Department of Health and Human Services

DEPARTMENTAL APPEALS BOARD

Civil Remedies Division

In the Case of:	)	
	)	
CSM Home Health Services, Inc.,	)	Date: October 11, 1996
	)	
Petitioner,	)	
	)	
- v. -	)	Docket No. C-96-363
	)	Decision No. CR440
Health Care Financing Administration.	)	
	)	

DECISION

I decide that the Health Care Financing Administration (HCFA) incorrectly determined to terminate the participation in the Medicare program of Petitioner, CSM Home Health Services, Inc. In this case, HCFA asserted that Petitioner failed to comply with four conditions of participation in Medicare. I find that the preponderance of the evidence is that Petitioner complied with all four of these conditions.[1]

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

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[1] I assigned to HCFA the burden of proving its assertions by a preponderance of the evidence. HCFA failed to meet its burden. However, I would find in favor of Petitioner even had I assigned the burden of persuasion to Petitioner. The preponderance of the evidence is that Petitioner complied with all of the conditions of participation that are at issue in this case.

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 Medicare 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 and when the plan must be reviewed (42 C.F.R. § 484.18(b)); and how a physician's orders, made 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 regulations. Act, section 1866(b)(2). The Secretary may terminate the participation in Medicare of a provider which the Secretary finds not to be complying substantially with participation requirements. Act, section 1866(b)(2)(A).

The process and criteria for determining whether a provider is complying substantially with Medicare participation requirements are established by regulations contained in 42 C.F.R. Part 488.[2]

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[2] In July 1995, the Part 488 regulations were revised and amended substantially as they apply to long-term care facilities, including nursing facilities and skilled nursing facilities. 42 C.F.R. § 488.301 et seq. The revisions and amendments are not at issue in this case because Petitioner is not a nursing facility or a skilled nursing facility.

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

HCFA may terminate the participation in Medicare of a provider that HCFA determines, either on its own initiative or based on a survey report from a State survey agency, is not complying with one or more Medicare conditions of participation. See 42 C.F.R. §§ 488.20, 488.24, 488.26.[3] 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); see 42 C.F.R. § 488.28(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 Medicare 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 circumstance 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 establishes that the provider cannot provide care consistent with that which is required by the Act and regulations.

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[3] The criteria which govern the circumstances under which HCFA may impose a remedy, including termination, against a nursing facility or a skilled nursing facility are stated at 42 C.F.R. §§ 488.402 - 488.456.

Generally, a determination as to whether a provider is not complying with a condition of participation depends on the extent to which that 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.

B. History of this case

On March 1, 1996, HCFA and the California State survey agency conducted a compliance survey of Petitioner. Based on that survey, Petitioner was found not to be complying with eight conditions of participation. HCFA Ex. 1. HCFA and the California State survey agency conducted a second survey of Petitioner which was completed on May 30, 1996. HCFA Ex. 3 at 2. On June 26, 1996, HCFA notified Petitioner that, based on the second survey, HCFA had determined that Petitioner was not complying with four conditions of participation. HCFA Ex. 2. These conditions are:

(1) 42 C.F.R. § 484.14 (Organization, services, and administration);

(2) 42 C.F.R. § 484.18 (Acceptance of patients, plan of care, and medical supervision);

(3) 42 C.F.R. § 484.30 (Skilled nursing services); and

(4) 42 C.F.R. § 484.52 (Evaluation of the agency's program).

Id. at 2. HCFA terminated Petitioner's participation in Medicare, effective July 25, 1996.[4]

Petitioner requested a hearing, and the case was assigned to me for a hearing and a decision. Petitioner requested that I expedite the hearing and, consequently, I held a hearing in Los Angeles, California, on August 12 - 15, 1996. I ordered the parties to submit posthearing briefs and reply briefs on an expedited schedule. The parties complied with this briefing schedule. I base my decision in this case on the governing law, the evidence I received at the hearing, and on the parties' arguments expressed in their briefs and reply briefs.

II. Issue, findings of fact and conclusions of law

A. Issue

The issue in this case is whether HCFA correctly determined to terminate Petitioner's participation in Medicare. As I have stated in Part I in this decision, HCFA may terminate a provider's participation in Medicare if that provider is not complying with a Medicare condition of participation. HCFA may not terminate a provider's participation in Medicare if that provider is not complying with standards of participation, but only if that noncompliance is not so egregious as to comprise a failure to comply with a condition of participation.

B. Findings of fact and conclusions of law

I base my decision that Petitioner did not fail to comply with any of the four conditions of participation which were cited by HCFA in its June 26, 1996 letter to Petitioner on the findings of fact and conclusions of law (Findings) which I set forth herein. I discuss each of my Findings, in detail, at Part III of this decision.

1. Petitioner has a right to a hearing.

2. The standard of participation contained in 42 C.F.R. § 484.14(b) requires a home health agency's governing body to assume full legal responsibility for the operation of the home health agency. It may be inferred that a home

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[4] At first, HCFA determined to terminate Petitioner's participation effective July 12, 1996. HCFA Ex. 3 at 1. However, Petitioner sought an injunction against termination, and the termination was delayed until July 25, 1996.

health agency has not complied with this standard where the agency systematically fails to comply with the Medicare participation requirements for home health agencies.

3. The standard of participation contained in 42 C.F.R. § 484.14(g) requires a home health agency to assure that there is effective communication and cooperation among its staff along with accurate documentation of whatever communication and cooperation that occurs. The standard does not suggest that such communication and cooperation is not attained simply because a home health agency is unable to attain all of the goals and objectives it establishes for the care of a patient.

4. The standard of participation contained in 42 C.F.R. § 484.18(a) requires that a home health agency assure that all pertinent diagnoses, treatments, and instructions for caring for a patient be included in a written plan of care. The standard of participation contained in 42 C.F.R. § 484.18(b) requires that the plan of care be reviewed at least once every 62 days.

5. The standard of participation contained in 42 C.F.R. § 484.30(a) requires that a registered nurse initiate a plan of care, initiate necessary revisions, and initiate appropriate rehabilitative and preventive nursing procedures. This standard means that a nurse must begin to implement and carry out all treatments that are ordered in a patient's plan of care. This standard does not impose on a registered nurse the duty of writing a plan of care or of making revisions to a plan of care.

6. Petitioner was not deficient in complying with standards of participation in providing care to Patient #s 1, 3, 5, 6, 7, 8, 10, 11, 13, and 15.

7. In providing care to Patient # 12, Petitioner failed to comply substantially with a standard of participation contained in 42 C.F.R. § 484.18. Specifically, Petitioner failed to follow a directive in the patient's plan of care that the skilled nurse assigned to Patient # 12 assess the progress of the patient's disease (insulin-dependent diabetes

mellitus), because the skilled nurse failed to assess the patient's complaints of blurred vision, a possible sign of diabetes mellitus.

8. In providing care to Patient # 12, Petitioner failed to comply substantially with a standard of participation contained in 42 C.F.R. § 484.18(b). Specifically, Petitioner failed to assure that the plan of care for Patient # 12 was revised to address a fungal infection that had been diagnosed by the patient's physician and for which the physician had prescribed medication.

9. In providing care to Patient # 12, Petitioner failed to comply substantially with a participation requirement stated in 42 C.F.R. § 484.30. Specifically, the nursing staff assigned to Patient # 12 failed to fully discharge its duties to the patient, by not assessing the patient's complaints of blurred vision.

10. Petitioner did not fail to conduct the management reviews and evaluations required under 42 C.F.R. § 484.52.

11. Petitioner did not fail to comply with the condition of participation stated in 42 C.F.R. § 484.14.

12. Although Petitioner, in two instances involving a single patient, failed to comply with a standard of participation contained in 42 C.F.R. § 484.18, Petitioner did not fail to comply with the condition of participation stated in 42 C.F.R. § 484.18.

13. Although Petitioner, in one instance involving one patient, failed to comply with a requirement of 42 C.F.R. § 484.30, Petitioner did not fail to comply with the condition of participation stated in 42 C.F.R. § 484.30.

14. Petitioner did not fail to comply with the condition of participation stated in 42 C.F.R. § 484.52.

15. Petitioner did not establish good cause for me to waive its share of the cost of the transcript.

III. Discussion

HCFA alleges that Petitioner failed in numerous instances to comply with Medicare participation requirements. Below, I explain why nearly all of HCFA's allegations are without merit.

HCFA's allegations constitute particularized statements of asserted failures by Petitioner to comply with Medicare participation requirements. I have analyzed these assertions on an item-by-item basis. But, it is apparent that many of HCFA's allegations share common features. My decision that nearly all of HCFA's allegations are without merit is, in some respects, based on the way I analyze these common features. The features which many of HCFA's allegations share, and my overall conclusions about these common features, are as follows.

- HCFA bases many of its allegations that Petitioner was deficient on an interpretation of a participation requirement in 42 C.F.R. § 484.30(a) which does not comport with the plain meaning of the language of the regulation. HCFA asserts that the regulation's requirement that a nurse "initiate" revisions to a patient's plan of care means that the nurse must make revisions to address new problems encountered by a patient or to fill in the gaps left in a patient's plan of care. I find that the regulation imposes no duty on a nurse to usurp the duty of a physician to write and revise a patient's plan of care. It requires only that a nurse begin to implement those revisions in a plan of care that are directed by a physician.

- HCFA asserts that the coordination of services and liaison among staff required by 42 C.F.R. § 484.14(g) must be judged by the results that are achieved in providing care to a patient. I find that the results attained in a particular case do not necessarily determine the efforts made to attain the goals set for a patient by a physician.

- HCFA argues, in some instances, that documentation of coordination of services and liaison must consist of reports of staff meetings. I find that, while a report of a staff meeting may document coordination of services and liaison, coordination of services and liaison is not necessarily absent in a case where there is no documentation of a staff meeting to discuss a patient's care.

• HCFA frequently bases multiple assertions of deficiencies on a single alleged event. I do not disagree with HCFA's conclusion that a single set of facts may evidence a failure by a provider to comply with more than one participation requirement. However, while that may be so, it is true also that where the facts are other than that which is alleged by HCFA, then HCFA's assertion of multiple deficiencies based on the alleged facts may be without foundation.

• In several instances in this case, HCFA asserts that a "discharge objective" in a patient's plan of care constitutes a treatment goal by the patient's physician. On that premise, HCFA asserts a multiplicity of failures by Petitioner including: failures to assure that the patient's plan of care contains orders for treatment to meet the asserted "goal"; failures of Petitioner's staff to attempt to meet the asserted "goal"; and failures of Petitioner's nurses to revise the plan of care to provide treatment regimes necessary to meet the asserted "goal."

I find, contrary to HCFA's assertions, that in many cases the physicians who treated the patients did not intend that the discharge objectives in the patient's plans of care be interpreted as stating treatment goals that the physicians sought to attain for their patients. Rather, the discharge objectives merely stated "best of all possible worlds" outcomes to cases, that no professional thought to be likely. This is significant, because I do not find that Petitioner was responsible for attaining results that the patients' physicians did not direct Petitioner to attain.

• In many instances, HCFA rests its allegations on characterizations of facts which are not supported by the evidence. In some instances, HCFA asserts that nurses employed by Petitioner failed to discharge specific directives in patients' plans of care when, in fact, the record proves that they did precisely what they were ordered to do. HCFA asserts also that Petitioner failed to conduct a required program evaluation despite overwhelming evidence that Petitioner performed the evaluation.

A. Whether Petitioner has a right to a hearing (Finding 1)

HCFA argued that Petitioner might no longer qualify as a provider and, therefore, might not have a right to a hearing. HCFA suggested that, perhaps, another entity should be substituted as a party in place of Petitioner. Alternatively, HCFA suggested that, perhaps, the matter

should be remanded to HCFA for a determination as to whether Petitioner is a party. Tr. at 15 - 25.

HCFA has not elaborated on its arguments in its posthearing brief. It has not explained why, assuming the facts that it alleges to be true, Petitioner has no right to a hearing. It may be that HCFA no longer is asserting that Petitioner may not have a right to a hearing.

HCFA based its motion on a memorandum, dated July 31, 1996, that was issued by Petitioner's administrator. HCFA Ex. 23.[5] In that memorandum, the administrator announced that Petitioner was merging with another facility. According to HCFA, the announced merger raised the possibility that Petitioner would no longer exist as an entity that qualified to be a provider under applicable regulations.

Petitioner responded to HCFA's motion with a declaration by its owner, Mariano Velez, dated August 15, 1996. P. Ex. 31.[6] In that declaration, Mr. Velez denies that Petitioner merged into another entity. He avers that Petitioner entered into an agreement with another facility to transfer patients to that facility temporarily. Additionally, pursuant to that agreement, the other facility will employ Petitioner's staff on a temporary basis. P. Ex. 31 at 2, 7 - 8.

HCFA has not identified the law or regulations that would operate to deny Petitioner the right to a hearing in this case, assuming that it did merge with another entity. In any event, I find from Mr. Velez' unrebutted declaration that Petitioner did not merge with another entity. Therefore, I do not accept as correct the premise of HCFA's motion.

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[5] HCFA did not designate this memorandum as an exhibit. In order to assure that the record of this case is complete, I have designated the memorandum as HCFA Ex. 23, and I am receiving it into evidence.

[6] The declaration contains two "exhibits" (Exhibits A and B). In order to assure that the record of this case is complete, I am designating the declaration and the two exhibits as a single exhibit, P. Ex. 31, and I am receiving it into evidence.

B. The participation requirements that are at issue (Findings 2 - 5)

HCFA asserts that Petitioner failed to comply with requirements that are expressed as conditions of participation or as standards of conditions under governing regulations. As a prerequisite to deciding whether HCFA's assertions are correct, I must decide what obligations these conditions and standards impose on Petitioner.

The question of interpretation of regulations is one which arises often in cases involving Medicare participation requirements. The Secretary has published comprehensive regulations governing the conditions for participation by a wide range of providers. But, no matter how comprehensive these regulations may be, questions of interpretation and application will arise inevitably. The ways in which health care providers provide care to their patients are so varied and complex, and so dependent on the unique circumstances pertaining to each patient, that it is not possible to write regulations that explicitly account for every fact situation that might arise.

HCFA is the agency that bears primary responsibility for the application of regulations governing participation in the Medicare program. Its reasonable interpretations of regulations must be given deference. I will not question HCFA's interpretation of a regulation, where that interpretation is reasonable, even if there may exist other, equally reasonable, interpretations of that regulation.

On the other hand, HCFA does not have carte blanche to interpret regulations as it sees fit. Where HCFA seeks to hold a provider accountable to an interpretation of a regulation, that interpretation must be reasonable. In order to be reasonable, the interpretation must comport with the meaning of the language of the regulation.

When the allegations contained in the survey report on which HCFA based its determination to terminate Petitioner's participation are read critically, it becomes apparent that HCFA is, in some instances, relying on its interpretations of regulations as a basis for asserting that Petitioner failed to comply with the standards contained in those regulations. HCFA Ex. 4. However, the question of whether HCFA is interpreting regulations reasonably is complicated by the fact that HCFA has not stated explicitly what its interpretations are. HCFA's interpretations must be inferred from the

allegations of failures to comply that are stated in the survey report.

Therefore, as a first step in deciding whether Petitioner failed to comply with Medicare participation requirements, I turn to the survey report and identify each requirement that HCFA asserts Petitioner failed to comply with. I decide whether, in asserting noncompliance with a requirement, HCFA is relying on the plain meaning of the requirement or an interpretation, and, if HCFA is relying on an interpretation, whether the interpretation is reasonable.

1. Condition of participation: Organization, services, and administration -- 42 C.F.R. § 484.14 (Findings 2 - 3)

HCFA asserts that Petitioner failed to comply with two standards prescribed under this condition, which are set forth at 42 C.F.R. §§ 484.14(b) and 484.14(g). HCFA Ex. 4 at 1 - 11. According to HCFA, the "systemic" failure of Petitioner to comply with these standards establishes Petitioner's failure to comply with the condition. Id. at 1.

a. Standard: Governing body -- 42 C.F.R. § 484.14(b)

This standard requires that a home health agency's governing body assert full control over the agency's operations. According to HCFA, Petitioner failed to comply with this standard because Petitioner's governing body failed to assume full responsibility for Petitioner's operations. HCFA Ex. 4 at 2. HCFA argues that Petitioner's failure to comply with this standard may be inferred from Petitioner's asserted failures to comply with standards of participation that govern the care that Petitioner must provide to its patients. This argument is made clear by the testimony of one of the surveyors who participated in the survey ending May 30, 1996, Helen Donna Dymon, Ph.D. Tr. at 225 - 227. HCFA's reading of the standard is not so much an interpretation as it is a statement of the evidence which may prove that the standard has not been complied with. I agree with HCFA that, where a home health agency is shown to have failed systematically to comply with Medicare participation requirements, an inference may be made that the agency's governing body failed to assume authority and responsibility for the agency's operations. However, the opposite inference may be made where there

is no evidence of systematic failure by a home health agency to comply with standards governing patient care.

b. Standard: Coordination of patient services -- 42 C.F.R. § 484.14(g)

This standard requires a home health agency to insure that all personnel furnishing services maintain liaison so that their efforts to provide care are coordinated effectively and support the objectives outlined in patients' plans of care. HCFA asserts that, in a number of instances, Petitioner failed to satisfy this requirement.

The standard contains the key words and phrases "liaison" and "effective interchange, reporting, and coordination of patient care." These are not defined. It is evident, however, that this standard requires a home health agency to assure that there is effective communication and cooperation among its staff along with accurate documentation of whatever communication and cooperation that occurs.

Many of the assertions made by HCFA concerning Petitioner's alleged failures to comply with the standard appear to be based on the plain meaning of the standard. However, HCFA appears also to argue that, to some extent, it is gauging the degree of liaison, cooperation, and coordination of services that Petitioner provided on the outcomes in individual cases. Thus, for example, HCFA asserts that, in providing care to Patient # 12, Petitioner failed to provide liaison or to coordinate services to assure that the patient could demonstrate foods from an exchange list because "there was no documentation that showed the patient could demonstrate foods from an exchange list . . . ." HCFA Ex. 4 at 3.

I do not agree that compliance with the standard depends on the outcome of care provided to a patient. The standard requires liaison and coordination of services in order to assure that the patient attains the best possible outcome, consistent with the goals established for that patient by the patient's plan of care. But, the regulation does not suggest that the degree of liaison and coordination that is attained necessarily may be measured by the home health agency's success in providing care to the patient.

Additionally, HCFA seems to be asserting that certain indicia of liaison and coordination must be present in a patient's record, either to establish that liaison and

coordination occurred in the care provided to that patient, or to establish documentation of the liaison and care that the home health agency provided. In some instances, HCFA asserts that documentation of case conferences held by Petitioner's staff failed to establish liaison or coordination of services provided to patients. For example, HCFA asserts that a case conference that was held to discuss care provided to Patient # 8 failed to document an asserted goal that the patient would no longer need a Foley catheter. HCFA Ex. 4 at 10 - 11.

HCFA's assertion is not so much an interpretation of the regulation as it is a statement of the evidence that is necessary to prove compliance with the regulation. I do not agree that the standard requires that a patient's record contain a specific type of document (such as a case conference report) in order to document liaison or coordination of care. Nor do I find that the standard requires that case conferences, as opposed to other types of communication, must occur in order for liaison and coordination of services to be present. The regulation does not specify the <u>type</u> of communications that must take place and be documented.

2. Condition of participation: Acceptance of patients, plan of care, and medical supervision -- 42 C.F.R. § 484.18 (Finding 4)

This condition of participation requires, among other things, that care provided to a patient by a home health agency follow a written plan of care. HCFA asserts that Petitioner failed to comply with the requirement of the condition that care provided to patients follow written plans of care. HCFA Ex. 4 at 12 - 15. HCFA asserts also that Petitioner failed to comply with the requirements of standards contained in 42 C.F.R. §§ 484.18(a) and (b). HCFA characterizes these asserted failures to comply with standards as "systemic" and concludes that they prove that Petitioner failed to comply with the condition of participation. HCFA Ex. 4 at 11.

a. Standard: Plan of care -- 42 C.F.R. § 484.18(a)

The standard stated in 42 C.F.R. § 484.18(a) requires that all pertinent diagnoses, treatments, and instructions for caring for a patient be included in a written plan of care. In asserting that Petitioner failed to comply with this standard, HCFA does not appear to be asserting that the standard means anything more than it plainly says.

However, HCFA's allegations that Petitioner failed to develop plans of care that comply with the standard depend heavily on HCFA's characterization of the contents of the individual plans of care that are at issue in this case. As I shall discuss below, in several instances I do not agree with HCFA's characterization of the contents of individual plans of care.

b. Standard: Periodic review of plan of care -- 42 C.F.R. § 484.18(b)

The standard requires that a physician and the home health agency staff review a plan of care as often as a patient's condition warrant, but at least once every 62 days. HCFA argues that, in some instances, Petitioner failed to assure that plans of care were reviewed as often as was necessary. HCFA alleges that, in other instances, Petitioner's staff failed to alert the patient's physician of changes that suggested a need to alter the patient's plan of care.

It does not appear from HCFA's characterization of Petitioner's alleged failures to assure review of patients' plans of care that HCFA is interpreting this standard in a way that deviates from the standard's plain meaning. The standard plainly requires that a patient's physician review the patient's plan of care where a change in the patient's condition necessitates the review. As I shall discuss below, the determinative question in the three instances cited by HCFA is whether HCFA is correct in its assertion that reviews were necessary in those instances.

Nor does it appear from HCFA's assertions about the alleged failures of Petitioner's staff to notify patients' physicians about changes in the condition of the patients that suggested a need to alter the patients' plans of care that HCFA is interpreting the standard in a way that departs from the standard's plain meaning. The standard requires that a home health agency's staff notify a patient's physician about any changes in a patient's condition which, based on the objective signs and symptoms manifested by the patient and on the professional training and judgment of the staff, might suggest a need to alter a plan of care. The dispositive question here is not one of interpretation but one of fact: whether HCFA is correct in asserting that there were changes in the conditions of patients that suggested a need to alter the patients' plans of care.

3. Condition of participation: Skilled nursing services -- 42 C.F.R. § 418.30 (Finding 5)

HCFA asserts that Petitioner failed to comply with the condition's requirement that a home health agency furnish skilled nursing services to each patient in accordance with a plan of care. In making this assertion, HCFA relies on the plain meaning of the language of the condition. The condition states, simply, that skilled nursing services must be furnished to a patient in accordance with the patient's plan of care. In each of the instances cited, HCFA alleges that the skilled nurse failed to make observations and assessments that the patient's physician directed the nurse to make. Therefore, the issue in resolving these allegations is one of fact, which I discuss below.

a. Standard: Duties of the registered nurse -- 42 C.F.R. § 484.30(a)

HCFA makes several assertions concerning Petitioner's alleged failures to comply with this standard. First, HCFA asserts that nurses employed by Petitioner failed to reevaluate regularly the needs of patients. HCFA Ex. 4 at 28 - 35. Second, HCFA asserts that nurses employed by Petitioner failed to initiate necessary revisions to patients' plans of care. HCFA Ex. 4 at 35 - 41. Third, HCFA asserts that nurses employed by Petitioner failed to initiate appropriate preventive and rehabilitative nursing procedures. HCFA Ex. 4 at 41 - 44. Finally, HCFA asserts that nurses employed by Petitioner failed to coordinate services to patients. HCFA Ex. 4 at 45.

The regulation requires the registered nurse to: assess a patient's problems and needs, to provide care to the patient, coordinate the care provided by other care givers, report to the physician any significant changes in a patient's condition, and keep accurate records of the care that the nurse provides. HCFA's assertions that, in specified instances, registered nurses failed to: reevaluate the needs of patients, assess the conditions of patients, or coordinate services rest on a straightforward application of the standard to the facts, as alleged by HCFA.

However, HCFA's allegations that registered nurses failed to initiate changes in plans of care or failed to initiate appropriate preventive and rehabilitate nursing procedures rest on an interpretation of the standard that does not comport with the standard's plain meaning and which is inconsistent with the Act and other Medicare

regulations. I do not find HCFA's interpretation to be reasonable.

The standard directs registered nurses to "initiate" a patient's plan of care and necessary revisions to the plan of care. 42 C.F.R. § 484.30(a). HCFA interprets the word "initiate" to mean that the registered nurse is charged with the independent responsibility to make changes in the patient's plan of care and in the treatments provided to the patient, where the plan of care fails to prescribe the appropriate treatment, or where there is a change in the patient's condition that might require a change in treatment.

Contrary to HCFA's assertion, the regulation does not impose on registered nurses employed by home health agencies the duty to make changes to patients' plans of care, even where changes are warranted. Under applicable participation requirements, only a physician may write or revise a plan of care, although the plan of care may be based on the assessments and advice provided by a nurse. But, the nurse's duty to provide advice is not congruent with the authority to write or to revise a plan of care.

The Act requires that each plan of care for each patient treated by a home health agency be established by a physician, and not by another care giver, such as a nurse. The Act states that home health services are enumerated services furnished to an individual who:

> . . . is under the care of a physician, . . . under a plan (for furnishing such items or services to such individual) <u>established and periodically reviewed by a physician</u> . . . .

Act, section 1861(m) (emphasis added).

The intent of Congress that only a physician may write a plan of care is restated in the regulations governing home health agencies. The regulations state that care provided by a home health agency follows a written plan of care established and periodically reviewed by a physician. 42 C.F.R. § 484.18. And, although this language is plain on its face, its purpose is underscored by the requirement that:

> Drugs and treatments are administered by agency staff <u>only as ordered by the physician</u>.

42 C.F.R. § 484.18(c) (emphasis added).

The standard contained in 42 C.F.R. § 484.30(a) does not suggest any inconsistency with these explicit requirements. The plain meaning of the language of the standard, including the word "initiate," is that the registered nurse is charged with the duty to begin and to carry out all treatments ordered by a physician. There is nothing in this language to suggest that a registered nurse is charged with the authority of revising a plan of care on his or her own volition, to assure that a patient receives the necessary care. The duty to "initiate" revisions to a plan of care and the duty to "initiate" appropriate nursing and rehabilitative procedures are not duties to use initiative to make changes to a plan of care.

The common and ordinary meaning of the word "initiate" is to cause or facilitate the beginning of an event, or to set something going. Webster's New Collegiate Dictionary, 594 (8th ed. 1967). Literally, "initiate" means to start something. Thus, when given its literal meaning, the word "initiate" in 42 C.F.R. § 484.30(a) means that the registered nurse is charged with the duty to start implementing those treatments that have been ordered by a physician. Nothing more is suggested by the word.

At the completion of the hearing, HCFA averred that it wished to call as a rebuttal witness a HCFA employee who participated in drafting regulations, including 42 C.F.R. § 484.30. The purpose of the testimony was to explain what HCFA meant by the use of certain words in the regulations. I ruled that testimony to be irrelevant, and I reaffirm that ruling here. Tr. at 1063 - 1065. There is nothing ambiguous about 42 C.F.R. § 484.30(a) which needs to be interpreted through extrinsic evidence. The language of the regulation is plain and self-evident. And, while it may be appropriate to use extrinsic evidence, such as interpretive guidelines, a regulation's preamble and comments, or an agency's official statements of interpretation, as a means of interpreting an unclear or arguably ambiguous regulation, it is not appropriate to use the opinions of agency employees who participated in drafting a regulation to establish the meaning of a regulation.

The purpose of a regulation is to provide a neutral standard which can be read, understood, and applied by those who are affected by it. Thus, the words in a regulation must be defined based on their common and ordinary meaning, or on any special meaning set forth in a regulation's definition, or in the legislative history to the regulation. The words in a regulation cannot be

defined after the fact by the testimony of the employee who used the words in drafting the regulation. If such were the case, then the regulation would lose any pretense of neutrality, and the concept of standards embodied in a regulation would be meaningless.[7] That is particularly evident where, as here, the key word "initiate" has a common and ordinary meaning, and where nothing in the regulations suggest that it was intended to be applied in another sense.

4. Condition of participation: Evaluation of the agency's program -- 42 C.F.R. § 484.52

HCFA asserts that Petitioner failed in a "systemic" way to comply with the condition's requirement that Petitioner: assess the extent to which its program was appropriate, adequate, effective and efficient; act upon the results of its evaluation; and, review its own administrative practices. HCFA Ex. 4 at 46 - 48. HCFA's interpretation of the requirements of this condition does not appear to depart from its plain meaning. The issue, as I see it, is one of fact and not of law.

a. Standard: Policy and administrative review -- 42 C.F.R. § 484.52(a)

HCFA is relying on the plain meaning of this standard in asserting that Petitioner failed to conduct requisite management reviews. The question as to Petitioner's compliance with this standard, therefore, is one of fact and not of law.

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[7] Also, I excluded an exhibit offered by Petitioner which is an affidavit by a lawyer who purports to be an expert in health care law and who offered his opinion as to the meaning of some of the relevant regulations. P. Ex. 3. I invited the parties to argue the meaning of the regulations in their post-hearing briefs and to supply me with any appropriate legislative history or other extrinsic material that would aid me in deciding the meaning of regulations, to the extent that I found any of them to be ambiguous. Tr. at 1063 - 1065. HCFA did not avail itself of that opportunity, either in its posthearing brief or in its reply brief.

C. HCFA's allegations that Petitioner was deficient in providing care to patients (Findings 6 - 9)

I now turn to a patient-by-patient discussion of each of the patients to whom HCFA alleges Petitioner provided substandard care. I evaluate each of HCFA's allegations based on the duties imposed on Petitioner under the relevant regulations, coupled with my analysis of the relevant evidence.

That evidence consists largely of the patients' treatment records. At the hearing, both HCFA and Petitioner introduced into evidence treatment records for the patients at issue. There is considerable overlap in the exhibits, in the sense that many of the pages of the records introduced by HCFA are contained also in the records introduced by Petitioner. However, HCFA's exhibits and Petitioner's exhibits are not congruent. There are records of treatment in HCFA's exhibits that do not appear in the corresponding exhibits introduced by Petitioner, and vice versa. Neither party offered an explanation for these differences. I find that, in order to get the best possible picture of the care provided by Petitioner to a patient, it is necessary to read both the relevant HCFA exhibit and the relevant Petitioner exhibit as comprising one record of the care provided to that patient.[8]

1. Patient # 1 (HCFA Ex. 5, P. Ex. 9)

HCFA alleges that, in providing care to Patient # 1, Petitioner failed to comply with the following Medicare participation requirements: 42 C.F.R. § 484.14(g) (HCFA Ex. 4 at 7 - 8); 42 C.F.R. § 484.18(b) (HCFA Ex. 4 at 21 - 22, 24 - 25); and 42 C.F.R. § 484.30(a) (HCFA Ex. 4 at 28, 30 - 32, 35 - 36, 41 - 42, 45). I find that Petitioner was not deficient in providing care to this patient.

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[8] The relevant treatment records, by patient are as follows: Patient # 1 -- HCFA Ex. 5, P. Ex. 9; Patient # 3 -- HCFA Ex. 6, P. Ex. 10; Patient # 5 -- HCFA Ex. 7, P. Ex. 11; Patient # 6 -- HCFA Ex. 8, P. Ex. 12; Patient # 7 -- HCFA Ex. 9, P. Ex. 13; Patient # 8 -- HCFA Ex. 10, P. Ex. 14; Patient # 10 -- HCFA Ex. 11, P. Ex. 15; Patient # 11 -- HCFA Ex. 12, P. Ex. 16; Patient # 12 -- HCFA Ex. 13, P. Ex. 17; Patient # 13 -- HCFA Ex. 14, P. Ex. 18; Patient # 15 -- HCFA Ex. 15, P. Ex. 19.

Patient # 1 was certified to be cared for by Petitioner beginning April 7, 1996 and ending June 7, 1996. HCFA Ex. 5 at 1, P. Ex. 9 at 1. Her principal diagnosis was a urinary tract infection. Id. Other diagnoses included: a decubitus ulcer, hypertension, ASCVD, and urinary incontinence. Id.

An evaluation of the patient, performed on April 2, 1996, showed that the patient was oriented to her name only, that she was disoriented and confused. HCFA Ex. 5 at 8 - 9, P. Ex. 9 at 3 - 4. She was observed to speak only when spoken to or stimulated. She manifested a flat affect and was withdrawn. HCFA Ex. 5 at 9, P. Ex. 9 at 4.

a. 42 C.F.R. § 484.14(g)

HCFA alleges that, in providing care to Patient # 1, Petitioner's staff failed to insure that the patient's clinical records or minutes of case conferences established effective interchange, reporting, and coordination of patient care. Specifically, HCFA asserts that the clinical notes and plan of care for this patient did not show documentation concerning coordination of the patient's care with consideration to the patient's emotional status concerning the patient's grief and depression, resulting from the suicide of the patient's grandson-in-law.

However, the record establishes otherwise. Petitioner's staff actively communicated with each other, with the patient's physician, with the social worker who was retained to provide specialized care, and with the patient's care giver, concerning the grief experienced by the patient and by the care giver. I find no deficiency in the coordination of care provided to Patient # 1.

On April 18, 1996, the registered nurse reported to the patient's physician that the patient's care giver needed more assistance because the care giver was overwhelmed with the care of the patient, and with the care of the care giver's two younger children. HCFA Ex. 5 at 4, P. Ex. 9 at 30. The nurse reported also that the care giver's husband had been hospitalized in an intensive care unit for an attempted suicide. Id. The nurse reported that she had offered the care giver intervention by a social worker to assist with the care giver's family situation, but that the care giver had declined the offer. Id.

On April 23, 1996, the registered nurse (who also served as Petitioner's Director of Nursing) left a message with the physician concerning the patient's need for counseling and crisis intervention. HCFA Ex. 5 at 6, P. Ex. 9 at 20. The nurse reported that the patient's grandson-in-law had expired two days previously. Id. The nurse informed the physician that the patient's care giver had stated that she would be unable to provide proper care for the patient due to the care giver's grief. Id. The nurse advised additionally that the patient also was in a state of grief and depression. Id. Later that day, the nurse called back to the patient's physician. The physician agreed to order a referral to a social worker for counselling and crisis intervention. Id. The nurse informed both the patient's care giver and the nurse's clinical supervisor of the physician's order. Id.

Pursuant to the physician's order, a social worker visited the patient and the care giver on April 25, 1996. P. Ex. 5 at 32, P. Ex. 9 at 60. The social worker reported the patient's mental status as being disoriented and confused at times. She reported also that the patient did not speak. Id. Additionally, the social worker reported that the patient's care giver was not coping with the patient's illness. Id. The social worker wrote a patient care plan for social services. P. Ex. 9 at 61.

On April 29, 1996, a meeting of Petitioner's staff was convened to discuss the care that Petitioner was providing to Patient # 1. Those present included two registered nurses, a home health aide, and a patient care coordinator. P. Ex. 9 at 37. At the meeting, it was reported that the patient's family was grieving the loss of a loved one. It was reported also that the interventions that had been provided to address this problem included allowing the family to ventilate its feelings, and providing emotional support. Id.

On May 24, 1996, the social worker wrote a discharge summary. HCFA Ex. 5 at 30, P. Ex. 9 at 62. The discharge summary repeats the finding that the patient did not speak. It noted that the social worker had provided counseling to family members of Patient # 1. Id. Also, on May 24, the social worker reported to the registered nurse. P. Ex. 9 at 33. The social worker enumerated the resources that she had provided to the patient's family and she stated that no further intervention was required. P. Ex. 9 at 33.

These interventions were discussed at a meeting of Petitioner's staff held on May 24, 1996. Present were a registered nurse, a home health aide, the patient care coordinator, and a social services worker. P. Ex. 9 at 38.

HCFA's major criticism of the interventions that were supplied to address the grief and distress caused by the suicide of the grandson-in-law of Patient # 1 is that not much was done for the patient directly. The proof relied on by HCFA is that the interventions provided by the social worker mainly were directed at addressing the concerns expressed by the patient's family.

But, this criticism begs the question of whether Petitioner's staff provided the coordination of care and liaison required under the regulation. The quality of care provided to the patient by the social worker is not at issue here. What is at issue is whether Petitioner's staff reacted appropriately to the information which was communicated to them by the social worker. From the record before me, it is evident that they did.

Contrary to HCFA's assertions of no coordination or liaison, the record establishes that a high degree of coordination and liaison occurred. The registered nurse communicated the problems being experienced by the patient and her family to the physician, who promptly order intervention by a social worker. The social worker communicated her findings and her interventions to the registered nurse, who promptly shared these findings and interventions with other members of Petitioner's staff who were concerned with providing care to the patient.

Although the quality of care provided by the social worker may not be relevant to deciding whether Petitioner provided appropriate liaison and coordination, I am not persuaded from the evidence that the interventions of the social worker were inappropriate or inadequate, given the circumstances she confronted. Patient # 1 was uncommunicative and withdrawn and her mental status was impaired. The social worker's notes establish that the patient did not speak in the social worker's presence. HCFA Ex. 5 at 32, P. Ex. 9 at 60. Given that, it was entirely logical for the social worker to have focused on the grief and distress being expressed by other members of the patient's family, especially that of the care giver.

Moreover, HCFA fails to acknowledge that it might have been beneficial to the welfare of Patient # 1 for the social worker to have focused on allaying the grief of

the care giver. The patient's care giver was an important member of the team of individuals who provided care to patient # 1. The care giver had told the patient's nurse that she was overwhelmed with grief and was unable to provide care, as a consequence. Dealing with that grief was an important issue for Petitioner to attempt to resolve.

At the hearing, one of the surveyors, Virgilio Resurreccion, testified that he had ascertained, by calling the patient's family, that there had been no further intervention by the social worker after May 24, 1996. Tr. at 437 - 438. That testimony is not inconsistent with the social worker's evaluation and discharge summary, however.

b. 42 C.F.R. § 484.18(b)

HCFA asserts that, in providing care to Patient # 1, Petitioner failed in two respects to comply with the standard contained in 42 C.F.R. § 484.18(b). First, HCFA argues that the patient's physician failed to review and revise the patient's plan of care to deal with the grief that the patient suffered as the result of the suicide of her grandson-in-law. HCFA Ex. 4 at 21 - 22. Second, the record failed to document that the physician was alerted to the social worker's findings that "suggested a need to alter the plan of care." Id. at 24 - 25. I have discussed the record of Petitioner's attention to the patient's grief, above.

The standard contained in 42 C.F.R. § 484.18(b) requires that a plan of care be revised by the physician, in consultation with a home health agency's staff, as often as the patient's condition requires, but at least once every 62 days. In this case, HCFA assumes, without offering evidence to support its assumption, that the patient's condition required a review of her plan of care within 62 days. However, it is evident from the record that the social worker who visited the patient and Petitioner's staff were in accord that any grief-related problems were not so severe as to require further intervention by the physician. HCFA has offered no evidence to suggest that this judgment is incorrect. Moreover, HCFA has made no assertion as to what it thought the patient's physician ought to have done other than what the physician did, which was to order intervention by a social worker.

Indeed, the judgment of Petitioner's staff and of the social worker is entirely consistent with what the patient's physician ordered. There is nothing in the

record to suggest that the physician believed that the patient required any intervention beyond that which was offered by the social worker. The physician did not order that the patient be seen by a psychiatrist or by a psychologist. The social worker did not report that such intervention was needed.

c. 42 C.F.R. § 484.30(a)

HCFA makes several allegations concerning Petitioner's alleged failure, in providing care to Patient # 1, to comply with the standard contained in 42 C.F.R. § 484.30(a). First, HCFA alleges that the registered nurse who treated the patient failed to reevaluate the patient's needs relative to the consultation between the patient, her care giver, and the social worker. HCFA Ex. 4 at 30. I find this allegation to be unsupported by the record. The premise for this allegation is that, after the social worker completed her intervention, there was a need for the nurse to reevaluate the patient's needs. However, the record establishes that, on May 24, 1996, the social worker advised the nurse that no further interventions were necessary in the case of Patient # 1. HCFA Ex. 5 at 30 - 32, P. Ex. 9 at 60 - 62. HCFA has not explained what reevaluation the nurse should have done in light of the social worker's report.

Second, HCFA asserts that the registered nurse failed to reevaluate the patient's need to use a Foley catheter. HCFA Ex. 4 at 31 - 32. HCFA premises this assertion on the argument that, under professionally recognized standards of care, a Foley catheter ought to be worn by a patient for the briefest period of time. HCFA Exs. 20 - 22. Here, according to HCFA, the nurse provided care to the patient without taking these standards of care into account, thus ignoring her obligation to make a judgment as to whether the patient would benefit from continued use of the catheter.

I am not persuaded that the registered nurse failed to discharge her duty to Patient # 1. It is evident from the records for the patient that the physician's objective with respect to Patient # 1 for the certification period ending on June 7, 1996 was to assure that the patient's Foley catheter was working properly and that the patient's urinary tract infection was resolved. HCFA Ex. 5 at 1, P. Ex. 9 at 1. The nurse was never charged with the responsibility of assessing whether continued use of the catheter was necessary. The patient's physician did not contemplate even the possibility that the patient would not need to wear the catheter throughout the certification period. In light

of that, it does not make sense to expect the nurse who visited the patient on behalf of Petitioner to determine whether continued use of the catheter was appropriate.[9]

The patient's physician prescribed a Foley catheter to be worn by the patient throughout the period of certification. HCFA Ex. 5 at 1, P. Ex. 9 at 1. The discharge plan statement in the patient's plan of care explicitly contemplated that the patient would be discharged when she had a patent catheter, without complications. HCFA Ex. 5 at 2, P. Ex. 9 at 2. Moreover, the records of treatment for Patient # 1 include communications between the nurses who treated the patient and the physician concerning the patient's ongoing urinary tract infection and discussing the care that the nurse was to provide, including management of the patient's Foley catheter. P. Ex. 9 at 22. There is nothing in these records to suggest that, at any time during the certification period ending on June 7, 1996, the patient's physician considered that a Foley catheter might not be appropriate for the patient.

Third, HCFA asserts that the registered nurses that Petitioner assigned to provide care to Patient # 1 failed to make necessary revisions to the patient's plan of care. HCFA Ex. 4 at 36. Specifically, HCFA asserts that there is no documentation in the patient's treatment records to establish that registered nurses made necessary revisions to the patient's plan of care to address the patient's grief over the suicide of her grandson-in-law. Id.

As I discuss at Part III.B.3.a. of this decision, HCFA misinterprets 42 C.F.R. § 484.30(a) to require nurses to make revisions to plans of care when, in fact, the regulation does not contain this asserted requirement. Thus, HCFA's assertion that Petitioner was deficient because registered nurses employed by Petitioner failed to revise the plan of care for Patient # 1 is without merit. Moreover, as I explain above in my discussion of Patient # 1, I am not persuaded that any revisions to the patient's plan of care were necessary in any event.

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[9] Furthermore, I am not convinced from the record of this case that a nurse would be qualified to make such an assessment. HCFA did not offer persuasive evidence to establish that the training and professional experience of a registered nurse would qualify the nurse to make such an assessment.

Fourth, HCFA asserts that the registered nurses failed to initiate appropriate preventive and rehabilitative nursing procedures for Patient # 1. HCFA Ex. 4 at 42. Specifically, HCFA asserts that the nurses failed to initiate "appropriate rehabilitative nursing procedures consistent with guidelines for assessment for continued use of Foley catheters." Id.

It is unclear what HCFA means by this allegation. However, when it is read in context with the other allegations that HCFA makes concerning Petitioner's care of Patient # 1, it appears that HCFA is again asserting that the nurses employed by Petitioner should have, on their own volition, made decisions about the patient's continued use of a Foley catheter. Such independent action is not contemplated by the regulation, which states only that the nurse shall "initiate" appropriate rehabilitative and nursing procedures. Moreover, as I have discussed above, the treatment record of Patient # 1 does not suggest that the patient's physician wanted anything done other than what had been ordered for that patient.

Finally, HCFA alleges that the registered nurses employed by Petitioner failed to coordinate the services that Petitioner provided to Patient # 1. HCFA Ex. 4 at 45. This assertion is a restatement, in the context of 42 C.F.R. § 484.30(a), that the nurses failed to coordinate the care provided to the patient to deal with the patient's grief following the suicide of the patient's grandson-in-law. I am not persuaded that there was a lack of coordination of care, for the reasons that I have discussed above.

2. Patient # 3 (HCFA Ex. 6, P. Ex. 10)

HCFA asserts that, in providing care to Patient # 3, Petitioner failed to comply with the following Medicare participation requirements: 42 C.F.R. § 484.18(a) (HCFA Ex. 4 at 16, 18) and 42 C.F.R. § 484.30(a) (HCFA Ex. 4 at 35, 38 - 40). I find that Petitioner was not deficient in providing care to Patient # 3.

The patient was certified to be cared for by Petitioner beginning May 8, 1996 and ending July 8, 1996. HCFA Ex. 6 at 1 - 2, P. Ex. 10 at 1 - 2. Her principal diagnosis was poisoning-cardiotonics. Additional diagnoses included: fracture of pubis, closed; atrial fibrillation; a urinary tract infection; cancer of the rectum; and senile dementia. Id.

a. 42 C.F.R. § 484.18(a)

HCFA asserts that Petitioner failed to develop a plan of care with its staff for Patient # 3 that covered all of the patient's pertinent diagnoses, nutritional requirements, medications and treatments, and instructions for timely discharge of the patient. Specifically, HCFA alleges that the plan of care for Patient # 3 stated that "the patient will have adequate pain relief management." HCFA Ex. 4 at 18. HCFA avers that the plan of care failed to address what would be done to achieve adequate pain relief.

Essentially, HCFA is asserting that the patient's plan of care ought to have specifically defined what would constitute adequate relief of the patient's pain and how that relief would be attained. According to HCFA, the plan of care did not do this. I find that, contrary to HCFA's assertion, the patient's plan of care did address the patient's pain, both in establishing a defined goal for pain relief and in prescribing the measures that would be employed to attain relief.

The plan of care did not, as HCFA avers, state simply that the patient would have adequate pain relief, without defining what adequate pain relief meant. The physician linked the patient's pain relief to increasing the patient's mobility and to her underlying medical condition. The precise goal stated in the plan of care was that the patient "will have adequate pain relief management and activity will increase within limits of disease process within 4wks. [four weeks]." HCFA Ex. 6 at 1, P. Ex. 10 at 1.

Furthermore, the patient's plan of care contained instructions to Petitioner's staff for addressing patient's pain. The patient was prescribed analgesics. The staff was instructed to make skilled observations and assessments of the patient's pain, including the location, intensity and type of pain, and the effectiveness of pain relievers. HCFA Ex. 6 at 1 - 2, P. Ex. 10 at 1 - 2.

It is unclear what more could have been done in the patient's plan of care to address the pain experienced by Patient # 3. HCFA has not explained what more it expected from Petitioner.

b. 42 C.F.R. § 484.30(a)

HCFA asserts that, in providing care to Patient # 3, Petitioner failed in two respects to comply with the standard of participation contained in 42 C.F.R. § 484.30(a). First, according to HCFA, the registered nurses assigned by Petitioner to provide care to the patient did not make necessary revisions to the patient's plan of care to address an asserted discharge "goal" of returning the patient to self-care status when she was no longer homebound. HCFA Ex. 4 at 39. HCFA avers that the plan of care did not define what would be meant by self-care status, and that the registered nurses assigned to the patient failed to make necessary revisions to the patient's plan of care to address the patient's discharge goals. Id.

It is not entirely clear what HCFA is alleging, but it appears to be saying two things. First, HCFA seems to be asserting that the plan of care contained a gap in that it stated a goal of discharging the patient to self-care status when the patient was no longer homebound, without defining what that goal really meant. Second, HCFA is asserting that the registered nurses were obligated to revise the patient's plan of care to assure that the undefined goal was defined and met.

As I find above, the Medicare participation requirements governing a home health agency do not impose on nurses employed by the agency the duty to revise plans of care. On this basis alone, I conclude that HCFA's assertion is without merit.

Moreover, I am not persuaded that the plan of care for Patient # 3 actually stated as a goal that the patient would attain a status where she would be capable of caring for her own needs. The statement relied on by HCFA was not asserted as a treatment goal to be attained during the period of the patient's certification for home health care, but as a discharge plan. HCFA Ex. 6 at 2, P. Ex. 10 at 2. When this discharge plan is read in the context of the patient's entire record, it is apparent that neither the patient's physician nor Petitioner's staff thought that the patient could attain a status where she could care for her own needs during the period of certification. HCFA is attempting to hold Petitioner responsible for not meeting an alleged goal that the patient's physician did not set for the patient.

Aside from the many illnesses that afflicted Patient # 3, this patient was an 89-year-old individual who suffered from senile dementia. HCFA Ex. 6 at 1 - 2, P. Ex. 10 at

1 - 2. Patient # 3 was oriented only to her name. Id. Prior to Patient # 3 coming under Petitioner's care, the patient had been a resident in a retirement home. I infer from the patient's record that she was dependent on the care of others prior to her being certified for care by Petitioner, and that her medical condition was such that it was extremely unlikely, if not impossible, that she would improve during the certification period to the point where she was capable of caring for her own needs. There is nothing about the treatment ordered by the patient's physician to suggest that the physician even contemplated the possibility that the patient would no longer be senile and, thus, become capable of self-care.

Petitioner's second alleged failure to comply with the requirements of 42 C.F.R. § 484.30(a), according to HCFA, lies in an additional alleged failure of the nurses who provided care to Patient # 3 to make necessary revisions to the patient's plan of care. HCFA asserts that the registered nurses failed to make necessary revisions to the patient's plan of care to address what "adequate" relief of pain constituted, or to define the meaning of the word "adequate." HCFA Ex. 4 at 39 - 40.

Again, I find no duty under 42 C.F.R. § 484.30(a) for the nurses to make revisions to a patient's plan of care, and, thus, I find no basis to sustain HCFA's allegation. Furthermore, there is nothing in the record of care provided to Patient # 3 to suggest that revisions were needed to the patient's plan of care to further define the meaning of the word "adequate." As I discuss above, the patient's physician defined what was meant by "adequate" relief of the patient's pain by addressing it in the context of improving the patient's mobility and in the context of the patient's disease process. HCFA has offered no explanation of what more could have or should have been done to define the meaning of the word "adequate" as it appears in the patient's plan of care.

3. Patient # 5 (HCFA Ex. 7, P. Ex. 11)

I find no deficiency in the care that Petitioner provided to Patient # 5. HCFA asserts that, in providing care to Patient # 5, Petitioner failed to comply with the requirements of 42 C.F.R. § 484.30(a). Specifically, HCFA asserts that the patient's plan of care contained a discharge "goal" to discharge the patient, an insulin-dependent diabetic, when the patient no longer needed insulin. HCFA Ex. 4 at 35 - 40. According to HCFA, the plan of care for Patient # 5 did not contain instructions designed to achieve this asserted goal. Id. HCFA argues that, in light of the failure of the plan of care to

contain instructions to end the patient's dependence on insulin, the registered nurses employed by Petitioner had a duty to revise the plan of care in order to write the necessary instructions. HCFA avers that the nurses failed to discharge this alleged duty, and, thus, Petitioner was deficient. Id.

Once again, HCFA seeks to impose a duty on Petitioner's staff which applicable participation standards do not impose. As I have explained above, it would be contrary to the requirements of the Act and regulations for nurses, on their own initiative, to make revisions to a patient's plan of care. For this reason alone, I find that Petitioner was not deficient in providing care to Patient # 5.

Moreover, I do not find that the patient's plan of care actually stated as a treatment goal that the patient would no longer be dependent on insulin. The plan of care establishes that the physician who treated the patient contemplated that the patient would remain insulin-dependent throughout the certification period. HCFA Ex. 7 at 1, P. Ex. 11 at 1.

The plan of care explicitly states as a goal that the patient would receive insulin, pursuant to the physician's prescription, for a period of nine weeks, a period of time which covered the entire period of certification. HCFA Ex. 7 at 1, P. Ex. 11 at 1. And, although the physician did say that the patient could be discharged if she no longer was dependent on insulin, that statement does not appear to express a treatment goal that the physician directed Petitioner to work to attain.

The patient's plan of care states as a "discharge objective" that the patient would be discharged when the patient no longer needed insulin or when an alternate care giver is identified for the patient. HCFA Ex. 7 at 1, P. Ex. 11 at 1. When read in its entirety, the plan for discharging the patient rationally envisions discharge either under the circumstance that the patient might no longer need insulin (highly unlikely, given the patient's condition and the care ordered by the patient's physician), or where an individual is identified who will administer insulin to the patient. HCFA has not asserted that Petitioner failed to assist Patient # 5 in finding an alternate care giver.

4. Patient # 6 (HCFA Ex. 8, P. Ex. 12)

HCFA asserts that, in providing care to Patient # 6, Petitioner failed to comply with the following participation requirements: 42 C.F.R. § 484.14(g) (HCFA Ex. 4 at 2, 6); 42 C.F.R. § 484.18(a) (HCFA Ex. 4 at 16, 19 - 20); and 42 C.F.R. § 484.30(a) (HCFA Ex. 4 at 35, 40). I do not find that, in providing care to Patient # 6, Petitioner failed to comply with any of these participation requirements.

Patient # 6 was certified to be given care by Petitioner beginning May 13, 1996 and ending July 13, 1996. HCFA Ex. 8 at 1, P. Ex. 12 at 1. The patient's principal diagnosis was insulin-dependent diabetes mellitus. The patient's additional diagnoses included congestive heart failure and hypertension. Id.

a. 42 C.F.R. § 484.14(g)

HCFA asserts that Petitioner failed to provide the necessary liaison to assure that the efforts of Petitioner's staff were coordinated to support the objectives outlined in the patient's plan of care. Specifically, HCFA argues that the discharge objective for the patient was to discharge the patient when the patient no longer needed insulin or when an alternate care giver was identified to care for the patient. HCFA Ex. 4 at 2, 6. According to HCFA, the clinical record of Patient # 6 failed to show how Petitioner's staff would work to attain independence from insulin. Id.

I am uncertain precisely what HCFA means by asserting that the patient's clinical record failed to show how Petitioner's staff would work to free the patient from dependence on insulin. The clinical record introduced into evidence by HCFA consists only of the patient's plan of care. HCFA Ex. 8 at 1 - 2. I do not know whether the surveyors reviewed other records during their survey of Petitioner.

Petitioner offered a more complete record of the care it provided to Patient # 6. P. Ex. 12 at 1 - 28. I am satisfied from review of that record that the patient's physician did not contemplate freeing the patient from insulin dependence as a goal that could be attained during the certification period. Id. Petitioner cannot be held accountable for failing to provide coordination and liaison to attain freedom from insulin dependence, because that was not a goal that the physician charged Petitioner with attaining.

The patient's chief complaint was that she was unable to self-administer insulin. P. Ex. 12 at 3. The patient was observed to be forgetful. Id. Nursing notes show that the patient was unable to administer insulin to herself due to: poor vision, poor eye-hand coordination, and confusion at times. P. Ex. 12 at 9. The notes show also that the patient lived in a board and care facility, and that the staff of that facility was unable to administer insulin to the patient. Id. Finally, the notes show that the patient was unable to find an alternate care giver to administer insulin to her. Id.

When the patient's plan of care is read in context with the nurses' observations of the patient, it is evident that the principal goal of the treating physician was to overcome the obstacles that existed to the patient receiving therapeutic doses of insulin. The plan of care specifically directed that the patient receive insulin injections for the entire certification period, pursuant to the physician's orders. HCFA Ex. 8 at 1, P. Ex. 12 at 1. There is nothing in the physician's orders to suggest that the physician thought that there was any likelihood that the patient would not need insulin injections throughout the certification period. Id.

Given that, I do not find the discharge plan to discharge the patient when the patient no longer needs insulin to comprise a treatment objective in the plan of care. See HCFA Ex. 8 at 1, P. Ex. 12 at 1. Petitioner and its staff had no duty to coordinate services to attain a goal that did not exist.

b. 42 C.F.R. § 484.18(a)

HCFA asserts that Petitioner failed to develop a plan of care with its staff that covered all pertinent diagnoses, nutritional requirements, medications and treatments, and instructions for a timely discharge of the patient. Specifically, HCFA alleges that the plan of care for Patient # 6 failed to recite instructions to attain the discharge "goal" to discharge the patient when the patient no longer needed insulin injections. HCFA Ex. 4 at 16 - 19.

I conclude that this allegation is without merit, essentially for the same reasons that I conclude that the preceding allegation is without merit. I do not find that the patient's physician ordered Petitioner and its staff to work to attain a goal of freeing the patient from dependence on insulin. Petitioner cannot be found deficient for failing to work to achieve a goal that was never stated by the physician.

c. 42 C.F.R. § 484.30(a)

HCFA asserts that there is no documentation that registered nurses who provided care to Patient # 6 made necessary revisions to the patient's plan of care to assure a timely discharge of the patient. HCFA Ex. 4 at 40. HCFA premises this assertion on its determination that the patient's plan of care included a goal of freeing the patient from dependence on insulin. HCFA premises this assertion also on its interpretation of 42 C.F.R. § 484.30(a) to require a nurse assigned to a patient by a home health agency to make such revisions as may be necessary to the patient's plan of care.

I have explained above why I do not find that Petitioner's nurses had any duty to make revisions to plans of care. Moreover, I am not persuaded that any revisions were necessary here. If, in fact, the patient's physician had sought to free the patient from dependence on insulin, then, perhaps, additional treatments might have been necessary for the patient. But, as I find above, the physician never contemplated attempting to free the patient from dependence on insulin.

5. Patient # 7 (HCFA Ex. 9, P. Ex. 13)

HCFA asserts that, in providing care to Patient # 7, Petitioner failed to comply with the following Medicare participation requirements: 42 C.F.R. § 484.14(g) (HCFA Ex. 4 at 2, 5 - 6); 42 C.F.R. § 484.18 (HCFA Ex. 4 at 12, 15); 42 C.F.R. § 484.18(a) (HCFA Ex. 4 at 16 - 17); 42 C.F.R. § 484.18(b) (HCFA Ex. 4 at 21, 23 - 24); 42 C.F.R. § 484.30 (HCFA Ex. 4 at 25 - 28); and 42 C.F.R. § 484.30(a) (HCFA Ex. 4 at 35 - 37, 45). I do not find Petitioner to have been deficient in providing care to patient # 7.

Patient # 7 was certified to be cared for by Petitioner beginning May 7, 1996 and ending July 7, 1996. HCFA Ex. 9 at 1, P. Ex. 13 at 1. The patient's principal diagnosis was chronic airway disease. The patient had additional diagnoses, including hypertension, angina pectoris, and insulin-dependent diabetes mellitus. Id.

a. 42 C.F.R. § 484.14(g)

HCFA asserts that, in providing care to this patient, Petitioner failed to insure that the personnel who provided services maintained liaison to insure that their efforts were coordinated effectively and supported the objectives outlined in the patient's plan of care.

Specifically, HCFA alleges that the plan of care stated as a goal that patient's shortness of breath would diminish as a result of activity tolerance within three to four weeks, and that the patient would show no shortness of breath and no signs and symptoms of pulmonary congestion within two to three weeks. HCFA Ex. 4 at 5. HCFA asserts that the patient's clinical record failed to document how Petitioner's personnel were working to achieve these alleged goals, inasmuch as the patient's congestion persisted from admission through the last clinical note dated May 27, 1996. Id. at 5 - 6.

HCFA seems to assert that Petitioner was deficient in coordinating services to Patient # 7 because the goal stated in the patient's plan of care was not attained. I am not persuaded by that argument. As I discuss above, at part III.B.1.b. of this decision, a finding of poor coordination of services does not follow necessarily from a failure to attain a goal contained in a plan of correction. It is evident that not every patient will respond to treatment as anticipated. Here, the evidence is that Petitioner did everything the physician ordered to provide care to the patient. Petitioner's staff coordinated its efforts in order to carry out the physician's orders. There is no evidence to suggest that the patient's failure to improve as much as had been hoped for was a consequence of a failure by Petitioner to deliver services to that patient.

Nursing notes show that nurses assigned to Patient # 7 worked diligently with the patient to achieve the goals stated in the plan of care. On every visit to the patient, the nurse made observations concerning the patient's breathing and exercise tolerance. On May 9, 1996, the nurse discussed with the patient how to conserve energy and to perform exercises within the patient's limitations. HCFA Ex. 9 at 43, P. Ex. 13 at 31. On May 11, the nurse discussed with the patient the administration of a medication that was prescribed to alleviate the patient's shortness of breath. The patient was shown procedures for deep breathing and expectorating. HCFA Ex. 9 at 42, P. Ex. 13 at 32. On May 12, the nurse instructed Patient # 7 in the use of a nebulizer for the patient's breathing problems. HCFA Ex. 9 at 41, P. Ex. 13 at 33. On May 14, the nurse discussed with the patient the course of the patient's pulmonary disease. HCFA Ex. 9 at 39, P. Ex. 13 at 36.

On May 16, the nurse worked with the patient on the patient's breathing techniques. HCFA Ex. 9 at 35, P. Ex. 13 at 39. On May 18, the nurse discussed with the patient the medication Cephalexin, an antibiotic for

respiratory tract infections. HCFA Ex. 9 at 33, P. Ex. 13 at 41. On May 20, the nurse discussed with the patient a cough syrup that had been prescribed by the patient's physician. HCFA Ex. 9 at 32, P. Ex. 13 at 42.

Furthermore, the record establishes communication, liaison, and coordination between the nurses who treated Patient # 7 and the patient's physician concerning the patient's respiratory problems. On May 15, 1996, the nurse contacted the patient's physician to report that the patient had a sore throat and chest pain when coughing. HCFA Ex. 9 at 45. The physician prescribed a cough syrup and an antibiotic for the patient. Id.

The record establishes that these efforts attained some degree of improvement in the patient's breathing problems, if not the degree of improvement which the plan of care cited as a goal. By May 30, 1996, the patient's exercise tolerance improved. P. Ex. 13 at 48. On May 8, 1996, the patient was reported to be short of breath after walking a distance of only five feet. HCFA Ex. 9 at 44, P. Ex. 13 at 30. However, by May 30, the patient's exercise tolerance improved, albeit only slightly, so that the patient was short of breath after walking 15 feet. P. Ex. 13 at 48.

b. 42 C.F.R. § 484.18

HCFA asserts that Petitioner failed to comply with the plan of care for treating the breathing problems experienced by Patient # 7. HCFA Ex. 4 at 15. In the surveyors' report that allegation is made in the context of the failure of the patient to improve as much as had been anticipated by the plan of care. Id. However, in its posthearing brief, HCFA asserts that Petitioner failed to follow the plan of care for Patient # 7 because Petitioner's staff allegedly failed to assess the patient's breathing problems. HCFA posthearing brief at 17.

Above, I have described the interventions made by Petitioner's staff to deal with the breathing problems experienced by Patient # 7. Petitioner provided the patient with the treatments and care ordered by the patient's physician. I find no merit in HCFA's argument that the staff failed to assess the patient's breathing problems. Virtually every nursing note contains an assessment of the patient's breathing problems. HCFA Ex. 9 at 31 - 40, P. Ex. 13 at 30 - 46. These assessments include assessments of the patient's exercise tolerance and of the breathing problems being experienced by the patient at each visit. Id.

c. 42 C.F.R. § 484.18(a)

HCFA asserts that, in the case of Patient # 7, Petitioner failed in two respects to develop a plan of care that covered all of the patient's needs. I am not persuaded that either of these alleged failures to comply with the standard of participation contained in 42 C.F.R. § 484.18(a) has merit.

First, HCFA asserts that the patient's plan of care did not address the specific interventions that would be employed by the nurses assigned to the patient to attain goals relative to the patient's blood pressure. HCFA Ex. 4 at 16 - 17. I am at a loss to understand HCFA's allegation, inasmuch as the plan of care for Patient # 7 addresses in detail the interventions that were expected of Petitioner's staff relevant to the patient's blood pressure.

The plan of care stated as a goal that the patient's blood pressure would, within two to three weeks, show systolic readings of between 120 and 140 and diastolic readings of between 80 and 90. HCFA Ex. 9 at 1, P. Ex. 13 at 1. The plan of care prescribes medications for the patient, including blood pressure medications, and the dosages of medications to be administered to the patient. Id. The plan of care directs Petitioner's staff to make skilled observations and assessments of, among other things, the patient's blood pressure. Id. Moreover, the patient's clinical record includes a patient care plan for skilled nursing, in addition to the physician's plan of care. HCFA Ex. 9 at 22. That plan specifically instructs the nurses to assess the patient's response and compliance with cardiac medications. Id.

Second, HCFA asserts that the treatment records of Patient # 7 show that Petitioner's nursing staff applied Sween Cream, an over-the-counter medication, to the patient. According to HCFA, the patient's plan of care was deficient because it failed to discuss administration of Sween Cream to the patient.

Sween Cream is an over-the-counter medication which is used to treat chapped skin. Tr. at 742 - 743. The treatment records of Patient # 7 establish that, after inception of the patient's care by Petitioner, and after the patient's plan of care had been written, the home health aide who treated the patient observed some slight redness in the patient's skin, and, on her own volition, applied Sween Cream to the patient. By May 30, 1996, the nurses treating the patient no longer observed any redness in the patient's skin. P. Ex. 13 at 48.

I find no evidence that the patient's chafing was of such severity as to require the intervention of a physician (who, under relevant regulations, would have had to write the patient's plan of care). Given that, I cannot comprehend how Petitioner was remiss in not including the administration of Sween Cream in the patient's plan of care. Furthermore, the original plan of care that was written for the patient would not, in any event, have addressed the redness in the patient's skin, inasmuch as that was a condition that developed after the inception of the plan of care.

d. 42 C.F.R. § 484.18(b)

HCFA asserts that the patient's physician and Petitioner's staff did not review the plan of care for Patient # 7 as often as the patient's condition required. First, HCFA notes that on several occasions, the patient's blood pressure differed from the blood pressure treatment objectives established in the patient's plan of care. HCFA Ex. 4 at 23. Almost without exception, these instances were instances where the patient's diastolic blood pressure was below 80. Id. HCFA asserts that Petitioner's staff and the patient's physician were remiss in not reviewing the patient's plan of care with respect to the blood pressure readings that were being obtained for the patient.

I am not persuaded that there existed a need to review or revise the patient's plan of care based on the patient's blood pressure readings. There is neither clinical evidence nor credible opinion evidence of record in this case to show that the blood pressure readings for Patient # 7 deviated from those established as goals for the patient to the extent that the patient's physician needed to be consulted. To the contrary, the credible evidence is that the patient's blood pressure, albeit slightly lower than what the physician directed, was acceptable. Tr. at 1015 - 1018.

Second, HCFA asserts that the patient's clinical record failed to document that the physician and staff reviewed the plan of care for Patient # 7 to address the change in the patient's skin condition which necessitated application of Sween Cream to the patient. HCFA Ex. 4 at 23 - 24.

Above, I have discussed the evidence which relates to this assertion. I find no deficiency here, because there is no evidence that the condition of the skin of Patient # 7 ever was of such severity as to necessitate the involvement of the patient's physician.

e. 42 C.F.R. § 484.30

HCFA asserts that Petitioner failed to provide skilled nursing services to Patient # 7 in accordance with the patient's plan of care. First, according to HCFA, Petitioner did not provide skilled nursing services in accordance with the patient's plan of care to attain the goals stated in the plan of care which addressed the patient's shortness of breath. HCFA Ex. 4 at 27 - 28.

Above, I have discussed the interventions that Petitioner's staff provided, pursuant to the patient's plan of care, to deal with the patient's breathing problems. I am unpersuaded by HCFA's characterization of these services as not being in accordance with the plan of care for Patient # 7. To the contrary, the evidence is that the nurses who provided care to Patient # 7 were diligent in carrying out the physician's instructions.

Second, according to HCFA, the nurses failed to follow instructions in the patient's plan of care to obtain compliance with the patient's dietary regime. HCFA Ex. 4 at 27 - 28. Specifically, HCFA asserts that the plan of care for Patient # 7 stated as a goal that, within two to three weeks of inception of the plan, the patient would be compliant with the dietary regime prescribed for the patient. Id. HCFA avers that the clinical notes for the patient failed to document that the nurses who attended the patient addressed this instruction. Id.

This allegation is unsupported by the record. Contrary to HCFA's assertion, the clinical records of Patient # 7 contain evidence that Petitioner's staff worked to assure that the patient was compliant with the diet that had been prescribed. On May 13, 1996, the nurse who visited the patient instructed the patient to maintain a good nutritional intake. HCFA Ex. 9 at 40, P. Ex. 13 at 34. On May 15, the skilled nurse and a licensed vocational nurse (the home health aide) conferred, and the notes of that conference show that one of the goals discussed was that the patient would be able to verbalize the importance of compliance with a prescription diet and dietary restrictions. HCFA Ex. 9 at 38, P. Ex. 13 at 37. On May 15, the skilled nurse instructed the patient as to compliance with dietary restrictions. HCFA Ex. 9 at 36, P. Ex. 13 at 38.

f. 42 C.F.R. § 484.30(a)

HCFA asserts that Petitioner failed in several respects to comply with the requirements of the standard contained in 42 C.F.R. § 484.30(a). These allegations are unsupported by the evidence in this case.

HCFA argues that, in three instances, registered nurses assigned to provide care to Patient # 7 failed to make necessary revisions to the patient's plan of care. HCFA Ex. 4 at 35, 36 - 37. According to HCFA, the nurses failed to make revisions to the patient's plan of care to address the changes in the patient's skin condition that necessitated application of Sween Cream to the patient. Id. Additionally, according to HCFA, the nurses failed to make necessary revisions to the patient's plan of care to address the patient's breathing problems. Id. Finally, HCFA asserts that the nurses failed to make necessary revisions to the patient's plan of care to address the patient's blood pressure problems. Id.

These assertions fail because, as I have held above, the regulations impose no duty on nurses to make revisions to a plan of care that is developed by a physician. Thus, even assuming changes to the plan of care for Patient # 7 were warranted, it was not the obligation of nurses to have made those changes.

Furthermore, I am not convinced from the record of this case that changes needed to be made to the patient's plan of care. HCFA has not explained what was inadequate about the treatments that were being prescribed and administered to the patient. It is true that the patient's breathing problems were not improving as quickly as the physician contemplated. But, that is not to say that additional interventions or treatments were warranted. HCFA has offered no evidence to prove that the patient's breathing problems might have benefitted from treatments or interventions that were not ordered for Patient # 7. As far as the patient's skin condition is concerned, I have held above that it did not rise to the level of severity as to necessitate involvement by the physician. HCFA has not offered any evidence to show what changes were necessary in the treatment that was being provided to address the patient's blood pressure.

Additionally, HCFA charges that the nurses assigned to Patient # 7 failed to coordinate the administration of services to the patient. HCFA Ex. 4 at 45. I am not persuaded that there is a factual basis for this allegation. The record establishes that, on May 15, 1996, the home health aide reported to the nurse that the

patient was experiencing skin irritation. HCFA Ex. 9 at 57, P. Ex. 13 at 74. The nurse recorded these findings in her notes of that same date. HCFA Ex. 9 at 36, P. Ex. 13 at 38. Thereafter, the nurse made observations as to the patient's skin condition until, on May 30, 1996, the nurse reported no redness. P. Ex. 13 at 48. The record thus proves that the nurse and home health aide discussed the patient's skin problem. The home health aide treated that problem, and the nurse reported on the problem until it was corrected. HCFA has not explained what more ought to have been done to address the patient's skin problem.

6. Patient # 8 (HCFA Ex. 10, P. Ex. 14)

HCFA asserts that, in providing care to Patient # 8, Petitioner failed to comply with the following Medicare participation requirements: 42 C.F.R. § 484.14(g) (HCFA Ex. 4 at 2, 4 - 5, 10); 42 C.F.R. § 484.18 (HCFA Ex. 4 at 12, 14 - 15); 42 C.F.R. § 484.18(a) (HCFA Ex. 4 at 16 - 18); 42 C.F.R. § 484.30 (HCFA Ex. 4 at 25 - 26, 27); and 42 C.F.R. § 484.30(a) (HCFA Ex. 4 at 28, 32 - 35, 38, 42 - 43). I do not find that, in providing care to this patient, Petitioner was deficient in complying with Medicare participation requirements.

Patient # 8 was certified to be provided care by Petitioner beginning February 29, 1996 and ending April 29, 1996. HCFA Ex. 10 at 3. The patient was recertified for care by Petitioner beginning April 29, 1996 and ending June 29, 1996. HCFA Ex. 10 at 1, P. Ex. 14 at 1. As of April 29, 1996, the patient's principal diagnosis was that she suffered from a urinary tract infection. Id. The patient's additional diagnoses included a neurogenic bladder, pneumonia, and Alzheimer's disease. Id. The patient was reported to be semicomatose, paralyzed, and suffering from contractures of her limbs. Id.

a. 42 C.F.R. § 484.14(g)

HCFA asserts that Petitioner failed in two respects to assure requisite liaison and coordination of services to this patient.

First, according to HCFA, there was no documentation in the patient's treatment records to show how Petitioner's staff was coordinating the administration of antibiotic therapy to the patient. HCFA Ex. 4 at 4 - 5. The gravamen of HCFA's assertion is that an unreasonable delay occurred between the ordering of antibiotics by the patient's physician and the administration of the antibiotics to the patient.

I do not find this assertion to be supported by the evidence. The evidence establishes that Petitioner's staff was diligent in attempting to obtain antibiotics for Patient # 8. The delays that occurred were due to an apparent failure by the patient's care giver to follow through on a telephone request to a pharmacist to fill a prescription and a delay by the pharmacist in filling the prescription. There is no evidence that lack of communication among Petitioner's staff contributed to the delay.

Patient # 8 had been prescribed an antibiotic, Cipro, to treat the patient's urinary tract infection. On May 6, 1996, the patient's nurse contacted the patient's treating physician to discuss the status of the patient's infection. HCFA Ex. 10 at 12, P. Ex. 14 at 27. The physician's office was closed, and the nurse made a follow-up call, during which she spoke with the physician. Id. The nurse advised the physician that the patient's prescription for Cipro had expired. The physician ordered a refill of the prescription. Id. On May 6, the nurse contacted the patient's care giver and directed the care giver to obtain a refill of the prescription for Cipro. Id.

On May 10, the nurses who provided care to Patient # 8 conferred to discuss whether the care giver was administering antibiotics to the patient pursuant to the instructions that had been given to the care giver. HCFA Ex. 10 at 10, P. Ex. 14 at 29. They ascertained then that the care giver had waited until May 8 to contact the pharmacist to have the prescription for Cipro refilled. Id. They discovered that the pharmacist had been unable to verify the physician's order and, so, had not refilled the prescription. Therefore, on May 10, one of the nurses contacted the treating physician and left a message, advising the physician of the problem. Id. The nurses conferred again on May 13. They verified that the patient had begun receiving Cipro again on May 11. Id.

There is no evidence that the nurses were ineffective in providing liaison or coordinating care to the patient. Plainly, the nurses assigned to the patient were relying on the patient's care giver to contact the patient's pharmacist to have the patient's prescription refilled. That the care giver was less than adept in accomplishing that is unquestionable. But, there is no evidence that the nurses were acting improperly when they reposed in the care giver the duty to have the prescription refilled, nor is there any evidence to show that the nurses were less than diligent in discharging their duties. Indeed, it was a second intervention by the

nurses that resulted in the patient receiving antibiotics after they ascertained that the care giver had failed to get the prescription refilled.

Second, according to HCFA, the plan of care for Patient # 8 contained a discharge "goal" for discharge of the patient when the patient's Foley catheter was discontinued. HCFA Ex. 1 at 1, P. Ex. 14 at 1. HCFA asserts that Petitioner's staff failed to maintain liaison in order to attain this "goal." Id.

I find no merit in this assertion. The plan of care for Patient # 8 did not contemplate removal of the patient's Foley catheter. It makes no sense to hold Petitioner accountable for failure to coordinate services to attain a goal that did not exist.

It is true that the patient's plan of care states a discharge objective, and not a treatment goal, that the patient will be discharged to the patient's care giver when all treatment goals are met and the patient no longer needs a Foley catheter. HCFA Ex. 10 at 1, P. Ex. 14 at 1. However, it is evident from reading this objective in the context of the entire plan of care that the patient's physician did not contemplate, as a serious treatment objective, that the patient would no longer need a Foley catheter.

This patient was comatose and paralyzed, with a neurogenic bladder. There is no evidence in the record that she was capable of voiding without the assistance of a catheter. Nor is there any evidence to suggest that the physician thought that the patient's coma would abate or that her paralysis would end. Furthermore, the plan of care makes it obvious that what the physician sought to accomplish during the second certification period was to manage the patient's catheter so that the patient's urinary pattern was stabilized. HCFA Ex. 10 at 1, P. Ex. 14 at 1. The plan of care contains not even a suggestion that removal of the catheter was contemplated by the physician.

The record does show, however, that substantial liaison occurred among Petitioner's staff and the patient's physician to address the treatment goals contained in the plan of care for Patient # 8. This included communications concerning the attempts to treat the patient's urinary tract infection. For example, a urine analysis was performed of the patient's urine on May 20, 1996, pursuant to the physician's orders that the analysis be done. These results were faxed to the physician and provided to the registered nurse assigned

to providing care to the patient. HCFA Ex. 10 at 7. On May 20, the registered nurse noted that the patient's condition was stabilizing, and the nurse recommended to the physician that the frequency of nursing visits to Patient # 8 be decreased. P. Ex. 14 at 57. On May 23, the registered nurse made a follow up call to the physician to assure that the physician had the results of the patient's urine analysis. P. Ex. 14 at 58.

Third, HCFA asserts that the clinical record of Petitioner's care of Patient # 8 fails to show effective interchange and reporting of patient care with respect to the "goal" of removing the patient's Foley catheter. HCFA Ex. 4 at 10. HCFA specifically identifies a case conference of May 17, 1996, and asserts that the participants at the conference did not discuss this asserted treatment "goal" at that time. Id.

I find this allegation to be without merit, for several reasons. The requirement for liaison and coordination of services contained in 42 C.F.R. § 484.14(g) does not specify the precise types of documents necessary to memorialize the liaison or coordination of services that occurs with respect to a patient. The requirement is only that liaison and coordination occur and be documented. Therefore, the fact that a particular conference does not address an issue is not dispositive of the question of whether liaison and coordination of services occurred. Furthermore, as I have found above, there was no "goal" to remove the patient's Foley catheter, so a finding of deficiency cannot be premised on the staff not conferring about this "goal." Finally, the record of the May 17 conference shows that there was liaison and coordination at that conference about the treatment objectives that were stated in the patient's plan of care, including resolving the patient's urinary tract infection. HCFA Ex. 10 at 39, P. Ex. 14 at 62.

b. 42 C.F.R. § 484.18

HCFA asserts that Petitioner failed to follow instructions in the plan of care of Patient # 8 to monitor the patient's intake and output and to assess the odor of the patient's urine. HCFA Ex. 4 at 14 - 15. HCFA bases this assertion on the alleged absence from the patient's treatment record of a nurse's assessment of intake and output or of the odor of the patient's urine. I disagree with HCFA's assertion that these assessments were not made. To the contrary, the nurse dutifully made the assessments ordered by the physician.

The patient's treatment record contains an "intake and output monitor" recording input of milk and water and output of urine and bowel movements, for the dates beginning April 29, 1996 and ending May 22, 1996. P. Ex. 14 at 79. The report contains assessments, both of the size and consistency of the patient's bowel movements. It is evident from this exhibit that the nurse was making assessments as to any abnormalities in the patient's intake and output. Id.

HCFA asserts that the nurse assigned to Patient # 8 was obligated, as part of the duty to assess the patient's intake and output, to assess the patient's skin turgor and color. HCFA argues that the nurse failed to make these assessments. In fact, the nursing notes for this patient contain assessments, both of the patient's skin color and of the presence or absence of edema. HCFA Ex. 10 at 41 - 64, P. Ex. 14 at 64 - 77.

HCFA is simply incorrect in asserting that the nurse failed to assess the odor of the patient's urine. The nurse assessed urine odor on: April 30 (HCFA Ex. 10 at 50, P. Ex. 14 at 71); May 1 (HCFA Ex. 10 at 49, P.Ex. 14 at 72); May 8 (HCFA Ex. 10 at 45, P. Ex. 14 at 75); May 13 (HCFA Ex. 10 at 42, P. Ex. 14 at 77); May 15 (HCFA Ex. 10 at 41); and May 20 (HCFA Ex. 10 at 38, P. Ex. 14 at 78), and, on each occasion, recorded the urine odor as being normal.

c. 42 C.F.R. § 484.18(a)

HCFA asserts that Petitioner failed to develop a plan of care for Patient # 8 that contained instructions to meet the discharge "goal" of discharging the patient when the patient no longer needed to wear a Foley catheter. HCFA Ex. 4 at 16 - 18. I am not persuaded by this allegation because, as I find above, the physician who treated Patient # 8 did not envision discontinuing the patient's use of a Foley catheter as a realistic treatment objective.

d. 42 C.F.R. § 484.30

HCFA alleges that the nurses assigned to Patient # 8 failed to carry out instructions in the patient's plan of care concerning assessment of the patient's intake and output and the odor of the patient's urine. HCFA Ex. 4 at 25 - 27. These allegations are a rehash of the allegations that HCFA makes pursuant to 42 C.F.R. § 484.18. I found the allegations made under that requirement to be without merit, and I find them to be without merit here, as well. The record proves that the

nurses assigned to the patient made the assessments that the patient's physician directed to be made.

e. 42 C.F.R. § 484.30(a)

HCFA asserts that, in providing care to Patient # 8, Petitioner failed in several respects to comply with this participation requirement. I find none of HCFA's allegations to be supported by the record.

First, HCFA asserts that the nurses assigned to providing care to the patient failed to reevaluate the patient's nursing needs. According to HCFA, the nurses failed to reevaluate the patient's needs with respect to the efficacy of irrigating the patient's bladder. HCFA Ex. 4 at 32 - 35. In making this allegation, HCFA refers to an irrigation of the patient's catheter which a nurse assigned to the patient performed on April 15, 1996. HCFA Ex. 10 at 66, P. Ex. 14 at 64. HCFA notes that, on March 26, 1996, the patient's physician directed that the nurse perform irrigations as needed for clogging of the catheter. HCFA Ex. 10 at 21, P. Ex. 14 at 18. Apparently, HCFA contends that the nurse assigned to the patient performed the irrigation on April 15, without assessing first whether the irrigation was needed.

In fact, the most reasonable inference that may be drawn from the treatment records is that the nurse performed precisely this assessment. The nurse's note of April 15 shows that the patient was manifesting increased sediments in her urine. HCFA Ex. 10 at 66, P. Ex. 14 at 64. An increase in sediments, if sufficiently large, may cause clogging of a catheter. Tr. at 800 - 803. It is true that the nurse's note did not contain the word "clogging." But the reasonable inference is that the nurse assessed the character of the patient's urine, found increased sediments, made a judgment that the catheter either was clogged or would soon be clogged, and performed an irrigation based on that assessment. That is what the participation requirement calls for and is consistent with what the physician ordered the nurse to do.

HCFA seems also to be asserting that the nurses assigned to Patient # 8 failed to make a requisite assessment as to whether continued use of a Foley catheter by the patient was medically appropriate. HCFA Ex. 4 at 32 - 33. I am not persuaded that the nurses had any duty to make such an assessment. The patient's physician explicitly ordered that the patient wear the catheter throughout the patient's certification period. HCFA Ex. 10 at 1, P. Ex. 14 at 1. There is nothing in the record

to suggest that the physician ever reconsidered this order or asked the nurses assigned to the patient to advise as to whether the order should be modified. I do not find that a nurse has a duty under the participation requirement stated in 42 C.F.R. § 484.30(a) to make an assessment as to the propriety of a physician's order. Moreover, there is no evidence in the record of this case to show that any nurse, including the nurses assigned to Patient # 8, would be qualified to make such an assessment.

Next, HCFA asserts that the nurses assigned to Patient # 8 failed to make necessary revisions to the patient's plan of care to address instructions for timely discharge of the patient. HCFA Ex. 4 at 38. As I have discussed above, the participation requirement in 42 C.F.R. § 484.30(a) imposes no duty on a nurse to revise a plan of care that has been written by a physician.

Finally, HCFA alleges that the nurses assigned to Patient # 8 failed to initiate appropriate preventive and rehabilitative nursing procedures with regard to the patient's use of a Foley catheter. HCFA Ex. 4 at 42. Although HCFA does not assert what preventive and rehabilitative nursing procedures are lacking in the care provided to Patient # 8, it is apparent from the allegations made by HCFA that, once again, HCFA is arguing that the nurses assigned to the patient ought to have made a determination as to whether the patient needed the catheter. I am not persuaded that the participation requirement imposes this duty on the nurses, where, as in this case, there is an explicit physician's order that the patient wear a catheter. Nor is there persuasive evidence that making such a determination is within the professional skill and training of nurses.

7. Patient # 10 (HCFA Ex. 11, P.Ex. 15)

HCFA alleges that, in providing care to Patient # 10, Petitioner failed to comply with the following Medicare participation requirements: 42 C.F.R. § 484.18(a) (HCFA Ex. 4 at 16, 20); and 42 C.F.R. § 484.30(a) (HCFA Ex. 4 at 35, 37 - 38). I find that Petitioner did not fail to comply with these participation requirements in providing care to Patient # 10.

Patient # 10 was recertified for care from Petitioner beginning April 20, 1996 and ending June 20, 1996. HCFA Ex. 11 at 1, P. Ex. 15 at 1. The patient's principal diagnosis was abnormal loss of weight. The patient had additional diagnoses, including: malnutrition to a

moderate degree, an open wound to her arm and knee, and rheumatoid arthritis. Id.

a. 42 C.F.R. § 484.18(a)

HCFA asserts that the patient's plan of care did not provide instructions for a timely discharge of the patient. HCFA Ex. 4 at 20. However, the record proves otherwise. It is evident from the plan of care that the physician thought that the patient would be a candidate for discharge at the end of the period of certification if the patient's treatment goals were met. HCFA Ex. 11 at 1 - 2, P. Ex. 15 at 1 - 2.

The plan of care contained explicit instructions for treating the patient with timetables for establishing treatment goals. The patient was ordered to receive adequate nutrition in order to gain between five and ten pounds within nine weeks. HCFA Ex. 11 at 1 - 2, P. Ex. 15 at 1 - 2. Nutrition was ordered to be administered through a gastrostomy tube during this period of time. Id. The plan of care contemplated that the patient's wounds would heal without complications within two to four weeks. Id.

b. 42 C.F.R. § 484.30(a)

HCFA asserts that the nurses who treated the patient failed to make necessary revisions to the patient's plan of care to provide instructions for timely discharge of the patient. HCFA Ex. 4 at 37 - 38. Again, I find that the standard imposed no duty on the nurses to revise the patient's plan of care. Furthermore, I am not persuaded that any revisions were necessary. As I find above, the patient's plan of care contained comprehensive treatment instructions intended to make the patient ready for discharge.

8. Patient # 11 (HCFA Ex. 12, P. Ex. 16)

HCFA asserts that, in providing care to Patient # 11, Petitioner failed to comply with the following participation requirements: 42 C.F.R. § 484.14(a) (HCFA Ex. 4 at 16, 20) and 42 C.F.R. § 484.30(a) (HCFA Ex. 4 at 35, 40 - 41). I do not find that Petitioner failed to comply with these requirements.

Patient # 11 was certified to be cared for by Petitioner beginning April 23, 1996, and ending June 23, 1996 (HCFA Ex. 12, at 1, P. Ex. 16 at 1). The patient's principal diagnosis was transcerebral ischemia. Id. The patient had recently undergone angioplasty and was recovering

from that procedure at the time of her certification to receive care from Petitioner. Id. The patient was discharged from Petitioner's care on May 28, 1996 (HCFA Ex. 12 at 3, P. Ex. 16 at 37).

a. 42 C.F.R. § 484.14(a)

HCFA asserts that Petitioner failed to comply with this requirement because the patient's discharge plan failed to contain instructions for timely discharge of the patient. HCFA Ex. 4 at 20. In fact, the plan of care contained instructions to make the patient eligible for discharge, and the patient was discharged based on the patient meeting the parameters set by the plan of care.

The plan of care contained a treatment goal that the patient's cardiac status would remain stable, without signs or symptoms of complications, within two to three weeks. HCFA Ex. 12 at 1, P. Ex. 16 at 1. It stated as an additional goal that the patient's groin wound would heal within two weeks. Id. The plan of care stated, as a discharge objective, that the patient would be discharged when the patient no longer needed skilled care. HCFA Ex. 12 at 2, P. Ex. 16 at 2. It is evident from this plan of care that the patient's physician assumed that the patient would no longer need skilled care when the treatment goals of the plan of care were met. Therefore, contrary to HCFA's allegation, the patient's plan of care explicitly stated what was necessary in order to discharge the patient.

In fact, the record proves that Patient # 11 was discharged when the patient met the treatment goals in the plan of care. On May 28, 1996, the nurse reported to the patient's physician that the patient was stable for discharge, that the patient's angioplasty site was clean and dry, and that no signs of infection were observed. P. Ex. 16 at 16. The physician ordered the patient to be discharged, based on that report. Id.

b. 42 C.F.R. § 484.30(a)

HCFA alleges that the registered nurses who treated Patient # 11 failed to make necessary revisions to the patient's plan of care to address the goal of a timely discharge of the patient. HCFA Ex. 4 at 40 - 41. As I have held repeatedly, the standard does not impose a duty on nurses to revise a plan of care created by a physician. Moreover, as I discuss above, there is no evidence here that the plan of care that the physician wrote was inadequate or incomplete.

9. Patient # 12 (HCFA Ex. 13, P. Ex. 17)

HCFA alleges that, in providing care to Patient # 12, Petitioner failed to comply with the following Medicare participation requirements: 42 C.F.R. § 484.14(g) (HCFA Ex. 4 at 2 - 4, 9 - 10); 42 C.F.R. § 484.18 (HCFA Ex. 4 at 12 - 14); 42 C.F.R. § 484.18(a) (HCFA Ex. 4 at 16, 17, 19); 42 C.F.R. § 484.18(b) (HCFA Ex. 4 at 21 - 24); 42 C.F.R. § 484.30 (HCFA Ex. 4 at 26 - 27); and 42 C.F.R. § 484.30(a) (HCFA Ex. 4 at 28 - 29, 35, 38, 41, 43). I find that, in three respects, Petitioner failed to comply with Medicare participation requirements in providing care to Patient # 12. Petitioner failed to comply with a participation requirement stated in 42 C.F.R. § 484.18. Petitioner failed also to comply with a participation requirement stated in 42 C.F.R. § 484.18(b). Additionally, Petitioner failed to comply with a participation requirement stated in 42 C.F.R. § 484.30. I find that Petitioner did not fail to comply with other Medicare participation requirements in providing care to Patient # 12.

Patient # 12 was first cared for by Petitioner beginning March 22, 1996. HCFA Ex. 13 at 1, P. Ex. 17 at 1. The patient's initial certification period ended on May 22, 1996. Id. The patient was recertified to receive care from Petitioner beginning on May 22, 1996 and ending on July 22, 1996. HCFA Ex. 13 at 3. For each period of certification, the patient's principal diagnosis was insulin-dependent diabetes mellitus. HCFA Ex. 13 at 1, 3.

A principal problem that Petitioner encountered in attempting to provide care to Patient # 12 was the inability to find an alternate care giver for the patient, to assume responsibility for testing the patient's blood sugar and to administer insulin to the patient. The nurses who treated the patient encountered resistance from the individual who had agreed to serve as the care giver, both in the administering of blood sugar tests, and in the preparation and administering of insulin to the patient. HCFA Ex. 13 at 36 - 123. The patient's treatment was complicated also by the patient's unwillingness or inability to test her own blood sugar or to self-administer insulin. Id.

a. 42 C.F.R. § 484.14(g)

HCFA asserts that Petitioner failed in several respects to provide liaison or to coordinate the care being provided to Patient # 12 to support the objectives outlined in the patient's plan of care. Specifically,

HCFA alleges that, during the certification period which ended on May 22, 1996, Petitioner's staff failed to maintain liaison or to coordinate services to achieve the following goals stated in the patient's plan of care: (1) that the patient would be able to demonstrate foods from an exchange list; (2) that the patient or the patient's care giver received or completed instruction concerning accurate use of a glucometer; and (3) that the patient's care giver learn how to accurately and safely administer insulin to the patient.

Additionally, HCFA asserts that the patient's plan of care stated a "goal" that the patient would be discharged when the patient no longer needed insulin. HCFA contends that Petitioner's staff failed to document how they would insure that this "goal" would be attained. Finally, HCFA alleges that the clinical record of Patient # 12 fails to establish that Petitioner's staff provided liaison or coordination of services concerning the care that they provided for the patient's fungal infection.

HCFA asserts that Petitioner and its staff are responsible for something over which Petitioner had no control -- the possible inability of the patient to learn, despite diligent attempts to teach her, and the refusal of the care giver to cooperate with Petitioner's staff -- and, from that, to conclude that Petitioner did not do what the standard required it to do. That is not reasonable. The reasonable way to measure Petitioner's compliance with the standard is to examine its efforts to comply. By that measure, the efforts that are documented in the patient's treatment records prove that Petitioner complied fully.

The patient's plan of care contained treatment goals which included training the patient or the care giver to: demonstrate food from an exchange list; use a glucometer accurately; and accurately and safely administer insulin. HCFA Ex. 13 at 1, P. Ex. 17 at 1. These goals were transmitted to the nurses who cared for Patient # 12. The nurses worked diligently to achieve them.

The nurses who visited Patient # 12 instructed the patient concerning the appropriate foods in the patient's diet and how to plan meals, on at least the following occasions: April 5 (HCFA Ex. 13 at 111); April 9 (HCFA Ex. 13 at 109); April 13 (HCFA Ex. 13 at 100 - 101); April 14 (HCFA Ex. 13 at 99); April 19 (HCFA Ex. 13 at 88); April 21 (HCFA Ex. 13 at 84 - 85); April 23 (HCFA Ex. 13 at 81); April 24 (HCFA Ex. 13 at 77 - 78); April 26 (HCFA Ex. 13 at 73 - 74); April 27 (HCFA Ex. 13 at 71); and April 28 (HCFA Ex. 13 at 70). It is unclear

from the record how well the patient learned the dietary restrictions and exchanges that the nurses attempted to teach her. On nearly each occasion, the nurse recorded verbalizations by the patient which showed that the patient was able to at least repeat back to the nurse some of the instructions that the nurse had given. Id.

The nurses also gave the patient and the care giver instruction concerning the use of the glucometer. Specific instruction was provided on April 23, 1996. HCFA Ex. 13 at 123. On several occasions, the nurse observed the care giver performing blood sugar testing of the patient. These instances included: March 28 (HCFA Ex. 13 at 119); March 29 (HCFA Ex. 13 at 118); March 30 (HCFA Ex. 13 at 117); March 31 (HCFA Ex. 13 at 116); April 1 (HCFA Ex. 13 at 115); and April 2 (HCFA Ex. 13 at 114). After April 2, the care giver was either unwilling to perform blood testing or was absent, and the nurses performed the blood testing.

The nurse's notes show also that the nurses attempted to teach the care giver to administer insulin to the patient. However, the care giver was either unwilling to administer insulin or not present at the time of visits. Thus, the nurses had no choice other than to administer insulin to the patient. See P. Reply Brief, attachment 2.

I do not find that Petitioner failed to utilize liaison and to coordinate services to attain a "goal" of discharging the patient when the patient no longer needed insulin, as HCFA alleges. A close reading of the patient's plan of care establishes that the physician did not establish a treatment goal of weaning the patient off insulin. In fact, the treatments prescribed by the physician were intended to assure that the patient and the patient's care giver were able to administer insulin. HCFA Ex. 13 at 1 - 2, P. Ex. 17 at 1 - 2.

I do not find an absence of liaison or coordination of services among Petitioner's staff in dealing with the patient's fungal infection. The record establishes that the patient's physician and the nurses who treated the patient coordinated their services to assure that the fungal infection was treated. The patient's records do not contain a physician's record of a diagnosis of the patient's fungal infection, nor do they contain an order from the physician that medication be given to the patient to treat the infection. See HCFA Ex. 13, P. Ex. 17. However, I infer that the physician diagnosed an infection in early April 1996 because, on April 3, 1996, the nurse's note records an instruction to apply a

fungicide, Spectazole. P. Ex. 17 at 47. The nurse gave further instructions the following day. Id. at 48. Thus, the physician's order was executed by the nurse. There is nothing in the record to suggest that additional coordination of services was necessary to treat the patient's fungus infection.[10]

b. 42 C.F.R. § 484.18

HCFA asserts that, in providing care to Patient # 12, Petitioner failed in three respects to provide care to the patient which followed directions in the patient's plan of care. I agree with HCFA that, in one respect, Petitioner failed to comply with the directions in the patient's plan of care. I do not agree that Petitioner failed to comply in other respects.

The patient's plan of care for the initial period of certification (March 22 - May 22, 1996) directed Petitioner's staff to assess the patient's: disease process and progression, fluid and dietary regimen, insulin preparation, and foot care. Additionally, the plan of care directed Petitioner's staff to instruct the patient as to blood sugar testing, travel restrictions, and alteration of insulin integrity. HCFA Ex. 13 at 1, P. Ex. 17 at 1. HCFA asserts, generally, that Petitioner failed to comply with the instructions in the plan of care.

I have discussed above many of the interventions performed by Petitioner's staff. I conclude that, contrary to HCFA's assertions of a general failure by Petitioner's staff to carry out the instructions in the plan of care of Patient # 12, Petitioner's staff was generally diligent in carrying out those instructions.

However, in one respect, Petitioner's staff failed to carry out all of the physician's orders. The physician who treated Patient # 12 directed that Petitioner's staff assess the progress of the patient's disease. Patient # 12 complained consistently of blurred vision, a sign of complications of diabetes. However, the record is devoid of any assessment by the staff as to the extent of the problem, whether it was becoming worse, or even whether it was related to the patient's diabetes.

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[10] However, as I discuss below, Petitioner should have assured that the patient's treatment record contained an amendment to the patient's plan of care to document the physician's diagnosis of a fungus infection and to document the treatment plan for that infection.

Petitioner argues that the patient's blurred vision may have been due to the effects of recent cataract surgery. It is certainly possible that the cause of the patient's vision problems were unrelated to her diabetes. However, the fact that the problems might be due to diabetes was ample reason for the staff to have assessed them.

HCFA asserts also that Petitioner's staff was deficient in carrying out the instructions in the plan of care in not assessing the patient's fungus infection, as part of assessing the progress of the patient's disease. I find that the staff did make the requisite assessments. The nursing record of Patient # 12 shows that the nurses who cared for the patient assessed the condition of the patient's skin at every visit. HCFA Ex. 13 at 36 - 123. On May 21, 1996, a registered nurse evaluated the patient's condition and reported the infection to be "clearing." HCFA Ex. 13 at 44, P. Ex. 17 at 89. HCFA asserts that the assessments that were made of the patient's skin condition were not detailed. However, they plainly addressed the appearance of the patient's skin and noted the improvement in the fungus infection.

c. 42 C.F.R. § 484.18(a)

HCFA asserts that Petitioner's staff failed in two respects to develop a plan of care that addressed all of the patient's problems and thus failed to comply with the standard contained in 42 C.F.R. § 484.18(a). These allegations are not supported by the evidence.

First, according to HCFA, the plan of care developed in March 1996 had a discharge "goal" to discharge the patient when the patient no longer needed to receive insulin or when an alternate care giver was identified. HCFA asserts that the plan of care failed to contain instructions as to how to wean the patient off insulin.

This allegation does not have merit, because it is evident from the plan of care that the patient's physician did not view getting the patient off insulin to be a realistic treatment objective. Petitioner cannot be held accountable for failing to assist in developing a mechanism to achieve a nonexistent goal.

Second, HCFA asserts that the plan of care developed in March did not contain instructions to treat the patient's fungus infection. That literally, is true. However, it is evident from the treatment records of Patient # 12 that the fungus infection was first diagnosed in early April 1996, after the creation of the March 1996 plan of care. Petitioner cannot be held accountable for not

anticipating a diagnosis that was made after the inception of the plan of care.

d. 42 C.F.R. § 484.18(b)

HCFA alleges that Petitioner failed to comply with this standard of participation in that it failed to revise the plan of care for Patient # 12 to address the fungus infection in the patient's toes. HCFA Ex. 4 at 22 - 23. Here, I agree that Petitioner was deficient.

It is unclear from the patient's treatment records when, or precisely how, the fungus infection was first diagnosed. The first reference to the infection appears in a nurse's note dated April 3, 1996. P. Ex. 17 at 47. On that date, the nurse records that Spectazole, a fungicide, was being administered to the patient, and that the patient's care giver was instructed as to how to administer the medication. It is reasonable to infer that, shortly prior to that date, the patient's physician diagnosed the fungus infection and prescribed the medication. But, there is nothing in the treatment records of Patient # 12 that memorializes either the diagnosis or the physician's treatment plan.

I find that the failure to memorialize the physician's diagnosis of a fungus infection and the physician's treatment plan for the infection is a deficiency. The regulation requires that a plan of care be revised as often as the patient's condition warrants. Patient # 12 had developed a potentially serious infection, warranting a revision to her plan of care. The regulation does not prescribe a format for revising a plan of care. However, the record of Patient # 12 ought to have contained at least an order by the patient's physician which recorded the physician's diagnosis and treatment plan for the fungus infection.

HCFA asserts also that a second deficiency exists under 42 C.F.R. § 484.18(b), in that Petitioner's staff failed to discharge their responsibility in not notifying the physician of Patient # 12 of a change in the patient's condition (the development of a fungus infection) warranting a revision to the patient's plan of care. HCFA Ex. 4 at 24. I am not persuaded that Petitioner is deficient here. The record does not suggest that Petitioner's staff first identified the fungus infection. To the contrary, the reasonable inference is that the infection was first diagnosed by the patient's physician.

e. 42 C.F.R. § 484.30

I find that, in one respect, Petitioner failed to comply with the requirements of 42 C.F.R. § 484.30 in providing care to Patient # 12. HCFA Ex. 4 at 26 - 27. The failure of the nurses assigned to Patient # 12 to assess the patient's complaints of blurred vision, as an aspect of the patient's diabetes mellitus, is a failure by the nurses to carry out their duties under the patient's plan of care.

My finding of a deficiency under 42 C.F.R. § 484.30 is based on the identical evidence which leads me to conclude that Petitioner was deficient under 42 C.F.R. § 484.18, in providing care to Patient # 12. The requirement of 42 C.F.R. § 484.18, that care follow a written plan of care, is virtually restated by the requirement in 42 C.F.R. § 484.30 that the nurse follow a plan of care. Thus, a deficiency under one regulation must inevitably be a deficiency under the other regulation as well, where the deficiency consists of a nurse failing to carry out a physician's orders.

f. 42 C.F.R. § 484.30(a)

HCFA asserts that Petitioner failed in several respects to comply with this participation requirement in providing care to Patient # 12. I am not persuaded that Petitioner failed to comply with this requirement.

First, HCFA asserts that Petitioner failed to reevaluate regularly the nursing needs of Patient # 12, in that the nurses who treated the patient failed to document any assessment of the condition of the patient's toes after the onset of the patient's fungal infection. HCFA Ex. 4 at 28 - 29. I find this assertion to be contradicted by the record, which I have discussed above. The nurses' notes show that the nurses routinely evaluated the appearance of the patient's skin (which I infer would have included an evaluation of the appearance of the patient's toes). The status of the patient's fungus infection was addressed specifically when the patient was evaluated for recertification.

Second, HCFA asserts that the nurses assigned to Patient # 12 failed to assess the effects of their instruction to the patient's care giver on the care giver's performance of blood sugar testing, drawing insulin, and administering insulin to the patient. HCFA Ex. 4 at 38. This assertion is contradicted by the evidence. The nurses' notes show that the care giver repeatedly refused to administer insulin or was not present at the time of

the nurses' visits to the patient. There is nothing in the record to suggest that any "assessment" was needed, beyond recording that the care giver would not cooperate.

Third, HCFA asserts that the nurses assigned to Patient # 12 failed to reevaluate the need to identify an additional care giver to the patient. This assertion also is contradicted by the evidence. The patient's treatment records establish that, on May 21, 1996, Petitioner's staff discussed the need to obtain an alternate care giver for the patient. HCFA Ex. 13 at 44, P. Ex. 17 at 89.

Fourth, HCFA asserts that the registered nurses assigned to Patient # 12 failed to make necessary revisions to the patient's plan of care to address the patient's fungal infection. HCFA Ex. 4 at 41. Above, I find that Petitioner was deficient in not assuring that the patient's plan of care was revised by the patient's physician to indicate the physician's diagnosis of a fungus infection, and the treatment that the physician prescribed for that infection. However, as I have found repeatedly in this decision, the duty to make any revisions in a plan of care may not be allocated to the nurses who are assigned to treat a patient.

Fifth, HCFA asserts that the registered nurses assigned to Patient # 12 failed to make necessary revisions to the patient's plan of care to include instructions to wean the patient off insulin. Again, I find that the nurses were under no obligation to make these revisions, assuming them to have been necessary. Moreover, I do not find that such revisions were necessary, in that the physician who treated Patient # 12 never stated a goal to end the patient's dependence on insulin.

Finally, HCFA asserts that the registered nurses assigned to Patient # 12 failed to initiate appropriate preventive and rehabilitative nursing procedures to address the lack of cooperation of the patient's care giver. HCFA Ex. 4 at 43. I am not persuaded that there was any failure of responsibility here. The fact is, that the care giver was uncooperative. HCFA has not suggested what "preventive and rehabilitative" procedures might be implemented to deal with a care giver who refuses to do what is needed to provide care to a patient. See P. Reply brief, attachment 2. The record establishes that, eventually, Petitioner's staff gave up on trying to educate the patient's care giver and began to search for an alternate care giver. I can envision no action more appropriate than what was eventually done by Petitioner's staff.

10. Patient # 13 (HCFA Ex. 14, P. Ex. 18)

HCFA asserts that, in providing care to Patient # 13, Petitioner failed to comply with the following Medicare participation requirements: 42 C.F.R. § 484.14(g) (HCFA Ex. 4 at 2, 6 - 7, 8 - 9); 42 C.F.R. § 484.18(a) (HCFA Ex. 4 at 16, 17); and 42 C.F.R. § 484.30(a) (HCFA Ex. 4 at 41, 44). I do not find that Petitioner failed to comply with these participation requirements in providing care to Patient # 13.

Patient # 13 was certified to be cared for by Petitioner from March 18, 1996 through May 18, 1996. HCFA Ex. 14 at 3 - 4, P. Ex. 18 at 3 - 4. The patient was recertified to be cared for by Petitioner from May 18, 1996 through July 18, 1996. HCFA Ex. 14 at 1 - 2, P. Ex. 18 at 1 - 2. In each certification, the patient's principal diagnosis was insulin-dependent diabetes mellitus. The patient's other diagnoses included: hypertension, peripheral vascular disease, osteoarthritis, and contact dermatitis.

a. 42 C.F.R. § 484.14(g)

HCFA asserts that Petitioner failed in two respects to comply with this participation requirement in providing care to Patient # 13. First, HCFA asserts that Petitioner's staff failed to provide liaison and coordination in attempting to meet a discharge "goal" to discharge the patient when the patient no longer needed insulin. HCFA Ex. 4 at 6 - 7.

I am not persuaded that either the first or the second plan of care for Patient # 13 actually had as a treatment goal the ending of the patient's dependence on insulin. Patient # 13 had been a diabetic for 10 years. P. Ex. 18 at 10. The physician's orders, memorialized in the patient's plans of care, focused on the objective of stabilizing the patient's blood sugar through the regulation of insulin administered to the patient. For example, in the May 18 - July 18 plan of care, the specific treatment order is that the skilled nurse would check the patient's blood sugar twice daily and administer insulin on each visit. HCFA Ex. 14 at 1, P. Ex. 18 at 1. The skilled nurse was instructed to notify the patient's physician if the patient's blood sugar exceeded 350 mg/dl. Id. There were no orders in the plan of care suggesting that the physician sought to wean the patient off insulin. Thus, the discharge objective, which HCFA defines as a "goal," to discharge the patient when the patient no longer needed insulin or when an alternate care giver was identified, cannot be

characterized as a treatment objective by the patient's physician to end the patient's dependence on insulin.

Second, HCFA asserts that a case conference held on May 17, 1996 failed to address findings made by a social worker concerning attempts to locate an alternate care giver for the patient. According to HCFA, this is proof of an absence of liaison and coordination of care. HCFA Ex. 4 at 8 - 9. I disagree with HCFA's conclusion. While it may be that a social worker's report was not discussed on May 17, the record of the care provided to Patient # 13 shows that there was considerable liaison and coordination among Petitioner's staff, and between Petitioner's staff and others to attempt to find an alternate care giver for Patient # 13. As I hold above, the test for liaison and coordination of services is not whether a subject is discussed at a particular meeting, but whether liaison and coordination actually occurs.

The record shows that a registered nurse assigned to provide care to the patient received the social worker's report on May 15, 1996. P. Ex. 18 at 80. The report states, among other things, that the patient was unwilling to accept an alternate care giver. Id. Notwithstanding, the social worker made contacts with outside agencies in an attempt to locate an alternate care giver for the patient. Id. On May 16, the nurse reported to her supervisor the communication that the nurse had received from the social worker. P. Ex. 18 at 83. The nurse related that the social worker would continue to look for other alternatives to the care relationship that the patient had at that time and would refer the patient to community resources. Id. The social worker followed up her May, 1996 visit with a second visit in June, 1996, which was given to the registered nurse and to the social worker's supervisor. P. Ex. 18 at 82.

b. 42 C.F.R. § 484.18(a)

HCFA avers that Petitioner failed to develop a plan of care for Patient # 13 that covered all of the patient's pertinent diagnoses, nutritional requirements, medications and treatments, and instructions for timely discharge of the patient. Specifically, HCFA asserts that the patient's plan of care contained a discharge "goal" to discharge the patient when the patient no longer needed insulin. HCFA Ex. 4 at 17. According to HCFA, the plan of care failed to include instructions to Petitioner's staff to end the patient's dependence on insulin.

I am unpersuaded by this assertion. As I discuss above, the patient's treatment records show plainly that the patient's physician never contemplated that, as a reasonable treatment objective, this patient could be weaned off insulin.

c. 42 C.F.R. § 484.30(a)

HCFA argues that the nurses assigned to the patient failed to initiate appropriate preventive and rehabilitative nursing procedures for the patient. Specifically, HCFA asserts that the nurses were remiss in not initiating procedures to cause the patient to lose weight. HCFA Ex. 4 at 44.

I do not find this allegation to have merit. The physician who treated Patient # 13 did not specifically identify the patient's obesity as a condition needing treatment. See HCFA Ex. 14 at 1 - 4, P. Ex. 18 at 1 - 4. I am not persuaded that, under the applicable participation requirement, the nurses should have instituted treatment for obesity in the absence of an order from the physician to do so. The physician did prescribe an ADA diet to the patient. Id. Possibly, this diet may have been prescribed in an attempt to address the patient's obesity, or to control her blood sugar, or both. The patient's records establish that the nurses assigned to Patient # 13 instructed the patient concerning her diet. HCFA Ex. 14 at 34, 41, 56. Thus, the nurses carried out the physician's orders by attempting to induce the patient to become compliant with an ADA diet.

11. Patient # 15 (HCFA Ex. 15, P. Ex. 19)

HCFA alleges that, in providing care to Patient # 15, Petitioner failed to comply with the following Medicare participation requirements: 42 C.F.R. § 484.18(a) (HCFA Ex. 4 at 16, 20); and 42 C.F.R. § 484.30(a) (HCFA Ex. 4 at 35, 41). I find no failure by Petitioner, in caring for Patient # 15, to comply with Medicare participation requirements.

Patient # 15 was certified to be cared for by Petitioner from May 16, 1996 through July 16, 1996. HCFA Ex. 15 at 1, P. Ex. 19 at 1. The patient's principal diagnosis was insulin-dependent diabetes mellitus. The patient's other diagnoses included hypertension, chronic renal failure, a fracture of the patient's left arm, and chronic obstructive airway disease. Id.

a. 42 C.F.R. § 484.18(a)

HCFA asserts that the patient's plan of care contained a treatment goal to discharge the patient when the patient was no longer dependent on insulin, or when an alternate care giver was identified. HCFA asserts that the plan of care failed to contain instructions for timely discharge of Patient # 15. HCFA Ex. 4 at 20. Specifically, HCFA asserts that the plan of care fails to explain how Petitioner and the patient's physician intended to end the patient's dependence on insulin.

I am not persuaded that the failure of this patient's plan of care to explain how the patient's insulin dependence would end is a deficiency. It is obvious from a dispassionate reading of the plan that the patient's physician did not contemplate that it was reasonably possible to end this patient's dependence on insulin.

As is the case with many of the other patients whose care is at issue here, I am not persuaded by the treatment record of Patient # 15 that the physician who treated the patient contemplated ending the patient's dependence on insulin as a treatment goal which could be attained. The plan of care does mention discharging the patient when the patient is no longer dependent on insulin or when an alternate care giver is identified. However, the plan of care plainly does not contemplate the likelihood that the patient might be weaned off insulin. In fact, the plan of care focuses on stabilizing the patient's blood sugar through the administration of insulin to the patient. HCFA Ex. 15 at 1 - 2, P. Ex. 19 at 1 - 2.

b. 42 C.F.R. § 484.30(a)

HCFA asserts that Petitioner was deficient, because the registered nurses assigned to Patient # 15 failed to make necessary revisions to the patient's plan of care to address the "goal" of a timely discharge of the patient. HCFA Ex. 4 at 41. As I hold above, the Medicare participation requirements which govern home health agencies do not assign to nurses the duty to revise plans of care. Nor, as I explain above, do I find the absence of instructions in this patient's plan of care addressing the "goal" of discharging the patient when the patient no longer depended on insulin, to be a deficiency.

D. HCFA's allegations that Petitioner failed to conduct requisite management reviews (Finding 10)

HCFA alleges that Petitioner failed to conduct the management reviews and assessments required under 42 C.F.R. §§ 484.52 and 484.52(a). The overwhelming evidence is that Petitioner dutifully conducted the requisite reviews and assessments. P. Ex. 21, 22, 30.

HCFA bases its assertion that Petitioner failed to comply with the requirements of 42 C.F.R. §§ 484.52 and 484.52(a), on the testimony of Mr. Raymond A. Montgomery, one of the surveyors who participated in the survey which ended on May 30, 1996,. Tr. at 389 - 424. Mr. Montgomery testified that he failed to see any documentation that Petitioner was addressing the requirements contained in the regulation. Tr. at 393 - 396.

Mr. Montgomery's testimony does not establish precisely which documents he reviewed at the survey ending on May 30, 1996. It is evident, however, that, whether or not Mr. Montgomery reviewed all of Petitioner's records, Petitioner performed the kind of self-evaluation and assessment that the regulation required. Indeed, Petitioner did what Mr. Montgomery testified he expected that Petitioner would have done. See Tr. at 393 - 396.

Pursuant to 42 C.F.R. § 484.52, a home health agency must conduct an overall evaluation of its program at least annually. Such evaluation must be performed by professional personnel, the agency's staff, and consumers, or by professional personnel from outside the agency working in conjunction with the agency. The evaluation must consist of an overall policy and administrative review and a review of clinical records. The evaluation must assess the extent to which the home health agency's program is appropriate, adequate, effective, and efficient. The report and results of the evaluation must be acted on by those who are responsible for operating the agency. The standard contained in 42 C.F.R. § 484.52(a) requires that, as part of the evaluation, the policies and administrative practices of a home health agency are reviewed to determine the extent to which they promote patient care that is appropriate, adequate, effective, and efficient.

Petitioner satisfied all of these requirements. It held an annual management review on May 9, 1996. P. Ex. 22. The management review of May 9, 1996 comprised a comprehensive evaluation by Petitioner of its overall program. It identified problems which might affect

adversely the appropriateness, adequacy, effectiveness, and efficiency of the care that Petitioner gave to its patients. It proposed solutions to these problems. Subsequently, these proposals were adopted by Petitioner's Board of Directors.

The participants at the May 9 review included management representatives consisting of Petitioner's President, Corporate Administrator, Director of Nursing, Clinical Supervisors and branch management. P. Ex. 22 at 361. The participants included professional personnel, including nurses and physicians. Id. A consumer representative was present at the meeting. Id.

The review included a review of the Petitioner's policies and procedures. These included a total quality management system, a performance system with four components intended to assure that Petitioner complied with quality of care requirements. P. Ex. 22 at 361 - 362. The review included also a review of Petitioner's costs and expenditures, including a review of overpayments to be repaid to the Medicare program. Id. at 364. The review included a review of the charts of discharged patients. Among other things, this review focused on whether patients who were recertified ought to have been recertified, and whether individual cases were managed properly. Id. The review included a review of the charts of active patients. This review addressed thirteen specific problem areas having to do with Petitioner's care of patients. P. Ex. 22 at 367.

Petitioner's management review consisted of more than a review of records. Specific proposals were discussed and adopted to address those problems which were identified. P. Ex. 22 at 361 - 367.

On May 30, 1996, Petitioner's Board of Directors held a special meeting. P. Ex. 30. At that meeting, the Board of Directors adopted the recommendations resulting from Petitioner's May 9, 1996 management review. Id.

E. HCFA's allegations that Petitioner failed to comply with conditions of participation (Findings 11 - 14)

The record does not support HCFA's assertion that Petitioner failed to comply with the condition of participation contained in 42 C.F.R. § 484.14. In part, HCFA premised its assertion that Petitioner failed to comply with this on allegations that, in a number of instances, Petitioner had not provided necessary liaison and coordination of services. I have reviewed each of

HCFA's allegations of alleged failure to provide liaison and coordination of services at Part III.C. of this decision, and I find them to be without merit.

HCFA premised its allegation that Petitioner's governing body failed to exercise the degree of control required under section 484.14 on HCFA's assertion that Petitioner had failed to comply systematically with Medicare participation requirements. I find this assertion to be without merit, because there is no evidence that Petitioner failed to comply systematically with Medicare participation requirements.

I am not persuaded that Petitioner failed to comply with the condition of participation contained in 42 C.F.R. § 484.18, the condition governing the creation and revision of plans of care. According to HCFA, Petitioner manifested a pattern of failures to comply with the requirements of the condition. HCFA asserts that this alleged pattern of failures to comply is proof that Petitioner failed to comply with the condition. There is persuasive evidence that in two instances involving Patient # 12, Petitioner failed to comply with the requirements of 42 C.F.R. § 484.18. Petitioner failed to assure that the patient's plan of care was revised to report a physician's diagnosis of the patient's fungus infection, and plan of treatment for the infection. Petitioner failed also to assure that the nurses assigned to Patient # 12 assessed the patient's complaints of blurred vision, which, arguably, might have been related to the patient's diabetes mellitus.

I do not find that the two instances of failures to comply with requirements contained in 42 C.F.R. § 484.18 is evidence of a pattern of failures to comply with these requirements, as is alleged by HCFA. Nor do I find that these two failures to comply show that Petitioner is incapable of complying with participation requirements. I am not downplaying the significance of Petitioner's failure to comply with participation requirements in providing care to Patient # 12. However, it is apparent from the total record of this case that these examples of failures to comply are isolated incidents which do not, in and of themselves, establish Petitioner to be incapable of providing care of the quality required under the Act and regulations.

I do not find that Petitioner failed to comply with the requirements of 42 C.F.R. § 484.30, the condition of participation governing nurses' performance of their duties. As with 42 C.F.R. § 484.14, HCFA asserts that Petitioner manifested a pattern of failures to comply

with the requirements of 42 C.F.R. § 484.30. The evidence establishes one failure by Petitioner to comply with participation requirements stated in 42 C.F.R. § 484.30. The nurses assigned to provide care to Patient # 12 failed to assess the patient's complaints of blurred vision as a possible sign of diabetes. However, that is the only instance in which I find a failure by Petitioner to comply with the requirements of the regulation. As with the two instances of failures to comply with the requirements of 42 C.F.R. § 484.18, this instance is neither proof of a pattern of failures to comply with the regulation nor is it proof that Petitioner is incapable of providing care required under the Act and regulations.

Finally, I do not agree with HCFA's assertion that Petitioner failed to comply with the self-evaluation requirements of 42 C.F.R. § 484.52. As I hold at Part III.D. of this decision, the overwhelming evidence is that Petitioner complied with this condition.

F. Petitioner's motion that I waive the requirement that it pay its share of transcript costs (Finding 15)

Prior to the hearing, I advised the parties that, pursuant to the requirements of 42 C.F.R. § 498.15, each of them would be assessed one-third the cost of the transcript of the hearing. I advised them that I would waive a party's share of the costs, only on a showing of good cause by that party.

After the hearing, Petitioner moved that I waive its share of the cost of the transcript. HCFA opposed the motion. I conclude, after reviewing Petitioner's motion, that there is no good cause for me to waive its share of the cost of the transcript.

Petitioner accompanied its motion with a declaration by Mariano Velez, Petitioner's sole owner and chief financial officer. P. Ex. 32.[11] In his declaration, Mr. Velez asserts that Petitioner received no payments for Medicare reimbursement after July 15, 1996. Id. Mr.

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[11] Petitioner did not designate this declaration by Mr. Velez as an exhibit. However, I have designated it as P. Ex. 32 and have admitted it into evidence. I have also designated as HCFA Ex. 26 and admitted into evidence the declaration of Ruth L. Beaird and attachments to the declaration, which HCFA submitted in opposition to Petitioner's motion to waive Petitioner's share of the cost of the transcript.

Velez asserts also that Petitioner has had to expend an enormous sum of money to defend itself against HCFA's actions. Id. Mr. Velez asserts that, based on these factors, Petitioner is without resources to pay for its share of the transcript cost.

The regulation which governs transcript costs does not specify what is good cause to waive a party's requirement to pay its share of the cost of a transcript. I find that financial destitution, if proven by a party, is good cause. Here, however, I am not satisfied that Petitioner proved that it is destitute. Mr Velez' assertion that Petitioner is without resources is not a persuasive statement that Petitioner lacks the wherewithal to pay for its share of the cost of the transcript. It is merely a conclusion, without actual proof of lack of resources.

IV. Conclusion

I am not persuaded by HCFA's allegations or by the evidence of record in this case that Petitioner failed to comply with a condition of participation in Medicare. I conclude that HCFA did not have a basis to terminate Petitioner's participation in Medicare.

/s/

Steven T. Kessel
Administrative Law Judge