Department of Health and Human Services

DEPARTMENTAL APPEALS BOARD

Civil Remedies Division

In the Case of:	)	
	)	
Guaynabo Hospice Care, Inc.,	)	DATE: May 8, 1995
	)	
Petitioner,	)	
	)	
- v.-	)	Docket No. C-94-362
	)	Decision No. CR374
Health Care Financing Administration.	)	
	)	

DECISION

This action was brought by the Guaynabo Hospice Care, Inc. (Petitioner), to challenge the actions of the Health Care Financing Administration (HCFA) to terminate Petitioner's participation in the Medicare program, effective June 9, 1994. I have reviewed the arguments of the parties as well as the evidence I received into the record during an in-person hearing in Puerto Rico.

ISSUE

The issue in this case is whether HCFA was authorized to terminate Petitioner's participation in the Medicare program after having conducted a survey on March 11, 1994 and a resurvey on June 6, 1994.

FINDINGS

Based on the record as a whole,[1] I find as follows on the issues of law and fact presented by the parties:[2]

1. HCFA has placed only one condition of participation ("physician services") in issue. (My reasons are set forth at p. 10.)

2. In this administrative hearing, the correct evidentiary standard is proof by the preponderance of the evidence, and HCFA has the burden of establishing the correctness of its findings and conclusions. (My reasons are set forth at 11 - 14.)

3. Based on only the March 1994 survey results, HCFA's determination of Petitioner's noncompliance with the physician services condition is sustainable.

A. The manner in which HCFA conducted the initial survey of March 1994 is valid, as are HCFA's reasons for conducting that survey.

B. HCFA reached valid factual findings and legal conclusions as a result of the March 1994 survey.

C. Petitioner's defenses are not sufficient to rebut the validity of HCFA's conclusions based on the March 1994 survey.

(My reasons are set forth at pp. 14 - 24.)

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[1] I refer to the parties' exhibits, their briefs, and the transcript of the hearing as follows:

Petitioner's exhibit	P. Ex. (number) at (page)
HCFA's exhibits	HCFA Ex. (number) at (page)
Petitioner's posthearing brief	P. Br. at (page)
HCFA's posthearing memorandum	HCFA Memo at (page)
Petitioner's additional brief	P. Supp. Br. at (page)
HCFA's supplemental brief	HCFA Supp. Br. at (page)

[2] I will be discussing in a separate section below my denial of HCFA's motion to correct the transcript of hearing.

4. Based on the results of the June 6, 1994 revisit survey, I set aside HCFA's determination that Petitioner was out of compliance with the requirements of the Medicare program, and I find no basis for terminating Petitioner's provider agreement.

A. After issuing the termination notice dated April 7, 1994, HCFA acted within its discretion to solicit and approve a plan of correction from Petitioner and to conduct a revisit survey to ascertain Petitioner's success in implementing its plan of correction.

B. After approving the revised plan of correction from Petitioner on May 20, 1994, HCFA was obligated to conduct its revisit survey and make determinations in a manner consistent with the terms of the approved plan and in accordance with its usual practices.

C. HCFA's findings from the June 1994 revisit survey concerning the plans of care for patients do not justify terminating Petitioner's provider agreement.

D. HCFA's findings from the June 1994 revisit survey concerning the failure of Petitioner's doctors to meet the general medical needs of patients do not justify terminating Petitioner's provider agreement.

E. HCFA selected inappropriate records for review during the revisit survey and reached conclusions concerning patient discharges, certifications, and recertifications that do not justify terminating Petitioner's provider agreement.

(My reasons are set forth at pp. 24 - 37.)

DISCUSSION

I. OVERVIEW OF RELEVANT LAWS AND REGULATIONS

Title XVIII of the Social Security Act (Act) established a national health insurance program which is now commonly known as Medicare. The Secretary of Health and Human Services (Secretary) is responsible for administering the Medicare program, and she is authorized to prescribe such regulations

as may be necessary to implement the requirements of the law. Section 1871(a)(1) of the Act. By regulation, the Secretary has delegated certain enforcement responsibilities under the program to HCFA. 49 Fed. Reg. 35,247 - 49 (1984).

Title A of the Medicare program entitles its beneficiaries to have payments made on their behalf to cover certain types of health care costs incurred when, for example, they are hospitalized, receive home health services, or receive hospice care.[3] See generally sections 1811 and 1812 of the Act. Section 1861 of the Act specifies those services that are "covered," for which payments may be made by the Medicare program. See 42 C.F.R. §§ 418.1, 418.301.

Those entities qualified to provide the covered health care services may participate in the Medicare program and become eligible to receive payments thereunder by filing an agreement with the Secretary to abide by certain terms specified by the Act. Section 1866(a)(1) of the Act.[4] However, the Secretary may refuse to enter into, refuse to renew, or terminate an agreement with a provider upon reasonable notice to the provider after the Secretary has determined that the provider ". . . fails to comply substantially . . . with the provisions of this title [i.e., Title XVIII] and regulations thereunder . . . [or] . . . fails substantially to meet the applicable provisions of section 1861 . . . ." Section 1866(b)(2) of the Act; 42 C.F.R. §§ 488.28, 489.53.

As applicable to providers of hospice services, the Secretary's implementing regulations explain that, in order to be approved for participation in the Medicare program, a provider seeking participation (i.e., a prospective provider) must meet the applicable statutory definition contained in section 1861 of the Act and be in compliance with the applicable conditions prescribed in part 418 of the

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[3] The beneficiary must elect to receive hospice care in lieu of other types of services. The election requirements are contained in section 1812(d)(1) of the Act.

[4] For example, the provider must agree to refrain from charging a Medicare beneficiary for an item or service payable by and under the program, and the provider must agree to make provisions for the return of any moneys incorrectly collected from Medicare beneficiaries or other persons. Section 1866(a)(1)(A), (C). See also, 42 C.F.R. § 489.20.

There is no allegation in this case that Petitioner had violated any of the terms or provisions specified in section 1866(a)(1) of the Act.

Secretary's regulations. 42 C.F.R. § 488.3(a).[5] After the provider has entered into a participation agreement under Medicare, HCFA has the authority to terminate the agreement for any one of the reasons enumerated by regulation, including where the provider is not complying with the provisions of Title XVIII and the applicable regulations of 42 C.F.R. Chapter IV, or when the provider no longer meets the appropriate conditions of participation. 42 C.F.R. § 489.53(a)(1), (3).

To provide "hospice care" under Medicare, a provider must satisfy the definition of a "hospice program." Section 1861(dd)(1) of the Act. The Act defines a "hospice program" in terms of "hospice care" and "terminally ill." "Hospice care" denotes only the eight statutorily enumerated types of services provided to a "terminally ill" Medicare beneficiary. Section 1861(dd)(1)(A) - (H) of the Act; 42 C.F.R. § 418.202. A Medicare beneficiary is considered "terminally ill" for purposes of receiving hospice care if he or she has a medical prognosis that his or her life expectancy is six months or less. Sections 1861(dd)(1) and (3)(A) of the Act. Thus, a "hospice program" is a public agency or private organization (or a subdivision thereof), which is primarily engaged in providing those hospice care and services covered by the program. Section 1861(dd)(2) of the Act.

The Secretary's regulations which implement the hospice care provisions of the Act's section 1861 are codified at Part 418 of 42 C.F.R. 42 C.F.R. § 418.1. According to the Secretary's interpretations, section 1861 of the Act specifies the services covered as hospice care and the conditions that a hospice program must meet in order to participate in the Medicare program. Id. Part 418

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[5] This regulation and others cited in this decision refer to both prospective providers and suppliers. However, a hospice is defined as "a provider of services or provider" and not a supplier. 42 C.F.R. § 488.1.

In addition, several of the regulations cited in this decision refer also to "conditions of coverage" (or whether a supplier is covered under Medicare) and "requirements." I note here for the sake of clarity that suppliers are entities, such as chiropractors and independent laboratories, that must meet "conditions for coverage," and suppliers that meet the conditions of coverage are then eligible to be "covered under the Medicare program." 42 C.F.R. §§ 488.1, 488.10(a)(2), 488.12(a)(1). Providers or prospective providers such as hospices or hospitals must meet "conditions of coverage," and the providers that meet such conditions are eligible to "participate in the Medicare program." Id. Skilled nursing facilities (SNFs) and nursing facilities (NFs) are a type of provider or prospective providers that must meet "requirements" in order to "participate in the Medicare program." Id.

underscores also the requirement that a hospice under the Medicare program must be primarily engaged in providing care to terminally ill individuals. 42 C.F.R. § 418.3.

Even though a hospice may arrange for another entity to deliver certain covered services, it retains its participatory status under Medicare only if it ". . . routinely provide[s] directly substantially all of each of the services described in subparagraphs (A), (C), (F), and (H)" of section 1861(dd)(1) -- i.e., nursing services, medical social services, physician services, and counseling services. Section 1861(dd)(2)(A)(ii)(I) of the Act. The Secretary refers to these four types of services as "core services" in her regulations, and, pursuant to her authority to administer the Medicare program, she has interpreted the manner in which these core services must be provided and designated them as "conditions of participation" for hospices. 42 C.F.R. § 418, subpart F; section 1866(b)(2) of the Act.

The Act expressly prohibits Medicare payments for any hospice item or service that is not reasonable and necessary for the palliation or management of a terminal illness. Section 1862(a)(1)(C) of the Act. To receive payment for reasonable and necessary services to a terminally ill Medicare beneficiary, a hospice provider also must submit the necessary documentation concerning the certification of terminal illness, the creation of a written plan of care and the periodic review of such a plan, and the delivery of care pursuant to the plan of care. Section 1814(a)(7) of the Act; 42 C.F.R. §§ 418.200 - 418.311. The Secretary's regulation summarizes these requirements thusly:

> (1) the service must be reasonable and necessary for the palliation or management of the terminal illness as well as related conditions;
>
> (2) before the service is provided, the individual must elect hospice care in accordance with 42 C.F.R. § 418.24 and a plan of care must be established as set forth in 42 C.F.R. § 418.58;
>
> (3) the service must be consistent with the plan of care; and
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> (4) a certification that the individual is terminally ill must be completed as set forth in 42 C.F.R. § 418.22.

42 C.F.R. § 418.200.

II. RELEVANT PROCEDURAL HISTORY

In the foregoing statutory and regulatory context, HCFA accepted Petitioner's application to participate in the

Medicare program as a provider of hospice services, effective March 13, 1992. P. Ex. 1. Also, HCFA notified Petitioner that its facility would be surveyed on a regular basis by HCFA's agent, the Puerto Rico Department of Health,[6] to determine the status of Petitioner's compliance with Medicare requirements. P. Ex. 1. With respect to any deficiencies that may be found pursuant to the surveys, HCFA informed Petitioner that:

> [a]ny deficiencies cited at the time of the . . . [survey] visits, that have not been completely corrected, are expected to be corrected as stated in your plan of correction.

P. Ex. 1.

On March 10 and 11, 1994, HCFA surveyed Petitioner's compliance under the program. HCFA Ex. 15; HCFA Ex. 54 at 12 - 13. The HCFA surveyors reported their findings and conclusions in a "Statement of Deficiencies" (SOD), which was sent to Petitioner on or about April 7, 1994. HCFA Ex. 15.

By letter dated April 7, 1994, HCFA notified Petitioner that it was found to be out of compliance with these four conditions of participation:

> 42 C.F.R. § 418.50 -- general provisions;
> 42 C.F.R. § 418.62 -- informed consent;
> 42 C.F.R. § 418.80 -- core services;
> 42 C.F.R. § 418.86 -- physician services.

HCFA Ex. 15. HCFA informed Petitioner that HCFA was also terminating Petitioner's Medicare contract effective June 9, 1994 because Petitioner was out of compliance with the above-cited four conditions of participation. Id. However, HCFA gave Petitioner an opportunity to continue participating in the program by providing HCFA with an acceptable plan of correction. Id.

Petitioner sent a plan of correction to HCFA on April 18, 1994. HCFA Ex. 16. HCFA did not find Petitioner's initial plan fully acceptable and explained its reasons to Petitioner by letter dated April 26, 1994. HCFA Ex. 17.

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[6] By law, HCFA is authorized to enter into agreements with State or local surveying agencies to determine whether providers or prospective providers meet the Medicare conditions of participation. 42 C.F.R. § 488.10 - .12.

On May 11, 1994, Petitioner submitted a revised plan of correction. HCFA Ex. 18.[7] On May 20, 1994, HCFA informed Petitioner by telephone that its plan of correction had been approved. HCFA Ex. 19.

On May 25, 1994, Petitioner submitted a request for hearing to challenge HCFA's determination that Petitioner had been out of compliance with four conditions of participation. Hearing Request. Petitioner contended, inter alia, that there was no evidence in HCFA's findings that Petitioner had failed to comply with 42 C.F.R. § 418.86 (physician services). Hearing Request.

On June 6, 1994, HCFA conducted a resurvey visit. HCFA Ex. 20. The purpose of the revisit survey was, according to HCFA, "to evaluate the facility's success in implementing its plan of correction." HCFA Ex. 21.

On June 7, 1994, HCFA notified Petitioner of the outcome of the June 6th resurvey. HCFA Ex. 21. HCFA determined that Petitioner's provider contract must be terminated effective June 9, 1994 because Petitioner had remained out of compliance with the following conditions of participation:

42 C.F.R. § 418.50 -- general provisions;
42 C.F.R. § 418.80 -- core services;
42 C.F.R. § 418.86 -- physician services.

HCFA Ex. 21.

III. RULING ON HCFA'S MOTION TO CORRECT TRANSCRIPT

Before discussing the merits of the case, I will first rule on HCFA's motion to correct the transcript.[8]

I rejected the first set of proposed changes contained in a 14-page handwritten document from HCFA, and I directed HCFA to refrain from unnecessarily increasing proceedings by submitting changes that were immaterial or not attributable to transcription errors. Order dated October 26, 1994. Subsequently, HCFA again submitted 152 proposed changes. Petitioner does not object to most of these proposed changes. Petitioner's actions in this regard are consistent with my

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[7] Pursuant to my February 14, 1995 Order Directing Additional Briefing by Parties, HCFA has resubmitted HCFA Ex. 18 on March 8, 1995 in order to include those attachments that were a part of Petitioner's revised plan of correction.

[8] Due to the different cultural customs reflected in the transcript of hearing, I was sometimes referred to as Judge Leahy and sometimes as Judge Hwang. Similarly, Petitioner's attorney was alternately referred to as Mr. Morales-Coll, Mr. Morales, or Mr. Coll.

directive to the parties that they avoid unnecessary proceedings and controversies. For the reasons that follow, I have decided to deny HCFA's motion to alter the transcript, except with respect to correcting the caption of this case to show that HCFA (and not the Inspector General) is the Respondent.

HCFA's proposed changes included many that were immaterial to the issues in this case. For example, HCFA proposed changing the title of HCFA's attorney from "Assistant Regional Attorney" to "Senior Trial Attorney;" changing "changed" to "changes;" inserting "that" after "mental status." HCFA Motion and Memorandum in Support of Corrections To the Guaynabo Transcript. There were other proposed changes that altered the meaning of the testimony I heard during hearing, such as HCFA's request to change "conditions" to "provisions;" to change "provisions" to "Physician Services;" to change "[19]94" to "[19]93" at four places; and to insert "of time given his natural course" after "period." Id. Some of the blanks in the transcript which HCFA attempts to fill in with its proposed words (e.g., substituting "____" with "Survey Protocol") may have been due to transcription error or equipment malfunction. However, and there was other evidence of record introduced also by HCFA (e.g., patient records and surveyors' written reports) which gave meaning to some of the incomplete sentences.

I have read the transcript of hearing with and without the proposed changes, and I did not arrive at different conclusions concerning the meaning of the testimony or the credibility of witnesses. Neither parties' arguments posthearing turned on any change proposed by HCFA. Moreover, some of HCFA's proposed changes reflect only HCFA's efforts to supplement or modify its witnesses' testimony when there was no longer an opportunity for cross-examination and after I had directed HCFA to refrain from proposing changes that were not attributable to transcription errors. Such proposed changes would also impact adversely on the opportunity I had to hear, observe, and request clarifications from HCFA's witnesses during the hearing. Additionally, having reviewed the record as a whole, I did not find those blanks in the transcript HCFA is seeking to fill in posthearing to have substantially effected the weight or substantive meaning of the testimony. In sum, I do not find it appropriate or necessary to set aside the court reporters' certification that a full, true, and correct transcription of the hearing had been made. I grant only the change in case caption to correctly identify HCFA as the respondent.

IV. ANALYSIS OF FACTS AND ARGUMENTS

A. HCFA has placed only one condition of participation in issue.

I find as a preliminary matter that the issue of Petitioner's compliance with 42 C.F.R. § 418.62 (informed consent) has become moot. HCFA did not find any problems relating to informed consent during the revisit survey. HCFA Ex. 20. In terminating Petitioner's provider agreement on June 9, 1994, HCFA did not rely on any asserted deficiencies under 42 C.F.R. § 418.62. HCFA Ex. 21. Therefore, it is not necessary for me to review the evidence on informed consent.

I find also that two of the regulations cited in HCFA's June 7, 1994 notice -- 42 C.F.R. § 418.50 (general provisions) and 418.80 (furnishing of core services) -- do not provide independent bases for terminating Petitioner's provider agreement.

To the extent 42 C.F.R. § 418.50 (general provisions) applies at all to HCFA's theory of the case, it is because said regulation incorporates the other two regulations cited by HCFA in its termination notice (42 C.F.R. §§ 418.86 (physician services) and 418.80 (core services). See HCFA Exs. 15,[9] 20; HCFA Memo at 5, n.2. As HCFA explained at hearing, "[i]f any condition is out, then General Conditions is out as a cross reference. So, General Conditions will be out for the same reason as the Provisions are . . . ." Tr. at 17. Similarly, HCFA alleges that Petitioner was out of compliance with 42 C.F.R. § 418.80 (core services) during the June 1994 survey only because HCFA had determined that Petitioner has failed to provide the core physician services specified in 42 C.F.R. § 418.86. The SOD from the June survey does not even mention 42 C.F.R. § 418.80 (core services) or any finding outside those the surveyors have attributed to physician services. HCFA Ex. 20.

In sum, the essence of HCFA's determination before me is that Petitioner was noncompliant with a single condition of participation -- the one for physician services at 42 C.F.R. § 418.86, which states:

> [i] In addition to palliation and management of terminal illness and related conditions, physician employees of the hospice, including the physician member(s) of the interdisciplinary group, must also meet the general medical needs of the patients to the extent that these needs are not met by the attending physician.

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[9] HCFA cited noncompliance with 42 C.F.R. §§ 418.80 and 418.86 among its findings that support Petitioner's noncompliance with 42 C.F.R. § 418.50.

B. HCFA has incorrectly stated the evidentiary standards and burdens for this administrative hearing: the correct standard is proof by the preponderance of the evidence, and HCFA must prove the correctness of its determination.

HCFA contends that "Petitioner is, in effect, asking for the benefit or privilege of being a Medicare provider entitled to federal funds to reimburse costs associated with the provision of services to patients in a hospice program who are eligible for Medicare hospice services." HCFA Memo at 23. HCFA notes that, in a long line of cases involving individuals applying for retirement or disability benefits under Title II of the Act, it has been held that those seeking to establish their entitlement to payments have the burden of establishing their eligibility to benefits. HCFA Memo at 23. HCFA therefore concludes that the burden of proof must be placed on Petitioner in this administrative hearing to demonstrate its entitlement to the privilege of receiving Medicare reimbursements for providing hospice services to program beneficiaries. HCFA Memo at 23 - 24.

HCFA seeks also to assign to itself the burden of introducing only substantial evidence in support of its position at hearing. It contends that the only issue in this case is whether HCFA's determinations are supported by substantial evidence. HCFA Memo at 5.

By contrast, HCFA seeks to have Petitioner bound by a much heavier evidentiary burden. HCFA argues that, because HCFA surveyors work within the framework set up by the survey and certification procedures of 42 C.F.R. Part 488, Petitioner must prove that the surveyors' interpretations of noncompliance are clearly erroneous. HCFA Memo at 29.

I find that HCFA has incorrectly stated the evidentiary standards and burdens for this administrative hearing. The correct standard is proof by the preponderance of the evidence -- not by substantial evidence for HCFA nor by the quantum of evidence necessary for Petitioner to establish HCFA's commission of clear error. HCFA must show the correctness of its contract termination action. The burden is not on Petitioner to prove entitlement to a benefit under the Act in this case.

Contrary to HCFA's view, Petitioner is not a prospective provider applying to form a contract with HCFA, and there is no request before me by Petitioner for any Medicare reimbursement. In March of 1992, HCFA had already determined that Petitioner met all requirements to participate in the program. P. Ex. 1. HCFA, as an administrator for our national health insurance program, entered into a contract with Petitioner under which HCFA agreed to reimburse Petitioner for the delivery of covered services to eligible Medicare beneficiaries. Pursuant to the laws and regulations discussed above, HCFA agreed to maintain such a contract with Petitioner so long as Petitioner continues to meet the

requirements of law. This case arose only because HCFA determined that Petitioner breached a condition of participation under the contract and HCFA initiated contract termination proceedings. Contrary to HCFA's arguments, the situation that gave rise to the disputes in this case is not at all analogous to one where an individual files an application with the Secretary in order to prove that she is entitled to receive monthly retirement or disability benefits.

I agree with Judge Kessel's opinions on the allocations of the burdens of coming forward with evidence and persuasion in cases where HCFA has terminated existing provider agreements. See Hospicio en el Hogar de Lajas, CR366 at 6 - 8, (1995); Arecibo Medical Hospice Care, CR363 at 8 - 13, (1995). I, too, emphasize that this is a de novo hearing, wherein an independent adjudicator (an administrative law judge) decides whether to affirm, modify, or reverse HCFA's termination decision based on the evidence presented by the parties. Section 1866(h)(1) of the Act (incorporating section 205(b) of the Act). HCFA, as agent for the Secretary, is supposed to have made findings of fact in reaching its decision to terminate a provider agreement. See id. The hearing rights conferred on the provider is only "with respect to such decision" made by HCFA. Id. In the hearing process, the administrative law judge's right to affirm, modify, or reverse is over HCFA's "findings of fact and . . . decision." Section 205(b)(1) of the Act. In other words, the correctness of HCFA's findings and determination are at the center of each case that is heard pursuant to section 1866(h)(1) of the Act. Therefore, it is both fair and consistent with the Act that HCFA should have the burden of persuasion and of coming forward with evidence to show that its findings and conclusions are correct.

In the context of conducting a de novo evidentiary hearing specified by the Act, I reject also HCFA's argument that it need support its position with only "substantial evidence." Substantial evidence is a reviewing standard the federal courts must apply in considering the factual basis of those final decisions issued for the Secretary after a de novo administrative hearing.[10] In such court reviews of the record from the evidentiary hearing below, the findings of fact made by or for the Secretary are "conclusive" if they are supported by substantial evidence. Section 205(g) of the Act (incorporated by section 1866(h)(1)). In contrast, hearings before administrative law judges are held in accordance with section 205(b) of the Act, which does not contain any reference to a "substantial evidence" standard of proof for either party. The conduct of hearing under

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[10] Substantial evidence means "more than a scintilla. It means such relevant evidence as a reasonable mind might accept to support a conclusion." Consolidated Edison Co. v. NLRB, 305 U.S. 197, 229 (1938).

sections 205(b) and 1866(h)(1) of the Act rest generally within the discretion of the presiding administrative law judge. Richardson v. Perales, 402 U.S. 389, 401 (1971).

The usual standard of proof in de novo evidentiary hearings is the preponderance of evidence. Neither the Act nor the Secretary's regulations implementing the Medicare statutes state otherwise. Moreover, there is no case precedent supporting HCFA's argument that it is entitled to prevail at hearing based on only substantial evidence; nor is there any case involving breach of contract allegations wherein the substantial evidence standard was applied at trial or at hearing to determine which party prevails. Therefore, in the absence of regulations, laws, or legal precedents specifying otherwise, I conclude that the truth of any material proposition in issue must be proven by a preponderance of the evidence.

For the same reasons, I reject also HCFA's contention that, in order for Petitioner to successfully refute the surveyors' interpretations of fact and law that have resulted from their use of professional judgment, Petitioner must show that the surveyors' interpretations are clearly erroneous. HCFA Memo at 29. This argument is legally untenable even if one of HCFA's two surveyors from the June 1994 revisit survey had not testified that she became employed as an inspector for the Puerto Rico Department of Health only on May 2, 1994; that she was receiving on-the-job training from May 2 until the end of June 1994; that she had conducted no surveys prior to May 2, 1994; and that her only experience with hospices was in inspecting them during her training period. E.g., Tr. at 331 - 34, 356 - 59.[11] In addition, every professional

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] [11] HCFA had every opportunity to elicit accurately this witness' participation in the June 1994 survey. Even before HCFA called this witness (Merta Fernandez) to testify, HCFA had elicited the information from another surveyor that Ms. Fernandez was present during the June survey to lend assistance and to receive "in-service training on how to survey hospice facilities." Tr. at 298. In answer to HCFA's question, the other surveyor testified that the "in-service training" for Ms. Fernandez consisted of her spending approximately one hour with Ms. Fernandez going over what they were looking for, reviewing hospice regulations, and discussing issues that arose at the survey site. Id.

During HCFA's direct examination of Ms. Fernandez, Petitioner objected repeatedly because HCFA appeared to suggest with its questions that Ms. Fernandez had more substantial participation in the June survey (e.g., making findings and reaching conclusions, as opposed to making recommendations) than implied by the contents of HCFA's list of proposed witnesses, which stated that Ms. Fernandez would testify concerning her "assistance." E.g., Tr. at 338, 339, 344,

(continued...)

witness can legitimately claim to have exercised professional judgment. The correctness of any professional's conclusions or findings can be ascertained only in light of the total evidentiary record, including what he considered, what he should have considered, and what he failed to consider, together with the laws that are applicable. Petitioner cannot be required to establish that HCFA's determinations are clearly erroneous when HCFA's determinations carry no presumption of correctness and may not be proven correct by a preponderance of the evidence.

In provider termination cases such as this, HCFA must at least show that all material conclusions it formulated in order to terminate the provider agreement are supported by a preponderance of the evidence and are based on a correct interpretation of the laws and regulations. Where, as here, HCFA has found a plan of correction acceptable and has conducted a resurvey visit to ascertain the provider's success in implementing that plan (HCFA Ex. 21), HCFA must establish also that the provider failed to implement that plan or failed to implement that plan in accordance with its stated terms. If HCFA's evidence establishes the prima facie validity of its position, then the burden of moving forward shifts to Petitioner to put on evidence in support of its arguments.

C. Based on only the March 1994 survey, HCFA's determination of Petitioner's noncompliance with the physician services condition was sustainable.

HCFA bases its termination action on the theory that Petitioner continued to violate the physician services condition from prior to the initial survey until the time of the resurvey, despite Petitioner's contention that it had implemented a plan of correction acceptable to HCFA. See Tr. at 50.

If HCFA had not accepted a revised plan of correction from Petitioner and if HCFA had not conducted the resurvey in June of 1994, I would affirm HCFA's determination to terminate Petitioner's provider contract.

1. The manner in which HCFA conducted the initial survey of March 1994 was valid, as were HCFA's reasons for conducting that survey.

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[11](...continued)
348. HCFA's counsel also took the position that Ms. Fernandez was acting as HCFA's agent in the June 1994 survey of Petitioner. Tr. at 348. I sustained the objections, remarked on the notice issue, and repeatedly instructed counsel for HCFA to first pose questions that would clarify the extent and nature of Ms. Fernandez's "assistance." Tr. at 338 - 49.

I especially note the context in which HCFA decided to conduct the survey in March 1994 because, as discussed herein, HCFA had valid reasons for not following the letter of the regulation applicable to most surveys. The Secretary's regulations on surveys provides as follows in relevant parts:

> (b) [t]he State agency must adhere to the following principles in determining compliance with participation requirements:
>
> > (2) [t]he survey process uses resident outcomes as the primary means to establish the compliance status of facilities. Specifically surveyors will directly observe the actual provision of care and services to residents, and the effects of that care, to assess whether the care provided meets the needs of individual residents;
> > .....
> >
> > (4) [f]ederal procedures are used by all surveyors to ensure uniform and consistent application and interpretation of [f]ederal requirements.
> > .....
>
> (d) The survey agency must ensure that a facility's actual provision of care and services to residents and the effects of that care on residents are assessed in a systematic manner.

42 C.F.R. § 488.26.

In this case, even though the Puerto Rico Department of Health was under contract to perform surveys for HCFA, HCFA conducted the survey of Petitioner due to fiscal considerations. HCFA Ex. 54 at 10, 12.

HCFA decided to survey all 46 hospice providers in Puerto Rico because, over an extended period of time, HCFA and its agents had received complaints about the services and "nonservices" rendered in Puerto Rico. HCFA Ex. 54 at 13 - 14. The complaints were primarily in areas that included hospices' failure to provide required services, the lack of terminal diagnosis, the inaccurate certification and recertification for benefits, the falsification of records, the payments made for referrals by doctors and others, and the "stealing and luring away" of patients from home health associations and other hospices. HCFA Ex. 54 at 14 - 16.

There is no complaint against Petitioner in evidence. However, HCFA considers all of the surveys it conducted in Puerto Rico to be "complaint surveys;" that is, the surveys were supposed to focus on specific areas within the

conditions of participation that correlated with the complaints received by HCFA. HCFA Ex. 54 at 21. HCFA instructed its surveyors to select records from the Puerto Rico hospice providers with groupings of diagnosis that have been referenced in the complaints. HCFA Ex. 54 at 22.[12] Also, HCFA told its surveyors that, due to time constraints and the number of facilities to be surveyed, the surveyors should limit their review of patient records. Tr. at 36, 45. According to a written "Modified Hospice Survey Protocol" issued by HCFA, those surveying Puerto Rican hospices with less than 200 patients were instructed to review 10 active patient records, to select active patient records containing certain specified diagnoses, and to visit 3 of the aforementioned active patients at home. HCFA Ex. 12; Tr. at 45.

On March 10 and 11, 1994, HCFA surveyors surveyed Petitioner by using the instructions and criteria issued by their office. They chose a total of 10 records of active patients who had a diagnosis of Alzheimer's disease and had been receiving Petitioner's services since 1992, or who had a diagnosis of cancer and had been receiving Petitioner's services for at least the first two election periods.[13] Tr. at 45. In addition, the surveyors randomly selected for review the records of two recently discharged patients to evaluate the reasons for their discharge. Tr. at 45.

Marilyn Stephens, the lead surveyor, reviewed 7 of the 10 active files and 2 of the discharge files; Nyda Del Moral, who assisted Ms. Stephens during the survey, reviewed the records of the 3 remaining active patients and visited them at home. Tr. at 36, 45. Ms. Stephens testified that the surveyors reviewed records in March 1994 by focusing on whether the patients met the regulatory criteria for receiving hospice services, on the information written by physicians concerning the patients' terminal illness, on the nature and extent of information that was made available to physicians when they formed their assessments, on whether pain management or palliative types of treatment were provided by physicians, and on whether physicians ordered restorative or aggressive treatment for the sampled patients. Tr. at 25 - 29.

Petitioner has not challenged the validity or reasonableness of the instructions and criteria applied by HCFA. Nor has

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[12] At hearing, HCFA explained that there is no list of illnesses that are considered to be terminal. Tr. at 24. HCFA makes case-by-case evaluations during its surveys. Id.

[13] A Medicare beneficiary may elect to receive hospice care for an initial period of 90 days, for a subsequent period of 90 days, for a subsequent period of 30 days, and for a subsequent extension period of unlimited duration during the beneficiary's lifetime. 42 C.F.R. § 418.21.

Petitioner challenged the size of the sample patients surveyed. I find that HCFA issued and implemented its instructions and criteria for the March 1994 survey within the proper exercise of its discretion to enforce the requirements of Medicare.

2. HCFA reached valid factual findings and legal conclusions as a result of the March 1994 survey.

In their SOD, the surveyors concluded, inter alia, that Petitioner was out of compliance with a standard for "Central clinical records" (42 C.F.R. § 418.74(a)) because, of the 10 active patients' records reviewed, there were documentation problems associated with the physicians' recertification of all 10 patients' terminal illness. HCFA Ex. 15. The surveyors used the documentation problems in nine of the same 10 patients' cases to explain their finding that Petitioner was out of compliance with 42 C.F.R. § 418.86 (physician services) because hospice doctors were providing palliative and management care to nine patients in the sample who did not meet the regulatory criteria (42 C.F.R. §§ 418.20, 418.22) for a terminal illness. HCFA Ex. 15 at 8.[14] In concluding that the patients who were receiving palliative or management care from Petitioner's doctors do not meet the criteria for terminal illness, the surveyors cited two regulations that are titled "Eligibility requirements" and "Certification of terminal illness," respectively. Id. The surveyors found, however, that the care provided by the doctors were of the palliative and management nature. HCFA Ex. 15 at 8.

In order to be eligible to elect and receive hospice services under the Medicare program, the individual must not only be a Medicare beneficiary, but he or she must also be certified as being terminally ill in accordance with § 418.22.[15] The hospice must obtain written certification of the terminal illness for each of the beneficiaries' election periods. 42 C.F.R. § 418.22. For the initial 90-day election period, the hospice must obtain the written certification from the beneficiary's attending physician and the hospice's medical director or the physician member of the hospice's interdisciplinary group. Id. For subsequent election periods, the certification must be made by the hospice's medical director or the physician member of the hospice's interdisciplinary group. Id. Each certification must specify that the beneficiary's prognosis is for a life

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[14] All of the pages in HCFA Ex. 15 were not numbered consecutively. Thus, I have renumbered the pages in this exhibit and the SOD begins on page 3.

[15] HCFA's witness explained also the certification requirements and their ramifications for Medicare beneficiaries. Tr. at 38 - 43, 108.

expectancy of six months or less if the terminal illness runs its normal course. Id.

In addition, the hospice must establish and maintain a clinical record for every individual receiving care and services in accordance with accepted principles of practice. 42 C.F.R. § 418.74.[16] Each clinical record is supposed to be a comprehensive compilation of information, which should include entries for all services provided, the initial and subsequent assessments of patients, the plan of care for patients, the patients' pertinent medical history, and complete documentation for all services and events such as evaluations, treatments, progress notes. 42 C.F.R. § 418.74(a). The hospice is charged with safeguarding the clinical records against loss or destruction. 42 C.F.R. § 418.74(b).

The evidence concerning the March survey establishes that, out of the 10 active records selected for review, Petitioner's documentation for nine patients' prognosis, life expectancy, history, progress, course of treatment, or reasons for receiving care from a hospice were inadequate, not present, contradictory, or otherwise fraught with problems. E.g., HCFA Ex. 15 at 3 - 13; Tr. at 58, 61. As summarized by HCFA's witness, "the paperwork was there" in most cases, but there was not enough assessment information to explain or substantiate that the nine active patients surveyed had terminal conditions within the definition of the Act that warranted their receiving hospice services, as opposed to other levels of Medicare covered services. Tr. at 40, 41, 58.

In one example cited by HCFA during hearing, Petitioner's records at the time of survey contained no indication of the patient's history, and no reasons were given on the physician referral form to explain why the doctor believed the patient to be terminally ill. Tr. at 61. In another sample patient's case, none of the forms signed by physicians to recertify the patient for the continued receipt of hospice care contained any indication of the patient's potential life expectancy at the time of recertification. HCFA Ex. 15 at 8. Even though the life expectancy of Petitioner's Medicare patients should be six months or less from the time of initial certification and each recertification, the available records on nine of the 10 patients reviewed by HCFA in March of 1994 showed that all nine patients had been receiving hospice care for more than six months, and some for two or more years. HCFA Ex. 15 at 3 - 13. In addition, instead of containing notations of the decline typical of people with six months or less to live from the time of admission to or recertification for hospice care, the patient records reviewed by the surveyors contained notations that one

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[16] In the SOD for the March survey, the surveyors noted a violation under 42 C.F.R. § 418.74(a). HCFA Ex. 15.

patient showed improvement after the doctor placed him on physical therapy for ambulation and to strengthen him; five patients had routine tests done repeatedly on physicians' orders with no indications of deterioration or changes; and the physician's progress notes for one patient described his condition as "stable." HCFA Ex. 15 at 8 - 13; see Tr. at 26 - 29.

Because 10 active patients' records were sampled and nine contained the serious and extensive problems discussed herein, HCFA's evidence on the March survey gives rise to the strong and reasonable inference that, in many different ways, Petitioner was not providing hospice services to Medicare beneficiaries in accordance with the letter or intent of the law. Dr. Alma Rivera, an expert witness for HCFA, specifically testified that it is a common practice in the medical field to write down everything that forms a basis of an opinion. Tr. at 406 - 08. Petitioner did not present any evidence to contradict Dr. Rivera's opinion. Therefore, I find it reasonable and proper for HCFA to conclude from the very poor and incomplete documentation it reviewed in March 1994 that Petitioner's doctors were providing palliative or management care to Medicare beneficiaries without having applied the assessment criteria specified in the Secretary's regulations. See HCFA Ex. 15 at 8.

I infer from HCFA's finding of a condition-level deficiency for physician services based on its March survey that HCFA believes that Petitioner's doctors were providing palliative and management care also to other similarly situated patients who cannot be considered to have met the criteria of terminal illness within the meaning of the Act; therefore, either Petitioner was substantially limited in its ability to render adequate care to patients, or the actions of Petitioner's doctors had adversely affected the health and safety of patients. As specified in the Secretary's regulations, the decision as to whether there is compliance with a particular condition of participation depends on the manner and degree to which the provider satisfies the various standards within each condition. 42 C.F.R. § 488.26. A provider is considered to be out of compliance with the conditions of participation where its deficiencies are of such character to substantially limit the provider's capacity to render adequate care or which adversely affect the health and safety of patients. 42 C.F.R. § 488.24.

Since a hospice provider under the Medicare program must be engaged primarily in caring for those who are terminally ill within the meaning of the law -- e.g., section 1861(dd)(2) of the Act and 42 C.F.R. § 418.3, Petitioner's failure to be in possession of adequate or necessary documentation on its Medicare patients' prognosis and life expectancy is persuasive proof that Petitioner has been substantially limited in its capacity to render the care required for participation in the Medicare program. Also, as discussed above, the Act and regulations contain a complex system of

coverage or reimbursement restrictions to discourage hospices from providing medically unnecessary or unreasonable services to Medicare beneficiaries who should be receiving a different or more aggressive level of care under the Act. E.g., 42 C.F.R. § 418, subpart F. The obvious intent of such restrictions is to ensure the health and safety of Medicare patients. Where, as here, the evidence shows that Petitioner's doctors have been giving Medicare beneficiaries hospice level care for extended periods of time on the basis of improperly or inadequately documented prognosis and life expectancies, such evidence logically implies significant health risks for the Medicare beneficiaries. As Dr. Alma Rivera testified, physicians need complete information on patients in order to plan properly for their care. Tr. at 423. In addition, proper and thorough documentation of the patients' past and present conditions enables other health care professionals to form opinions for reasons other than those gathered from personal examinations of the patients. Tr. at 408.

3. Petitioner's defenses are not sufficient to rebut the validity of HCFA's conclusions based on the March 1994 survey.

The totality of evidence relevant to the March 1994 survey, including Petitioner's defenses discussed below, convinces me that HCFA correctly cited Petitioner for failure to comply with the physician services condition of participation pursuant to the March 1994 survey.

a. HCFA countered Petitioner's challenges to the surveyors' qualifications to make medical diagnosis or prognosis.

Petitioner has pointed out consistently that HCFA's surveyors are nurses, and, therefore, they are not qualified to make medical diagnoses, determine whether a patient is terminally ill, or decide what kind of treatment a patient should receive. E.g., Tr. at 34 - 35. I agree. Moreover, Petitioner's patients were never examined by the nurse surveyors or the physician HCFA called as an expert to testify at hearing. Tr. at 34, 428. Even HCFA's termination notice contains no allegation concerning the true medical conditions of those receiving hospice level care from Petitioner's doctors. In fact, HCFA merely had suggested as follows in its April 7, 1994 notice to Petitioner:

> . . . there are indications that Medicare beneficiaries may be receiving inappropriate services.

HCFA Ex. 15 at 2.

However, I find also that the true medical conditions of those patients surveyed in March 1994 should not be in

controversy before me. It was an illusory issue unnecessarily interposed by counsel for both sides during the hearing process. For example, HCFA appears to have misinterpreted evidence such as its surveyors' reference to "patients . . . who do not meet the criteria of having a terminal illness as defined in CFR 418.20 [Eligibility requirement] and CFR 418.22 [Certification requirement]." HCFA Ex. 15 at 8. Noting that HCFA may look behind certifications and recertification to determine whether, in fact, Petitioner's patients needed or received palliative care for the treatment of a terminal illness, HCFA's counsel contends incorrectly that HCFA has demonstrated conclusively that Petitioner's doctors were treating patients who were not, in fact, terminally ill. HCFA Memo at 5, 10, 25.

HCFA has not demonstrated conclusively or by a preponderance of the evidence that Petitioner's doctors were treating patients who were not, in fact, terminally ill at the time of certification or recertification. Nevertheless, the validity of HCFA's determination under physician services does not turn on whether HCFA has succeeded in proving that, at the time of each certification or recertification, Petitioner's patients had life expectancies of more than six months if their terminal illnesses ran their normal course. Even though attorneys for both parties attempted to cast the surveyors' conclusions as diagnoses of medical illnesses during hearing, I note that Ms. Stephens, the lead surveyor, specifically explained that she and other surveyors were not auditing the physicians' medical determinations during the survey. Tr. at 320.

The surveyors were questioning the assessment system used by Petitioner's physicians and its interdisciplinary team, which must have a physician member. Tr. at 320; 42 C.F.R. § 418.68. Ms. Stephens testified that she could not find evidence in the record concerning why Petitioner's doctors made the terminal illness decisions; therefore, she questioned the assessment procedure that was used by the hospice and its physicians. Tr. at 318, 319. She disagreed with the doctors' prognosis on life expectancy of six months or less based on the absence of documentary support and, as in one example she used, because the patient has been receiving Petitioner's services for 18 months. Tr. at 319.

Ms. Stephen's explanations are consistent with HCFA's correspondence with Petitioner concerning appropriate corrective actions after the March 1994 survey. For example, HCFA informed Petitioner in writing that it needed to give assurances concerning the implementation of systems and criteria. HCFA Ex. 17. Later at hearing, Ms. Stephens explained also that she and HCFA expected Petitioner to analyze its systems and procedures which caused HCFA to determine deficiencies in the first instance. Tr. at 94.

b. <u>HCFA countered Petitioner's defense that it maintained poor records</u>.

In essence, the problems determined by HCFA under physician services in March 1994 were that Petitioner's doctors failed to apply the evaluation and documentation systems required by law prior to delivering palliative and management care to Medicare beneficiaries. After receiving the SOD, Petitioner conceded that its documentations were poor and informed HCFA that "due to incomplete documentation the hospice criteria was not specified in these [nine] cases." HCFA Ex. 16 at 11. In response to the deficiencies cited in individual cases, Petitioner then summarized its physician's reasons for having found eight of the nine patients with a terminal illness or life expectancy of six months or less. Id. at 11 - 17. (Petitioner's doctor found that one patient, # 120, did not have a terminal prognosis. Id. at 14.)

Petitioner's responses in individual cases were not accompanied by the types of documentation missing from the March 1994 survey. Moreover, these summaries of Petitioner's doctors addressed only the eight patients' status or life expectancy during the most recent recertification. Therefore, I agree with HCFA that Petitioner's responses were inadequate for addressing the deficiencies cited, which included the doctor's enabling Medicare beneficiaries to begin receiving hospice level care without proper certification and then allowing these beneficiaries to continue receiving hospice care during various election periods without a proper assessment of their continued eligibility to receive such care. I reject the defense that Petitioner was at fault merely for having maintained poor records in March of 1994.

c. I reject the distinction drawn by Petitioner between the physician services condition of participation and the requirements for certification of a Medicare beneficiary's eligibility.

Petitioner alleges further that HCFA has incorrectly equated a violation of a provider's condition of participation in the program with a patient's eligibility to receive hospice services under the program. P. Br. at 8. Petitioner notes, for example, that the certification and recertification requirements discussed by HCFA are not contained in any subpart listing a provider's conditions of participation. P. Br. at 6. The requirements for Petitioner's doctors to provide certifications and recertification are contained in subpart B, titled "Eligibility, Election and Duration of Benefits." 42 C.F.R. § 418.20. By contrast, all conditions of participation are listed in subparts C, D, and E of 42 C.F.R. Part 418.

I reject the distinction drawn by Petitioner, for several reasons. First, HCFA was not limited to using a condition of participation to terminate Petitioner's provider agreement. HCFA was authorized also to terminate Petitioner on the basis of Petitioner's substantial failure to comply "with the

provisions of Title XVIII and the applicable regulations of this chapter [Chapter IV] . . . ." 42 C.F.R. § 489.53(a)(1).[17] This section of the regulation is consistent with section 1866(b)(2) of the Act, which states that the Secretary may terminate agreements when a provider "fails to comply substantially . . . with the provisions of this title [i.e., Title XVIII] and regulations thereunder . . . [or] . . . fails substantially to meet the applicable provisions of section 1861 . . .." Section 1866(b)(2)(A), (B) of the Act. If, as suggested by Petitioner's affirmative arguments, HCFA may terminate provider agreements only if the violation corresponds to a condition of participation listed in the regulations, then 42 C.F.R. § 498.53(a)(1) would become superfluous.

The requirement for Petitioner's doctors to certify and recertify terminal illnesses as defined by the Act and regulations is contained in section 1814(a)(7) of the Act; this requirement is implemented by the Secretary's regulations at 42 C.F.R. § 418.22 (certification of terminal illness). In addition, other regulations are relevant, including 42 C.F.R. § 418.66 (condition of participation--quality assurance) and 418.74 (condition of participation--central clinical records).[18] The evidence showing the substantiality of Petitioner's failure to comply with these provisions of the Act and regulations are the same as those that led HCFA to determine the deficiencies related to physician services. Thus, even if HCFA had incorrectly concluded that Petitioner was out of compliance with the physician services' requirement as opposed to other requirements or criteria of the law, Petitioner has not proven that the March 1994 survey findings are inadequate to support the contract termination action.

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[17] I read this subsection of the regulation as applicable to those situations where the consequences of the provider's noncompliance are as serious as if the provider had a violation of a condition of participation, but no condition of participation precisely describes the noncompliance. See 42 C.F.R. §§ 488.24, 488.26.

[18] I have discussed earlier the relevant requirements for Petitioner to meet the condition of participation for central clinical records. Under the quality assurance condition of participation, Petitioner should have been conducting ongoing, comprehensive, and integrated self-assessments of the quality and appropriateness of the care provided. The findings from such self-evaluations should have been used to correct identified problems and to revise hospice policies if necessary. 42 C.F.R. § 418.66. The problems discerned by HCFA's surveyors during March 1994 could have just as properly been attributed to Petitioner's noncompliance with the conditions of participation for quality assurance or central clinical records.

I conclude that HCFA also reasonably linked the certification and recertification problems to the ensuing delivery of physician services under 42 C.F.R. § 418.86. Each regulation does not correspond to only one requirement specified in the Act. The Act provides that, when a Medicare beneficiary makes an election for hospice care, he does so at the exclusion of all other types of Medicare covered services. Section 1812(d)(1) of the Act. Therefore, for the health and safety of the beneficiary, it is incumbent upon the provider to ensure, through the certification process and the documentation requirements encompassed by the certification process, that this program beneficiary is indeed terminally ill within the meaning of the law and that, moreover, hospice services are medically reasonable and necessary to the individual's condition. E.g., section 1862(a)(1)(C) of the Act.

While certification is listed as an eligibility criterion for program beneficiaries under 42 C.F.R. § 418.20, Petitioner's doctors are the only ones who can make a Medicare beneficiary legally eligible for hospice care. 42 C.F.R. §§ 418.20, 418.22. Petitioner and its doctors have no one to blame except themselves for their subsequent delivery of physician services to people whom they have not properly determined to meet the Medicare criteria for receiving palliative and management services. Petitioner is wrong in drawing lines between the various regulations which, in their totality, implement the interrelated statutory requirements for the participation of a hospice in the program.

D. Based on the results of the June 6, 1994 revisit survey, I set aside HCFA's determination that Petitioner was out of compliance with the requirements of the Medicare program, and I find no basis for terminating Petitioner's provider contract.

1. After issuing the termination notice dated April 7, 1994, HCFA acted within its discretion to solicit and approve a plan of correction from Petitioner and to conduct a revisit survey to ascertain Petitioner's success in implementing its plan of correction.

HCFA was not required by the Act or the Secretary's regulations to offer Petitioner an opportunity to submit and implement a plan of correction acceptable to HCFA following the March 1994 survey. Nor was HCFA required by law to conduct another survey after it approved a plan of correction. The regulation cited by Petitioner, 42 C.F.R. § 488.28, applies to situations where HCFA finds that a provider has deficiencies in one or more standards.[19] See P.

[19] Compliance with a condition depends on the manner and degree to which the provider satisfies the various standards (continued...)

Br. at 4. The regulation does not state that, when HCFA finds noncompliance with a condition of participation, HCFA must also grant the provider a reasonable time to achieve compliance. 42 C.F.R. § 488.28.

Nevertheless, HCFA did offer Petitioner an opportunity to submit a plan of correction, and HCFA accepted a revised plan of correction from Petitioner on or about May 20, 1994. HCFA Exs. 15 - 19. HCFA then conducted a revisit survey on June 6, 1994 in order to evaluate Petitioner's success in implementing its plan of correction. HCFA Ex. 20.

HCFA explained that its usual survey process includes the solicitation and review of a plan of correction to remedy condition-level noncompliance. HCFA Ex. 54 at 11, 26 - 31; Tr. at 311. If HCFA finds the plan unacceptable in whole or in part, HCFA gives its reasons for having found the plan unacceptable. HCFA Ex. 54 at 28. Before the date set by HCFA for terminating a provider agreement, HCFA will generally work with a provider to bring about an acceptable plan of correction; in some cases, HCFA has "gone back" to providers three or four times concerning a plan of correction. HCFA Ex. 54 at 29.

If HCFA receives a plan of correction that it finds acceptable, HCFA will schedule a revisit survey after the last date for correction under the plan but prior to the date of termination itself. HCFA Ex. 54 at 29; Tr. at 311. According to HCFA, it would never terminate a provider's participation agreement before such a revisit survey. Id. In some cases, HCFA has "pushed back" the termination date to accommodate the revisit surveys. HCFA Ex. 54 at 29, 30.

According to HCFA's explanations of its usual practices, a revisit survey is not a full survey. HCFA Ex. 54 at 30. The surveyors conducting the revisit surveys are supposed to examine only those conditions cited in the earlier notice of deficiencies. HCFA Ex. 54 at 30. If the surveyors discover that the provider is now in compliance with the conditions cited earlier by HCFA -- but the provider is now out of compliance with other conditions -- HCFA would need to rescind its earlier initiated termination action and begin the foregoing process anew based on its new findings. HCFA Ex. 54 at 30.

HCFA states that, in Petitioner's case, it followed its usual procedures for soliciting and reviewing plans of correction and for conducting a revisit survey. HCFA Ex. 54 at 30 - 31. I find HCFA's solicitation, review, and acceptance of a plan

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[19](...continued)
within each condition. 42 C.F.R. § 488.26. HCFA is not authorized to terminate a provider agreement due to deficiencies in standards which do not amount to condition-level noncompliance. 42 C.F.R. § 489.53.

of correction from Petitioner, as well as HCFA's use of revisit surveys in general, to be permissible exercises of HCFA's authority to enforce those requirements providers must satisfy to maintain participation in the Medicare program. Before actually terminating a provider's Medicare participation agreement, HCFA has the discretion to enforce the various conditions of participation in a manner it deems appropriate. Even though the regulations do not require HCFA to make available to providers the opportunity to remedy condition-level noncompliance, neither do the regulations bar HCFA from offering such opportunities or implementing generally applicable procedures for the effectuation of its enforcement goals. It is reasonable for HCFA to encourage providers to remedy their problems. It is reasonable also for HCFA to cooperate with providers in their efforts to avoid termination of their participation agreement.

2. After approving Petitioner's revised plan of correction on May 20, 1994, HCFA was obligated to conduct its revisit survey and make determinations in a manner consistent with the terms of the approved plan and in accordance with its usual practices.

HCFA contends that it conducted the June 6, 1994 revisit survey and provided notice of the problems in accordance with its usual practices, as discussed above. HCFA Ex. 54 at 30, 31. HCFA has presented also no legitimate reason which would justify treating Petitioner differently than HCFA treats similarly situated providers. Therefore, I find that HCFA was required to conduct the revisit survey and provide notice of problems in accordance with its usual practices, as explained by HCFA.

I find also that HCFA is bound by the terms of the revised plan it approved. The correctness of HCFA's reasons for finding Petitioner's revised plan acceptable is not reviewable since Petitioner has no hearing rights on that issue. 42 C.F.R. § 498.3. However, the provider agreement HCFA wishes to terminate in this case is the equivalent of a contract between HCFA and Petitioner. HCFA and Petitioner had the right to reach agreements on the supplementation of those contractual terms that are required by law, and the parties had the right to stipulate to the methods for correcting alleged breaches and for verifications of such corrections. The supplemental agreements discussed herein, which were reached after the initial survey by HCFA, are not prohibited by law, and they were reached by the parties voluntarily.

The evidence establishes that, in addition to HCFA's claim to have followed its usual practices discussed above, HCFA informed Petitioner repeatedly that it would be resurveyed on the basis of its plan of correction that HCFA found acceptable. When initially notifying Petitioner that its

application to become a Medicare provider had been accepted, HCFA stated the following term to Petitioner:

> [a]ny deficiencies cited at the time of the . . . [survey] visits, that have not been completely corrected, are expected to be corrected as stated in your plan of correction.

P. Ex. 1. Thereafter, when HCFA was notifying Petitioner of the findings from the March survey and the date on which the provider agreement would terminate, HCFA again told Petitioner:

> [s]hould your Plan of Correction provide reasonable assurance that condition level compliance will be attained, a follow up survey will be conducted . . .

HCFA Ex. 15. Even after HCFA had completed the revisit survey and decided to terminate the provider agreement, HCFA again told Petitioner that the purpose of the revisit survey had been:

> . . . to evaluate the facility's success in implementing its plan of correction.

HCFA Ex. 21.

Petitioner has never objected to or refused to follow the process outlined by HCFA. Prior to HCFA's terminating its provider contract on June 9, 1994, Petitioner took certain actions based on HCFA's representations. For example, on April 15, 1994, Petitioner submitted a plan of correction, which HCFA did not find fully acceptable. HCFA Exs. 16, 17. With respect to physician services, HCFA stated the following to Petitioner:

> 1) The POC [plan of correction] is unacceptable because it does not identify the primary systems breakdown in admission assessments and certification of patients with non-terminal diagnosis. What system and criteria will be implemented to ensure that hospice services are provided only to those who have a terminal diagnosis which will result in death within 6 months based on the normal progress of the disease?
>
> 2) Use of a voluntary program as identified in addendum 1 does not meet hospice regulation because patients in the indefinite period should be a rarity and not a common occurrence[.] [T]herefore, the establishment of specific criteria for hospice admission is a necessity.

HCFA Ex. 17 at 2.

In response to the foregoing criticisms, Petitioner submitted a revised plan, which HCFA found acceptable. HCFA Exs. 18, 19.

With respect to physician services in the revised plan found acceptable by HCFA, Petitioner represented that, in order to ensure that hospice services are provided only to those patients who have a terminal diagnosis that will result in death within six months based on the normal progress of the disease, Petitioner has now included the hospice eligibility requirements in its Administrative Manual, and Petitioner is now using those requirements in its referral and admission procedures. HCFA Ex. 18 at 3, 5.[20] Petitioner then went on to identify in its revised plan of correction the important aspects of the referral and admission procedures it has placed into effect on May 5, 1994. HCFA Ex. 18 at 3 - 4. Petitioner stated, for example, that its interdisciplinary group "will meet" to establish and revise plans of care, and "the group will monitor" the status of the patients' terminal illness and deterioration of their condition during the recertification process; the attending physician "is included" more actively in the evaluation process, so that the physician "will" confirm the terminal diagnosis in accordance with Petitioner's recertification procedure; and after the patient "is admitted," the patient's clinical record "is audited" by quality assurance personnel, and if there are insufficient findings of a terminal condition, the information "will be" brought to the attention of the interdisciplinary group for decision on recertification or discharge. HCFA Ex. 18 at 4 - 5, 11 - 16.

In the revised plan of correction accepted by HCFA, Petitioner made no commitment to revise or alter the certifications or other documents already in existence prior to May 5, 1994, when it placed its new procedures into effect. Nothing of record shows that HCFA had conditioned its acceptance of Petitioner's plan based on Petitioner's reevaluating all patients admitted, referred, or certified prior to May 5, 1994. Petitioner's revised plan states on its face that Petitioner had instituted certain policy changes on May 5, 1994, and, by using the future tense of verbs -- e.g., "will meet," "will monitor," "will be confirmed," (HCFA Ex. 18 at 5) -- Petitioner indicated that those changes would be carried out with respect to patients who were admitted, referred, certified, or recertified on and after May 5, 1994.

For the foregoing reasons, I find that the terms of the revised plan are binding on both parties on the issue of whether Petitioner was in compliance with the condition of physician services by the time of the revisit survey, and

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[20] By "referral," Petitioner means a referral from, or the receipt of a referral form from, attending physicians, hospitals, or community health facilities. HCFA Ex. 18 at 4.

HCFA was required to follow its usual procedures with respect to the revisit survey.

3. HCFA improperly terminated the provider agreement with Petitioner pursuant to the June 6, 1994 revisit survey results.

On June 6, 1994, HCFA reviewed the records of six active patients and six recently discharged patients. HCFA Ex. 20 at 2. Based on such a review, the surveyors concluded that Petitioner's physicians were not involved in assessing, planning, or providing for the medical needs of eight patients. HCFA Ex. 20 at 2. HCFA surveyors further concluded that some of these same eight patients' records also show that Petitioner's physicians were not evaluating and recommending them for certifications of eligibility based on the regulatory definition of terminal illness. HCFA Ex. 20 at 4. HCFA classified all these problems under physician services and notified Petitioner by letter dated June 7, 1994 that the revisit survey conducted "to evaluate the facility's success in implementing its plan of correction" showed that Petitioner remained out of compliance with 42 C.F.R. § 418.86 (physician services). HCFA Ex. 21. Therefore, HCFA was to terminate Petitioner's participation in the Medicare program effective June 9, 1994. HCFA Ex. 21.

a. HCFA's findings concerning the plan of care are without basis.

I agree with Petitioner that, where Petitioner's doctors were allegedly not planning for patients' care, HCFA is not permitted to conclude that Petitioner was out of compliance with physician services during the revisit survey and terminate the provider agreement as a consequence. P. Br. at 5.

In the first place, HCFA's notice letter and SOD from the first survey never mentioned problems with physicians' participation in the plan of care. There is also a separate condition of participation for plan of care (42 C.F.R. § 418.58), which was not cited pursuant to the first survey. Even though Petitioner's revised plan of correction did mention plan of care, Petitioner's words cannot be read fairly as meaning that Petitioner was on notice for or intended to correct the type of planning problems listed in HCFA's resurvey visit SOD. See HCFA Exs. 18, 20.

Even more importantly, a plan of care is not established by the hospice physicians alone; it is established by the hospice physicians, the patient's attending physician (who may not be an employee of the hospice), and the hospice's interdisciplinary team. 42 C.F.R. § 418.58(a). Problems with patients' plans of care cannot be fairly or properly placed under a provider's obligation to provide physician services as a core service. If the plan of care problems discerned during the revisit survey were substantial, then

HCFA would need to rescind its prior notice of termination based on physician services and proceed under plan of care, in accordance with the normal process described by HCFA. HCFA Ex. 54 at 30.

b. HCFA's findings concerning the failure of Petitioner's doctors to meet the general medical needs of patients are without basis.

I find untenable as well HCFA's argument that Petitioner violated physician services because the regulation states in part that "physician employees of the hospice . . . must also meet the general medical needs of the patients to the extent that these needs are not met by the attending physician." 42 C.F.R. § 418.86; HCFA Memo at, e.g., 12, 16. In contending that Petitioner's doctors failed to meet the general medical needs of patients, such as one patient's one-arm pain, another patient's obstetrical/gynecological problems, and another patient's decubitus ulcer (HCFA Memo at 12, 16), HCFA introduced no evidence to show that attending physicians were also not meeting such problems. There is no indication, for example, that the attending doctors of hospice patients were even contacted by the surveyors on this issue.

Moreover, HCFA's position under physician services appears to be that, even though HCFA does not consider a hospice patient to be truly terminally ill, the hospice doctors must meet that individual's "general medical needs" nonetheless. Tr. at 398. I find this position to be flawed. By definition, the hospice must be primarily engaged in providing palliative and management care. See 42 C.F.R. §§ 418.3, 418.86. In addition, treatment should be provided only by a hospice if the hospice level of care is medically reasonable and necessary for the patient's terminal condition. See 42 C.F.R. § 418.200. When HCFA believes that the hospice doctor has misdiagnosed or has not adequately assessed whether their patients have a terminal illness in the first instance, it does not follow logically that certain medical problems should then be designated as the patients' "general medical needs," which the hospice doctor must meet "[i]n addition to palliation and management of terminal illness and related conditions[.]" 42 C.F.R. § 418.86. Interpreting the regulation as HCFA does can raise concerns for the health and safety of those patients who have not been properly evaluated by the hospice doctor for the existence of a terminal illness and related condition, as distinguished from their other "general medical needs."

c. HCFA conducted the revisit survey in an invalid manner.

Finally, I find that HCFA failed to conduct the revisit survey in a manner consistent with its obligation to ascertain whether Petitioner had implemented the plan of correction approved by HCFA. As already discussed,

Petitioner represented that it had put into place on May 5, 1994 certain procedures for evaluating the patients's medical condition for admissions, certifications, and recertification. These procedures were devised to especially address HCFA's requirement for identification of "the primary systems breakdown in admission assessments and certifications of patients with non-terminal diagnosis." HCFA Ex. 17 at 2.

All of the procedures described in the approved plan of correction have prospective application only. The manner in which Petitioner receives referral of patients from other sources and admits them under its new procedures cannot be applied retrospectively. (That is to say, admissions and receipt of referrals can happen only once in time; once the referral is accepted and the patient is admitted, the patient stays admitted until discharged.) The certifications and recertification for terminal illness must take place at the times and with the intervals set by law. 42 C.F.R. §§ 418.21, 418.22. In its revised plan of correction, Petitioner specified, for example, that its interdisciplinary group "will collect recertification dates on each patient on a monthly basis," and all recertified patients "will continue receiving services until the next evaluation date . . .." HCFA Ex. 18 at 14, 16.

When HCFA was reviewing Petitioner's plan of correction, HCFA did not require Petitioner to redo any certification or recertification that existed or should have existed prior to Petitioner's implementation of its plan. HCFA approved Petitioner's plan without any such commitment by Petitioner. The tense of verbs used repeatedly by Petitioner establishes that Petitioner was seeking to remedy its prior noncompliance by applying its new procedures to admissions, referrals, and certifications that occur on and after May 5, 1994. HCFA Ex. 18.

Yet, when HCFA resurveyed Petitioner on June 6, 1994, it looked at records of only those people who were admitted or referred during prior years. E.g., HCFA Supp. Br. at 6. Similarly, nearly all of the certifications and recertifications reviewed by HCFA predated May 5, 1994, the date on which Petitioner implemented its approved plan of correction. E.g., HCFA Memo at 12 - 22; HCFA Ex. 20. A few of the patients were discharged prior to or shortly after May 5, 1994, but HCFA cited these discharges as evidence of Petitioner's noncompliance with physician services as well. HCFA Ex. 20 at 4 - 6.

As I noted earlier, during this revisit survey, one surveyor was receiving "in-service training" by reviewing five patients' records and interviewing one patient; most of the deficiencies listed on the SOD corresponded to the patient records reviewed by this trainee surveyor. HCFA Ex. 20; Tr. at 298, 299, 331 - 59; see also n.10. HCFA's witnesses did not testify as to why they chose to review the records they did on June 6, 1994. Nothing of record indicates that, in

providing in-service training to the new surveyor by allowing her to review records and help formulate findings, HCFA informed her of the approved plan of corrections or how the plan's contents should correspond to the manner in which the revisit survey is conducted and the conclusions that were to be drawn.

After I raised these and like problems posthearing and directed counsel to submit supplemental briefs on the issues, HCFA's counsel argued that the surveyors used these four document-selection criteria on June 6, 1994:

> 1) active records of new patients who were admitted after the March 1994 survey;
>
> 2) active patients who were admitted in late 1993 who have been recertified at least once between the March 1994 survey and the June 1994 revisit survey;
>
> 3) patients who were admitted following the March 1994 survey and were revoked or discharged before the revisit survey in June 1994, or patients who revoked their hospice election or were discharged between March and June 1994 regardless of whether they were admitted;
>
> 4) patients who had been recertified in the extension period of unlimited duration since January 1994 with diagnoses that were questionable as terminally ill.

HCFA Supp. Br. at 5.

There is no witnesses' testimony concerning such criteria. I do not construe counsel's arguments to be evidence, and I do not consider the use of such criteria to be proven facts. Moreover, these criteria are specious, and even the application of these criteria would not render the resurvey results valid.

> (1). <u>HCFA's arguments concerning the selection of active records of new patients who were admitted after the March 1994 survey are not persuasive</u>.

With respect to the first criterion, HCFA asserts without any evidentiary foundation that Petitioner did not provide HCFA with active records of anyone who was admitted after March of 1994 because there was no such admissions. HCFA Supp. Br. at 6. Even assuming that admissions records from prior to May 5, 1994 would be relevant, the mere absence of new admissions records from March until June 6, 1994 shows that HCFA lacked certain essential facts for proving that Petitioner failed to implement its new admissions and referral criteria in accordance with its plan of correction.

There is nothing improper to be inferred from the absence of new admissions between March and June of 1994. I note, for example, that HCFA's April 7, 1994 letter "strongly urged" Petitioner to refrain from admitting any new Medicare patients "effective with the date of receipt of this letter, until such time as this office has determined that all Conditions of Participation are met." HCFA Ex. 15 at 2.

> (2). HCFA's arguments and evidence concerning the records of patients who were admitted following the March 1994 survey and were revoked or discharged before the revisit survey in June 1994, or patients who revoked their hospice election or were discharged between March and June 1994 regardless of whether they were admitted are not persuasive.

With respect to the third selection criterion alleged by HCFA, HCFA contends that the criterion was applied to ascertain whether the discharges resulted from the interdisciplinary group's implementation of the revised plan of correction and determination of nonterminal illness, or whether the discharges occurred for other reasons, such as the patient's revocation of his election or insistence by the family. HCFA Supp. Br. at 6. Whether or not records were selected on this basis, the reasons for the discharges do not support HCFA's decision to terminate Petitioner's provider agreement.

HCFA reviewed discharge records in the first survey but found no problems with physician services in those discharge records. HCFA Ex. 15 at 3 - 11. Yet in citing Petitioner for noncompliance with physician services after the June 6, 1994 revisit survey, HCFA's SOD listed at least three instances where patients were discharged. HCFA Ex. 20. There was no evidence that the discharges were inappropriate or in contravention of the plan of correction.

In addition, HCFA has never explained its reasons for differentiating between discharges based on the medical diagnosis, the patients' revocation of their elections, or the family's insistence for another type of care. All are permissible reasons for a hospice to discharge a patient. There is no showing by HCFA, for example, that patients revoked their election or the family removed the patients from the hospice shortly after Petitioner's doctors had certified them as eligible under the revised plan of correction.

HCFA uses the evidence from these discharged patients' records to draw conclusions which I do not find to be appropriate. I note as an example the situation of one

patient (# 5 or # 308)[21] whose records were placed into evidence by HCFA. After the date on which Petitioner was to have implemented its revised plan of correction, the physician's progress notes of June 4, 1994 indicated that the patient had improved and had a life expectancy of more than six months. Tr. at 135 - 36. This patient's recertification was scheduled for June 7, 1994; but, as of June 4, 1994, Petitioner had learned that the patient's family wished to move him out of Puerto Rico. HCFA Ex. 41 at 12. HCFA did not allege that this patient's subsequent discharge proved noncompliance on its SOD. HCFA Ex. 20. However, HCFA's surveyor described the foregoing events, including the circumstances concerning the patient's discharge, to support the conclusion that Petitioner was out of compliance with physician services, because the patient was not terminally ill. Tr. at 135. I do not agree that the foregoing evidence establishes noncompliance as of the revisit survey date. If anything, the evidence shows that after Petitioner was supposed to have implemented its revised plan, Petitioner's doctor began evaluating this patient properly and this patient was discharged based on the family's decision made prior to the scheduled date for his recertification.

HCFA states also in its supplemental brief that patient # 1f was discharged on April 4, 1994 because Petitioner determined him not to be terminally ill. HCFA Supp. Br. at 15. However, instead of conceding that Petitioner acted correctly in discharging him, HCFA takes the position that this patient's discharge proves Petitioner understood the Medicare requirement of terminal illness in April and Petitioner should have "taken measures to correct this problem through the recertification process of each patient to determine whether they were terminally ill." See HCFA Supp. Br. at 14 - 15. HCFA's attribution of fault is unfounded when it has not shown when all patients of the hospice were due for recertification and, as discussed below, it cited Petitioner for having improperly recertified patients before Petitioner even submitted its revised plan for approval.

I conclude on the record as a whole that HCFA's evidence concerning the discharge of patients between March and June 6, 1994 does not support the conclusion that Petitioner's provider contract was properly terminated.

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[21] I have avoided identifying patients more frequently in this case due to the time consuming nature of explaining the identification processes. HCFA used two systems for identifying patients by numbers after having entered into record the relevant documents containing the patients' names. (The last page of HCFA Ex. 20 provides a cross-reference for the various patient numbers applicable to the resurvey.) During hearing, Petitioner used the patients' names of record as well as one or more of HCFA's identification numbers.

3. HCFA's arguments and evidence concerning active patients who were admitted in late 1993 and have been recertified at least once between the March 1994 survey and the June 1994 revisit survey, and patients who had been recertified in the extension period of unlimited duration since January 1994 with diagnosis that were questionable as terminally ill are not persuasive.

With respect to the second and fourth selection criteria, HCFA contends that they were used to assure that Petitioner "had corrected the existing systemic problem and had established new on-going procedures to assure the systemic problems would not recur." HCFA Supp. Br. at 6. HCFA contends that correcting existing problems means that Petitioner must take actions such as recertifying each of its patients to determine whether they were terminally ill. HCFA Supp. Br. at 14. The fundamental flaw in these arguments is that when HCFA accepted the revised plan of correction, HCFA agreed for Petitioner to correct the existing systemic problems through the prospective application of certain specified new procedures.

HCFA's letter dated April 7, 1994 required only a plan that provides "reasonable assurances that conditional level compliance will be attained . . .." HCFA Ex. 15 at 2 (emphasis added). During the hearing, I asked HCFA's lead surveyor during both the March and June surveys whether it was necessary for a provider to have corrected all of the problems by the time of the revisit survey. Tr. at 99. I note specifically the following part of her answer, which contradicts HCFA's current contention that Petitioner should have reevaluated every patient by the time of the resurvey:

> We wouldn't expect that every patient that we went back to see, that we would pull those old records and that things had been corrected with those patients, but what we would look for is to say "all right, this is what you said you were going to do, now you've admitted X number of people in this period of time; have you followed your plan of correction," and you know, if it's shown that they have followed the plan of correction, then they would be back into compliance. We don't expect total perfection, but we expect enough corrections to have taken place to show that they understand what the original deficiency was and that they are working towards it not re-occurring.

Tr. at 100.

HCFA attempts to circumvent the terms of Petitioner's revised plan and its usual expectations on revisit surveys by arguing that it reviewed records under criteria 2 and 4 because Petitioner was on notice since at least April of 1994 that it was required to correct existing problems by treating and

meeting the medical needs of the terminally ill. HCFA Supp. Br. at 6, 9. (HCFA uses the April date because the SOD from the first survey was sent to Petitioner on April 7, 1994. HCFA Ex. 15.) This type of argument ignores the parties' actions since HCFA issued its April 7, 1994 letter.

The evidence of record shows that nearly all of the problems that may be associated with the use of these two criteria arose prior to May 5, 1994. E.g., HCFA Memo at 11 - 22; HCFA Ex. 20.[22] HCFA did not identify in its briefs even one instance of improper recertification or failure to timely recertify that which occurred after May 5, 1994. Instead, HCFA improperly relies on certifications such as the one done on April 12, 1994, for which HCFA concludes that supporting documentation and a prognosis were lacking. HCFA Ex. 20 at 5. I agree with Petitioner that HCFA improperly used other examples as well to allege noncompliance when the certifications in those examples occurred before the date Petitioner implemented the revised plan. P. Supp. Br. at 2 - 4.

As an example, I note that HCFA specifically introduced testimony to establish the impropriety of various certifications that were made prior to May 5, 1994 for one patient (patient # 6 or # 277). Tr. at 281 - 97. Yet, the documents submitted by HCFA show also, as correctly noted by Petitioner (P. Supp. Br. at 3 - 4), that this patient underwent the recertification process after May 5, 1994 and was discharged on June 29, 1994 pursuant to the results of the interdisciplinary group meeting. HCFA Ex. 42 at 6. The available evidence concerning Petitioner's actions on this patient after May 5, 1994 does not indicate deviation from the revised plan of care. In addition, since Petitioner did not receive the resurvey SOD until after July 14, 1994 and HCFA did not allege any problems with this particular patient until the time of hearing, there is no evidence that Petitioner specifically discharged this patient due to HCFA's revisit survey findings. HCFA Exs. 20, 22, 23.

After reviewing the other relevant exhibits and testimony concerning recertification done after May 5, 1994, I found only information that did not amount to a substantial deviation from Petitioner's obligation to implement its revised plan of correction. For example, for one patient

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[22] As parts of certain exhibits, HCFA did submit some documents that it could not have reviewed during the June 6, 1994 resurvey. For example, there is a page showing a notation on June 16, 1994, indicating that the doctor will visit patients soon to decide whether to continue "illegible;" there is another notation dated June 29, 1994 indicating that the same patient was found not to be terminally ill and would be discharged. HCFA Ex. 42 at 6. I assume HCFA came into possession of such documents pursuant to prehearing discovery.

whose records HCFA reviewed (see HCFA Ex. 41), the interdisciplinary group's minutes of May 19 and June 2, 1994 were not in the file at the time of the revisit survey on June 6. Tr. at 135. However, Petitioner told HCFA surveyors that the minutes were being typed at that time. Tr. at 135. HCFA did not present any evidence to contradict Petitioner's explanation.

Nor did I find persuasive HCFA's argument that its fourth criteria (selecting records of patients recertified in the extension period of unlimited duration since January 1994 with diagnoses that were questionable as terminally ill) was based on Petitioner's statements in its revised plan of correction at Addendum I, items 11 and 13. HCFA Supp. Br. at 5. Item 11 of Addendum I cited by HCFA states that Petitioner's interdisciplinary group "will monitor" the status of a patient as part of the recertification process. HCFA Ex. 18 at 5. Item 13 of Addendum I cited by HCFA refers to an audit to be conducted by Petitioner's quality assurance personnel after a patient is admitted. Id. According to the revised plan of correction, the purpose of the audit is to ensure that the documentation in the record evidences the patient's terminal prognosis and, "[i]f there is not sufficient findings of the terminal condition, this information will be brought to the attention of the Interdisciplinary Group for decision making for recertification or discharge (Enclosure 8)." Id.

The words in the part of the revised plan cited by HCFA do not support HCFA's contention that it may properly evaluate Petitioner's success in implementing the revised plan for physician services by surveying the records of patients who were recertified in the extension period of unlimited duration since January of 1994. As earlier noted, Petitioner's new recertification procedures were to involve the taking of specified actions on or shortly before the date each patient was due for recertification. See HCFA Ex. 18 at 14 - 16. For example, the interdisciplinary group "will collect recertification dates on each patient on a monthly basis." HCFA Ex. 18 at 14. Moreover, in arguing that item 13 of Addendum I supports HCFA's selection of records for the revisit survey, HCFA failed to include the "Enclosure 8" referenced in said item.[23] The information before me does not indicate that, as a part of its revised plan of correction Petitioner had committed to reassess or recertify those patients whose records HCFA said it reviewed under the fourth criteria.

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[23] When I ordered the parties to submit supplemental briefs, I gave them the opportunity to file any "enclosure" referenced in the revised plan of correction. Order of February 14, 1995. HCFA then resubmitted its exhibit 18 with additional pages but without "Enclosure 8."

CONCLUSION

For all of the reasons stated above, I set aside HCFA's decision of June 7, 1994 to terminate Petitioner's provider agreement effective June 9, 1994 based on the results of the June 6, 1994 revisit survey. See HCFA Ex. 21.

However, if HCFA wishes to pursue those plan of care problems noted during the June 6, 1994 revisit survey, HCFA may follow its usual procedures by proceeding with a new notice to Petitioner based on the plan of care condition of participation. In addition, HCFA may take other actions not inconsistent with my findings in this decision with respect to physician services.

I note especially my finding that HCFA's evidence from the March 1994 survey adequately supported the conclusion that Petitioner was out of compliance with the physician services condition as of March 1994. I have not held in this decision that Petitioner has implemented its revised plan of correction as alleged or has come into compliance with the condition of participation of physician services. My ruling against HCFA on the termination issue is based on HCFA's failure to sustain its burden of proof with respect to the June 6, 1994 revisit survey, the results of which HCFA used to justify terminating the provider agreement on June 9, 1994. HCFA Ex. 21. Primarily because HCFA had selected inappropriate patient records for review during the June 6, 1994 revisit survey, HCFA lacked the requisite relevant evidence for proving that Petitioner failed to remedy its physician services problems in accordance with the plan of correction approved by HCFA. HCFA is not precluded by this decision from taking other actions to ascertain and enforce Petitioner's compliance with the physician services condition of participation.

/s/

Mimi Hwang Leahy
Administrative Law Judge