Department of Health and Human Services

DEPARTMENTAL APPEALS BOARD

Civil Remedies Division

In the Case of:	)	
	)	
Arecibo Medical Hospice Care,	)	DATE: March 14, 1995
	)	
Petitioner,	)	
	)	
- v. -	)	Docket No. C-94-363
	)	Decision No. CR363
Health Care Financing Administration.	)	
	)	

DECISION

Petitioner requested a hearing to oppose a determination by the Health Care Financing Administration (HCFA) to terminate Petitioner's participation in the Medicare program. The case was assigned to me for a hearing and a decision. I conducted a hearing in San Juan, Puerto Rico, on August 30 - 31, 1994. The parties submitted posthearing briefs and posthearing reply briefs.

I have considered the applicable law and regulations, the evidence which I received at the hearing, and the parties' arguments. I conclude that HCFA proved, by the preponderance of the evidence, that Petitioner failed to comply with a regulation which governed its participation in Medicare. Therefore, HCFA was authorized to terminate Petitioner's participation in Medicare.

I. Issues, findings of fact, and conclusions of law

The issue in this case is whether HCFA was authorized to terminate Petitioner's participation in the Medicare program. In deciding that HCFA was authorized to terminate Petitioner's participation, I make specific findings of fact and conclusions of law. After each

finding or conclusion, I cite to the page or pages of the decision at which I discuss the finding or conclusion.

1. HCFA may terminate a provider's participation in the Medicare program when the provider is not complying with regulations that govern its participation in Medicare. Pages 5 - 8.

2. HCFA did not deny Petitioner due process when it terminated Petitioner's participation agreement after its May 5, 1994 resurvey of Petitioner, when HCFA did not afford Petitioner the opportunity to correct the deficiencies that were identified at the resurvey. Pages 5 - 8.

3. In a case where a provider requests a hearing from a determination by HCFA to terminate its participation in Medicare, HCFA must come forward with evidence that the determination to terminate the provider's participation agreement is authorized. HCFA must prove, by a preponderance of the evidence, that the determination to terminate the provider's agreement is authorized. Pages 8 - 13.

4. A hospice which participates in the Medicare program is required by regulation to establish a written plan of care for each individual admitted under its care, which states a schedule for review of the plan of care by the attending physician, the hospice medical director or physician designee, and by the hospice's interdisciplinary group. Pages 13 - 18.

5. HCFA proved, by the preponderance of the evidence, that Petitioner did not establish plans of care for individuals admitted under its care which specified the dates or events when the plans of care would be reviewed by the requisite individuals or by Petitioner's interdisciplinary group, and which were reviewed according to schedules established in the plans. Pages 19 - 22.

6. HCFA proved, by the preponderance of the evidence, that Petitioner did not comply with a regulation which governed its participation as a hospice in the Medicare program. Pages 16 - 22.

7. HCFA was authorized to terminate Petitioner's participation in the Medicare program. Pages 25 - 26.

II. Discussion

A. Background

Petitioner is a hospice, operating in Arecibo, Puerto Rico. A hospice coordinates and manages the medical and associated care provided to terminally ill individuals. Transcript (Tr.) of hearing August 30, 1994 (8/30) at 90 - 91. The term "hospice" is described under section 1861(dd)(1) of the Social Security Act (Act) as a Medicare provider which offers care and services to a terminally ill beneficiary pursuant to a written plan of care established and periodically reviewed by the beneficiary's attending physician, the hospice's medical director, and its interdisciplinary group.[1]

A hospice provides its care and services in the beneficiary's home, on an outpatient basis, and in some instances, on a short-term inpatient basis. Social Security Act, section 1861(dd)(2)(A)(ii). Hospice services include: nursing care, physical and other therapy, medical social services, home health aide services, medical supplies, physicians' services, short-term inpatient care, and counseling. Id., section 1861(dd)(1)(A) - (H). In addition, a hospice provides bereavement counseling for the immediate family of a terminally ill beneficiary. Id., section 1861(dd)(2)(A)(i).

On February 17, 1994, Petitioner was surveyed on behalf of HCFA by the Puerto Rico Department of Health. HCFA Ex. 15 at 1. The purpose of the survey was to determine whether Petitioner was conducting its operations in compliance with the requirements of the Medicare program. On March 11, 1994, HCFA advised Petitioner that it had determined that Petitioner was not in compliance with Medicare conditions of participation. Id. HCFA advised Petitioner that it would terminate Petitioner's participation as a provider of services in the Medicare program.

On March 24, 1994, Petitioner submitted a plan of correction to HCFA, in which Petitioner proposed to correct the deficiencies that the Puerto Rico Department of Health had identified in its operations. HCFA Ex. 16.

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[1] Under the Medicare program, an individual is considered to be "terminally ill" if that individual has a medical prognosis that he or she is expected to live six months or less. Social Security Act, section 1861(dd)(3)(A).

On May 5, 1994, HCFA conducted a second survey of Petitioner in order to determine whether Petitioner was complying with the requirements for participation in Medicare. HCFA found that, notwithstanding the plan of correction, Petitioner continued to be noncompliant with a regulation which governed its participation in Medicare. HCFA Ex. 18. On May 23, 1994, HCFA advised Petitioner of this finding. HCFA advised Petitioner further that HCFA had affirmed its previous determination to terminate Petitioner's participation in the Medicare program. HCFA Ex. 19.

The regulation which HCFA found Petitioner to continue to contravene is 42 C.F.R. § 418.58 (1993).[2] That regulation governs the plans of care which hospices must create and maintain for Medicare beneficiaries whose care they manage. The regulation provides, as a condition for participation, that a hospice must establish and maintain a written plan of care for each beneficiary that it provides care to and that all care provided to a beneficiary must be provided in accordance with that beneficiary's plan of care. Id.

The regulation contains three subparts which establish standards of participation under the plan of care condition. 42 C.F.R. § 418.58(a) - (c). The standards set forth in these subparts are captioned: "Establishment of plan," "Review of plan," and "Content of plan." Id. At the survey conducted on May 5, 1994, HCFA's surveyor found that Petitioner was not complying with all three of these standards. HCFA Ex. 18.[3]

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[2] In its March 11, 1994 notification to Petitioner, HCFA advised Petitioner that HCFA had determined that Petitioner was not complying with two regulations governing hospices' participation in Medicare. These were 42 C.F.R. § 418.58 (plan of care) and 42 C.F.R. § 418.62 (informed consent). HCFA does not contend that, as of May 5, 1994 (the date of the second survey), Petitioner continued to fail to comply with 42 C.F.R. § 418.62. Thus, this case involves only the issue of whether HCFA was authorized to terminate Petitioner's participation in Medicare based on its failure to comply with 42 C.F.R. § 418.58.

[3] Below, I discuss the contents and meaning of these standards, HCFA's allegations about Petitioner's performance under each of these standards, and my conclusions.

B. Circumstances under which HCFA may terminate a provider's participation in Medicare

Regulations contained in 42 C.F.R. Part 488 govern the way in which HCFA monitors providers to assure that they comply with Medicare participation requirements. Regulations contained in 42 C.F.R. Part 489 describe the circumstances under which HCFA may terminate its relationship with providers that do not comply with Medicare participation requirements. When these regulations are read together, they afford a deficient provider a limited opportunity to cure deficiencies in order to avoid a termination by HCFA of the provider's participation in Medicare.

The Part 488 regulations provide for periodic surveys of providers by State survey agencies in order to assure that they remain in compliance with Medicare participation requirements. 42 C.F.R. §§ 488.11, 488.20. The regulations state that, if it is determined during a survey that a provider is not in compliance with one or more of the standards for participation in Medicare, the provider will be granted a reasonable time to achieve compliance. 42 C.F.R. § 488.28(b).

HCFA may terminate a participation agreement with a provider if it finds that the provider:

> is not complying with the provisions of title XVIII and the applicable regulations of this chapter or with the provisions of the [participation] agreement.

42 C.F.R. § 489.53(a)(1).

The regulations do not define the phrase "not complying with." However, under 42 C.F.R. § 489.53(a)(1), HCFA has at least the authority to terminate a provider's Medicare participation agreement where that provider substantially fails to comply with a participation requirement that is stated in a regulation.

On its face, 42 C.F.R. § 489.53(a)(1) authorizes HCFA to terminate a provider agreement if it determines that a provider substantially fails to comply with any participation requirement that is stated in a regulation. Read in isolation, this regulation does not impose a requirement on HCFA that it afford a deficient provider the opportunity to correct deficiencies in order to avoid termination of its provider agreement, nor does it give a deficient provider any right to attempt to cure deficiencies.

However, 42 C.F.R. § 488.28(b) requires HCFA to afford a deficient provider the opportunity to correct a deficiency where that deficiency consists of a failure to meet a "standard" for participation in Medicare. The term "standard" has significance here. The regulations that establish the criteria for participation in Medicare generally state "conditions" for participation as broad requirements for participation and "standards" for participation as specific duties that providers must perform in order to meet the general "conditions." For example, the regulation which is at issue in this case, 42 C.F.R. § 418.58, establishes as a general condition for participation in Medicare that a hospice must establish plans of care for each of its patients. It imposes specific requirements on hospices in the creation and maintenance of plans of care as standards set forth in 42 C.F.R. § 418.58(a), (b), and (c).

The requirement under 42 C.F.R. § 488.28(b) that HCFA afford a provider that is not complying with a standard of participation with the opportunity to correct that deficiency is a limited exception to the general rule that HCFA may terminate a deficient provider's participation. For example, where deficiencies are so severe as to rise to the level of a failure to meet a general condition of participation, then HCFA is not obligated to afford the deficient provider the opportunity to correct the deficiency before effectuating termination of that provider's participation agreement. Furthermore, I do not read 42 C.F.R. § 488.28(b) as requiring HCFA to allow a provider who remains deficient subsequent to submitting a plan of correction to continue to participate as a provider.

As I discussed above, Petitioner was surveyed on behalf of HCFA in February 1994. Petitioner responded to HCFA's initial termination notice with a plan of correction. HCFA resurveyed Petitioner on May 5, 1994. HCFA determined from its resurvey that Petitioner had not complied with a condition of participation in Medicare, and so it effectuated its determination to terminate Petitioner's participation agreement.

In this case, HCFA determined initially that Petitioner was not in compliance with the conditions for participation in Medicare stated in 42 C.F.R. §§ 418.58 and 418.62. HCFA Ex. 15 at 1. As I interpret 42 C.F.R. §§ 488.28(b) and 489.53(a)(1), HCFA was not obligated to afford Petitioner the opportunity to correct the deficiencies that HCFA had determined to exist, before effectuating termination of Petitioner's participation agreement, because these deficiencies consisted of

failure to comply with conditions of participation. However, HCFA did afford Petitioner that opportunity.

Petitioner notes that, based on the May 5, 1994 resurvey of Petitioner, HCFA found Petitioner to be noncompliant with all three subsections of 42 C.F.R. § 418.58, whereas HCFA had previously found Petitioner to be noncompliant with only two of the three subsections of the regulation. See HCFA Ex. 16 at 5 - 7; HCFA Ex. 18.[4] Petitioner argues that HCFA's determination at the resurvey that Petitioner was not in compliance with an additional standard contained in 42 C.F.R. § 418.58(a), mandated HCFA to initiate a new termination process, under which Petitioner should have been afforded the opportunity to submit a new plan of correction. Petitioner thus asserts that HCFA's determination to effectuate its termination of Petitioner's participation agreement denied Petitioner the right to correct the additional deficiency identified at the May 5, 1994 survey before HCFA effectuated termination.

I do not agree with this argument. First, the additional subsection with which Petitioner was found to be noncompliant has no bearing on my decision in this case. As I find at Part G of this discussion, HCFA proved at the hearing of this case only that Petitioner had failed to comport with the plain meaning of 42 C.F.R. § 418.58(b), a subsection which was cited in the findings from both the February 1994 survey and the May 1994 resurvey. Based on the resurvey, HCFA would have had a reason to terminate Petitioner's participation in Medicare even if it made no findings at the resurvey as to Petitioner's compliance with 42 C.F.R. § 418.58(a).

Second, I do not read the limited right created by 42 C.F.R. § 488.28(b) for a provider to correct its noncompliance with a standard as giving that provider unqualified additional opportunities to correct additional deficiencies that HCFA may find upon resurvey of that provider. A provider is not entitled to file an additional plan of correction if, on a resurvey of that

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[4] Based on the February 17, 1994 survey, HCFA found Petitioner to be noncompliant with 42 C.F.R. § 418.58(b) and (c). HCFA Ex. 16 at 5 - 7. Based on the May 5, 1994 resurvey, HCFA found Petitioner to be noncompliant with 42 C.F.R. § 418.58(a), (b), and (c). HCFA Ex. 18.

provider, additional deficiencies are identified, and these deficiencies are condition-level.[5]

Petitioner's argument would turn the limited opportunity for a provider to correct a standard-level deficiency, stated in 42 C.F.R. § 488.28(b), into a general right to correct condition-level deficiencies which supersedes HCFA's authority, under 42 C.F.R. § 489.53(a)(1), to terminate the participation of noncompliant providers. Taken to its logical end, Petitioner's argument would mean that there could be some circumstances under which HCFA would not be able to terminate a noncompliant provider's participation in Medicare. Under Petitioner's theory, HCFA would be required to afford a noncompliant provider the opportunity to submit a plan of correction after each survey it conducted, so long as that provider was noncompliant with a different condition of participation at each survey. Conceivably, a provider could never be in compliance with all of the applicable participation requirements, and HCFA would be precluded from terminating that provider's participation in Medicare, so long as each time HCFA resurveyed it the provider was not in compliance with a different participation requirement.

C. HCFA's burdens of coming forward with evidence and persuasion

HCFA argues that, in a hearing concerning a determination by HCFA to terminate a provider's participation agreement, the provider has the burden of proving that it is in compliance with participation requirements. HCFA's argument suggests that it has no burden of proving that its determination is reasonable. HCFA seems to be asserting that its determination ought to be sustained, even if it offers no evidence in support of that determination, if the provider whose participation agreement has been terminated cannot prove that the determination is incorrect.

I conclude that HCFA bears the burdens of coming forward with evidence and persuasion. HCFA must establish by the preponderance of the evidence that its determination is correct. Where HCFA proves a prima facie case and a provider offers evidence to rebut the evidence offered by HCFA, the question will be whether the evidence offered

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[5] As a matter of discretion, HCFA may afford providers opportunities to correct condition-level deficiencies identified at resurveys.

by the provider is sufficient to overcome the prima facie case established by HCFA.

Holding HCFA to this standard of proof is both fair and efficient. HCFA is in the best position to present facts which establish that a provider is not complying with Medicare participation requirements. For that reason, HCFA should be required to prove a case supporting its determination. That case ought to be strong enough to overcome evidence that a provider might offer in opposition to HCFA's determination.

An administrative hearing involving a determination by HCFA to terminate a provider's participation in Medicare is governed by regulations contained in 42 C.F.R. Part 498. These regulations do not state specifically which party has the burden of coming forward with evidence or of persuasion in a hearing concerning a determination to terminate a provider's participation. The regulations impose broad discretion on the administrative law judge to govern the manner in which evidence is received and weighed. They state only that:

> The ALJ [administrative law judge] decides the order in which the evidence and the arguments of the parties are presented and the conduct of the hearing.

42 C.F.R. § 498.60(b)(3).

I do not read the Part 498 regulations as containing any statement by the Secretary as to who should bear the burdens of coming forward with evidence and persuasion in a hearing concerning termination of a provider's participation in Medicare. The regulations' silence on these issues, coupled with the broad discretion which the regulations repose in the administrative law judge to regulate the conduct of the hearing, suggest that the Secretary has left open the issues of coming forward with evidence and persuasion, to be resolved by the administrative law judge based on the requirements of due process.[6]

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[6] My conclusion that the Secretary has left it to the administrative law judge in Medicare provider termination hearings to decide who has the burden of proof, consistent with due process, is not inconsistent with the Secretary's policy in other types of cases. In regulations governing other types of cases, the Secretary has explicitly conferred on administrative law judges the

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HCFA relies on the process by which termination is effectuated to support its argument that the provider has the burden of persuasion. Under the regulations, a determination by HCFA to terminate a provider's participation in Medicare becomes the Secretary's final decision, unless the provider requests a hearing. 42 C.F.R. § 498.25; see 42 C.F.R. § 498.40. HCFA reasons that, if the determination is final unless a hearing is requested, the burden should fall on the provider requesting the hearing to prove that the determination is incorrect. This analysis ignores the fact that administrative hearings as to the propriety of determinations by HCFA are de novo and not appellate reviews. Given that, no special weight should apply to HCFA's determination once that determination is challenged in the context of an administrative hearing.

HCFA cites three sources of authority to support its argument that, in a case involving termination of a participation agreement, the provider should bear the burden of persuasion as to the reasonableness of HCFA's determination. I have considered these authorities. They do not provide substantial support for HCFA's argument.

First, HCFA relies on a canon of administrative law which states that, in an administrative proceeding, the general rule is that an applicant for relief, benefits, or privilege has the burden of persuasion. HCFA posthearing brief at 6. In the past, the Secretary has applied this canon to require applicants for benefits to prove that they are entitled to benefits. For example, the general rule is that the burden of persuasion lies on the applicant in a case in which an applicant argues that he or she is entitled to Social Security disability benefits. 20 C.F.R. § 404.1512(a).[7] That makes sense,

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[6](...continued)
authority to apportion burden of proof. Regulations which govern hearings involving certain determinations by the Department of Health and Human Services' Inspector General to exclude individuals and entities from participating in Medicare and other federally funded health care programs state that the administrative law judge shall decide who bears the burden of proof in those hearings. 42 C.F.R. § 1005.15(c).

[7] That rule has exceptions, however. For example, courts have held routinely that, where an applicant for disability benefits proves that he or she
(continued...)

because the applicant is more likely to be in possession of facts which support his or her contention that he or she is entitled to benefits.

However, a different dynamic applies in the instance of a provider whose participation agreement is terminated by HCFA after a survey conducted by or for HCFA at which deficiencies have been identified. In that instance, HCFA determines to end a relationship that was established previously. HCFA makes the determination based on facts in its possession which HCFA obtained at the survey. Inasmuch as HCFA is relying on facts that it obtained, it ought to be in the best position to prove those facts.

In contrast, it is not reasonable to expect a provider to prove a negative proposition -- that it has not contravened provider participation requirements -- in the absence of affirmative proof that it has contravened those requirements. Imposing this burden on a provider would inject a note of uncertainty into the administrative hearing process, because the provider could never be sure what or how much evidence it would be required to offer to rebut HCFA's unsubstantiated determination. The consequence might be to invite a massive and unfocused submission of evidence from that provider.

Furthermore, it is not reasonable to characterize a provider whose participation in Medicare has been terminated by HCFA as an <u>applicant</u> for relief, benefits, or a privilege. The reality is that such a provider is no longer an applicant, but, in fact, has an established relationship with HCFA, based on the participation agreement and the law and regulations which govern that agreement. That provider will have made financial commitments and have established business relationships in reliance on that agreement. That reliance does not establish an unqualified entitlement to participate in Medicare. However, it would ignore the reality of that provider's ongoing business in reliance on the participation agreement to characterize it merely as an "applicant," and to aver from that characterization that the provider has a burden of proving that any determination by HCFA is unreasonable.

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[7](...continued)
is unable to perform his or her past work activity, then the burden shifts to the Administration to prove that there exist jobs that the applicant can perform.

Second, HCFA relies on judicial decisions which hold that, in administrative hearings, the burden of persuasion rests upon the party that files a claim with an administrative agency. HCFA posthearing brief at 7. As with the general rule of administrative law that HCFA relies on, these decisions address the situation where an applicant for benefits or relief seeks redress for a determination denying eligibility or entitlement. I do not find the principle stated in these decisions to be applicable to the case involving termination of participation in Medicare, for the same reason that I do not find the general principle of administrative law relied on by HCFA to be applicable.

Finally, HCFA relies on a decision by the Social Security Administration Office of Hearings and Appeals Council in a case involving termination of an entity's participation in Medicare. Jefferson Memorial Hosp. Ass'n v. Health Care Financing Administration, Docket No. PS-109, at 17 (1983); HCFA posthearing brief at 8 - 9.[8] In that decision, the Appeals Council stated that it rejected an administrative law judge's conclusion that the Secretary had the burden of proving that "significant changes or violation" of a participation agreement entitled the Secretary to terminate the agreement. Id. The Appeals Council held that HCFA:

> has the initial burden of coming forth with evidence of statutory and/or regulatory violations showing that a provider's agreement with the Secretary should be terminated. Once this occurs, as in the instant case, the ultimate burden of responsibility and the burden of proof for compliance remains with the provider for it must show that it is still in continuing compliance with the applicable conditions of participation.

Id. This is not an entirely clear statement of who actually has the burden of persuasion in a case involving termination of a provider's participation agreement.[9] A

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[8] This decision is attached to HCFA's posthearing brief as Addendum 1.

[9] The ambiguity in the Appeals Council's allocation of burden may, in some respect, reflect the even greater ambiguity in the administrative law judge's allocation of burden. I do not know what the administrative law judge meant by the phrase "significant changes or violations."

fair reading of this statement, however, is that HCFA bears the burden of coming forward with evidence and proving a prima facie case for termination of a provider's participation agreement. Thus, although the Appeals Council rejected the administrative law judge's statement of the parties' burdens, it imposed an order of proof and a burden of persuasion which may be the same as that which I find to be reasonable.

D. HCFA's arguments as to Petitioner's responsibilities under the regulations

HCFA asserts that, when it resurveyed Petitioner on May 5, 1994, Petitioner was not in compliance with any of the subsections of 42 C.F.R. § 418.58, which governs plans of care that hospices establish and maintain for individuals under their care. The regulation at issue establishes as a condition for participation by a hospice that:

> [a] written plan of care must be established and maintained for each individual admitted to a hospice program and the care provided to an individual must be in accordance with the plan.

42 C.F.R. § 418.58.

Each of the three subsections of 42 C.F.R. § 418.58 contains requirements that a hospice must comply with in creating and maintaining plans of care for its patients. The subsection which contains the standard entitled "Establishment of plan" states that, for each patient:

> [t]he plan must be established by the attending physician, the medical director or physician designee and interdisciplinary group prior to providing care.

42 C.F.R. § 418.58(a).[10]

The subsection which contains the standard entitled "Review of plan" states that, for each patient:

> [t]he plan must be reviewed and updated, at intervals specified in the plan, by the attending physician, the medical director or physician designee and interdisciplinary group. These reviews must be documented.

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[10] There is a separate regulation which governs the composition and duties of a hospice's interdisciplinary group. 42 C.F.R. § 418.68.

42 C.F.R. § 418.58(b).

The subsection which contains the standard entitled "Content of plan" states that, for each patient:

> [t]he plan must include an assessment of the individual's needs and identification of the services including the management of discomfort and symptom relief. It must state in detail the scope and frequency of services needed to meet the patient's and family's needs.

42 C.F.R. § 418.58(c).

HCFA's argument that Petitioner contravened all three of these subsections rests heavily on its interpretation of the meaning of the subsections and on its assertion that Petitioner was charged with the duty to be aware of and comply with HCFA's interpretation. HCFA admits that the language of these subsections may not "list enormously detailed requirements for each condition, and were not intended to do so." HCFA posthearing brief at 10. However, HCFA argues that a broader meaning can be read into these subsections than is encompassed by the literal wording of the subsections. According to HCFA, the regulations subsume generally accepted standards of practice for hospices. HCFA posthearing brief at 9. Thus, HCFA argues that it is reasonable to read the three subsections of 42 C.F.R. § 418.58 as imposing obligations on hospices which are consistent with generally accepted practices among hospices, even if the subsections cannot be read unambiguously to impose those obligations on hospices.

HCFA argues also that, in interpreting the regulations, considerable deference must be paid to the judgment and expertise of the individuals who serve as HCFA's agents to survey providers. In this case, HCFA's representative is Ms. Marjorie S. Finnigan, who conducted the May 5, 1994 resurvey of Petitioner. Tr. 8/30 at 70 - 242. Therefore, according to HCFA, Ms. Finnigan's interpretation of the regulations should be accepted if it is grounded on practices that are accepted generally by hospices.

1. <u>The planning and documentation requirements which HCFA argues are embodied in the plan of care regulation</u>

HCFA interprets the plan of care regulation to impose specific planning and documentation requirements on hospices which are not necessarily encompassed within the

literal words of the regulation. According to HCFA, the three subsections of the regulations should be interpreted to require the following:

o The requirement contained in 42 C.F.R. § 418.58(a) that a plan of care must be established for a patient prior to providing care to that patient means that any changes in a patient's condition must be addressed and documented, either in a new plan of care or in a revision to that plan. It is not sufficient for a hospice to establish an overall plan of care for a patient and then fail to establish additional specific plans to deal with problems that a patient later develops. HCFA posthearing brief at 11 - 12.

o The requirement contained in 42 C.F.R. § 418.58(a) that a plan of care be established by the attending physician, the medical director, and the interdisciplinary group, coupled with the general requirement contained in 42 C.F.R. § 418.58 that treatment be provided to a hospice patient in accordance with a plan of care, means that a member of the hospice staff may not treat a patient for a problem without consulting the interdisciplinary group, and without the interdisciplinary group documenting the consultation in a plan of care. HCFA's post-hearing brief at 12.

o The requirement contained in 42 C.F.R. § 418.58(b) that a plan of care must be reviewed and updated, at intervals specified in the plan, by the attending physician, the medical director or physician designee, and the interdisciplinary group, and that review must be documented means that any change in a patient's condition must be addressed and documented, either in a new plan of care, or in a revision to an existing plan of care. HCFA posthearing brief at 12 - 13.

o The requirement contained in 42 C.F.R. § 418.58(b) that a plan of care must be reviewed and updated, at intervals specified in the plan, means that the plan itself must specify when it will be reviewed, and the plan must be reviewed according to the established schedule. HCFA posthearing brief at 13.

o The requirements contained in 42 C.F.R. § 418.58(c) that a plan of care contain an assessment of the patient's needs and identification of the services, including the management of discomfort and symptom relief, and that the plan state in detail the scope and frequency of services needed to meet the patient's and his or her family's needs, mean that the plan of care

must identify which discipline is responsible for the interventions and treatments established in the plan. These requirements mean also that the plan must identify the specific medicine to be administered to a patient and the frequency of administration of that medicine. HCFA posthearing brief at 13 - 14.

2. HCFA's arguments concerning Petitioner's duty to be aware of and comply with HCFA's interpretation of the regulation governing plans of care

HCFA asserts that the statement of deficiencies which was sent to Petitioner after the February 17, 1994 survey of Petitioner provided Petitioner with ample notice of HCFA's interpretation of the regulation which governs plans of care. HCFA posthearing brief at 15 - 17; see HCFA Ex. 16 at 5 - 9. HCFA argues, alternatively, that it had no duty to advise Petitioner of its interpretation of the regulation, inasmuch as HCFA bases its interpretation on practices which are generally accepted by hospices. HCFA posthearing brief at 21. According to HCFA, Petitioner was obligated to know what these practices are and to anticipate HCFA's interpretation of the regulations. Id.

E. HCFA's contentions of fact

HCFA contends that, on May 5, 1994, when it resurveyed Petitioner, Petitioner was noncompliant with all three subsections of 42 C.F.R. § 418.58. HCFA premises its contentions on its interpretation of the meaning of the three subsections (which I have described at Part II D of this decision), coupled with the specific findings of the surveyor who conducted the May 5, 1994 resurvey. To support its contentions, HCFA offered the testimony of the surveyor, Ms. Finnigan (Tr. 8/30 at 70 - 242), notes she made at the resurvey (HCFA Exs. 26 - 30), the statement of deficiencies that she prepared after completing the resurvey (HCFA Ex. 18), and excerpts from treatment records of some of the patients cared for by Petitioner that Ms. Finnigan reviewed during the resurvey (HCFA Exs. 21 - 25).

HCFA makes the following contentions of fact:

o Relying on its interpretation of 42 C.F.R. § 418.58(a) and 42 C.F.R. § 418.58(b) that a revised or new plan of care must be created to address any change in a patient's condition, HCFA contends that Petitioner failed to revise plans of care or to write new plans of care to deal with changes in the condition of patients under its

care. HCFA posthearing brief at 29 - 35. Relying also on its interpretation of 42 C.F.R. § 418.58(a) that practitioners may not treat a patient of a hospice without first consulting the hospice's interdisciplinary group, and that the consultation must be documented, HCFA contends that practitioners treated Petitioner's patients without prior consultation, and Petitioner's interdisciplinary group failed to document these treatments. Id.

HCFA supports these contentions with references to excerpts of treatment records of four patients who were cared for by Petitioner. These are Patient # 9 (HCFA Ex. 21), Patient # 6 (HCFA Ex. 24), Patient # 1 (HCFA Ex. 23), and Patient # 3 (HCFA Ex. 25). With respect to these patients, HCFA contends that Petitioner contravened 42 C.F.R. § 418.58(a) as follows:

> a. In the case of Patient # 9, the nurse who treated that patient failed to contact Petitioner's interdisciplinary group to discuss an order by the patient's treating physician to administer intravenous (IV) fluids. The records fail to document any review by the interdisciplinary group of the need to administer IV fluids. There is no plan of care in Patient # 9's records addressing the administration of IV fluids. HCFA posthearing brief at 30 - 32; see HCFA Ex. 21.
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> b. In the case of Patient # 6, this patient was treated for an ulcer involving the patient's left foot. The patient's treatment records do not contain a plan of care addressing this specific problem. HCFA posthearing brief at 32 - 33; see HCFA Ex. 24.
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> c. In the case of Patient # 1, there exists no plan of care in the patient's treatment records addressing the bereavement of the patient's family resulting from the patient's death. HCFA posthearing brief at 33; see HCFA Ex. 23. HCFA asserts also that the failure of Petitioner to create a bereavement plan of care for the family of Patient # 1 violates 42 C.F.R. § 418.88, which governs the duty of a hospice to provide for the bereavement of the families of individuals under the hospice's care.[11]

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[11] In either the statement of deficiencies it prepared after the May 5, 1994 resurvey or in the notice (continued...)

d. In the case of Patient # 3, there exist no plans of care which address changes in the medications administered to this patient, and no bereavement plan of care. HCFA posthearing brief at 34 - 35; see HCFA Ex. 25.

o Relying on its interpretation of 42 C.F.R. § 418.58(b) that a plan of care must specify the dates when it will be reviewed, and that a plan must be reviewed according to the established schedule, HCFA contends that none of the ten patient records reviewed by Ms. Finnigan contained plans of care establishing review schedules or documented reviews according to an established schedule. HCFA posthearing brief at 35 - 36.

As specific examples, HCFA cites the records of Patient # 9, Patient # 6, and Patient # 3. Id. HCFA contends also that none of the patient records reviewed by Ms. Finnigan evidenced reviews by Petitioner's interdisciplinary group to recertify patients for hospice care. HCFA posthearing brief at 38 - 39. Furthermore, the records fail to contain recertification forms which comport with requirements governing recertification of patients stated in 42 C.F.R. § 418.22.

o Relying on its interpretation of 42 C.F.R. § 418.58(c), that a plan of care must state which discipline is responsible for each intervention identified in the plan, and must state which medicine must be administered to a patient, and the frequency of administration of medication, HCFA contends that none of the treatment records identify the discipline responsible for providing the interventions which are identified in the patient's plan of care. HCFA posthearing brief at 40 - 42. To support this contention, HCFA cites the failures of plans of care for patient # 9, Patient #6, and Patient # 1, to identify the disciplines responsible for specific interventions.

F. Petitioner's arguments and contentions of fact

As I discuss at Part II B of this decision, Petitioner asserts that HCFA has denied it due process of law by not giving it the opportunity to correct the additional deficiencies which HCFA found at its May 5, 1994 resurvey of Petitioner. Petitioner argues also that HCFA's

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[11](...continued)
it sent to Petitioner on May 23, 1994, HCFA did not assert that Petitioner contravened this regulation . See HCFA Exs. 18, 19.

interpretation of 42 C.F.R. § 418.58 is not reasonable. Specifically, Petitioner asserts that 42 C.F.R. §§ 418.58(a) and (b) cannot be read reasonably to require a hospice to revise a plan of care, or to create a new plan of care, to address every change in a patient's condition. Petitioner argues also that 42 C.F.R. § 418.58(b) cannot be read reasonably to require that each plan of care maintained by a hospice specify a review date.

Petitioner disputes also some of HCFA's contentions of facts. In response to HCFA's contention that in its plans of care Petitioner failed to specify the dates when the plans would be reviewed, Petitioner argues that the treatment records in evidence show that in fact these plans were reviewed. Petitioner contends that HCFA did not prove that Petitioner failed to provide proper treatment to any patient.

G. Analysis of the parties' arguments and contentions

HCFA proved that 42 C.F.R. § 418.58(b) put Petitioner on notice that each plan of care that it created for each of its patients should have specified a schedule by which that plan would be reviewed by the patient's attending physician, Petitioner's medical director or physician designee, and Petitioner's interdisciplinary group. The preponderance of the evidence is that Petitioner did not comply with this requirement. The fact that Petitioner actually may have reviewed some of the plans of care for some of its patients does not constitute compliance with the requirement of 42 C.F.R. § 418.58(b) that it establish a schedule for review of each plan of care.

I find that HCFA did not prove that Petitioner failed to comply with the requirements of 42 C.F.R. § 418.58(a) and (c), or with the requirements of 42 C.F.R. § 418.58(b). HCFA's assertion that Petitioner failed to comply with these subsections rests on an interpretation that is not within the plain language of the regulations, which HCFA did not communicate to Petitioner. Given that, it would not be reasonable to expect Petitioner to have complied with HCFA's interpretation.

1. Petitioner's failure to comply with the requirement that it establish a schedule for review of each plan of care and its failure to conduct reviews in accordance with that schedule

Although 42 C.F.R. § 418.58 may not "list enormously detailed requirements" for creation and maintenance of plans of care by hospices, it does state some requirements unambiguously. See HCFA posthearing brief at 18. The requirement contained in 42 C.F.R. § 418.58(b) states that a hospice must review each plan of care that it creates for a patient at intervals stated in the plan. That requirement can only be read to require a hospice to establish a schedule for review of each plan of care that it creates, and to state that schedule in the plan itself. The regulation leaves it to the discretion of the hospice to define the events or circumstances which would mandate a review of the plan of care. But there can be no doubt that for every plan of care, the regulation requires that a review schedule be established and stated in the plan.

A hospice does not meet the requirements of this subsection by conducting reviews of its plans of care, without establishing a schedule for a review in each plan. The regulation contains an explicit directive to hospices by the Secretary that, for each plan of care, a review schedule be established and that the schedule be complied with.

The Secretary's purpose is apparent here. By definition, hospice patients are in the last stages of their lives. The purpose of a hospice is to manage these patients' care to assure that they are made as comfortable as possible and that they die with dignity. The Secretary's intent in requiring hospices to establish a schedule for the review of each plan of care, stated in that plan, is to assure that each hospice patient's needs are attended to regularly. It is to assure also that, as each hospice patient proceeds through the process of dying, that the care provided to that patient is adjusted to address the patient's changing condition.

Furthermore, a hospice cannot justify its failure to comply with a specific requirement stated in a regulation by asserting that, notwithstanding its failure to comply, it provided care which addressed its patients' needs. The fact that a hospice may review some patients' plans of care may demonstrate that the hospice is attending to some of those patients' needs. But if that hospice does not establish a schedule for review in each plan of care, and follow that schedule, there can be no guarantee that the hospice is attending to all of the needs of all of its patients with regularity.

The preponderance of the evidence in this case is that Petitioner did not comply with the requirement of 42 C.F.R. § 418.58(b) that it review the plans of care it created for its patients at intervals specified in the plans. Ms. Finnigan testified that she reviewed ten of Petitioner's patients' treatment records. She testified credibly that none of them contained plans of care which stated the intervals at which they would be reviewed. HCFA Ex. 18, pages 5 - 6; Tr. 8/30 at 190.

The excerpts from patients' treatment records that HCFA offered as evidence are consistent with Ms. Finnigan's testimony. HCFA Exs. 21 - 25. None of these excerpts contain a plan of care which establishes a schedule for review of the plan.

Petitioner did not rebut this evidence. It did not offer plans of care for the ten patients whose records Ms. Finnigan reviewed to show that there exist plans which did establish review schedules. Petitioner's President, Alejandro Perez, testified on behalf of Petitioner. Tr. 8/31 at 7 - 9. He testified that Petitioner had an interdisciplinary group, and that Petitioner prepared plans of care for each of its patients. Id. However, he did not aver that, generally, the plans of care established review schedules. Nor did Mr. Perez deny Ms. Finnigan's testimony that none of the records she reviewed contained plans of care with review schedules.

Petitioner contends that the patient records introduced into evidence by HCFA contain plans of care, and that at least some of these plans of care were reviewed by Petitioner's staff. However, the fact that the records contain plans of care, or that some of them may have been reviewed does not prove that Petitioner established plans of care for its patients which established a schedule for review, nor does it prove that the plans were reviewed according to a schedule, as is required by 42 C.F.R. 418.58(b).

For example, HCFA Ex. 21 contains excerpts from the treatment records of Patient # 9 that were reviewed by Ms. Finnigan at the May 5, 1994 resurvey. Those excerpts include several plans of care. HCFA Ex. 21 at 3 - 9. It is apparent from these plans that they were created by Petitioner's staff or interdisciplinary group to address specific problems which Patient # 9 manifested during the period when she was cared for by Petitioner. Id. However, none of these excerpts establish a schedule for review of Patient # 9's problems, as the regulation requires.

HCFA Ex. 21 consists only of excerpts from Patient # 9's treatment records. Similarly, HCFA Exs. 22 - 25 consist only of excerpts from the treatment records of Patients # 5, # 1, # 6, # 4, and # 3, respectively. Petitioner did not argue that portions of these patients' records that were not offered by HCFA contain plans of care which include schedules for review of the plans. Nor did Petitioner offer as evidence portions of these patients' treatment records that were not offered by HCFA, to rebut HCFA's contention that the records did not contain plans of care that comported with the requirements of 42 C.F.R. § 418.58(b).

2. HCFA's failure to give Petitioner notice of its interpretation of the regulation governing plans of care

HCFA's interpretation of 42 C.F.R. § 418.58 (a) and (c), and in some respects, its interpretation of 42 C.F.R. § 418.58(b), is not within the plain meaning of these subsections. HCFA had an obligation to communicate its interpretation to Petitioner as a prerequisite to insisting that Petitioner comply with it. HCFA failed to meet this obligation. Therefore, HCFA may not hold Petitioner accountable for Petitioner's asserted failure to comply with HCFA's interpretation of the regulation.

I reach no conclusions here as to whether HCFA's interpretation of a hospice's obligations under 42 C.F.R. § 418.58 is reasonable. Nor do I make findings as to whether the evidence proves that Petitioner failed to comply with HCFA's interpretation of its obligations. It is not necessary for me to reach such conclusions or make such findings in this case.

The regulations which the Secretary publishes governing the participation of providers in the Medicare program do not address and provide standards for every detail of those relationships. As comprehensive as these regulations may be, there exist a myriad of circumstances which the Secretary, or her delegate, HCFA, may find a need to address, which are not addressed specifically in the regulations. HCFA has authority to interpret the regulations and to inform providers of its interpretations in order to assure that providers comply. Furthermore, HCFA's reasonable interpretations of regulations should be accorded deference.

Providers must comply with HCFA's reasonable interpretations of regulations where HCFA communicates those interpretations to providers. But having the authority to interpret regulations and to insist that

providers comply with reasonable interpretations does not permit HCFA to interpret regulations in a way which exceeds their plain meaning, not communicate its interpretations to providers, and then insist that providers be held accountable if they fail to divine HCFA's intent.

HCFA's interpretation of 42 C.F.R. §§ 418.58(a) and (b) is that these subsections require a hospice to create a new or revised plan of care to deal with any change in a patient's condition. HCFA's contention that Petitioner was not in compliance with 42 C.F.R. § 418.58(a) is premised on this interpretation. Its contention that Petitioner was not in compliance with 42 C.F.R. § 418.58(b) is in part premised on this interpretation.[12] I do not find this interpretation to be subsumed within the plain meaning of either 42 C.F.R. §§ 418.58(a) or (b). On their face, these subsections require that a hospice create a plan of care for each of its patients that is reviewed pursuant to a schedule determined by the hospice. While it may not be unreasonable to interpret these sections to require that hospices create a plan of care for each new problem that a patient develops, or to revise a global plan of care to deal with each new problem that a patient develops, that is not what the subsections call for specifically.

HCFA's interpretation of 42 C.F.R. § 418.58(a) to require a practitioner to consult the hospice's interdisciplinary group before treating a patient's new problems, and to require that the consultation and intervention be documented in a plan of care, is not within the plain meaning of this subsection. The subsection requires that the plan of care be established before care is provided. It can be interpreted to mean what HCFA asserts it means only if HCFA's interpretation that a new or revised plan of care must be created to deal with every change in a hospice patient's condition is a reasonable interpretation of the regulation. As I find above, that interpretation is not within the plain meaning of the regulation.

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[12] As I find above, HCFA contends also that Petitioner was not in compliance with the requirement of 42 C.F.R. § 418.58(b) that it create a plan of care for each of its patients which contains a review schedule and that the plan of care be reviewed according to that schedule. I have found that that requirement is stated explicitly in 42 C.F.R. § 418.58(b) and that Petitioner did not comply with it.

HCFA's interpretation of 42 C.F.R. § 418.58(c) to require that each plan of care identify the discipline that is responsible for a particular intervention, to identify each medication that is to be administered to a patient, and to state the frequency of administration of each medication, is not within the plain meaning of this subsection. The subsection plainly requires that the plan of care include an assessment of the patient's needs and identification of the services to be provided to a patient. It requires also that the plan of care state in detail the scope and frequency of services needed to meet the patient's needs and those of the patient's family. It may not be unreasonable to interpret this subsection as requiring the specificity which HCFA asserts is required. However, on its face, the regulation does not require the degree of detail which HCFA interprets it to require. The subsection does not explicitly state that a hospice must identify the particular discipline assigned to provide a particular type of care. Nor does it explicitly require a hospice to identify each medication to be provided to a patient or the frequency of administration of that medication.

HCFA did not communicate to Petitioner its interpretation of the subsections of 42 C.F.R. § 418.58. There is no evidence in this case that HCFA made any general announcement of its interpretation, for example, in the form of a bulletin to hospices. Furthermore, I am not persuaded that HCFA communicated its interpretation specifically to Petitioner. Simply, I do not agree with HCFA's assertion that the report of deficiencies which was provided to Petitioner after the February 17, 1994 survey provided it with adequate notice of HCFA's interpretation of the three subsections of 42 C.F.R. § 418.58. See HCFA Ex. 16 at 5 - 9.

HCFA Ex. 16 does not state HCFA's interpretation of 42 C.F.R. §§ 418.58(a) and 418.58(b). Indeed, it does not assert that Petitioner failed to comply with the requirements of 42 C.F.R. § 418.58(a). It does not set out an interpretation of 42 C.F.R. § 418.58(b) that deviates from the subsection's plain meaning. HCFA Ex. 16 at 5. It states that Petitioner failed to comply with 42 C.F.R. § 418.58(c) by not providing in its plans of care an identification of the frequency of the services to be provided and who is responsible for the plan's implementation. Id. at 6 - 7. However, this does not support HCFA's interpretation that each plan of care must identify precisely which discipline is responsible for each intervention, the medications which are to be administered to the patient, and the frequency of administration of each medication.

I do not agree with HCFA's argument that a provider is charged with knowing and complying with HCFA's interpretation of a regulation, where HCFA's interpretation is other than the regulation's plain meaning, and where HCFA has not communicated that interpretation to providers. HCFA asserts that its interpretation of the subsections of 42 C.F.R. § 418.58 comports with standards that are accepted generally by hospices. If so, that may support HCFA's argument that its interpretation of the subsections is reasonable. However, the fact that an interpretation of a regulation comports with generally accepted practices does not excuse HCFA from the obligation of putting providers on notice of its interpretation and its expectation that providers comply with that interpretation.

It is true that the regulations governing hospices' participation in Medicare state as a general requirement that hospices provide services in a manner that is consistent with accepted standards of practice. 42 C.F.R. § 418.50(b)(3). However, I do not read this section to require a hospice to be aware of and to comply with an interpretation of a regulation by HCFA that is not apparent from the regulation's plain meaning and which has not been communicated to hospices.

HCFA asserts that my decision in Long Medical Laboratory, DAB CR334, at 11 - 12 (1994), implicitly supports its argument that HCFA has no duty to acquaint providers with generally accepted standards of practice, where HCFA interprets those standards to be incorporated within regulations. HCFA posthearing brief at 21. HCFA's reliance on the Long Medical Laboratory decision is misplaced. In that case, I found that the petitioner was obligated to be aware of and to comply with a condition for participation in Medicare that is stated explicitly in the Act. HCFA was not obliged to communicate further to Petitioner the requirement that it abide by this condition, inasmuch as the Act stated the condition explicitly. The case did not involve an interpretation of the Act or of a regulation that was not within the plain meaning of the language of the Act or regulation and which HCFA had not communicated to providers.

H. HCFA's authority to terminate Petitioner's participation in Medicare

As I find in Part B of this discussion, HCFA may terminate a provider's participation in Medicare where it establishes that the provider is not complying materially or substantially with a participation requirement stated in a regulation. HCFA is not obligated to afford a

provider the opportunity to correct its deficiency before terminating that provider's participation.

Here, the preponderance of the evidence establishes that Petitioner failed to comply with a participation requirement that is explicitly stated in 42 C.F.R. § 418.58(b). This failure was substantial. The uncontroverted evidence is that Petitioner did not establish nor comply with a schedule to review the plan of care for all ten of the patients whose records were reviewed by HCFA. Furthermore, this failure by Petitioner was not merely a technical error. The Secretary has determined that the requirement for a hospice to schedule and conduct reviews of each plan of care that it creates for each patient is an essential element of the relationship between that hospice and the Medicare program.

I find Petitioner's violation of 42 C.F.R. § 418.58(b) to be so substantial as to rise to the level of a violation of the condition of participation stated in the regulation. The requirement that a hospice plan the care of its patients and to regularly address, and, if necessary, adjust that care, is an essential element of the services which hospices provide. Tr. at 77 - 78. Integral to the planning of a hospice patient's care is the requirement that the appropriate individuals meet regularly to review, and if necessary, adjust that care. Id. at 79. When a plan of care is not reviewed regularly, there is a risk that the hospice will not attend to the patient's needs. Id. at 79 - 80. Petitioner was utterly derelict in meeting this requirement. By not attending systematically to the needs of its patients, Petitioner violated the condition that it establish and maintain plans of care for the individuals in its care.

III. Conclusion

I conclude that HCFA proved by the preponderance of the evidence that Petitioner failed to comply with a requirement for participation in Medicare as stated in 42 C.F.R. § 418.58(b). HCFA was authorized to terminate Petitioner's participation in Medicare, and I sustain HCFA's determination to do so.

/s/

Steven T. Kessel
Administrative Law Judge