetheless find that the skilled nurse did not convey the changes in the patient's nutritional status to the physician in a timely fashion. Petitioner's reliance on the July 29 summary progress note is misplaced. First, this note was written some six weeks after the first concerns about the patient's nutrition were raised on June 17. Second, a review of the summary progress note, which is forwarded to the physician, reveals that it does not contain sufficient information, as envisioned by this standard, to inform the physician that a change in the patient's condition has occurred. The notation as to "poor nutrition/hydration longterm" is an inadequate method to communicate a change in condition leading to a possible change in treatment. This status note covers many issues and only a careful reading discloses the patient's nutritional status, and even then it suggests no change in the patient's condition. This is in direct conflict with the June 11 and August 11 POCs which have differing diagnoses concerning the patient's nutritional status. I find that this failure to communicate the problems

with the patient's nutrition to her physician had the potential to cause harm to this patient.

I therefore find that the failure by the skilled nurse to inform the physician of the changes in the patient's nutritional needs constituted a deficiency in Petitioner's provision of care to this patient.

b. This alleged deficiency involves the same factual situation discussed for this patient under Tag G 173. Under Tag G 176, however, HCFA is alleging that Petitioner's skilled nurse, in addition to revising the patient's POC to indicate the Coumadin testing, also bore the responsibility of coordinating the services to ensure that the ordered lab tests were performed and of informing the patient's physician of the missed lab test, regardless of the existence of the physician's independent system for the tracking of the performance of the Coumadin tests. Ms. Patience testified that merely communicating that a lab draw was missed to the physician's office was not sufficient to meet this standard; instead, it was necessary that the physician actually receive the information and become aware of the missed lab test, as shown by some type of response from the physician. Tr. at 599 - 600.

Petitioner argued that there is no HCFA standard or regulation that mandates that a home health agency report missed lab work to the physician, or coordinate laboratory services, if the agency is not ordered to perform the lab work, obtain the results, or report the results to the physician. Petitioner contended that pursuant to HCFA's own interpretive guidelines to the conditions, a skilled nurse is only required to coordinate the home health services the home health agency is actually ordered by the physician to perform, not all medical procedures the patient is receiving. P. Attachment 5. Petitioner reasoned that since the skilled nurse was not ordered to perform the protime levels, obtain the lab results, or report these results to the physician, the skilled nurse cannot be held responsible by HCFA for coordinating these services or even for notifying the physician of missed lab draws. Petitioner contended that its skilled nurse's professional courtesy in notifying the physician's office of the missed lab work is now being used by HCFA against Petitioner to argue that the skilled nurse was deficient in not asking the physician for an order to monitor the Coumadin testing. Petitioner maintained that the failure of the skilled nurse to intervene in the protime monitoring had no detrimental effect on the patient's care and, therefore, should not constitute either a standard-level deficiency or a portion of a condition-level deficiency.

Once again, there is nothing in this patient's record that there was a system in place for the monitoring of the Coumadin testing. The nurse's telephone call to the physician's office was inadequate. While the telephone call did inform the physician's office of the missed lab work, the call did nothing to resolve the conflicting instructions/duties in the POC, i.e., the patient to "receive anticoagulant therapy as ordered w/out complications." HCFA Ex. 8, at 11. This, to me, is the essence of both the cited deficiencies involving the Coumadin treatment. Contrary to Petitioner's protestations, the physician, by signing the POC, placed certain responsibilities on the skilled nurse for safety measures and for ensuring that no complications arose from the anticoagulant therapy. Accordingly, this placed Petitioner and its skilled nurses in the process for the Coumadin treatment and consequent care for the patient. I would agree with Petitioner that if there were no reference to any duties on the home health agency or its nurse in the POC concerning anticoagulant therapy, no responsibility would exist and no deficiency would lie. But once the duty was placed there to ensure that anticoagulant therapy was received without complications and issues arose as to the implementation of the Coumadin (through the missed lab work), Petitioner had a responsibility under the cited regulations to take action to clarify the POC as to where the specific responsibilities lay as to the Coumadin therapy and to notify the physician of any complications or problems with the Coumadin therapy. The telephone call to the physician's office regarding the missed lab work should have triggered a more complete communication by the skilled nurse inquiring into the issues I have enumerated. The responsibility imposed by the regulation on the skilled nurse to coordinate services should have resulted in a clarification of the POC as to how the Coumadin therapy was to be provided and in a coordination of services to ensure that the Coumadin treatment was done properly.

I therefore find that the failure by the skilled nurse to coordinate the services regarding the delivery of the Coumadin therapy for this patient constituted a deficiency in Petitioner's provision of care to this patient. As I have previously state such failure to obtain clarification of the treatment to be provided to the patient potentially could place the patient at risk and jeopardize the patient's health.

Patient 8

The surveyors made the following assertions concerning the care Petitioner gave to Patient 8:

> Patient #8's initial plan of care dated 7/15/96 listed phlebitis and deep vein thrombosis (6/15/96) as the primary diagnosis with cellulitis of leg (6/5/96) listed as one of the secondary diagnoses. The initial skilled nursing

> assessment dated 7/15/96 indicated "redness RLE (right lower extremity) below calf, skin taut, mult. tiny fluid blisters." The skilled nurses notes dated 7/16/96 indicated that the patient had 2+ to 3+ non-pitting edema to the right lower extremity, primarily in the foot and ankle. There was no documented evidence that the registered nurse informed the physician of the 2+ to 3+ edema of the patient's right foot and ankle.

HCFA Ex. 2, at 27.

State surveyor Sabino testified the basis for this alleged deficiency was that while the nursing assessment on July 15 (HCFA Ex. 12, at 12) stated that this patient had numerous tiny fluid blisters on the lower right leg, the nurse's notes for July 16 (HCFA Ex. 12, at 15) describe the existence of a 2+ to 3+ edema on the lower right leg, with no documentation in the record that the skilled nurse notified the physician of this change in the patient's condition. Tr. at 385 - 86.

HCFA's expert medical witness, Dr. Mindel Spiegel, testified that an edema is generally a gathering of fluid underneath the skin, or within the tissues under the skin, with a pitting edema being where the fluid underneath the skin is sufficiently mobile so that when a finger is placed on it, a depression or pit will be left. Tr. at 1601. Dr. Spiegel explained that a non-pitting edema is an edema where the fluid under the skin is more or less congealed or solid, so that pressure on the skin will not produce a depression. Id. Dr. Spiegel further explained that the degree of pitting is measured on a scale in terms of one to plus four. Id. Dr. Spiegel examined the July 15 assessment and the July 16 nursing notes and concluded that a significant change had occurred in the patient's condition that merited the physician being notified. Tr. at 1604. Dr. Spiegel testified that she could not discern whether the blisters described on the July 15 assessment constituted an edema, but even if they did, the description of a consolidated edema on the July 16 nursing notes would represent a change in the patient's condition. Tr. at 1615 - 16, 1618. Dr. Spiegel testified that the increase in the edema might be evidence that a clot had increased, with the worst possibility being that the patient might lose the foot. Tr. at 1618 - 19.

Petitioner contended that there was no reason to notify the physician of the patient's condition on July 16, since the patient's condition had not changed, and may even have improved, from the condition noted on July 15, and the physician was already aware of the patient's condition on admission. Petitioner further argued that its position is supported by the fact that the patient continued to improve under its care and showed no signs of deterioration.

Dr. Narian, Petitioner's Medical Director in 1996, testified that this patient had a history of deep venous thrombosis, chronic obstructive pulmonary disease, and cellulitis of the right leg. Tr. at 936; P. Ex. 3, at 1 - 2. Dr. Narian testified that the patient was on Lasix, a diuretic, and was required to use compression stockings to treat these conditions. Tr. at 937; HCFA Ex. 12, at 10. According to Petitioner, diuretics and compression stockings are used to decrease an edema. Dr. Narian testified that as an edema worsens, the skin becomes "taut" or tight and shiny, as described on the July 15 nursing assessment. Tr. at 939 - 40; HCFA Ex. 12, at 12. Dr. Spiegel also admitted that the patient's skin being noted as "taut" could be another description of an edema. Tr. at 1613.

Dr. Narian further testified that the description of the patient's lower right extremity on the July 15 nursing assessment, "skin taut, mult[iple] tiny fluid filled blisters," was consistent with the presence of a 3+ edema, the maximum level of edema possible. Tr. at 959. According to Petitioner, the July 16 nurse's note which describes an edema on the lower right extremity as 2+/3+ shows then that there was no deterioration, but possibly even an improvement, in the patient's condition since July 15 that would not have necessitated contacting the physician. HCFA Ex. 12, at 15. Petitioner additionally maintained that Dr. Narian's testimony on edemas is more credible than Dr. Spiegel's, because Dr. Narian is an actively-practicing, Board certified physician in Geriatrics and Internal Medicine, while Dr. Spiegel practiced in anesthesiology and had not practiced actively for 11 years.

Petitioner further argued that its position is supported by the fact that the physician saw the patient on July 18 and appeared to have no concern about the patient's condition, since no significant changes were made in the patient's POC. P. Ex. 3, at 4. Petitioner also noted that in the ensuing weeks the level of the patient's edema steadily decreased until the patient's goals were met and the patient was discharged on September 13. Tr. at 960 - 61; P. Ex. 3, at 4, 5, 6, 6a, 9, and 13.

In assessing the parties' arguments here, it is important to ascertain what measurement should be applied in determining whether an observation by a skilled nurse represents a need to inform the physician of "changes in the patient's condition and needs" as required by 42 C.F.R. § 484.30(a). Contrary to Petitioner's arguments, I am of the view that the measurement is what a reasonable interpretation by a skilled nurse would be regarding whether the recorded findings indicate a change in condition. If the record supports that it is reasonable to conclude that a skilled nurse could interpret the findings in a patient evaluation as representing a "change" in the patient's condition, then the standard is triggered. It does not relieve the home health agency, or its skilled nurse, from initiating

contact with the physician because a subsequent opinion of the physician shows that the physician did not agree or concluded that the findings actually supported a determination of a "change" in the patient's condition. The regulatory standard is to ensure that potential changes which may affect patient care are brought to the attention of the treating physician. Obviously, it does not require that frivolous claims of changes be brought which could interfere with the physician's treatment of the patient. But where the record supports the conclusion that a reasonable skilled nurse could conclude that there is a change in the patient's condition, then it is important that these findings are brought to the attention of the physician to make the ultimate determination whether the findings represent a change in circumstances warranting a change in treatment. The consequences of not reporting a finding which might represent a change in the patient's condition support a balance of requiring more reporting than less.

Nor do I accept Petitioner's argument that the testimony of Dr. Spiegel should be given less weight than Dr. Narian's testimony. I agree with HCFA that Dr. Spiegel is qualified to give an opinion of edema, and, more importantly, is more qualified than Dr. Narian to describe the responsibilities of skilled nurses in terms of the regulatory standards. While I am not in a position to resolve their differences, I do find that Dr. Narian's attempt to describe a non-pitting edema with the pitting scale begs credulity. Also, while Petitioner challenges the conclusions of Dr. Spiegel, it never presented rebuttal evidence on this point, such as treatises, even when I afforded Petitioner the opportunity to do so. Consequently, if I conclude that the evidence is equal on both sides of the edema issue, Petitioner still loses, since it has the burden of persuasion under Hillman and it failed to meet that burden here.

I find that a fair reading of the findings in the July 15 and 16 reports could lead to a reasonable conclusion by a skilled nurse that there may have been a change in the patient's condition warranting an initiation of a new treatment for the patient. The skilled nurse should have presented these facts to the physician for the ultimate decision on what action to take. Here, the contact with the physician on July 15, as reported in the clinical record, did not involve any discussion of the findings relating to edema. The testimony of the skilled nurse is not reliable absent any notation in the clinical record to support the nurse's assertion.

I further agree with HCFA that it is not an appropriate defense to this deficiency that the patient's condition ultimately improved. The potential for harm was present in light of the patient's existing diagnoses as of July 15.

Thus, I find that there is sufficient evidence under the applicable regulatory criteria that Petitioner violated this standard by the failure of the skilled nurse to notify the physician of the changes in this patient's condition regarding the edema in the lower right leg.

Summary of deficiencies under the condition at 42 C.F.R. § 484.30

11. The deficiencies found in the standards under the condition set forth at 42 C.F.R. § 484.30 are of such character as to substantially limit Petitioner's capacity to furnish adequate care or which adversely affect the health and safety of its patients.

In this case, I found, in examining the alleged deficient standards HCFA cited with regard to the condition of participation for Skilled Nursing Services, that Petitioner was: 1) deficient regarding five incidents involving five patients and not deficient regarding one incident involving one patient cited under Tag G 170, the standard requiring that the home health agency furnish skilled nursing services in accordance with the plan of care; 2) deficient regarding one of four patients cited under Tag G 172, the standard requiring that the home health agency's registered nurse regularly re-evaluate the patient's nursing needs; 3) deficient regarding both patients cited under Tag G 173, the standard requiring that the registered nurse initiate the plan of care and necessary revisions; 4) not deficient regarding the one patient cited under Tag G 175, the standard requiring that the registered nurse initiate appropriate preventive and rehabilitative nursing procedures; and 5) deficient regarding three incidents involving the two patients cited under Tag G 176, the standard requiring that the registered nurse prepare clinical and progress notes, coordinate services, and inform the physician of changes in the patient's condition and needs.

Under Tag G 170, the requirement that the home health agency furnish skilled nursing services in accordance with the plan of care, I found that the deficiencies essentially paralleled those cited under Tag G 158. I found that Petitioner has proved by a preponderance of the evidence that the skilled nurse's one-time use of comfeel powder on Patient 1 did not constitute a deviation from the plan of care for the patient. I also found, however, that in five other instances Petitioner failed to show that it provided skilled nursing services in accordance with the plans of care for patients 1, 3, 5, 6, and 8.

I therefore find that, in regard to the standard set forth in 42 C.F.R. § 484.30 requiring a home health agency provide skilled nursing services in accordance with the plan of care, HCFA has established the existence of deficiencies in Petitioner's care that justifies a certification of non-compliance as provided for

in 42 C.F.R. § 488.24(b), in that said deficiencies are of such character as to substantially limit Petitioner's capacity to furnish adequate care and which deficiencies adversely affect the health and safety of patients.

Under Tag G 172, the duty of the skilled nurse to regularly re-evaluate the patient's nursing needs, I sustained only the deficiency for Patient 8. For Patients 9, 3, and 4, I found that either HCFA did not establish a prima facie case or that Petitioner has proved by a preponderance of the evidence that its skilled nurse did re-evaluate the patients' nursing needs. I find that the one instance involving Patient 8 does not establish a pattern of behavior on Petitioner's part that its skilled nurses were not regularly re-evaluating patients' nursing needs. I therefore find that, in regard to this standard of 42 C.F.R. § 484.30(a), Petitioner was complying substantially with the Medicare requirements established by the Act and regulations and that, therefore, there is no basis for terminating Petitioner's participation in the Medicare program under either of the elements of 42 C.F.R. § 488.24(b).

Under Tag G 173, the duty of the skilled nurse to initiate and make necessary revisions to the plan of care, I sustained deficiencies for the two patients cited, Patients 4 and 3. The skilled nurse should have revised the POC for Patient 4 to reflect the Coumadin process in place, while Patient 3's use of a splint/sling should have been detailed in that patient's POC. Without these revisions, the patients' POCs did not accurately reflect the treatment the patients were receiving.

I therefore find that, in regard to the standard set forth in 42 C.F.R. § 484.30(a) requiring a home health agency's skilled nurse to initiate and make necessary revisions to the plan of care, HCFA has established the existence of deficiencies in Petitioner's care that justifies a certification of non-compliance, as provided for in 42 C.F.R. § 488.24(b), in that said deficiencies are of such character as to substantially limit Petitioner's capacity to furnish adequate care and which deficiencies adversely affect the health and safety of patients.

Under Tag G 175, the duty of the skilled nurse to initiate appropriate preventive and rehabilitative nursing procedures, I found no deficiency for the only patient cited, Patient 6. I therefore find that, in regard to this standard as set forth in 42 C.F.R. § 484.30(a), Petitioner was complying substantially with the Medicare requirements established by the Act and regulations and that, therefore, there is no basis for a termination of Petitioner's participation in the Medicare program under either of the elements of 42 C.F.R. § 488.24(b).

Under Tag G 176, the duty of a skilled nurse to coordinate services and to inform the physician of changes in the patient's condition and needs, I found that in three incidents involving Patients 4 and 8 Petitioner failed to prove by a preponderance of the evidence that its skilled nurse either coordinated services (in the Coumadin issue for Patient 4), or notified the physician of changes in the conditions of Patient 4 (poor nutrition) and Patient 8 (the growth of an edema in the right lower extremity).

I therefore find that, in regard to the standard set forth in 42 C.F.R. § 484.30(a) requiring a home health agency's skilled nurse to coordinate services and inform the physician of changes in the patient's condition and needs, HCFA has established the existence of deficiencies in Petitioner's care that justifies a certification of non-compliance, as provided for in 42 C.F.R. § 488.24(b), in that said deficiencies are of such character as to substantially limit Petitioner's capacity to furnish adequate care and which deficiencies adversely affect the health and safety of patients.

III. Conclusion

12. Petitioner's failure to meet the conditions of participation set forth at 42 C.F.R. §§ 484.18 and 484.30 demonstrates that Petitioner is substantially incapable of providing care consistent with Medicare participation requirements, justifying its termination from participation in the Medicare program.

A provider of home health services, such as Petitioner, will be deemed as failing to comply with a condition of participation 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 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 meet a condition of participation. 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. That finding, which I set forth on page three of this decision, 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."

Here I have concluded that the record supports a finding that Petitioner was substantially out of compliance with the conditions of participation set forth at 42 C.F.R. §§ 484.18 and 484.30. Accordingly, I conclude that HCFA did have a basis for terminating Petitioner's participation in the Medicare program.

/s/

Edward D. Steinman
Administrative Law Judge