

Department of Health and Human Services

DEPARTMENTAL APPEALS BOARD

Civil Remedies Division

In the Case of:)	
Hospicio en el Hogar de Lajas,)	DATE: March 31, 1995
Petitioner,)	
- v.-)	Docket No. C-94-361
Health Care Financing)	Decision No. CR366
Administration.)	

DECISION

Petitioner requested a hearing on 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 scheduled a hearing to be held in San Juan, Puerto Rico, beginning November 1, 1994. At the commencement of the hearing, the parties advised me that neither of them desired to offer in-person testimony. They agreed that they would offer exhibits and briefs.

I have considered the applicable law and regulations, the exhibits, and the parties' arguments.¹ I conclude that HCFA proved, by the preponderance of the evidence, that Petitioner failed to comply with a condition 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

¹ HCFA offered HCFA exhibits 1 - 29 as evidence. Petitioner did not offer any exhibits. I afforded Petitioner the opportunity to object to HCFA's exhibits. Petitioner did not object. I admit into evidence HCFA exhibits 1 - 29.

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 a condition that governs its participation in Medicare. Pages 9, 21.

2. In a case where a provider requests a hearing on 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 6 - 8.

3. HCFA did not deny Petitioner due process when it effectuated termination of Petitioner's participation agreement after its May 2 - 3, 1994 resurvey of Petitioner without first affording Petitioner the opportunity to correct deficiencies that were identified at the resurvey. Pages 8 - 10.

4. HCFA proved, by the preponderance of the evidence, that Petitioner failed to establish plans of care for its patients which met the condition of participation established by 42 C.F.R. § 418.58. Pages 17 - 20.

5. HCFA was authorized to terminate Petitioner's participation in the Medicare program. Page 21.

II. Discussion

A. Background

Petitioner is a hospice, operating in Lajas, 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 8, 1994, Petitioner was surveyed on behalf of HCFA by the Puerto Rico Department of Health. HCFA Exhibit (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 23, 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 April 6, 1994, Petitioner submitted a plan of correction to HCFA in which it proposed to correct the deficiencies which the Puerto Rico Department of Health had identified in its operations. HCFA Ex. 16. On April 19, 1994, HCFA notified Petitioner that it had found the plan to be not fully acceptable. HCFA Ex. 17. On April 28, 1994, Petitioner submitted a revised plan of correction to HCFA. HCFA Ex. 18. HCFA did not send a response to Petitioner advising it whether HCFA found the revised plan to be acceptable or unacceptable.

Neither HCFA nor Petitioner offered evidence to show whether HCFA found the revised plan of correction to be acceptable. Petitioner has not contended that HCFA accepted the revised plan. Petitioner has not argued that, if HCFA had accepted the revised plan of correction, its relationship with HCFA would be governed by the terms of that revised plan. Nor has Petitioner asserted that, by virtue of HCFA's alleged acceptance of

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).

the revised plan of correction, Petitioner would be entitled to a period of time in which to conform its operations to the corrective actions it pledged to take. Therefore, I make no findings in this decision as to whether HCFA accepted Petitioner's revised plan of correction. Furthermore, I make no findings as to whether acceptance of a plan of correction by HCFA would entitle a provider to any rights precluding HCFA from terminating its participation in Medicare. I note however, that it is not HCFA's practice always to notify a provider that it finds a plan of correction to be acceptable. HCFA Ex. 28 at 27 - 28.

On May 2 - 3, 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 regulations which governed Petitioner's participation in Medicare. HCFA Ex. 20. The regulations which HCFA found Petitioner to continue to contravene are 42 C.F.R. §§ 418.50 and 418.58. On May 20, 1994, HCFA advised Petitioner of these findings, and advised it further that it had affirmed its previous determination to terminate Petitioner's participation in the Medicare program. Id.

In its notification to Petitioner of the results of the March survey, HCFA had advised Petitioner that it had determined that Petitioner was not complying with six regulations which state conditions governing hospices' participation in Medicare. These were: 42 C.F.R. §§ 418.50 (general provisions); 418.58 (plan of care); 418.62 (informed consent); 418.74 (general clinical records); 418.92 (physical therapy, occupational therapy, and speech language pathology); and 418.94 (home health aide and homemaker services). HCFA does not contend that, as of May 2 - 3, 1994 (the dates of the second survey), Petitioner continued to fail to comply with 42 C.F.R. §§ 418.62, 418.74, 418.92, and 418.94.

This case addresses the issue of whether HCFA was authorized to terminate Petitioner's participation in Medicare based on Petitioner's failure to comply with conditions of participation stated in 42 C.F.R. §§ 418.50 and 418.58. Petitioner's alleged previous noncompliance with other regulations is not an issue. Furthermore, HCFA now argues that it derives its finding that Petitioner failed to comply with 42 C.F.R. § 418.50 from its finding that Petitioner failed to comply with 42 C.F.R. § 418.58. HCFA's Brief at 18, n.4. Therefore, the evidence in this case addresses only the question of

whether Petitioner failed to meet the requirements of 42 C.F.R. § 418.58.

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 to whom it provides care 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. Based on the survey conducted on May 2 - 3, 1994, HCFA found that Petitioner was not complying with all three of these standards and with the condition for participation stated in the regulation. HCFA Ex. 20.³

B. Discussion of legal arguments

This case involves legal issues concerning the interpretation and application of the Act and relevant regulations. The parties' arguments on these issues are similar to those raised by the parties in Arecibo Medical Hospice Care, DAB CR363 (1995).⁴ I reach essentially the same conclusions of law in this case as I did in the Arecibo case.

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.

⁴ As in this case, Arecibo involved the propriety of a termination by HCFA of a hospice's participation in the Medicare program. Both this case and Arecibo present very similar facts and involve the application of the same regulation. The same attorney represented the petitioners in both Arecibo and the present case. The briefs which HCFA submitted in the two cases presented identical arguments regarding HCFA's position as to the legal issues.

The legal issues, my analysis, and my conclusions are as follows:

1. Burdens of coming forward with evidence and persuasion

HCFA argues that Petitioner should bear the burden of persuasion to prove that HCFA's determination to terminate Petitioner's participation in Medicare is not authorized. I am not persuaded by HCFA's arguments. I conclude that HCFA bears the burdens of coming forward with evidence and persuasion to establish that its determination to terminate Petitioner's participation in Medicare is justified. Arecibo at 8 - 13.

Neither Congress nor the Secretary has allocated the burdens of coming forward with evidence and persuasion in a hearing involving the propriety of a determination to terminate a provider's participation in Medicare. The Act provides for a de novo hearing in such a case, governed by section 205 of the Act. Act, sections 205(b), 1866(b)(2), 1866(h)(1). The Act does not state who shall bear the burdens of coming forward and persuasion in an administrative hearing concerning whether a determination to terminate a provider's participation in Medicare is justified. Regulations published by the Secretary to govern such a hearing do not allocate the burdens of coming forward with evidence and persuasion. See 42 C.F.R. Part 498.

However, the Secretary has reposed broad discretion in administrative law judges to decide the manner in which evidence is presented and received in such a hearing. 42 C.F.R. § 498.60(b)(3). I do not read this regulation or the other regulations in Part 498 as containing a statement by the Secretary as to who should bear the burdens of coming forward with evidence and persuasion in a provider termination hearing. I read the regulations' silence on this question, coupled with the broad grant of discretion conferred by 42 C.F.R. § 498.60(b)(3), to constitute a decision by the Secretary to give administrative law judges the authority to allocate such burdens consistent with the requirements of due process. Arecibo at 9.

In this case, as in most cases involving determinations by HCFA to terminate providers' participation in Medicare, HCFA has obtained the facts which justify its determination through a survey of Petitioner's operations. HCFA thus knows the facts on which it relies to support its determination and is in the best position to prove those facts. Id. It is therefore both fair and

efficient to require HCFA to come forward with evidence sufficient to prove, by a preponderance of the evidence, that its determination to terminate a provider's participation in Medicare is justified under the Act and regulations.

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. I conclude here, as I did in Arecibo, that 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. Id. at 11. The consequence might be to invite a massive and unfocused submission of evidence from that provider. Id.

HCFA relies on the same arguments here as it did in Arecibo to support its assertion that Petitioner bears the burden of persuasion. HCFA asserts that a provider who challenges an adverse determination by HCFA ought to bear the burden of showing that the determination is not justified, inasmuch as the determination is final if a hearing is not requested. This argument ignores the fact that a hearing as to the propriety of a determination by HCFA made under the authority of section 1866 of the Act is de novo.

HCFA argues also that, as a general principal of administrative law, it is the applicant for relief, benefits, or privilege that bears the burden of persuasion in a hearing to contest the denial of those benefits. While I do not take issue with that general principal, it is not applicable in this case. Petitioner is no longer an applicant, but is instead an entity with an established, quasi-contractual relationship with HCFA. As I observed in Arecibo, a provider who has this quasi-contractual relationship with HCFA will have made financial commitments and have established business relationships based on that relationship. Id. at 11. Although the quasi-contractual relationship does not establish an unqualified entitlement to participate in Medicare, it would ignore the reality of the provider's reliance on that relationship to characterize the provider merely as an "applicant," in order to impose on the provider the burden of proving that any determination by HCFA is unreasonable. Id.

HCFA relies also on judicial decisions and on a decision by the Office of Hearings and Appeals and Appeals Council of the Social Security Administration to support its argument as to allocation of the burden of persuasion. I discussed these decisions in Arecibo. Id. at 12. I do not find them to be persuasive. The judicial decisions simply restate the general rule as to allocating the burden of persuasion to applicants for benefits, in cases concerning denials of applications for benefits. I do not find these decisions to be applicable here, for the reasons which I explain above and in Arecibo. The Appeals Council decision does not state expressly that the burden of persuasion falls on the party whose participation in Medicare has been terminated by HCFA. Jefferson Memorial Hosp. Ass'n v. Health Care Financing Administration, Docket No. PS-109, at 17 (1983). Indeed, that decision may support my allocation of the burden of persuasion to HCFA. Id.; Arecibo at 12.

2. Alleged denial of due process to Petitioner

As was argued by the petitioner in Arecibo, Petitioner asserts that HCFA denied it due process of law by not permitting it the opportunity to submit a plan of correction to address the noncompliance which HCFA found as a consequence of the May 2 - 3, 1994 resurvey. Petitioner argues that, where HCFA finds a provider to be deficient in complying with a standard contained in a regulation, it is obligated to afford that provider the opportunity to submit a plan of correction, prior to taking any action to terminate that provider's participation in Medicare. 42 C.F.R. § 488.28.

Petitioner points to the statement of deficiencies generated as a result of the May 2 - 3, 1994 resurvey as evidence that, at the resurvey, HCFA found Petitioner to be out of compliance with a standard under 42 C.F.R. § 418.58 which was not cited in the statement of deficiencies generated as a result of the March 8, 1994 survey. HCFA Ex. 16 at 2 - 7; HCFA Ex. 19 at 2 - 8.⁵ Petitioner argues that, as a consequence of HCFA's determination that Petitioner was not complying with an additional standard under the regulation, Petitioner was entitled to submit a new plan of correction to HCFA.

⁵ Based on the March 8, 1994 survey, HCFA found that Petitioner was not in compliance with 42 C.F.R. § 418.58(a) and (b), whereas based on the May 2 - 3, 1994 resurvey, HCFA found that Petitioner was not in compliance with 42 C.F.R. § 418.58(a), (b), and (c).

I am not persuaded that HCFA denied Petitioner due process. HCFA was under no obligation to give Petitioner the opportunity to submit a plan of correction to cure the deficiencies identified at the May 2 - 3, 1994 resurvey of Petitioner. Arecibo at 5 - 8.

HCFA is not obligated to give a provider the opportunity to submit a plan of correction where it identifies a failure by that provider to comply with a condition of participation in Medicare. Here, the deficiencies which HCFA identified in Petitioner's operations, both at the March 1994 survey, and the May 1994 resurvey, constituted failures to comply with conditions of participation. The regulations authorize HCFA to terminate a provider's participation in the Medicare program if the provider fails to comply with any condition of participation. 42 C.F.R. § 489.53(a)(1), (3). Petitioner had no right to expect that HCFA would give it the opportunity to submit plans of correction to correct the condition-level deficiencies which HCFA identified at either survey.

The regulations which govern participation of hospices in the Medicare program state broad conditions of participation which hospices must comply with in order to participate in Medicare. 42 C.F.R. Part 418. These regulations also contain standards of participation, which constitute the criteria which a hospice must meet under each condition of participation.

HCFA may determine that a hospice fails to comply with a standard of participation under a given condition, and it may conclude also that the severity of the noncompliance is not so great as to constitute a failure to comply with the overall condition of participation. In that event, HCFA must afford the provider the opportunity to submit a plan of correction to HCFA to redress the noncompliance. 42 C.F.R. § 488.28. However, where HCFA finds that the failure of a hospice to comply with standards of participation is so egregious as to constitute a failure to **comply** with the broad condition that encompasses those **standards**, then HCFA is not required to give that hospice the **opportunity** to submit a plan of correction to redress the noncompliance. Id.

In this case, HCFA found, both at the initial survey and the resurvey which it conducted of Petitioner, that Petitioner was not complying with conditions of participation in Medicare. HCFA was not obligated, as a result of these findings, to give Petitioner the opportunity to file plans of correction. The fact that HCFA gave Petitioner that opportunity after the March

survey did not obligate HCFA to give Petitioner the same opportunity after the May resurvey.

It is true, as Petitioner points out, that based on the May resurvey, HCFA found that Petitioner failed to comply with all three standards under the condition stated in 42 C.F.R. § 418.58, whereas, in the March survey, HCFA found that Petitioner failed to comply with only two of the three standards under that condition. However, in both the March survey and the May resurvey, HCFA found that Petitioner's noncompliance with the standards stated in 42 C.F.R. § 418.58 was so egregious as to amount to a failure to comply with the overall condition of participation contained in the regulation. Petitioner did not gain the right to submit a plan of correction in response to the May survey by virtue of the fact that HCFA found Petitioner to be deficient under an additional standard of the regulation, inasmuch as HCFA's central finding was that Petitioner was not complying with the overall condition of participation expressed in that regulation.

C. Analysis of the plan of care requirement for hospices

The regulation that is principally at issue in this case is 42 C.F.R. § 418.58, which establishes the general condition of participation for a hospice that it establish and maintain a plan of care for each of its patients and that it provide treatment in accordance with the plan of care. This general condition is implemented in three subsections.

1. 42 C.F.R. § 418.58(a)

The hospice's medical director or physician designee and the hospice's interdisciplinary group must establish a plan of care for each patient before the hospice provides care to that patient. 42 C.F.R. § 418.58(a). On its face, the requirements of this subsection are plain. A hospice may not provide care to a patient until it has reviewed that patient's needs and problems and established a plan of care to deal with them. The subsection plainly envisions a plan of care as constituting an overall blueprint of care to be provided to each hospice patient.

HCFA appears to interpret this subsection to impose additional requirements on hospices which are not evident from the subsection's plain meaning, but which may not necessarily be unreasonable. HCFA appears to be arguing that this subsection requires that a new or revised plan

of care be created to deal with each new problem manifested by a hospice patient as it arises. See HCFA's Brief at 21 - 22 (In Arecibo, HCFA made this argument explicitly.)

2. 42 C.F.R. § 418.58(b)

Each plan of care must be reviewed and updated, at intervals specified in the plan, by the patient's attending physician, the hospice medical director or physician designee, and the hospice's interdisciplinary group. These reviews must be documented. 42 C.F.R. § 418.58(b). The unambiguous requirement of this section is that in each plan of care that a hospice establishes for each of its patients, it must establish a schedule by which it reviews that plan of care. Furthermore, each review must be documented by the appropriate individuals and by the hospice's interdisciplinary group. Plainly, the intent of this subsection is to assure regular, scheduled reviews of each hospice patient's condition which are documented. The intent also is to assure that no hospice patient receives sporadic or unsystematic treatment of his or her problems.

The term "intervals specified in the plan" can be read reasonably to require either that a hospice establish specified dates for review of each patient's plan of care or specified events which would trigger a review. The subsection appears to repose some discretion on a hospice to choose the schedule by which it elects to review each patient's plan of care.

3. 42 C.F.R. § 418.58(c)

Each plan of care must include an assessment of the patient's needs and must identify the services to be provided to address those needs, including services to manage discomfort and symptom relief. Furthermore, each plan of care must state in detail the scope and frequency of services needed to meet the patient's and his or her family's needs. 42 C.F.R. § 418.58(c). As with the other subsections of the regulation, this subsection contains unambiguous requirements. It requires that a plan of care provide a specific statement of the needs of the patient and a specific statement as to how those needs will be addressed by the hospice and its personnel.

In Arecibo and in this case, HCFA asserts an interpretation of this subsection which would impose requirements on hospices which go beyond the subsection's plain meaning. HCFA argues that this subsection should be read to reinforce its interpretation of 42 C.F.R. §

418.58(a) to require that a hospice create a new or revised plan of care to address each new problem that a patient develops.

HCFA argues also that 42 C.F.R. § 418.58(c) means that a plan of care must specify the specific discipline that will be providing each service to a patient pursuant to the plan. Furthermore, according to HCFA, the subsection should be interpreted to require that a plan of care specify the name and frequency of administration of each medication administered to a patient.⁶ I find these interpretations also to be beyond the plain meaning of the subsection.

D. HCFA's duty to communicate to providers its interpretation of regulations

HCFA does not deny that its interpretations of the three subsections of 42 C.F.R. § 418.58 may go beyond the plain meaning of these subsections. However, HCFA appears to be arguing that, as the entity vested with the authority to implement the regulations, it must be vested also with the authority to interpret these regulations reasonably.⁷ Furthermore, according to HCFA, hospices in general and Petitioner in particular have a duty to be aware of and to understand and comply with HCFA's interpretation of regulations. Thus, according to HCFA, a hospice may not use its ignorance of HCFA's interpretation of the regulations as an excuse to avoid its duty to comply with HCFA's interpretation.

I held in Arecibo, as I hold here, that HCFA certainly has the authority to interpret regulations in a reasonable way to account for and to address circumstances that may not fall within the plain meaning of the regulations. However, HCFA is not entitled to make its interpretation binding on any provider to which it has not communicated that interpretation. Providers cannot be expected to divine HCFA's interpretation of a regulation where that interpretation departs from the plain meaning of the regulation or where it addresses and resolves ambiguous language.

⁶ HCFA argued this identical interpretation in Arecibo. Arecibo at 15 - 16, 23 - 24.

⁷ HCFA does not assert this position as explicitly here as it did in Arecibo. Arecibo at 14 - 16, 22 - 23. However, it is clear from the context of HCFA's arguments that it has not modified its position.

HCFA argues here, as it did in Arecibo, that providers have a duty to be aware of and abide by HCFA's interpretation of regulations where that interpretation comports with practices that are generally accepted and followed by providers. HCFA can find support for the reasonableness of its interpretation of regulations where its interpretation comports with practices that are accepted and followed by providers. But the fact that an interpretation of a regulation comports with accepted practices does not excuse HCFA from the duty of communicating its interpretation to providers, where the interpretation is not apparent from the plain meaning of the regulation.

In both Arecibo and this case, HCFA asserts that its position as to the duty of providers to be aware of and comply with HCFA's interpretation of regulations is consistent with my holding in Long Medical Laboratory, DAB CR334 (1994). In the Long Medical Laboratory case I held that the petitioner had a duty to be aware of its obligations to comply with provisions of the Clinical Laboratories Improvement Amendments. But, what distinguishes the Long Medical Laboratory case from the present case is that the Long Medical Laboratory case involved a provider's failure to comply with an unambiguous statutory requirement, whereas, in this case, the alleged failure to comply is with interpretations of regulations that depart from the plain language of the regulations. The Long Medical Laboratory case did not involve any issue of interpretation of the statutory requirement.

My analysis here is entirely consistent with my analysis in the Long Medical Laboratory case. Petitioner is required to be aware of, and to comply with, the unambiguous requirements of the Act and regulations, as well as any reasonable interpretations of law which HCFA has communicated to providers. However, that duty does not extend to interpretations by HCFA which have not been communicated to providers.

HCFA contends that, in any event, it communicated to Petitioner its interpretation of the three subsections of 42 C.F.R. § 418.58 in the statement of deficiencies which was sent to Petitioner after the March 8, 1994 survey. HCFA Ex. 16 at 2 - 7. I am not persuaded from my review of this exhibit that it communicates precisely to Petitioner HCFA's interpretation of the three subsections of 42 C.F.R. § 418.58. Nowhere does the statement of deficiencies state explicitly the interpretation now advocated by HCFA.

Arguably, a provider might be in a position to infer from the specific deficiencies described in the statement that HCFA is advocating an interpretation that imposes additional requirements to those which are stated in the plain language of the regulation. For example, the specific deficiencies which the statement identifies under 42 C.F.R. § 418.58(a) could lead a provider to conclude that HCFA was interpreting the subsection to require at least that a plan of care be amended to deal with new problems as they arise. HCFA Ex. 16 at 3 - 5. However, where HCFA interprets a regulation to impose requirements on providers that exceed those which are stated in the plain language of the regulation, it owes a duty to those providers to state its interpretation plainly and directly. Giving providers a statement from which they might be able to infer an interpretation will not suffice.

I conclude that HCFA did not prove that it communicated its interpretation of the three subsections of 42 C.F.R. § 418.58 to Petitioner sufficiently to put Petitioner on notice that HCFA was requiring it to comply with requirements that depart from the plain meaning of the subsections. Therefore, I analyze HCFA's contentions that Petitioner remained out of compliance with the requirements of the regulation, using only the plain meaning of the regulation.

E. Analysis of HCFA's allegations of noncompliance

I conclude from my review of the evidence that HCFA established by a preponderance of the evidence that, as of the May 8, 1994 resurvey, Petitioner was not complying with plain and specific requirements of 42 C.F.R. § 418.58(b). I do not agree with HCFA's assertions that Petitioner was not complying with the provisions of 42 C.F.R. § 418.58(a) and (c).

The weight of the evidence supports HCFA's contentions of fact as to the way in which Petitioner generated and reviewed its plans of care. However, HCFA's assertion from these facts that Petitioner was not complying with 42 C.F.R. § 418.58(a) and (c) relies on its interpretation of the requirements of these subsections. As I hold above, HCFA's interpretation was not within the plain meaning of the subsections' language. There is no evidence that HCFA communicated its interpretation to Petitioner.

There were no witnesses called by either party. The parties agreed to rely solely on the exhibits which are in evidence and their analysis of those exhibits. The

evidence which I find to be relevant to my conclusion that Petitioner was not complying with 42 C.F.R. § 418.58(b) consists of the following exhibits: HCFA Ex. 19 (the statement of deficiencies which was prepared after the May 2 - 3, 1994 resurvey); HCFA Exs. 21 - 24 (excerpts from records of patients that were reviewed at the May 2 - 3, 1994 resurvey, portions of which have been translated into English); HCFA Ex. 25 (notes made by one of the surveyors who participated in the May 2 - 3, 1994 resurvey); and HCFA Exs. 26 - 27 (the curriculum vitae of the surveyors who conducted the May 8, 1994 resurvey).⁸

The statement of deficiencies which was prepared after the May 8, 1994 resurvey of Petitioner is an unsigned document. HCFA Ex. 19. However, there is no dispute that this exhibit constitutes the results of a survey conducted principally by Ms. Marjorie Finnigan, a HCFA employee. Thus, the statement of deficiencies may be considered as a statement by Ms. Finnigan in lieu of her in-person testimony.

Petitioner has not challenged Ms. Finnigan's credibility, although it has challenged the probative value of HCFA Ex. 19. I find Ms. Finnigan's statement to be credible, in the absence of any meaningful challenge to her credibility. Furthermore, Ms. Finnigan's credibility is bolstered by her curriculum vitae, which establishes that she has substantial experience conducting surveys on behalf of HCFA, professional experience in nursing, and professional education in public health administration. HCFA Ex. 26.

The statement of deficiencies asserts broadly that Petitioner was not complying with the overall condition of participation expressed in the regulation. HCFA Ex. 19 at 1 - 2. This assertion is premised on the conclusions that, based on a review of ten patient records, Petitioner failed to develop plans of care to meet all of the needs of eight of ten of these patients and failed to establish time frames for the review of the plans of care for all ten of these patients. *Id.* at 2. It is premised also on findings that Petitioner was not

⁸ I am not fluent in Spanish. Therefore, I draw no inferences or conclusions from those portions of HCFA Exs. 21 - 24 which have not been translated into English. I gave Petitioner the opportunity to object to, or to offer supplements to, translations that were offered by HCFA. Petitioner neither objected to HCFA's translations nor offered supplements.

in compliance with each of the subsections of 42 C.F.R. § 418.58. Id.

1. Allegations of Petitioner's noncompliance with 42 C.F.R. § 418.58(a)

The statement of deficiencies generated after the May 1994 resurvey asserts that Petitioner's failure to comply with the requirements of 42 C.F.R. § 418.58(a) is supported by a review of ten patient records. It concludes that this review shows that, in all ten cases, Petitioner failed to consider all of the patients' needs and problems. HCFA Ex. 19 at 3. Furthermore, in eight of the ten cases, care plans were not developed to address the patients' changing needs. Id. The statement recites specific examples to support this latter conclusion. These involve patients who are identified in the statement as Patients # 9, # 3, and # 7. Id. at 3 - 7.

A close review of the examples cited in the statement of deficiencies leads me to conclude that the finding that plans of care were not being developed to address patients' changing needs emanates from HCFA's interpretation of 42 C.F.R. § 418.58(a) to require that a hospice create a new or revised plan of care to address each new problem manifested by a patient. Thus, Petitioner's failure to develop a specific plan of care to deal with the consequences of Patient # 9's relocation is cited as a deficiency under 42 C.F.R. § 418.58(a). HCFA Ex. 19 at 4. Similarly, Petitioner's failure to develop a specific plan of care to address an episode of pain and vomiting which patient # 3 experienced on April 3, 1994 is cited as a deficiency under 42 C.F.R. § 418.58(a). Id. at 4 - 5.

I am not persuaded that HCFA proved, by a preponderance of the evidence, that Petitioner was not complying with the plain meaning of 42 C.F.R. § 418.58(a). Although the specific findings of failures by Petitioner to develop plans of care may be factually accurate (indeed, Petitioner has not offered persuasive evidence to refute these findings, and they are supported by the excerpts of treatment records which HCFA offered in HCFA Exs. 21 and 22), they relate to an interpretation of the regulation which exceeds the regulation's plain meaning and which HCFA has not communicated precisely to Petitioner.

As I hold above, the plain meaning of 42 C.F.R. § 418.58(a) cannot be read to encompass the requirement that a new or revised plan of care be prepared by a hospice to address each new problem manifested by a

patient under hospice care. The specificity which HCFA reads into this subsection is more precise than is required on its face. Thus, while I do not dispute the accuracy of the survey's findings as to 42 C.F.R. § 418.58(a), I conclude that they do not describe a failure to comply with the plain requirements of the subsection.

2. Allegations of Petitioner's noncompliance with 42 C.F.R. § 418.58(b)

The statement of deficiencies asserts that Petitioner was not reviewing and updating plans of care in compliance with 42 C.F.R. § 418.58(b). This assertion is based on the finding that, in the records of ten patients that were reviewed by the surveyors, there was no evidence that the plans of care specified the dates when they were to be reviewed by Petitioner's interdisciplinary group. HCFA Ex. 19 at 6 - 7. Furthermore, according to the statement of deficiencies, the records did not contain evidence that plans of care actually were being reviewed by Petitioner's interdisciplinary group. Id.

The surveyors found specifically that, although plans of care in patients' records did specify dates of review, they did not specify that Petitioner's interdisciplinary group would be reviewing the plans. Id. The surveyors found also that the review dates were for reviews by specific disciplines and not by Petitioner's interdisciplinary group. Id.

HCFA proved by a preponderance of the evidence that Petitioner failed to comply with the requirements of 42 C.F.R. § 418.58(b). The excerpts of treatment records which are in evidence substantiate the findings contained in the statement of deficiencies concerning Petitioner's compliance with 42 C.F.R. § 418.58(b). HCFA Exs. 21 - 24. The records contain documents which are headed "interdisciplinary care plan" or "interdisciplinary group care plan." See, e.g., HCFA Ex. 21 at 2, 4, 6, 8, and 10. Each of these plans state a date which may be a planned review date. For example, in HCFA Ex. 21, the plans contained on pages 2, 4, 6, 8, and 10 each recite a date at the bottom of the page which may be a review date (although, from the context of the date, it may also be the date when the plan itself was prepared). However, none of the records in evidence, including the plans themselves, show that a schedule for regular reviews has been established by the hospice's interdisciplinary group or that the plans actually have been reviewed by the interdisciplinary group.

Petitioner argues that there is no requirement in 42 C.F.R. § 418.58(b) that a plan of care state the dates when it is to be reviewed. As I have found above, the regulation permits a hospice to schedule reviews of a plan of care according to intervals stated in the plan. A review schedule does not necessarily have to be by date, based on the plain language of the regulation.

However, a hospice cannot avoid the requirement that there be periodic reviews of each plan of care based on a schedule (whether governed by the calendar or changes in a patient's condition) established in the plan of care itself. Nor can a hospice avoid the requirement that reviews be conducted by, among others, the hospice's interdisciplinary group, and that the reviews be documented. These requirements are stated plainly in the regulation. Here, the essentially un rebutted evidence is that Petitioner was not reviewing its plans of care according to schedules established in the plans, nor was it assuring that the reviews be accomplished by the interdisciplinary group and documented.

3. Allegations of Petitioner's noncompliance with 42 C.F.R. § 418.58(c)

HCFA's assertion that Petitioner was not complying with 42 C.F.R. § 418.58(c) is based on the surveyors' finding that in none of the ten records reviewed is there evidence that the plans of care specified the discipline that would be responsible for the interventions and care described in the plans. HCFA Ex. 19 at 7 - 8. It is based also on HCFA's interpretation that the subsection requires each plan of care to identify the specific discipline that is responsible for each intervention identified in the plan. Id. Petitioner has not offered any evidence to controvert the evidence offered by HCFA.

However, I cannot conclude that this evidence proves that Petitioner was not in compliance with 42 C.F.R. § 418.58(c). HCFA grounds its assertion that Petitioner was not complying with this subsection on an interpretation of the subsection which does not fall within the plain meaning of the subsection's language. I do not find that HCFA communicated its interpretation to providers. I do not find that Petitioner is obligated to comply with HCFA's interpretation absent evidence that HCFA communicated its interpretation to providers.

F. Petitioner's failure to comply with a condition for participation in Medicare

I conclude that HCFA proved that Petitioner failed to comply with a condition for participation stated in 42 C.F.R. § 418.58. I do not conclude that HCFA proved that Petitioner also failed to comply with a condition for participation stated in 42 C.F.R. § 418.50.

1. 42 C.F.R. § 418.58

The preponderance of the evidence establishes that, as of May 2 - 3, 1994, Petitioner remained out of compliance with the standard of participation contained in 42 C.F.R. § 418.58(b). Petitioner was not scheduling reviews of its plans of care at intervals specified in the plans. Nor was Petitioner's interdisciplinary group conducting reviews according to a schedule or schedules of review. Finally, Petitioner was not documenting any reviews that it may have been conducting.

The fact that a provider may not be complying with one standard of several contained in a regulation does not preclude a finding that the egregiousness of the noncompliance is such as to constitute a failure to comply with the overall condition for participation contained in the regulation. I conclude that the level of severity of Petitioner's noncompliance with 42 C.F.R. § 418.58(b) is sufficient to prove that Petitioner was not complying with the condition for participation contained in 42 C.F.R. § 418.58.

The circumstances where a failure by a provider to comply with participation requirements constitutes a failure to meet a condition of participation are defined in 42 C.F.R. § 488.24(a). That section specifies that a deficient provider will be found to no longer comply with a condition of participation where the deficiency is:

. . . of such character as to substantially limit the provider's . . . capacity to render adequate care or which adversely affect[s] the health and safety of patients; . . .

This definition of a condition-level deficiency implements the Act's grant of authority to the Secretary to terminate a provider's participation in Medicare where the Secretary determines that the provider fails to comply "substantially" with the provisions of the provider agreement, the Act, regulations, or a mandated corrective action. Act, section 1866(b)(2)(A).

I am satisfied that Petitioner's failure to develop plans of care in compliance with the requirements of 42 C.F.R. § 418.58(b) substantially limited Petitioner's capacity to render adequate care to its patients and potentially affected adversely the health and safety of Petitioner's patients. Thus, Petitioner's deficiency was a failure to meet the overall condition of participation stated in 42 C.F.R. § 418.58.

What is evident here is not simply a failure to comply with a technical record keeping requirement. The evidence is that, in all ten of the treatment records reviewed by the surveyors on May 2 - 3, 1994, there was no indication that plans of care were being reviewed according to a schedule, that Petitioner's interdisciplinary group was performing reviews, or that reviews were being documented. This evidence proves a systematic failure by Petitioner to fulfill its obligation to plan care according to the requirements of the regulation.

The essential requirement of 42 C.F.R. § 418.58 is that each patient who is being provided care by hospices be provided care according to a plan of care that is created and maintained specifically for that individual. By definition, hospice patients are in the last stages of their lives. The critical role of hospices is to manage the care provided to dying patients to maximize their physical comfort and to relieve the patients and their families, to the extent possible, of the emotional distress caused by the patients' imminent deaths. I cannot envision how a hospice can perform this role if it does not review its plans of care according to an established schedule, if it does not assure that plans are reviewed by those who are responsible for reviewing the plans, and if it does not document the reviews. Because I conclude that Petitioner failed to comply with the condition of participation identified at 42 C.F.R. § 418.58, HCFA was authorized to terminate Petitioner's provider agreement.

2. 42 C.F.R. § 418.50

I do not agree with HCFA's argument that Petitioner should also be found to be noncompliant with the requirements of 42 C.F.R. § 418.50. This regulation states the general conditions for participation as a hospice. Subsection (a) requires hospices to "maintain compliance with the conditions of this subpart." From this, HCFA reasons that, if a provider is not complying with a condition contained in a regulation governing

hospices, then it must also be found to be not complying with 42 C.F.R. § 418.50.

It may be true literally that a provider who is not complying with a condition for participation stated elsewhere in the regulation governing hospices is also not complying with the requirement in 42 C.F.R. § 418.50(a) that it comply with all conditions for participation. However, I do not read 42 C.F.R. § 418.50(a) as directing a finding that a provider who is found to be noncompliant with one condition of participation must therefore be found to be noncompliant with two conditions, thus implying a higher degree of noncompliance. Such a reading would suggest an intent by the Secretary to make noncompliance with a condition of participation appear to be more serious in every case than in fact it is.

The failure of a provider to comply with even one condition for participation in Medicare provides HCFA with grounds to terminate that provider's participation in Medicare. 42 C.F.R. § 489.53(a)(1), (3). It would add nothing to the analysis of a hospice's deficiencies under 42 C.F.R. Part 418 to find an additional condition-level deficiency exists under 42 C.F.R. § 418.50 each time a condition-level deficiency is found under one of the other regulations in 42 C.F.R. Part 418 which establish the conditions for participation by a hospice.

III. Conclusion

Under both the Act and regulations, HCFA may terminate a provider's participation in Medicare where the provider is not complying with a condition for participation in Medicare. Act, section 1866(b)(2)(A); 42 C.F.R. § 489.53(a)(1), (3). The preponderance of the evidence in this case is that, as of the May 2 - 3, 1994 resurvey of Petitioner, Petitioner was not complying with the condition for participation stated in 42 C.F.R. § 418.58. Based on this, I conclude that HCFA had authority to terminate Petitioner's participation in Medicare.

/s/

Steven T. Kessel
Administrative Law Judge