Department of Health and Human Services

DEPARTMENTAL APPEALS BOARD

Civil Remedies Division

In the Case of:	)	
	)	
Hospicio en el Hogar de Utuado,	)	DATE: April 24, 1995
	)	
Petitioner,	)	
	)	
- v. -	)	Docket No. C-94-360
	)	Decision No. CR371
Health Care Financing Administration.	)	
	)	

DECISION

Petitioner requested a hearing from 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. On November 1, 1994, I conducted a hearing in San Juan, Puerto Rico.

I have considered the applicable law and regulations, the evidence which I received at the hearing, and the parties' arguments.[1] I conclude that HCFA proved, by a preponderance of the evidence, that Petitioner failed to comply with conditions governing 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.

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[1] In this decision, I refer to specific excerpts from the transcript of the hearing as "Tr. at (page)."

1. In a case where a provider requests a hearing from a determination by HCFA to terminate its participation in Medicare, HCFA must prove, by a preponderance of the evidence, that the determination to terminate the provider's agreement is authorized. Pages 6 - 10.

2. The elements of HCFA's burden of persuasion consist of proving that:

   a. There exist participation requirements to which Petitioner may be held accountable. Pages 10 - 11.

   b. Petitioner has not complied with Medicare participation requirements. Pages 11 - 12.

   c. Petitioner's failure to comply with Medicare participation requirements substantially limits Petitioner's capacity to render adequate care or adversely affects the health and safety of Petitioner's patients. Pages 12 - 13.

3. HCFA did not deny Petitioner due process when it terminated Petitioner's participation in Medicare after a May 6, 1994 resurvey of Petitioner without first affording Petitioner the opportunity to correct deficiencies that were identified at the resurvey. Pages 13 - 15.

4. HCFA proved, by the preponderance of the evidence, that Petitioner failed to comply with conditions of participation in the Medicare program. HCFA proved that Petitioner failed to comply with conditions:

   a. establishing the duties of the medical director of a hospice, contained in 42 C.F.R. § 418.54. Pages 21 - 25.

   b. requiring the creation and revision of a plan of care for each patient of a hospice, contained in 42 C.F.R. § 418.58. Pages 25 - 28.

   c. defining the duties of a hospice's interdisciplinary group, contained in 42 C.F.R. § 418.68. Pages 28 - 29.

5. HCFA was authorized to terminate Petitioner's participation in the Medicare program. Pages 29 - 30.

II. Discussion

A. Background

Petitioner is a hospice, operating in Utuado, Puerto Rico. A 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.[2]

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. 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 March 10, 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 complying with the requirements of the Medicare program.

On March 23, 1994, HCFA advised Petitioner that it had determined that Petitioner was not complying with Medicare conditions of participation. HCFA Ex. 15 at 1. HCFA advised Petitioner that it had determined that Petitioner was not complying with seven conditions governing Petitioner's participation in Medicare. Id. These conditions are found in the following regulations: 42 C.F.R. §§ 418.50 (general provisions); 418.54 (medical director); 418.58 (plan of care); 418.62 (informed consent); 418.80 (core services); 418.86 (physician

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[2] 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. Act, section 1861(dd)(3)(A).

services); and 418.92 (physical therapy, occupational therapy, and speech-language pathology).[3]

HCFA advised Petitioner that, based on the findings that Petitioner was not complying with conditions of participation in Medicare, HCFA intended to terminate Petitioner's participation as a provider of services in the Medicare program. However, HCFA invited Petitioner to submit a plan of correction to HCFA to correct the deficiencies that had been identified at the March 10 survey. HCFA Ex. 15 at 2. HCFA implied that, if Petitioner submitted a plan of correction which HCFA found to be acceptable, and the deficiencies were found to be corrected at a resurvey of Petitioner, then HCFA would not terminate Petitioner's participation in Medicare. Id.

On April 7, 1994, Petitioner submitted a plan of correction to HCFA. HCFA Ex. 16. On April 19, 1994, HCFA notified Petitioner that HCFA had found the plan not to be fully acceptable. HCFA Ex. 17. In this communication to Petitioner, HCFA advised Petitioner that it could submit a revised plan of correction within 10 days. Id. There is no evidence that Petitioner submitted a revised plan of correction to HCFA.

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[3] HCFA now asserts that, in its original notice to Petitioner, it advised Petitioner that it was not complying with eleven conditions of participation in Medicare. The additional conditions of participation which HCFA found Petitioner not to be complying with are found at 42 C.F.R. §§ 418.56 (professional management); 418.68 (interdisciplinary group); 418.74 (central clinical records); and 418.88 (counseling services). HCFA concedes that the March 23, 1994 notification to Petitioner did not mention these four additional conditions. However, the statement of deficiencies which was prepared after the March 10 survey, and which was transmitted to Petitioner along with the March 23, 1994 notice, did cite these additional conditions. HCFA Ex. 15 at 10 - 12, 19 - 30, 34 - 35. I make no findings in this decision as to whether the notice which HCFA sent to Petitioner on March 23, 1994 adequately notified Petitioner of the additional deficiencies found by HCFA. My reason for not doing so is that the findings made by HCFA based on the May 6, 1994 resurvey of Petitioner supersede those made at the initial survey of March 10, 1994.

On May 6, 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 Petitioner continued to be noncompliant with conditions of participation in Medicare. HCFA Exs. 18, 19. The conditions of participation which HCFA found Petitioner to continue to contravene are contained in regulations at 42 C.F.R. §§ 418.50 (general provisions); 418.54 (medical director); 418.58 (plan of care); and 418.68 (interdisciplinary group). On May 23, 1994, HCFA advised Petitioner of these findings, and advised it further that HCFA had affirmed its previous determination to terminate Petitioner's participation in the Medicare program. HCFA Ex. 19.

This case addresses the issue of whether HCFA was authorized to terminate Petitioner's participation in Medicare due to Petitioner's failure to comply with any of the four conditions of participation which HCFA found Petitioner not to be complying with, based on the May 6, 1994 resurvey of Petitioner.

Petitioner's alleged previous failure to comply with other conditions of participation is not at issue.[4]

B. The parties' arguments as to issues of law

This case involves issues of law concerning the interpretation and application of the Act and relevant regulations. I decided some of these same issues in Arecibo Medical Hospice Care, DAB CR363 (1995) and in

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[4] This case does not involve the issue of whether, at the resurvey of Petitioner, HCFA would be required to evaluate Petitioner's compliance based on what Petitioner had promised in its plan of correction. That is so because HCFA never accepted the plan of correction. However, had HCFA accepted the plan of correction, then I would have had to decide whether the terms of the plan became the operative criteria for assessing whether Petitioner was complying with the conditions of participation addressed in the plan. And, had I found that the terms of the plan became the operative criteria, then I would have had to evaluate the evidence in this case on the basis of whether it proved that Petitioner was not complying with the terms of the plan of correction.

Hospicio en el Hogar de Lajas, DAB CR366 (1995).[5] As to those issues, I reach the same conclusions here as I did in Arecibo and Lajas.

1. Burden of persuasion

a. Allocation to HCFA of the burden of persuasion

In Arecibo and Lajas, I held that HCFA had the burdens of coming forward with evidence and proving, by the preponderance of the evidence, that its determination to terminate the providers' participation in Medicare was justified.[6] Arecibo at 8 - 13; Lajas at 6 - 8. I conclude the same here. I do not agree with HCFA's argument that the burden of persuasion should be allocated to Petitioner.

Neither the Act nor regulations governing hearings in provider termination cases specifically allocate the burden of persuasion to a particular party. Act, sections 205(b), 1866(b)(2)(A), (h)(1); 42 C.F.R. Part 498; Lajas at 6. However, the Secretary has given administrative law judges broad authority to manage the presentation and receipt of evidence in hearings concerning whether terminations of participation are justified. 42 C.F.R. § 498.60(b)(3). From this, I conclude, as I did in Arecibo and Lajas, that administrative law judges who preside over hearings concerning the propriety of terminations of participation in Medicare have discretion to allocate the burden of persuasion consistent with the requirements of due process.

It is both consistent with the requirements of due process and efficient to allocate to HCFA the burdens of coming forward and proving, by a preponderance of the

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[5] As in this case, Arecibo and Lajas involved the propriety of terminations by HCFA of hospices' participation in the Medicare program. The same attorney represented the petitioners in Arecibo, Lajas, and the present case. The briefs which HCFA and the petitioners submitted in Arecibo, Lajas, and this case make the same arguments as to the legal issues which are common to the three cases.

[6] In this decision, I use the term "burden of persuasion" to refer collectively to the burdens of coming forward with evidence of a fact and of proving that fact by a preponderance of the evidence.

evidence, that Petitioner failed to comply with conditions of participation in Medicare. As I held in Arecibo and Lajas, in a termination case, HCFA will have obtained from a survey of the provider the facts which HCFA believes justify the determination that the provider is not complying with conditions of participation. HCFA is thus in the best position to identify the facts which support its determination and to prove those facts.

Allocating the burden of persuasion to the provider would be neither fair nor efficient. The provider would be placed in the position of having to prove a negative proposition -- that it did not fail to comply with conditions of participation -- without knowing what or how much evidence might be necessary to establish that proposition. Allocating the burden of persuasion to the provider would invite a massive and unfocused submission of evidence from the provider.

HCFA advances two arguments to support its assertion that the burden of persuasion should be allocated to Petitioner. HCFA's first argument is that the administrative hearing is essentially an appellate review of the interpretations of law and the findings of fact of the State agency surveyors who performed the survey on which HCFA bases its determination to terminate a provider's participation.

HCFA asserts that the surveyors must be deferred to because they have professional expertise. HCFA posthearing memorandum at 25 - 28. HCFA argues that, given the professional expertise of the surveyors, their interpretations of regulations and their fact findings and opinions are presumptively correct and must be accorded "immense weight." Id. at 28. Based on this analysis, HCFA argues that a provider who challenges a surveyor's interpretation of a regulation, or who challenges a surveyor's findings of fact, must prove that the surveyor's interpretation or findings are "clearly erroneous" in order to prevail. Id. HCFA asserts, alternatively, that findings made by surveyors must be sustained if they are supported by "substantial evidence." Id. at 8.

This analysis mischaracterizes the purpose of the administrative hearing guaranteed to providers by Congress. It mischaracterizes also the role of the State agency surveyors in conducting inspections on behalf of HCFA. HCFA's characterization of the hearing as an appellate review of interpretations and findings made by surveyors ignores the fact that Congress directed that providers whose participation in Medicare is terminated

by HCFA be afforded de novo hearings. Congress directed that the provider whose participation in Medicare is terminated under the authority of section 1866(b) of the Act be afforded a right to a hearing to the same extent as that which is offered to claimants for Social Security benefits under section 205(b) of the Act. Act, section 1866(h)(1). Section 205(b) has been interpreted uniformly and often as conferring a right to a de novo hearing.

The purpose of an administrative hearing in a case involving a determination by HCFA to terminate a provider's participation under the authority of section 1866(b) of the Act is to decide whether the applicable law and the evidence establish a basis for termination. In a de novo hearing, no presumption of correctness attaches to HCFA's determination. The administrative law judge must evaluate the law and evidence independently.

The regulations which govern surveys of providers by State agency surveyors provide that surveyors are "professionals who use their judgment, in concert with Federal forms and procedures, to determine compliance . . . ." 42 C.F.R. § 488.26(a)(3). The regulations affirm that surveyors are supposed to have expertise in the activities of the providers which they survey, as well as knowledge of applicable law and regulations. Surveyors are expected to use their expertise in conducting surveys and in evaluating the facts that they uncover at surveys.

In a hearing concerning the results of a survey, a surveyor may qualify as an expert witness.[7] His or her opinion as to the meaning of facts may be instructive, particularly as to the effect that failure by a provider to comply with Medicare participation requirements may have on that provider's ability to provide care to patients consistent with the requirements of the Act and regulations. The credible opinion of a surveyor as to an issue of fact may be dispositive if not rebutted by evidence offered by the provider.

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[7] I do not read the regulation as qualifying all surveyors as expert witnesses. The regulation establishes the criteria for surveyors' performance. In a hearing concerning a survey, HCFA may qualify a surveyor to be an expert witness. A provider may challenge a surveyor's qualifications to testify as an expert witness. HCFA bears the burden of proving that any purported expert has the qualifications to testify as an expert witness.

But the fact that surveyors may qualify as expert witnesses does not suggest that they have been vested with the authority to interpret the law on behalf of the Secretary. Neither does it suggest that their opinions are entitled to a presumption of correctness. There is nothing in the Act or in regulations that vests State agency surveyors with authority to interpret law or which requires their opinions to be afforded special weight.

HCFA's second argument is that a provider whose participation in Medicare has been terminated by HCFA should be regarded as an applicant for relief, benefits, or a privilege. HCFA couples this characterization of providers with the general principle of administrative law that, in administrative hearings, the burden of persuasion is on the applicant, to argue that the burden of persuasion falls on Petitioner.

HCFA made the identical argument in Arecibo and Lajas. I found it to be unpersuasive in both cases. Arecibo at 11 - 13; Lajas at 7 - 8. It is not reasonable to characterize a provider as an "applicant" who seeks relief, benefits, or a privilege from HCFA. It is a much more accurate characterization to view the provider as having a quasi-contractual relationship with Medicare that HCFA intends to terminate. In a case involving a determination to terminate a provider's participation in Medicare, the provider has already received a privilege from HCFA which HCFA has determined to extinguish. That provider's ongoing business activities -- and, in some cases, its very existence -- will be ended as a consequence of HCFA's termination of the provider's participation in Medicare.

A provider does not have an unqualified right to retain its provider status. A provider's relationship with HCFA and the Medicare program is governed by the Act, regulations, and the provider agreement. HCFA may terminate a provider's participation in Medicare when the provider has not complied substantially with the requirements of participation.

In Arecibo and Lajas, I discussed the authorities which HCFA relies on to support its characterization of Petitioner as an "applicant." Arecibo at 10 - 13; Lajas at 8. I concluded that those authorities were not persuasive. The text on administrative law and the judicial decisions cited by HCFA to support its argument restate the general principle that, in an administrative hearing, the burden of persuasion should be allocated to the applicant. I am not questioning those authorities.

However, for the reasons I have explained above, it is not reasonable to characterize Petitioner as an "applicant."

HCFA relies also on a decision by the Appeals Council of the Social Security Administration Office of Hearings and Appeals, Jefferson Memorial Hosp. Ass'n v. Health Care Financing Administration, Docket No. PS-109, at 17 (1983), to support its argument that the burden of persuasion should be allocated to Petitioner. As I explained in Arecibo, I do not find that decision to be persuasive authority to allocate the burden of persuasion to Petitioner. Indeed, it may be read to support my conclusion that the burden of persuasion should be allocated to HCFA. Arecibo at 12 - 13.

b. The elements of HCFA's burden of persuasion

HCFA's burden of persuasion in a case involving a determination to terminate a provider's participation in Medicare consists of three elements. The three elements are: (1) the existence of participation requirements which Petitioner allegedly has not complied with; (2) the facts which establish that Petitioner has failed to comply with a Medicare participation requirement; and (3) that Petitioner's failure to comply with participation requirements is so substantial as to justify terminating Petitioner's participation in Medicare.

First, HCFA must prove the existence of the participation requirements which it alleges that Petitioner has not complied with. Participation requirements are stated both in the Act and in implementing regulations. For example, 42 C.F.R. Part 418 contains numerous regulations which express both conditions and standards of participation for a hospice.

If HCFA is relying on the plain language of a section of the Act or a regulation, it need only identify that language in order to meet this first element of its burden of persuasion. For example, in Arecibo and Lajas, HCFA asserted that the providers failed to comply with the plain language of 42 C.F.R. § 418.58(b), a section which governs the way in which hospices are required to review patient plans of care and to document their reviews. Arecibo at 19 - 22; Lajas at 17 - 18.

HCFA assumes additional burdens when it relies on an interpretation of law that is not apparent from the plain meaning of the law. In that event, HCFA must prove that

its interpretation is reasonable and that the provider had notice of that interpretation.

In both Arecibo and Lajas, I held that the Secretary delegated authority to HCFA to interpret reasonably the criteria which governed the participation of providers. Arecibo at 22; Lajas at 12 - 13. There may be ambiguities in some regulations which are susceptible to reasonable interpretation by HCFA. However, the authority to interpret regulations does not translate into authority to write requirements into regulations which are not reasonably described by the language of those regulations. HCFA does not have the authority to use the vehicle of interpretation to create participation requirements which exceed the specific requirements of the Act or regulations. Nor does HCFA have authority to interpret ambiguous language in a way that is not reasonable.

HCFA has the duty to communicate its reasonable interpretations of the Act or regulations to providers as a prerequisite to holding providers accountable for complying with those interpretations. In Arecibo and Lajas, I held that HCFA could not hold the providers responsible for complying with an interpretation of a regulation which was not apparent from the face of the regulation and which HCFA had not communicated to the providers. Arecibo at 25; Lajas at 13.

HCFA argues that providers have a duty to comply with applicable participation requirements. HCFA asserts that this duty extends to complying with HCFA's interpretations of law even if HCFA does not communicate these interpretations to providers. I do not disagree with HCFA that providers are obligated to comply with HCFA's interpretations of the law, where HCFA interprets the law reasonably, and where HCFA puts providers on notice of its interpretations. However, providers are not obligated to divine HCFA's interpretation of a law where the interpretation, albeit reasonable, is not apparent from the face of the law, and where HCFA has not communicated the interpretation to providers.

HCFA asserts that I have held previously that providers have the duty to comply with HCFA's interpretations, citing my decision in Long Medical Laboratory, DAB CR334, at 11 - 12 (1994). In the Long Medical Laboratory case, I held that the provider had a duty to comply with an unambiguous and explicit requirement of the Act. Where a requirement stated in the Act or in a regulation is explicit, HCFA has no obligation to communicate the requirement to a provider as a prerequisite to holding

the provider accountable to it. But, the Long Medical Laboratory decision did not hold that HCFA may hold a provider accountable to an interpretation of law which is not apparent from the plain meaning of the enactment, without first communicating that interpretation to the provider.

The second element of HCFA's burden of persuasion is to prove the facts which establish that a provider has failed to comply with a Medicare participation requirement. The evidence which proves these facts may consist of the testimony of surveyors as to the findings that they made when they surveyed the provider. It may consist also of supporting materials, such as patient records, obtained by the surveyors from the provider.

HCFA must establish contested facts by a simple preponderance of the evidence. In other words, the weight of the evidence offered by HCFA must be sufficient to establish a prima facie case and to overcome any rebuttal evidence offered by the provider.

Finally, HCFA must prove, again by a preponderance of the evidence, that a provider's failure to comply with participation requirements is so substantial as to justify terminating the provider's participation in Medicare. The Act authorizes the Secretary to terminate a provider's participation in Medicare where the provider fails to comply substantially with the provisions of the provider participation agreement, the Act, and implementing regulations, or with a mandated corrective action plan. Act, section 1866(b)(2)(A). The Secretary has delegated this authority to HCFA. 42 C.F.R. § 489.53(a)(1), (3).

The Act does not define what is meant by failure to comply substantially. Regulations establish a test for substantial noncompliance by stating that a provider will be found to have failed to comply with conditions of participation in Medicare where its deficiencies are of such character as to substantially limit its capacity to render adequate care or where they adversely affect the health and safety of patients. 42 C.F.R. § 488.24(a). Thus, in order to prove a basis to terminate a provider's participation in Medicare, HCFA must prove that the provider's deficiencies are substantial within the meaning of 42 C.F.R. § 488.24(a).

Termination of participation is a remedy to protect against possible future failures of performance by a provider, and not a punishment for past wrongs. In any case in which HCFA seeks to justify terminating a

provider's participation in Medicare, the ultimate question is whether the deficiencies established by HCFA predict a likelihood that the provider will not be able to deliver care in the future consistent with the requirements of the Act and regulations. The Act and regulations make it plain, however, that an inference may be drawn from substantial failure by a provider to comply with participation requirements that the provider is likely to remain deficient.

There are circumstances where the impact of a provider's deficiency on that provider's capacity to provide care or on the health and safety of patients is evident from the deficiency itself. For example, in Arecibo and Lajas, I held that the providers' failure to schedule reviews of patient plans of care or to document reviews of those plans constituted failure to comply with a basic requirement of hospice operations, that being the need to plan the care provided to patients and to monitor and evaluate the effects of the care that the patients were receiving from the hospice and its personnel. Arecibo at 26; Lajas at 19 - 20. The providers' failure to plan care was on its face a failure to comply with a fundamental prerequisite for participation in the Medicare program. It was apparent from the failure of the providers to plan their patients' care that they were not capable of providing care consistent with the requirements of the Act and regulations.

There may be circumstances where the impact of a deficiency on a provider's ability to provide care or on the health and safety of patients is not apparent from the facts establishing the existence of the deficiency. A finding that a provider has violated a condition of participation does not necessarily flow automatically from a finding that the provider has not complied with a Medicare participation requirement. See Lajas at 19. Moreover, evidence of isolated examples of deficiencies in providing care may not be sufficient to establish an overall failure by the provider to provide care consistent with the requirements of the Act or regulations.

Thus, in some cases, HCFA may have to prove not only the existence of a deficiency, but may have to offer additional evidence to prove that the deficiency is substantial within the meaning of 42 C.F.R. § 488.24(a) and the Act. That evidence may consist of evidence which proves the impact of the deficiency on the provider's ability to provide care or on the health and safety of patients. In proving impact, expert opinion as to the

likely impact of the deficiency on the capacity of the provider to provide care may be important.

2. Alleged denial of due process to Petitioner

Petitioner asserts that HCFA denied Petitioner the opportunity to comply with Medicare participation requirements, in violation of the requirements of 42 C.F.R. § 488.28. Petitioner posthearing brief at 7 - 9. This alleged failure by HCFA, according to Petitioner, denied Petitioner due process. Id. The providers in Arecibo and Lajas made the same argument. Arecibo at 5 - 8; Lajas at 8 - 10. In both of those cases, I found the argument to be unpersuasive. Id. I find the argument to be unpersuasive in this case as well.

Petitioner bases its argument on its contention that, at the May 6, 1994 resurvey, the surveyors found Petitioner to be out of compliance with a standard contained in a regulation which the surveyors who conducted the March 10, 1994 survey had not cited as a basis for their conclusion that Petitioner was deficient.[8] According to Petitioner, the fact that it was found to be deficient with respect to a standard not cited previously, gave it the right to submit a new plan of correction to HCFA to address that deficiency and all other deficiencies that were identified at the May 6, 1994 resurvey.

The regulation that Petitioner relies on to support its argument is 42 C.F.R. § 488.28. This regulation provides that, where HCFA determines that a provider is not complying with a standard of participation established in a regulation, it will give that provider an opportunity to submit a plan of correction explaining how the provider will correct the deficiency.

The regulations which govern a provider's participation in Medicare as a hospice state broad conditions of participation in the Medicare program. 42 C.F.R. Part 418. For each of the conditions, the regulations state specific performance criteria as subparts. These performance criteria are the standards which are referred to in 42 C.F.R. § 488.28. In surveying a provider for compliance with Medicare participation requirements, HCFA may determine that a provider is not complying with one

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[8] The standard is set forth at 42 C.F.R. § 418.58(b) and is part of the condition governing plans of care that hospices create and maintain for their patients.

or more standards of participation, without concluding that the provider's failure to comply is so substantial as to constitute a failure to comply with a condition of participation. In that event, HCFA is obligated, under 42 C.F.R. § 488.28, to give the provider an opportunity to correct the deficiency. But, where HCFA determines that a failure by a provider to comply with a standard or standards is so substantial as to constitute a failure to comply with an overall condition of participation, HCFA is not obligated to give that provider the opportunity to correct the deficiency.

HCFA was not required by 42 C.F.R. § 418.28 to give Petitioner an opportunity to correct the deficiencies that were identified at the May 6, 1994 resurvey. It is true, as Petitioner asserts, that the surveyors who resurveyed Petitioner on May 6, 1994 found that Petitioner failed to comply with standards of participation, including a standard which was not cited in the report of deficiencies generated after the initial survey on March 10, 1994. However, the surveyors, and HCFA, concluded that Petitioner's failure to comply with these standards was so substantial as to constitute a failure to comply with conditions of participation.

C. Analysis of the parties' arguments and contentions concerning Petitioner's compliance with conditions of participation for hospices

HCFA asserts that, as of the May 6, 1994 resurvey of Petitioner, Petitioner was not complying with four conditions of participation in Medicare. These conditions are stated in 42 C.F.R. §§ 418.50, 418.54, 418.58, and 418.68. I analyze HCFA's and Petitioner's arguments and the evidence offered by the parties relevant to each of these four conditions of participation pursuant to the elements of HCFA's burden of persuasion that I have described at Part II.B.1.b. of this decision.

1. Petitioner's alleged failure to comply with the general provisions condition of participation stated in 42 C.F.R. § 418.50

HCFA makes two arguments concerning Petitioner's alleged failure to comply with the requirements of 42 C.F.R. § 418.50. First, HCFA asserts that the regulation states, as a condition of participation in the hospice program, that hospices comply with conditions stated elsewhere in 42 C.F.R. Part 418. HCFA avers that Petitioner failed to comply with this asserted condition of participation because it failed to comply with conditions of

participation stated elsewhere. Second, HCFA asserts that the regulation may be read, along with other regulations, to establish as a condition of participation that hospices provide laboratory services to their patients. HCFA avers that Petitioner failed to comply with this asserted condition because Petitioner did not provide laboratory services to a patient.

I do not find that Petitioner failed to comply with the requirements of 42 C.F.R. § 418.50. Moreover, even if Petitioner may have failed technically to comply with the requirements of this regulation, the evidence does not establish the deficiency to be so substantial as to prove that Petitioner failed to comply with a condition of participation in Medicare.

I do not agree with HCFA's assertion that 42 C.F.R. § 418.50 recites a condition of participation in Medicare that hospices comply with conditions of participation stated elsewhere in the regulations. This assertion relies on the language of 42 C.F.R. § 418.50(a). That subsection states, as a standard of participation, and not as a condition of participation, that "[a] hospice must maintain compliance with the conditions of this subpart and subparts D and E of . . . [42 C.F.R. Part 418]."

Contrary to HCFA's argument, 42 C.F.R. § 418.50(a) does not say that a failure by a hospice to comply with any condition of participation in 42 C.F.R. Part 418 shall also be a failure to comply with the condition of participation stated in 42 C.F.R. § 418.50. It states, at most, that a failure to comply with a condition of participation stated elsewhere in the regulations may be construed to constitute a failure to comply with one of the standards contained in 42 C.F.R. § 418.50. HCFA has offered no evidence to establish how a failure by a hospice to comply with this standard, based on its failure to comply with a condition stated elsewhere, would satisfy the test for a condition-level deficiency contained in 42 C.F.R. § 488.24.

More important, I am not persuaded by HCFA's argument because it would lead to a result which is unnecessary and which the Secretary did not intend. HCFA's argument is an attempt to turn every failure by a hospice to meet a condition of participation into a failure by that hospice to meet two conditions of participation. I considered this argument in Lajas, and concluded there, as I do here, that the Secretary did not intend that a hospice's failure to comply with a condition of participation should be construed automatically to

constitute a failure to comply with two conditions of participation. Lajas at 20 - 21.

A finding that a hospice manifests a condition-level deficiency justifies termination of that hospice's participation in Medicare. The finding that a hospice has failed to comply with a condition of participation is a finding that the hospice cannot deliver care consistent with the requirements of the Act and regulations or that it is jeopardizing the health and safety of its patients. It is wholly unnecessary to make a condition-level deficiency appear more egregious than it actually is by tacking on automatically to each finding of a condition-level deficiency a finding of a second condition-level deficiency.

HCFA bases its second argument that Petitioner failed to comply with the condition of participation stated in 42 C.F.R. § 418.50 on the findings of the surveyor who performed the May 6, 1994 resurvey and its assertion that the participation requirements for hospices required Petitioner to provide laboratory services to its patients. In this instance, the facts are not contested. However, HCFA's assertion that the conditions for participation of hospices in Medicare include a requirement that hospices provide laboratory services to their patients is not supported either by the plain meaning of the regulations or by a reasonable interpretation of those regulations. Moreover, even if I were to find that this asserted obligation is implied in the regulations, there is no evidence in this case that HCFA ever communicated it to Petitioner.

At the May 6, 1994 resurvey of Petitioner, HCFA's surveyor selected at random 10 patient records for review. These records included the patient records of an individual known for purposes of this case as patient # 2. HCFA Ex. 21. The records of patient # 2 establish that, on March 18, 1994, a physician ordered that a blood test be administered to the patient. Id. at 3 - 4. The nurse who performed the test gave the specimen to the patient's family. She instructed the family to take the specimen to a laboratory, and to provide the hospice with the test results that the laboratory reported. Tr. at 86. The surveyor who conducted the May 6, 1994 resurvey learned from Petitioner's staff that, as of the date that the blood test was performed on patient # 2, Petitioner did not have an agreement with a laboratory to provide laboratory services for Petitioner's patients. Id. at 86 - 87.

HCFA argues that hospice participation requirements include the requirement that hospices provide laboratory services to their patients. HCFA argues that Petitioner's failure either to provide laboratory services on its own, or to have an agreement with a laboratory to provide such services, is a failure to comply with this requirement. HCFA asserts that the alleged requirement that hospices provide laboratory services to their patients is either stated or implied in the regulations which govern hospices and is incorporated by reference into 42 C.F.R. § 418.50(b)(2) and (3), either as an "other covered service," as a "reasonable and necessary service," or as a service that is consistent with "accepted standards of practice."

The general provisions regulation states, at 42 C.F.R. § 418.50(b), that a hospice must be primarily engaged in providing the care and services described at 42 C.F.R. § 418.202. Additionally, it states that a hospice must:

> (1) [m]ake nursing services, physician services, and drugs and biologicals routinely available on a 24-hour basis;
>
> (2) [m]ake all other covered services available on a 24-hour basis to the extent necessary to meet the needs of individuals for care that is reasonable and necessary for the palliation and management of terminal illness and related conditions; and
>
> (3) [p]rovide these services in a manner consistent with accepted standards of practice.

42 C.F.R. § 418.50(b)(1) - (3).

Laboratory services are not among the services listed in 42 C.F.R. § 418.202. HCFA argues that the obligation to provide laboratory services may be found in 42 C.F.R. § 418.92(b). From this, HCFA asserts that laboratory services are among the "other covered services" described in 42 C.F.R. § 418.50(b)(2) that hospices are obligated to provide to their patients.

HCFA argues also that laboratory services are "reasonable and necessary for the palliation and management of terminal illness and related conditions." From this, HCFA asserts that the obligation of a hospice to provide laboratory services to its patients is implied in 42 C.F.R. § 418.50(b)(2).

Finally, HCFA asserts that "accepted standards of practice" for hospices includes providing laboratory services. HCFA asserts that the requirement that a hospice provide laboratory services to its patients is therefore implied by 42 C.F.R. § 418.50(b)(3).

None of these arguments relate reasonably to the language of the regulations. For that reason, I find them to be without merit.

Neither the Act nor regulations support HCFA's contention that the "other covered services" that a hospice must provide include laboratory services. There is no explicit requirement in the Act or in the regulations that hospices provide laboratory services to their patients. As HCFA concedes, the Act says nothing about an obligation to provide laboratory services. Furthermore, there is not even an implied obligation in the regulations for a hospice to provide laboratory services to its patients.

First, I do not read 42 C.F.R. § 418.50 as requiring hospices to provide services to their patients beyond those that are listed as "covered services" in 42 C.F.R. § 418.202. The covered services described in 42 C.F.R. § 418.202 are a complete list of services that a participating hospice is required to provide to its patients and to members of patients' families. The phrase "other covered services" in 42 C.F.R. § 418.50(b)(2) does not refer to services in addition to those which are described in 42 C.F.R. § 418.202. It refers only to the manner in which a hospice must provide those services which are described in 42 C.F.R. § 418.202 and which are not enumerated in 42 C.F.R. § 418.50(b)(1). Thus, "other covered services" means services not listed in 42 C.F.R. § 418.50(b)(1) that are listed in 42 C.F.R. § 418.202.

Moreover, even if 42 C.F.R. § 418.202 did not comprise a complete list of the services that hospices are obligated to provide, there is no requirement stated elsewhere in the regulations that hospices provide laboratory services. The regulation which HCFA relies on as allegedly directing hospices to provide laboratory services as other covered services, 42 C.F.R. § 418.92, cannot be construed reasonably to require hospices to provide laboratory services.

That regulation governs only the manner in which a hospice must provide laboratory services <u>if</u> it chooses to provide them. It contains two relevant subparts. 42 C.F.R. § 418.92(b)(1) states that:

> [i]f the hospice engages in laboratory testing outside of the context of assisting an individual in self-administering a test . . ., such testing must be in compliance with all applicable requirements of part 493 of this chapter.

The other relevant subpart, 42 C.F.R. § 418.92(b)(2), states that:

> [i]f the hospice chooses to refer specimens for laboratory testing to another laboratory, the referral laboratory must be certified . . . in accordance with the applicable requirements of part 493 of this chapter.

Neither of these subparts require a hospice to provide laboratory services. They may be read reasonably only to impose requirements on hospices to assure that tests are performed consistent with the requirements of 42 C.F.R. Part 493, to the extent that hospices elect to perform the tests or to refer them elsewhere.

I make no finding as to whether HCFA is correct in its assertion that laboratory services are reasonable and necessary for the palliation and management of terminal illnesses and related illnesses. I do not, because such services are not covered services. It may be reasonable or even good medical practice for hospices to provide laboratory services to patients. However, the issue is not whether hospices ought to provide laboratory services but whether, under the regulations governing their participation in Medicare, they are required to provide such services.

HCFA reads 42 C.F.R. § 418.50(b)(3) as requiring hospices to provide to their patients all services that are generally accepted by the hospice community as being within that community's standards of practice. That is not what the regulation requires. The term "these services" in 42 C.F.R. § 418.50(b)(3) can be construed reasonably to mean only those services described elsewhere in the regulations which govern hospices as covered services that hospices are obligated to provide to their patients. The subsection requires that covered services be provided in a manner that is consistent with accepted standards of practice. It does not impose on hospices any obligation to provide services in addition to those services described elsewhere in the regulations as covered services. For the reasons which I discuss above, laboratory services are not covered services.

I would not find Petitioner to have failed to comply with a requirement that it provide laboratory services to its patients even if I were to conclude, as HCFA urges, that the requirement is implied in the regulations. It would not be reasonable to find that a hospice should infer from the regulations that it is required to provide laboratory services. The regulations do not mention this requirement. HCFA has offered no evidence to show that it ever communicated to Petitioner its conclusion that the regulations contain an implied requirement that hospices provide laboratory services.

2. Petitioner's alleged failure to comply with the medical director condition of participation stated in 42 C.F.R. § 418.54

HCFA argues that Petitioner failed to comply with the condition of participation stated in 42 C.F.R. § 418.54. This regulation describes the duties of a hospice's medical director. It states that:

> [t]he medical director must be a hospice employee who is a doctor of medicine or osteopathy who assumes overall responsibility for the medical component of the hospice's patient care program.

The regulation does not define the terms "overall responsibility" or "medical component." However, these terms are not ambiguous. The plain meaning of this regulation is that the medical director of a hospice must assume supervisory and management responsibility for the medical services that the hospice provides to its patients.

HCFA asserts that Petitioner failed to comply with the requirements of this regulation in two respects. First, HCFA argues that Petitioner's medical director failed to discharge his responsibility to assure that Petitioner's interdisciplinary group participated in the planning of patient care as is required under the regulations. Second, HCFA asserts that Petitioner's medical director failed to assure that Petitioner obtain properly executed certifications of terminal illness for its patients.

Petitioner did not comply with the medical director requirement in 42 C.F.R. § 418.54. Petitioner's medical director was obligated, as part of the responsibility to manage the medical component of Petitioner's operations, to assure that Petitioner's interdisciplinary group participated in the planning of patient care as is required by the regulations. Petitioner's medical

director bore responsibility for assuring that Petitioner obtained a properly executed certification of terminal illness for each of Petitioner's patients. The preponderance of the evidence establishes that Petitioner's medical director failed to perform these obligations.

HCFA bases its arguments on the following evidence.

- The surveyor who conducted the May 6, 1994 resurvey of Petitioner testified that in none of the 10 treatment records that she reviewed was there evidence that Petitioner's interdisciplinary group periodically reviewed the patient's plan of care according to a schedule established in the plan of care. Tr. at 98 - 99.

- The surveyor testified also that in none of the patient records she reviewed was there evidence that Petitioner had obtained certifications that the patients were eligible for continued hospice care after their initial period of care. Id. at 98.

I find this evidence to be persuasive.

Petitioner did not rebut credibly HCFA's evidence as to failure of Petitioner's interdisciplinary group to perform regularly scheduled reviews of plans of care. Petitioner offered the testimony of Dr. Dimas Broco Hernandez, Petitioner's medical director. Tr. at 218 - 22. Dr. Broco Hernandez testified that Petitioner's interdisciplinary group would meet weekly to discuss patients' cases. Tr. 219 - 20. Dr. Broco Hernandez asserted that the hospice staff was supposed to have made a written record of the weekly meetings. However, Petitioner did not offer any written evidence of such alleged weekly reviews to corroborate Dr. Broco Hernandez' testimony. Moreover, Petitioner did not offer any documents from the records of the 10 patients reviewed by the surveyor to impeach her testimony.

It is apparent from the scheme of hospice operations envisioned by the regulations that a hospice's medical director bears responsibility for assuring that the hospice's interdisciplinary group discharge its functions properly. While the regulations do not charge the medical director explicitly with supervising the activities of the interdisciplinary group, the regulations do require the medical director to supervise the entire medical component of hospice operations. 42

C.F.R. § 418.54. This responsibility includes supervision of the activities of the interdisciplinary group, inasmuch as the interdisciplinary group is central to the medical component of a hospice's services.

The planning and management of patient care through the development and revision of plans of care is an essential element of the medical component of hospice operations. 42 C.F.R. § 418.58. A hospice's interdisciplinary group plays a critical role in the planning of care to be administered by a hospice to its patients. The interdisciplinary group bears direct responsibility, along with the medical director of the hospice, for creation of and review of plans of care. Id.; 42 C.F.R. § 418.68. The interdisciplinary group is thus a central player in the administration of the medical component of a hospice's operations. It is the explicit duty of the medical director to participate in the establishment of and review of plans of care. 42 C.F.R. § 418.58(a), (b).[9]

I conclude also that Petitioner's medical director was responsible for assuring that Petitioner obtain properly executed certifications of terminal illness for each of Petitioner's patients. The preponderance of the evidence in this case is that Petitioner failed systematically to obtain properly executed certifications for its patients. The systematic failure to obtain properly executed certifications is a failure to perform the supervisory responsibilities described in 42 C.F.R. § 418.54.

A hospice's medical director bears responsibility for supervising the certification of patients to receive hospice care. Consistent with requirements in the Act, the regulations which govern hospices require that patients who receive care from hospices be certified as having a terminal illness. 42 C.F.R. §§ 418.20, 418.22. The regulations make it the responsibility of the hospice to obtain these certifications. 42 C.F.R. § 418.22. Certifications must be obtained at intervals specified in

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[9] This regulation provides that plans of care must be established and reviewed by, among others, the medical director or "physician designee." The regulation does not define of whom a "physician designee" consists. Apparently, however, the physician designee would be an individual who is designated by the hospice to serve in lieu of the medical director in establishing and reviewing plans of care. Petitioner has not argued that it appointed a physician designee to serve in lieu of its medical director.

the regulations. 42 C.F.R. §§ 418.21, 418.22(a). Each certification of terminal illness must specify that the patient's prognosis is for a life expectancy of six months or less if the patient's illness runs its normal course. 42 C.F.R. § 418.22(b).

The regulations specify that initial and subsequent certifications of a patient's terminal illness must be signed by the hospice's medical director or by a member of the interdisciplinary group. 42 C.F.R. § 418.22(c)(1)(i), (2).

This requirement makes it plain that certification of patients as being eligible to receive hospice care is a part of the medical component of hospice operations, even as is the administration of care to hospice patients. A hospice's medical director is responsible for assuring that certifications are made in compliance with the Act and regulations as part of his or her responsibility for supervising the medical component of hospice operations.

Petitioner argues that failure by a hospice to obtain properly executed certifications of eligibility for hospice care for its patients relates only to the question of whether the hospice should receive reimbursement from Medicare for its services. Petitioner asserts that there is no requirement in the conditions of participation that a hospice obtain properly executed certifications of eligibility. Therefore, according to Petitioner, it cannot be held accountable under the medical director condition of participation for failure to obtain properly executed certifications.

I do not agree with this argument. It is true, as Petitioner asserts, that the regulations governing patient certifications are in a different subpart of 42 C.F.R. Part 418 than are the conditions of participation. The certification regulations are in Subpart B of Part 418, whereas the conditions of participation are in Subparts C, D, and E of Part 418. However, that does not suggest that certifications are outside of the medical component of hospice operations. I conclude that obtaining certifications of terminal illness for patients is a part of the medical component of a hospice's operations. The certification is based on a medical diagnosis. It is the document which authorizes a hospice to assume responsibility for a patient's care and to provide palliative, as opposed to curative, care.

The regulations do not state, as a condition of participation, that hospices obtain properly executed certifications. However, inasmuch as certifications fall

within the medical component of hospice operations, the regulations must be read as requiring that a hospice medical director assure that properly executed certifications be obtained.

There remains the question of the impact of the failure of Petitioner's medical director to discharge the supervisory responsibilities required by the regulation. I conclude that the failures in this case are so substantial as to establish a failure to comply with the condition of participation described in 42 C.F.R. § 418.54.

The requirement that a hospice's interdisciplinary group actively participate in the planning of patients' care is a central element in the scheme of operations to which the regulations require hospices to adhere. It is manifest from the regulations that a hospice cannot provide care adequately to its patients unless its interdisciplinary group assumes the required role in planning and monitoring patient care. So also is it evident from the regulations that a hospice cannot provide care adequately to its patients unless it assures that these patients are indeed terminally ill. The purpose of hospice care is palliative. The providing of palliative care to a patient on the assumption that the patient is terminally ill, without the requisite certification of terminal illness, may jeopardize that patient's health and safety, because if the patient is not, in fact, terminally ill, he or she may require more aggressive medical treatment than the hospice is in a position to provide.

3. Petitioner's alleged failure to comply with the plan of care condition stated in 42 C.F.R. § 418.58

HCFA argues that Petitioner failed to comply with the condition stated in 42 C.F.R. § 418.58. This regulation governs the plans of care that hospices are obligated to create and review for each of their patients.[10] The regulation requires a hospice to establish and maintain a written plan of care for each of its patients. It requires also that care provided to each hospice patient must be in accordance with a plan of care.

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[10] The central issue in the Arecibo and Lajas cases was whether the providers in those cases complied with the plan of care regulation. I discussed the requirements of the plan of care regulation in both cases. Arecibo at 13 - 16, 19 - 25; Lajas at 16 - 19.

The regulation contains three subparts which enunciate standards that a hospice must adhere to in establishing and reviewing its plans of care. For each patient, a plan of care must be established by the patient's attending physician, the hospice's medical director or physician designee, and the hospice's interdisciplinary group, prior to providing care to that patient. 42 C.F.R. § 418.58(a). Each plan of care must be reviewed and updated at intervals specified in the plan by the patient's attending physician, the hospice's medical director or physician designee, and the hospice's interdisciplinary group. 42 C.F.R. § 418.58(b). All reviews must be documented. Id. Each plan of care must include an assessment of the patient's needs and must identify the services to be provided to the patient, including the management of discomfort and symptom relief. 42 C.F.R. § 418.58(c). Each plan of care must state in detail the scope and frequency of services needed to meet the patient's needs, as well as those of the patient's family. Id.

HCFA's central assertion concerning Petitioner's alleged noncompliance with the plan of care regulation is that Petitioner's interdisciplinary group failed to conduct the reviews mandated under 42 C.F.R. § 418.58(b). HCFA asserts also that, in one instance, Petitioner failed to meet the needs of a patient's family as is required under 42 C.F.R. § 418.58(c).

The evidence which HCFA relies on to support these assertions consists of excerpts of the medical records of four patients (patients # 2, # 5, # 6, and # 7), as well as the testimony of the surveyor who conducted the May 6, 1994 resurvey of Petitioner. The evidence establishes that, for all of these patients, extensive periods of time elapsed without documented reviews of the patient's plan of care by Petitioner's interdisciplinary group.

The essentially unrefuted evidence is that Petitioner's interdisciplinary group had not reviewed the plan of care for patient # 2 between June 18, 1993 and May 6, 1994, the date of the resurvey. Tr. at 119. The interdisciplinary group had not reviewed the plan of care for patient # 6 in the five months that preceded the resurvey. Tr. at 126. The plan of care for patient # 7 had not been reviewed in the three months that preceded the resurvey. Tr. at 125.

Furthermore, the weight of the evidence is that Petitioner did not establish schedules pursuant to which plans of care were supposed to be reviewed. Neither the records of patient # 6 or # 7 stated a schedule for

reviewing the plans of care for these patients. HCFA Exs. 23, 24.

The only evidence which Petitioner offered to counter this evidence was the testimony of Dr. Broco Hernandez. However, his testimony that Petitioner's interdisciplinary group met weekly to discuss plans of care is not corroborated by any documentation. See Tr. at 219 - 20. Indeed, it is undercut substantially by the evidence that HCFA obtained which shows that plans of care were not reviewed according to any cognizable schedule.

Petitioner argues that HCFA's allegation of noncompliance with the provisions of 42 C.F.R. § 418.58(b) is based on an incorrect interpretation of the regulation. HCFA, according to Petitioner, is misreading this subsection to require plans of care to state the dates when reviews will be conducted. This requirement is not found in the regulation, according to Petitioner.

I am not persuaded by this argument. The provider made the same argument in Lajas. The regulation requires a hospice to conduct reviews of each of its plans of care "at intervals specified in the plan . . . ." 42 C.F.R. § 418.58(b). I read this requirement to give the hospice the option to establish a review schedule based either on the calendar or on some event specified in the plan of care such as a change in the patient's condition. Lajas at 11. However, what the evidence establishes in this case is that Petitioner's plans of care were not reviewed according to any cognizable schedule. The deficiency is Petitioner's failure to conduct regular reviews of its plans of care and to document reviews.

The preponderance of the evidence in this case proves that Petitioner was neither scheduling periodic reviews of the plans of care for its patients, nor was it reviewing the plans according to a schedule. The evidence establishes further that, if Petitioner was conducting any scheduled reviews of plans of care, it was not documenting those reviews. These failures by Petitioner are failures to comply with the explicit requirements of 42 C.F.R. § 418.58(b).

I do not find that Petitioner failed to comply with the requirements of 42 C.F.R. § 418.58(c). HCFA bases its assertion that Petitioner did not comply with this subsection on unrefuted evidence that Petitioner failed to establish a bereavement plan of care to deal with the death of patient # 5. Tr. at 122. HCFA's assertion that Petitioner failed to comply with this subsection rests

ultimately on an interpretation of the subsection to require a hospice to create a new or revised plan of care to address any change in a patient's condition. HCFA made that same argument in Arecibo. I concluded that this requirement, while not necessarily unreasonable, was not apparent from the face of the subsection. Arecibo at 22 - 25. I found that HCFA had not communicated this interpretation to the provider. I reach that same conclusion and finding here.

The failure of Petitioner's interdisciplinary group to conduct reviews of Petitioner's plans of care and to document those reviews is so substantial as to constitute a violation of the condition of participation stated in 42 C.F.R. § 418.58. In Arecibo and Lajas, I held that the requirement that plans of care be reviewed periodically by a hospice's interdisciplinary group and that these reviews be documented is fundamental to the appropriate discharge of a hospice's treatment obligations to its patients. Arecibo at 25 - 26; Lajas at 19 - 20.

A hospice cannot meet its critical responsibility to manage the care it provides to its dying patients to maximize the patients' physical comfort and to relieve the patients and their families of the emotional stress caused by the patients' death without planning the patients' care and without systematically reviewing that care. Lajas at 20. Petitioner's failure to perform this essential function substantially limited its capacity to render adequate care. Furthermore, its failure had the potential to adversely affect the health and safety of Petitioner's patients.

4. Petitioner's alleged failure to comply with the interdisciplinary group condition of participation stated in 42 C.F.R. § 418.68

HCFA argues that Petitioner failed to comply with the condition of participation stated in 42 C.F.R. § 418.68. This regulation establishes the condition that a hospice create an interdisciplinary group or groups to manage the care of its patients. It requires that the interdisciplinary group participate in the establishment of each plan of care that a hospice prepares for a patient. 42 C.F.R. § 418.68(b)(1). It requires also that the interdisciplinary group participate in the periodic review and updating of each plan of care. 42 C.F.R. § 418.68(b)(3). These requirements thus mirror the requirement contained in 42 C.F.R. § 418.58 that a

hospice's interdisciplinary group participate in the creation and revision of each patient's plan of care.

HCFA asserts that Petitioner's interdisciplinary group failed generally to participate in the review of plans of care. It supports this assertion with the same evidence it offered to show that plans of care were not being reviewed by Petitioner's interdisciplinary group in accordance with the requirements of 42 C.F.R. § 418.58. I discussed that evidence in the preceding section of this decision. For reasons that I have stated, I find it to be persuasive.

HCFA argues also that, with respect to patient # 8, there was a failure by Petitioner's interdisciplinary group to participate in the planning of the patient's care. That assertion is based on the fact that, while the patient was listed by Petitioner as one of its patients, the patient was being cared for by another hospice. Petitioner asserts that this de facto transfer of the patient was due to the remote location of Utuado and the difficulties that Petitioner experienced in attending to the patient's needs. It is unnecessary for me to make findings as to patient # 8 to resolve any of the issues in this case, and I do not.

The failure of Petitioner's interdisciplinary group to participate in the planning of care and in reviews of plans of care is a failure of the condition of participation stated in 42 C.F.R. § 418.68. The regulation makes it plain that the obligation to plan care is a critical element of the interdisciplinary group's duties. It reinforces the requirements of the plan of care regulation. As I find above, it is not possible for a hospice to discharge its obligations to its patients consistent with the requirements of law if it does not utilize its interdisciplinary group in the manner required by the regulations.

III. Conclusion

HCFA proved by a preponderance of the evidence that, as of May 6, 1994, Petitioner was not complying with three conditions of participation stated in 42 C.F.R. Part 418. These conditions are: medical director (42 C.F.R § 418.54); plan of care (42 C.F.R. § 418.58); and interdisciplinary group (42 C.F.R. § 418.68). Essentially, HCFA proved that Petitioner was derelict in its responsibility to manage and care for the needs of its patients in a way that jeopardized Petitioner's capacity to render adequate care and which had the

potential to affect adversely the health and safety of Petitioner's patients. Based on this, HCFA had the authority to terminate Petitioner's participation in Medicare.

/s/

Steven T. Kessel
Administrative Law Judge