Department of Health and Human Services

DEPARTMENTAL APPEALS BOARD

Civil Remedies Division

In the Cases of:	
Nazareno Medical Hospice Fajardo, Caguas, Cayey,	DATE: August 18, 1995
Petitioners,	Docket Nos. C-94-383 C-94-384 C-94-386
- v. -	Decision No. CR386
Health Care Financing Administration.	

DECISION

These are my decisions in the above three captioned cases. I am issuing the decisions as a single document.[1] I do so for the following reasons. The cases involve common issues of law. Each Petitioner provides hospice care to Medicare beneficiaries. The Petitioner in each of these cases is owned by the same corporation and each Petitioner is represented by the same counsel. The cases involve similar, but not identical, facts.

Although I have consolidated my decisions in a single document, I have not consolidated the cases. My decision in each case is separate. To the extent that a party wishes to appeal any of these decisions, that party should specifically appeal that decision.

In each of these cases, the Health Care Financing Administration (HCFA) terminated the Petitioner's participation in Medicare, based on its determination that the Petitioner failed to comply with conditions of participation in the Medicare program. In each case, I conclude that HCFA failed to prove, by a preponderance of

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[1] There is a fourth case which I heard along with the three cases decided herein. That is the case of Nazareno Medical Hospice Carolina, Docket No. C-94-385. I am issuing a separate ruling in that case.

the evidence, that the Petitioner did not comply with conditions of participation. Therefore, in each case, I issue a decision that HCFA did not prove a basis for terminating the Petitioner's participation in Medicare.

Each Petitioner requested a hearing and the cases were assigned to me for hearings and decisions. I conducted hearings in San Juan, Puerto Rico, on March 21 - 23, 1995.[2] After HCFA had rested in each of the cases, the Petitioner requested leave to move for a decision in its favor on the grounds that HCFA had failed to meet its burden of persuasion.[3] HCFA did not object to deferring the Petitioners' presentation of evidence so that the Petitioners could submit their proposed motions. I deferred the Petitioners' presentation of evidence so that they could submit their motions.

It is not customary for me to issue a decision in a case without first having heard all of the evidence offered by each party to that case. Here, however, I conclude that the evidence adduced by HCFA did not establish a basis for HCFA's determinations to terminate the participation in Medicare of these Petitioners. No legitimate purpose would be served here in requiring the Petitioners to offer evidence, inasmuch as HCFA failed to meet its burden of coming forward with evidence and establishing a prima facie case against each Petitioner.

I have organized these decisions in the following manner. First, I provide a consolidated background for the three cases. I then identify issues of law which are present in all of the cases and I decide those issues of law as common issues. Then, I identify the issues which are

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[2] The parties agreed to present evidence in a consolidated form, rather than in separate hearings for each Petitioner. In part, this process was the consequence of the fact that State agency surveyors who testified on behalf of HCFA often participated in the survey of more than one of the Petitioners. It would not have been efficient to recall these witnesses to testify separately as to each Petitioner. However, I made it a point to have each witness identify the Petitioner about which the witness was testifying. See, e.g., Tr. at 104.

[3] The consolidated hearings included a hearing as to Petitioner Carolina in the case of Nazareno Medical Hospice Carolina, Docket No. C-94-385. Petitioner Carolina moved also for a decision based on the evidence adduced by HCFA. As I note above, I am issuing a separate ruling as to Petitioner Carolina.

unique to each case and I make findings of fact and conclusions of law which pertain only to that specific case.

I. Background

The facts and law which I recite as background to these cases are not in dispute. The Petitioners in these cases are the following entities: Docket No. C-94-383, Nazareno Medical Hospice Fajardo (Petitioner Fajardo); Docket No. C-94-384, Nazareno Medical Hospice Caguas, (Petitioner Caguas); Docket No. C-94-386, Nazareno Medical Hospice Cayey (Petitioner Cayey). Each of the Petitioners is owned by Nazareno Medical Hospice Care, Inc., which is not a party to any of these cases.

In each of these cases, the Petitioner is a hospice which did business in a community in 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. 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 central purpose of a hospice is to provide dying beneficiaries with palliative, rather than curative, care. Hospice care enables the beneficiary to select an alternative to traditional care which, hopefully, alleviates the beneficiary's symptoms and provides peace of mind to the beneficiary and his or her family.

Under Medicare, 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).

The Secretary of the United States Department of Health and Human Services (Secretary) has published regulations which govern the manner in which hospices participate in

the Medicare program. These are contained in 42 C.F.R. Part 418. These regulations establish the basic conditions of participation for a hospice. 42 C.F.R. §§ 418.50 - 418.100. They define the circumstances under which a beneficiary may be eligible to receive hospice care. 42 C.F.R. § 418.20. The regulations define the circumstances under which a hospice may provide care to eligible beneficiaries. 42 C.F.R. §§ 418.21 - 418.30. They identify the services that a hospice must provide to beneficiaries under its care. 42 C.F.R. §§ 418.200 - 418.204.

The Act and regulations governing the Medicare program establish the procedure whereby HCFA, acting as the Secretary's delegate, assures that providers comply with participation requirements. Pursuant to section 1864(a) of the Act, the Secretary has entered into agreements with State survey agencies to survey providers for compliance with Medicare participation requirements and to report their findings to HCFA. Act, section 1864(a); 42 C.F.R. §§ 488.10 - 488.11.

Each of the Petitioners was surveyed in April 1994 by surveyors from the Puerto Rico Department of Health, the State survey agency for Puerto Rico. Petitioners Fajardo and Caguas were surveyed on April 19, 1994, and Petitioner Cayey was surveyed on April 26, 1994. The surveyors concluded that each of the Petitioners was not in compliance with conditions of participation in Medicare. C-94-383, HCFA Ex. 15; C-94-384, HCFA Ex. 15; C-94-386, HCFA Ex. 15.[4]

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[4] In each of these cases, I received into evidence exhibits that are unique to that case. Also, I received into evidence a number of exhibits that are common to all of the cases and one exhibit that is common to two of the cases. An exhibit which is in evidence only in a particular case is marked with the docket number of that case and with the unique exhibit number for that exhibit. Thus, C-94-383, HCFA Ex. 15 is an exhibit which is in evidence only in Docket No. C-94-383 (Petitioner Fajardo) and is not in evidence in any other case.

An exhibit which is in evidence in all of the cases is marked with the docket numbers of all of the cases as well as the exhibit number. The exhibits which are in evidence as common exhibits in the three cases which I have decided here are in evidence also in a fourth case, Nazareno Medical Hospice Carolina, Docket No. C-94-385, which I have not decided here. In that fourth case, I

Based on these survey results, HCFA advised each Petitioner that it intended to terminate that Petitioner's participation in Medicare. However, HCFA afforded each Petitioner the opportunity to submit to HCFA a plan of correction to address the deficiencies that the State agency had identified in April 1994. Each Petitioner submitted a plan of correction to HCFA. On June 23, 1994, HCFA accepted revised plans of correction from Petitioners Fajardo, Caguas, and Cayey. C-94-383, HCFA Ex. 19; C-94-384, HCFA Ex. 18; C-94-386, HCFA Ex. 20.

At HCFA's direction, State survey agency surveyors resurveyed each of the Petitioners. The Petitioners were resurveyed on the following dates: July 6, 1994, Petitioner Fajardo; July 8, 1994, Petitioner Caguas; and July 20, 1994, Petitioner Cayey. The surveyors found that each of the Petitioners continued to be deficient in complying with conditions of participation in Medicare. C-94-383, HCFA Ex. 21; C-94-384, HCFA Ex. 19; C-94-386, HCFA Ex. 21. Based on these findings, HCFA terminated the participation in Medicare of each of the Petitioners.

The Petitioners and HCFA simultaneously filed briefs and reply briefs. I base my decisions in these cases on the law, the evidence which was received at the hearings, and the parties' arguments.

II. Common legal issues and conclusions of law

The parties have raised legal issues which are common to all of these cases. These are:

1. Which party has the burdens of coming forward with evidence and proof?

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have issued a ruling separately in which I conclude that additional proceedings may be necessary. The exhibits which I admitted as common exhibits in all of the cases are C-94-383 - C-94-386, HCFA Exs. 7 - 9, 12 - 14, and 62.

The exhibit which I received as a common exhibit in two of the cases only is C-94-383 - C-94-386, HCFA Ex. 4. This exhibit was admitted in the cases of Petitioners Fajardo and Caguas.

Finally, I rejected certain exhibits which HCFA offered as common exhibits in all of the cases. These exhibits are C-94-383 - C-94-386, HCFA Exs. 1 - 2 and 10 - 11.

2. What effect does a plan of correction that has been accepted by HCFA have on a provider's obligation to comply with conditions of participation in Medicare?

I reach the following conclusions as to these issues of law. After each conclusion, I cite to the page or pages of these decisions at which I discuss my conclusions in detail.

1. HCFA has the burdens of coming forward with evidence and proving, by a preponderance of the evidence, that its determination to terminate a provider's participation in Medicare is justified (I refer to these burdens collectively as the burden of persuasion). Pages 6 - 17.

2. The terms of a plan of correction that has been accepted by HCFA define the provider's obligation to comply with those participation requirements that are addressed in the plan. Where HCFA determines to terminate a provider's participation in Medicare after it has accepted a plan of correction from that provider, HCFA must prove, by a preponderance of the evidence, that the provider is not complying with the terms of the plan of correction, to the extent that those terms address conditions of participation with which HCFA contends the provider is noncompliant. Pages 19 - 23.

A. Burden of persuasion

1. Allocation to HCFA of the burden of persuasion

HCFA has the burdens of coming forward with evidence and proving, by the preponderance of the evidence, that its determination to terminate each Petitioner's participation in Medicare is justified. This conclusion is identical to that which I made in Hospicio en el Hogar de Utuado, DAB CR371, at 6 - 10 (1995); Hospicio en el Hogar de Lajas, DAB CR366, at 6 - 8 (1995); and in Arecibo Medical Hospice Care, DAB CR363, at 8 - 13 (1995). Administrative Law Judge Leahy held the same in Guaynabo Hospice Care, Inc., DAB CR374, at 11 - 14 (1995).

Neither the Act nor regulations allocate the burden of persuasion to a specific party in a case involving termination of a provider's participation in Medicare.

See Act, sections 205(b), 1866(b)(2)(A), (h)(1); 42 C.F.R. Part 498. 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 Utuado, Lajas, and Arecibo, 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.

The criteria which I use to allocate the burden of persuasion are fairness and efficiency. In a case involving termination by HCFA of a provider's participation in Medicare, it is both consistent with the requirements of due process and efficient to allocate to HCFA the burden of persuasion.[5] As Judge Leahy observed in Guaynabo, "the correctness of HCFA's findings and determination are at the center of each case that is heard pursuant to section 1866(h)(1) of the Act." Guaynabo at 12. In such a case, HCFA will have obtained facts -- usually as a result of a survey of the provider -- 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.

It would be neither fair nor efficient to allocate to the provider the burden of persuasion in a case involving HCFA's determination to terminate that provider's participation in Medicare. 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 necessarily knowing what or how much evidence might be needed to establish that

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[5] I am not suggesting here that the burden of persuasion should be allocated to HCFA in every case involving a dispute between HCFA and a provider or an applicant for participation in Medicare. There are circumstances where it may be appropriate to allocate the burden of persuasion to a party other than HCFA. For example, in a case where the issue involves the date when deficiencies have been corrected by an applicant for participation (for example, in a case where the correct date of certification is at issue), it may be appropriate to allocate to the applicant the burden of proving the date that it corrected the deficiencies.

proposition. Allocating the burden of persuasion to the provider would invite a massive and unfocused submission of evidence from the provider. This would be an inappropriate allocation of the burden of persuasion in light of the fact that HCFA ought to be in possession of facts sufficient to justify its determination to terminate a provider's participation in Medicare.

HCFA has not claimed in any of these cases that imposing the burden of persuasion on it would be unfair or unreasonable. Notwithstanding, HCFA asserts that its determination to terminate a provider's participation in Medicare must be presumed to be correct unless the provider proves otherwise.[6]

HCFA asserts that there is a presumption of correctness attached to its determination that a provider is not complying with conditions of participation. It asserts, in effect, that the administrative hearing in a case involving termination of a provider's participation in Medicare is essentially an appellate review of HCFA's determination. In Utuado, HCFA argued that, in order to prevail, a provider must prove HCFA's determination to be incorrect with "clear and convincing evidence." Utuado at 7. HCFA argued also in Utuado and Guaynabo that its findings must be sustained if they are supported by "substantial evidence." Utuado at 7; Guaynabo at 12.[7]

HCFA argues that it would not be unfair or inefficient to impose the burden of persuasion on the Petitioners. HCFA asserts that the Petitioners ought to know what evidence to produce on their behalf, because they are on notice of HCFA's specific allegations of failure to comply with conditions of participation. According to HCFA, the specifics of its allegations are set out in the statements of deficiencies which were produced by State survey agency surveyors and provided to the Petitioners,

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[6] HCFA does not object to coming forward first, in an administrative hearing, with evidence supporting its determination. There is an absence of logic to HCFA's position. If, in fact, HCFA's determination is presumed to be correct, then HCFA would have no burden of coming forward with evidence to support its determination.

[7] HCFA did not reiterate explicitly in these cases the arguments it made in Utuado and Guaynabo, aside from asserting that its determinations are presumptively correct. However, HCFA has not retreated from these arguments.

recording the results of surveys. See, e.g., in the case of Petitioner Fajardo, C-94-383, HCFA Ex. 21.

I do not find that the statements of deficiencies describe HCFA's findings with such precision that a Petitioner would know what evidence to offer to rebut those findings. Indeed, even HCFA is not confident that the statements of deficiencies describe completely its cases against Petitioners, as is demonstrated by HCFA's presentation of additional evidence in these cases.

The statements of deficiencies are not sufficiently precise to allow a Petitioner to rebut HCFA's allegations of noncompliance completely. They do not enunciate, except in sketchy terms, the evidence on which HCFA relies to justify its determinations. For example, in the case of Petitioner Fajardo, HCFA made a finding based on the July 6, 1994 resurvey that the condition for participation stated in 42 C.F.R. § 418.54 (medical director) had not been met. The rationale for this finding is that:

> Based on record review of ten active and five inactive records done on July 6, 1994 and review of minutes of discussion by the Interdisciplinary Group, it was determined that the Medical Director is not carrying out full responsibility for the coordination of hospice care.

C-94-383, HCFA Ex. 21 at 3.

This rationale goes on to state that the findings "include but are not limited to" certain specified examples. Id. The examples listed thereafter include examples from some, but not all, of the "ten active and five inactive records" that the surveyors reviewed. The examples do refer to deficiencies in specified patient records. However, they do not identify the documents in those records on which the surveyors relied as evidence for their findings.

It is not possible to ascertain from the statement of deficiencies resulting from the resurvey of Petitioner Fajardo which of Petitioner Fajardo's records, aside from those few that are specifically cited as examples, form the basis for the surveyors' findings. The statement of deficiencies does not contain a list of the "ten active and five inactive records" reviewed by the surveyors, nor is there evidence in the case that HCFA provided Petitioner Fajardo with that list. There is no evidence that HCFA provided Petitioner Fajardo with a list of the

specific documents in any patient records which formed the basis for the surveyors' findings. Nor do the findings specify which minutes of meetings of Petitioner Fajardo's interdisciplinary group the surveyors relied on for their findings.

In order for Petitioner Fajardo to rebut HCFA's findings, assuming the findings are presumed to be valid, Petitioner Fajardo would have to guess which of its active and inactive records, other than those cited in the statement of deficiencies, were the "ten active and five inactive records" to which the surveyors were alluding. It would have to guess also which specific documents formed the basis for the findings cited more specifically in the statement of deficiencies. Petitioner Fajardo would have to guess which of its interdisciplinary group's minutes were allegedly deficient.

Also, Petitioner Fajardo would find it difficult to gauge the significance of the alleged deficiencies from the statement of deficiencies sent to it by HCFA. As I discuss at Part II.A.2. of this decision, in order to sustain a determination to terminate a provider's participation in Medicare, HCFA must prove not only the presence of deficiencies, but must prove also that the deficiencies are substantial.

As HCFA concedes, there is nothing in either the Act or the regulations which supports HCFA's assertions that its determinations are presumptively correct and that administrative hearings are only appellate reviews of HCFA's determinations. HCFA bases its assertions on what it argues are the implications of the regulations and on its interpretation of principles of administrative law. There are three elements to HCFA's argument:

- HCFA observes that, under 42 C.F.R. §§ 498.25 and 498.40, an administrative determination by HCFA becomes final unless an affected provider requests a hearing from that determination. From this, HCFA argues that logic dictates that the burden of persuasion should fall on the provider who requests a hearing, inasmuch as that provider is seeking to overturn a decision by HCFA that would be final.

- HCFA avers that an established principle of administrative law is that an agency's action is presumptively correct. It characterizes its determinations in these cases as agency actions and argues, therefore, that they are presumptively correct.

- HCFA asserts that, ordinarily, in an administrative hearing, the burden of persuasion falls on the applicant for relief, benefits, or a privilege. It characterizes Petitioners as applicants, and argues, therefore, that the burden of persuasion falls on them.

I am not persuaded by HCFA's analysis. HCFA mischaracterizes the purpose of the administrative hearing guaranteed to providers by Congress. Congress did not afford a provider whose participation in Medicare has been terminated by HCFA only an appellate review of HCFA's determination. Congress directed that such a provider be afforded a de novo hearing at which the evidence is reviewed independently by the Secretary or her delegate, an administrative law judge. Furthermore, HCFA misconstrues the basic principles of administrative law on which it has relied in support of its argument.

A provider whose participation in Medicare has been terminated by HCFA pursuant to section 1866(b) of the Act is afforded a right to a hearing 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. Robert M. Matesic, R.Ph., DAB 1327 (1992); Bernardo G. Bilang, M.D., DAB 1295 (1992). In a de novo hearing, the administrative law judge makes an independent decision, based on the weight of the evidence admitted at the hearing. Neither party's actions are entitled to a presumption of correctness. Section 205(b) provides specifically that, in any case brought pursuant to it, the decision shall be based "on evidence adduced at the hearing." This section neither states nor suggests that, in such a hearing, an appellate standard of review shall apply, nor that the Secretary's determination is entitled to a presumption of correctness.

Regulations which provide that a determination by HCFA becomes final unless a hearing is requested neither state nor suggest that the determination is presumptively valid if challenged. There is no general rule to that effect in administrative law. In fact, the general rule is to the contrary. Both in civil money penalty cases brought under section 1128A of the Act and 42 C.F.R. Part 1003, and in exclusion cases brought under section 1128 of the Act and 42 C.F.R. Part 1001, the administrative determination is final if a hearing is not requested by the affected individual or entity. However, if a hearing is requested, the burden falls on the Secretary or her delegate (in such cases, the Inspector General) to prove

by a preponderance of the evidence that the determination is justified.

HCFA misinterprets the doctrine of presumptive validity which, in law, attaches to the final actions of administrative agencies. See Maryland-National Capital Park & Planning Comm'n v. Lynn, 514 F.2d 829, 834 (D.C. Cir. 1975); Mazaleski v. Treusdell, 562 F.2d 701, 717 n.38 (D.C. Cir. 1975). These decisions, cited by HCFA as support for its argument that its determinations are presumptively valid, do not hold that an agency determination must be presumed to be valid when it is reviewed at an internal administrative hearing. Rather, they hold that the final determination of an administrative agency is presumed to be valid if challenged in a suit in a federal court. These decisions confirm that, normally, federal courts conduct an appellate review of agency determinations if those determinations are challenged.

Consistent with this concept, section 205(g) of the Act adopts a substantial evidence standard of review for any challenge brought in federal district court to a hearing decision made under section 205(b) of the Act. Under section 205(g), the "final" decision which is entitled to a presumption of validity is the administrative law judge decision, or if that decision is reviewed by the Departmental Appeals Board, the decision of the Departmental Appeals Board.

HCFA asserts unrealistically that the Petitioners are merely applicants for relief, benefits, or a privilege. Guaynabo at 11; Utuado at 9; Lajas at 7 - 8; Arecibo at 11 - 13. In a case involving a determination to terminate a provider's participation in Medicare, the provider is not an applicant for a privilege, but, in fact, 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.

Thus, it is incorrect to characterize the Petitioners as applicants. Providers who are participants in Medicare, including the Petitioners, have a contractual relationship with HCFA. The terms of these contracts are stated in the Act, in applicable regulations, and in the participation agreements executed by providers. And, as I describe in Part II.B. of these decisions, these terms are stated also in the plans of correction that HCFA accepted. Judge Leahy found in Guaynabo that that case

arose only because HCFA determined that the petitioner "breached a condition under the contract and HCFA initiated contract termination proceedings." Guaynabo at 13. I reach the same conclusion in these cases.

In Arecibo and Lajas, I discussed the authorities on which HCFA relies to support its characterization of Petitioners as "applicants." Arecibo at 10 - 13; Lajas at 8. It is unnecessary for me to discuss these authorities again, except to say that HCFA has offered no new arguments here which would support HCFA's assertions that these authorities are precedent for deeming the Petitioners to be "applicants." I note however, that my decision in SRA, Inc., d/b/a St. Mary Parish Dialysis Center, DAB CR341 (1994), on which HCFA appears to rely as authority for its argument that Petitioners have the burden of persuasion, and which HCFA did not cite as authority in Arecibo and Lajas, does not support HCFA's argument. The Petitioner in SRA was an applicant for certification as a Medicare supplier. The case did not involve a determination by HCFA to terminate a contract with a provider or a supplier.

HCFA argues also that the Petitioners in this case occupy the same status in the administrative proceeding as do beneficiaries in Social Security disability cases. HCFA contends that beneficiaries in Social Security disability cases are regarded as applicants, even after they are found to be entitled to benefits, and are under a continuing burden to prove their entitlement. This argument misstates the law. The decision cited by HCFA in its briefs, Mathews v. Eldridge, 424 U.S. 319 (1976), no longer describes the operative law governing a beneficiary's continuing entitlement to disability benefits. Indeed, and as HCFA concedes, the current law places the burden of proof on the Secretary to show that a beneficiary's medical condition has improved, as a prerequisite to terminating that beneficiary's entitlement to disability benefits. 20 C.F.R. § 404.1594(b)(2) - (5).

In sum, I conclude that I have the discretion to allocate the burden of persuasion in these cases. Considerations of fairness and efficiency direct me to allocate that burden to HCFA. I am not persuaded by HCFA's arguments that I am required to allocate this burden to Petitioners.

2. The elements of HCFA's burden of persuasion

HCFA's burden of persuasion in these cases consists of three elements.[8] In order to establish a basis for terminating a provider's participation in Medicare, HCFA must prove the following:

- The existence of the participation requirements which a provider has allegedly not complied with. As I discuss below at Part II.B. of these decisions, these requirements may necessarily include the terms of a corrective action plan.

- The facts which establish that the provider failed to comply with a Medicare participation requirement.

- That a provider's failure to comply with a Medicare participation requirement is so substantial as to justify terminating that provider's participation in Medicare.

Participation requirements are stated both in the Act and in implementing regulations and may be stated also in a corrective action plan entered into between a provider and HCFA. Many of these requirements are stated plainly and unambiguously. If HCFA is relying on the plain language of the Act, a regulation, or an agreement with a provider, as establishing a requirement for participation, HCFA need only identify that requirement in order to satisfy the first element of its burden of persuasion. For example, in Arecibo and Lajas, HCFA asserted that the Petitioners failed to comply with the plain language of 42 C.F.R. § 481.58(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 that law. In that event, HCFA must prove that its interpretation is reasonable and that the provider had notice of the 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

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[8] My analysis here is substantially the same as in Utuado. Utuado at 10 - 14.

ambiguities in some regulations which are susceptible to reasonable interpretation by HCFA.[9] 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.[10] Nor does HCFA have the authority to interpret ambiguous language unreasonably.

Furthermore, HCFA has the duty to communicate its interpretations to providers as a prerequisite for holding providers accountable to such interpretations. A provider is not required to divine HCFA's intent from language that is unclear. In Utuado, Lajas, and Arecibo, HCFA argued that providers were required to comply with HCFA's interpretations of the Act or regulations even if HCFA did not communicate its interpretations to providers. I found that position to be unreasonable in those cases, and reaffirm my conclusion here. Utuado at 11 - 12; Lajas at 13; Arecibo at 25.

HCFA meets the second element of its burden of persuasion, the burden of proving that there exist facts which justify its determination, by proving the existence of those facts by a simple preponderance of the evidence. Evidence proving those facts may consist of the testimony by State survey agency surveyors concerning their fact findings. It may also consist of supporting materials, such as patient records.

HCFA meets the third element of its burden of persuasion, the burden of proving that a failure to comply with a participation requirement is substantial, by proving that the noncompliance substantially limits the provider's

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[9] As an appellate panel of the Departmental Appeals Board noted in Center Clinical Laboratory, DAB 1526 at 11, n.4 (1995), where a regulation is susceptible to more than one reasonable interpretation, the interpretation advocated by the agency is entitled to deference.

[10] For example, in Utuado, I held that HCFA could not use its authority to interpret regulations to read into the regulations a requirement that was not specified in the regulations. In Utuado, HCFA argued that the regulations subsumed a requirement that a hospice provide laboratory services to its patients. I concluded that there was no such requirement in the regulations and that HCFA could not use the vehicle of "interpretation" to create such a requirement, where the requirement did not exist. Utuado at 17 - 21.

capacity to render adequate care or that it adversely affects the health and safety of patients. Utuado at 12; 42 C.F.R. § 488.24(a).

Termination of a provider's participation in Medicare is a remedy and not a punishment. Thus, the paramount question which must be resolved in deciding whether termination is reasonable is whether a provider's failure to comply with participation requirements predicts a likelihood that the provider will not be able to deliver care in the future consistent with the requirements of the Act and regulations. However, as I held in Utuado, the Act and regulations make it plain that an inference may be drawn from a provider's substantial failure to comply with participation requirements that the provider is likely to remain deficient in the future. Utuado at 13.

Some of the criteria for participation are so fundamental to the requirement that a provider render adequate care, or so necessary to protect the health and safety of patients, that a failure to comply with any of those criteria is on its face a substantial deficiency justifying termination of participation. Utuado at 13. That is evident where the deficiency is a failure to meet a broadly stated condition of participation. It may be evident also where the deficiency constitutes a systematic or wholesale failure to comply with a participation requirement.

There may also be circumstances where a deficiency is not, on its face, substantial. That is particularly true where the evidence of the deficiency addresses a standard of participation, and not a broad condition of participation.

The regulations establishing participation criteria for hospices often state broad conditions of participation and state additionally components of those conditions as standards. For example, 42 C.F.R. § 418.68 requires a hospice, as a condition of participation, to designate an interdisciplinary group composed of individuals who provide or supervise the services provided by the hospice. It states also as standards specific requirements for the performance of the interdisciplinary group. 42 C.F.R. § 418.68(a) - (d).

Failure by a hospice to establish an interdisciplinary group would, on its face, be a failure to comply with the condition of participation and would be a substantial deficiency. Failure by a hospice to comply with one of the standards governing its interdisciplinary group might

be so egregious as to constitute a failure of the overall condition of participation. However, that would depend on the evidence. Isolated examples of failure to comply with one of the standards might not be persuasive evidence of failure to comply with the overall condition. Evidence of systematic failure to comply with one of the standards might be persuasive evidence of failure to comply with the overall condition.

Therefore, in some cases, HCFA may have to prove not only the presence of a deficiency, but may have to prove also that the deficiency is substantial. 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.

3. Testimony offered by State survey agency surveyors

In these three cases, as it has in previous cases, HCFA urges that I accord a great deal of importance to the testimony offered by State survey agency surveyors. For example, in the case of Petitioner Caguas, HCFA argues that the opinions of State survey agency surveyors are expert opinions which should be given "immense weight." HCFA posthearing brief (Caguas) at 17. Indeed, HCFA seems to be saying in the case of Petitioner Caguas that an unrebuttable presumption of validity attaches to the opinions expressed by State survey agency surveyors. Id. In Utuado, HCFA argued also that the findings and opinions of State survey agency surveyors should be sustained unless a provider could prove them to be "clearly erroneous." Utuado at 7.

State survey agency surveyors may qualify as expert witnesses and may offer expert opinion on issues of fact. However, I do not accept HCFA's assertion that the opinions of State survey agency surveyors qualify automatically as "expert" opinion which must be presumed to be correct.

The regulations which govern surveys by State survey agency surveyors state 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 possess expertise in the activities of the providers which they survey, as well as knowledge of applicable law and regulations.

But that is not to say that every individual who conducts a survey qualifies automatically as an expert. Neither

do the regulations state or suggest, as HCFA has at times appeared to argue, that surveyors are vested with authority to issue fact findings, or to interpret law and regulations, definitively on behalf of the Secretary. Nor do the regulations imply that even the qualified expert opinions of surveyors are vested with a presumption of correctness.

In order for a State survey agency surveyor to qualify as an expert witness, that individual must demonstrate expertise in the area about which he or she is testifying. The credibility of that individual's opinion as to facts will depend in large measure on the degree of expertise that the individual possesses concerning the subject area of those facts, as well as on the extent to which the facts are proven.

Furthermore, the fact that a State survey agency surveyor may qualify as an expert in a particular subject does not suggest that the surveyor is qualified to testify about all related subjects. For example, as I shall discuss in my analysis of the individual cases, the State agency surveyors whose testimony HCFA presented in these cases are nurses who are qualified experts to testify in the field of nursing. That expertise is limited, however. I do not find that any of the nurses whose testimony HCFA presented are qualified to opine as to the propriety of care ordered or provided by physicians.

In Center Clinical Laboratory, the appellate panel concluded that, in making a finding of immediate jeopardy in a case involving a clinical laboratory's failure to comply with CLIA (Clinical Laboratory Improvement Amendments of 1988) and implementing regulations, HCFA "had relied on the judgment of state survey officials, which it clearly had the right to do under the statute and regulations." Center Clinical Laboratory at 22. The appellate panel's decision addressed a situation where a State survey agency had brought to the attention of HCFA exigent circumstances which the State survey agency concluded would jeopardize the health and safety of the public if not addressed immediately by HCFA. As described by the appellate panel, the situation called for an immediate response by HCFA.

That circumstance is distinguishable from an administrative hearing held after the fact which addresses the propriety of a remedy imposed by HCFA. There, the issue is not whether HCFA should react immediately to the findings brought to its attention in order to deal with exigent circumstances, but whether, in light of the evidence, HCFA's action was appropriate. In

the context of the hearing and HCFA's overall burden of persuasion, it is reasonable to require HCFA to prove that its action was justified. Furthermore, it is reasonable at a hearing to require HCFA to prove that the surveyors upon whom HCFA relied possess expertise sufficient to make credible their findings. The judgment of the surveyors will be found to be reliable where HCFA proves that the surveyors have the requisite expertise to make judgments and where the surveyors' findings are supported by the evidence.

The dichotomy between an agency's right to rely on information brought to its attention by its agents and its burden of proving that that information is reliable at a subsequent administrative hearing is illustrated precisely in section 1128(b)(7) of the Act. That section permits the Secretary, or her delegate, the Inspector General (I.G.), to exclude individuals or entities, who are engaging in fraud or unlawful kickbacks with respect to federally funded health care programs. In the usual case, an exclusion under this section becomes effective only after an administrative hearing held pursuant to section 205(b) of the Act resulting in findings favorable to the Secretary. Act, section 1128(f)(2). An exclusion may go into effect prior to the administrative hearing where the Secretary determines that the health or safety of individuals receiving services warrants the exclusion taking effect earlier. Id.

However, the fact that the Secretary or the I.G. may determine to impose an exclusion under section 1128(b)(7) prior to an administrative hearing does not mean that the I.G.'s burden of persuasion at the hearing is less, or that the witnesses called by the I.G. are vested automatically with greater credibility. Whether the exclusion is imposed prior to or after the hearing, the same standards of proof apply.

B. The significance of a corrective action plan

In each of these cases, HCFA and the Petitioner entered into a corrective action plan to address the deficiencies that were identified at the first survey of that Petitioner.[11] In each of these cases, the Petitioner was resurveyed after the date HCFA had accepted that Petitioner's corrective action plan. Based on these resurveys, HCFA concluded that each Petitioner continued

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[11] The specific provisions of each corrective action plan vary, depending on the deficiencies that were addressed by the plan.

to be deficient in complying with conditions of participation that were addressed in that Petitioner's corrective action plan.

These facts raise a question which is common to these cases. To what extent does a corrective action plan agreed to by a provider and HCFA define that provider's obligations and duties? I conclude that a corrective action plan that has been accepted by HCFA becomes an element of the contract between HCFA and the provider. The corrective action plan defines the manner in which a provider is expected to remedy deficiencies addressed in the plan. HCFA may not ignore a corrective action plan once it has accepted it. In determining whether a provider is complying with conditions of participation, HCFA is obligated to consider the provider's compliance with the terms of the corrective action plan, to the extent that they address any condition for which compliance is being evaluated.

My conclusions here are essentially the same as those which Judge Leahy made in Guaynabo. Guaynabo at 14, 26. The Utuado, Lajas, and Arecibo cases are distinguishable from these cases in that in none of those cases did the petitioner argue that its relationship with HCFA was governed by a corrective action plan.

HCFA appears to argue that the corrective action plan which it entered into with each Petitioner in these cases is irrelevant to the issue of whether that Petitioner failed to comply with conditions of participation. First, HCFA seems to assert that it may predicate its determination to terminate a Petitioner's participation in Medicare on evidence predating the acceptance date of a corrective action plan, even where the evidence pertains to deficiencies that the plan proposes to address prospectively. According to HCFA, a determination to terminate participation based on preplan evidence must be sustained even if the plan of correction promises that, prospectively, the Petitioner will undertake steps to bring it into compliance.

Second, HCFA seems to argue that a corrective action plan cannot supplant the specific compliance requirements set forth in regulations. Thus, if there exists any difference between what is required by the regulations and what might be promised in a corrective action plan, the requirements of the regulations must prevail. Alternatively, HCFA argues that a corrective action plan should be construed to impose requirements on a provider in addition to what is stated in regulations.

In sum, HCFA is arguing that it is free to disregard the terms of a corrective action plan that it has accepted, except to the extent that failure by the provider to comply with the plan gives HCFA an additional ground upon which to premise its determination to terminate that provider's participation. I find HCFA's position to be untenable. HCFA's arguments ignore the purpose of a corrective action plan.[12]

Where HCFA finds that a provider is not complying with a condition of participation, it is not required to offer the provider the opportunity to submit a corrective action plan or to accept such a plan from the provider. In the case of a condition-level deficiency, HCFA may simply terminate the deficient provider's participation in Medicare. See 42 C.F.R. § 488.28. In such a case, HCFA has also the option, in lieu of immediate termination, of offering the provider the opportunity to submit a corrective action plan and of accepting that plan, assuming HCFA finds that it proposes a satisfactory remedy for the provider's deficiencies. That is the option HCFA chose with each of the Petitioners in these cases.

Once HCFA accepts a corrective action plan, both HCFA and the provider are bound by its terms. Where HCFA opts to accept a corrective action plan which addresses condition-level deficiencies, in effect HCFA tells the provider that, if the provider does what it has promised to do in the plan, it will be deemed to have corrected the deficiencies. Thus, compliance by a provider with a corrective action plan becomes the measure of whether the provider has corrected the deficiencies that are addressed by the plan.

Furthermore, where a plan proposes to address deficiencies prospectively, and HCFA accepts the plan, in effect it tells the provider that HCFA will evaluate its

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[12] What HCFA did not argue in these cases, but which would not be an unreasonable position for HCFA to advocate, is that a corrective action plan becomes a basis for future performance evaluation by HCFA for only those deficiencies addressed in the plan. Thus, if HCFA were to resurvey a provider pursuant to a plan and were to find that provider to be failing to comply with some condition of participation other than that which is addressed by the plan, HCFA would be within its rights to terminate that provider's participation based on the provider's failure to comply with that additional condition of participation.

compliance with the conditions addressed in the plan beginning with the date of the plan, and pursuant to the remedies identified in the plan. Under those circumstances, evidence as to deficiencies predating the plan may be irrelevant to the issue of compliance.

It would be punitive, and inimical to the remedial purpose of the corrective action plan, for HCFA to agree to accept a plan from a provider and then to terminate that provider's participation for deficiencies which predate the plan, but which the plan proposes to correct prospectively. It would be punitive also for HCFA to disregard what it had agreed to accept from a provider as a method of compliance with participation requirements.

HCFA argues that, in these cases, it advised each Petitioner that HCFA would hold it accountable not only for compliance with the terms of the corrective action plan, but also for compliance with arguably different requirements. See, e.g., in the case of Petitioner Fajardo, C-94-383, HCFA Ex. 19. The advisory language relied on by HCFA to support this argument tells each Petitioner that a resurvey of that Petitioner "will evaluate whether or not you have successfully implemented your plan of correction and achieved compliance with the Medicare Hospice Conditions of Participation." Id.

I do not read this statement as telling the Petitioners, as HCFA seems to be arguing, that HCFA would be evaluating their performance both pursuant to the terms of the corrective action plans and under separate (and arguably different) conditions of participation. Rather, I believe that this statement must be taken to mean what it says. It says, simply, that HCFA would be evaluating each Petitioner's performance under that Petitioner's corrective action plan and, from that evaluation, would determine whether the Petitioner met conditions of participation.

Furthermore, I am troubled by the implications of HCFA's argument. HCFA seems to be saying that the terms of a corrective action plan may relate to remedies that address something in addition to what is contained in the regulations governing Medicare participation. That is not what a corrective action plan is intended to achieve. The purpose of a corrective action plan is to bring a deficient provider into compliance with Medicare participation requirements. It would make no sense whatsoever for HCFA to enter into a corrective action plan with a provider unless HCFA concluded that, by complying with the elements of the plan, the provider would remedy the deficiencies addressed by the plan and

would thereby be in compliance with Medicare participation requirements.

III. Analysis of the issues and evidence relating to Petitioner Fajardo (Docket No. C-94-383)

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

At the July 6, 1994 resurvey of Petitioner Fajardo, the State survey agency surveyors found that Petitioner Fajardo failed to comply with conditions of participation stated in the following regulations: 42 C.F.R. § 418.50 (general provisions); 42 C.F.R. § 418.54 (medical director); 42 C.F.R. § 418.62 (informed consent); and 42 C.F.R. § 418.86 (physician services). The issue in this case is whether Petitioner Fajardo failed to comply with any of these conditions of participation.

I base my analysis of this issue on the evidence admitted at the hearing, the parties' arguments, and the applicable law (which includes my general conclusions of law stated at Part II of these decisions). I make the following findings of fact and conclusions of law. After each finding or conclusion, I state the page or pages of this decision at which I discuss the finding or conclusion in detail.

1. HCFA did not prove that Petitioner Fajardo failed to comply with the condition of participation contained in 42 C.F.R. § 418.50. Page 24.

2. HCFA did not prove that Petitioner Fajardo failed to comply with the condition of participation contained in 42 C.F.R. § 418.54. Pages 24 - 28.

3. HCFA did not prove that Petitioner Fajardo failed to comply with the condition of participation contained in 42 C.F.R. § 418.62. Pages 28 - 30.

4. HCFA did not prove that Petitioner Fajardo failed to comply with the condition of participation contained in 42 C.F.R. § 418.86. Pages 30 - 41.

5. HCFA did not prove a basis for terminating the participation in Medicare of Petitioner Fajardo. Page 41.

B. The alleged failure of Petitioner Fajardo to comply with the general provisions condition of participation contained in 42 C.F.R. § 418.50

According to HCFA, 42 C.F.R. § 418.50 imposes on a hospice as a condition of participation the requirement that the hospice comply with all other conditions of participation stated in the regulations. Thus, a failure by a hospice to comply with a condition of participation stated elsewhere in the regulations is automatically a failure by that hospice to comply with the condition of participation contained in 42 C.F.R. § 418.50. HCFA contends that Petitioner Fajardo failed to comply with this condition of participation because it failed to comply with conditions of participation stated elsewhere.

I find this argument to be moot, because HCFA did not prove that Petitioner Fajardo failed to comply with conditions of participation stated in regulations other than 42 C.F.R. § 418.50. It is, therefore, not necessary for me to analyze in this case HCFA's arguments concerning the meaning of 42 C.F.R. § 418.50.

However, in Utuado and Lajas, I concluded that the Secretary did not intend 42 C.F.R. § 418.50 to inflate a hospice's failure to comply with conditions of participation. Utuado at 16 - 17; Lajas at 20 - 21. HCFA has not made any new arguments here that would cause me to question the analysis I made in those decisions.

C. The alleged failure of Petitioner Fajardo to comply with the medical director condition of participation contained in 42 C.F.R. § 418.54

HCFA argues that, when it resurveyed Petitioner Fajardo on July 6, 1994, Petitioner Fajardo failed to comply in two respects with the medical director condition of participation contained in 42 C.F.R. § 418.54. First, the medical director was not assuring that patients were being certified for hospice services in accordance with Medicare certification requirements. C-94-383, HCFA Ex. 21 at 3; HCFA posthearing brief (Fajardo) at 16 - 17. Second, the medical director had failed to discharge his responsibilities by allowing Petitioner Fajardo to treat patients who were not eligible for hospice care. C-94-383, HCFA Ex. 21 at 5; HCFA posthearing brief (Fajardo) at 18.[13]

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[13] The surveyors who conducted the July 6, 1994 resurvey of Petitioner Fajardo identified a third alleged failure of this Petitioner to comply with the medical

HCFA failed to meet its burden of persuasion with respect to both of these assertions. I find that HCFA's proof is deficient in the following respects:

- The performance of Petitioner Fajardo's medical director was made subject to the terms of a corrective action plan accepted by HCFA on June 23, 1994. HCFA has the burden of proving that, after June 23, 1994, Petitioner Fajardo failed to comply with the corrective action plan. However, HCFA failed to offer the relevant parts of the plan as evidence, and, therefore, the record is devoid of the operative document by which the performance of the medical director must be measured.

- Even if the relevant part of the corrective action plan had been offered by HCFA, HCFA failed to offer evidence which relates to the performance of Petitioner Fajardo's medical director after the critical date of June 23, 1994.

- HCFA's assertion that the medical director allowed Petitioner Fajardo to treat patients who were not eligible for hospice care is not supported by credible evidence.

The regulation governing the duties of a hospice medical director states, as a condition of participation, 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.

42 C.F.R. § 418.54.

In Utuado, I analyzed the requirements of this regulation. Utuado at 21 - 22. I held that the plain meaning of the regulation is that a hospice medical

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director condition of participation. This had to do with alleged failure of the medical director to assure that patient plans of care were being reviewed and revised as necessary. C-94-383, HCFA Ex. 21 at 3 - 5. However, HCFA did not make any arguments concerning this alleged deficiency in its posthearing brief. See HCFA posthearing brief (Fajardo) at 15 - 18. Thus, I conclude that HCFA is no longer asserting that this alleged deficiency establishes a violation of the medical director condition of participation.

director must assume supervisory and management responsibility for the medical services that the hospice provides to its patients. Id. In Utuado, I held further that the duties of a hospice medical director included assuring that patients of the hospice be certified as being eligible for hospice care, pursuant to the requirements of applicable regulations. Id. at 23 - 24. Finally, I held that the duties of a hospice medical director included supervising the performance of the hospice's interdisciplinary group. Id. at 22 - 23.

The medical director condition was a condition that HCFA had concluded Petitioner Fajardo was not complying with as a consequence of the initial survey of Petitioner Fajardo, conducted in April 1994. C-94-383, HCFA Ex. 15. On May 16, 1994, Petitioner Fajardo submitted its proposed corrective action plan to HCFA. Among other things, this proposed plan addressed the deficiencies which HCFA found in Petitioner Fajardo's compliance with the medical director condition. C-94-383, HCFA Ex. 16 at 5 - 6.

On May 31, 1994, HCFA advised Petitioner Fajardo that it found the proposed corrective action plan to be unacceptable insofar as it addressed the role of the medical director. C-94-383, HCFA Ex. 17.[14] Specifically, Petitioner Fajardo had proposed to prepare a manual which outlined the duties of its medical director. HCFA refused to accept the corrective action plan, insofar as it addressed the duties of the medical director, without first reviewing and approving the manual. C-94-383, HCFA Ex. 17 at 2.

On June 14, 1994, Petitioner Fajardo submitted a revised corrective action plan to HCFA which included a medical director manual. C-94-383, HCFA Ex. 18 at 2. HCFA accepted the revised corrective action plan on June 23, 1994. C-94-383, HCFA Ex. 19.

The medical director manual, which is a part of the final corrective action plan accepted by HCFA from Petitioner Fajardo, is not in evidence in this case. HCFA did not

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[14] Also, HCFA found the corrective action plan to be unacceptable because of the manner in which Petitioner Fajardo proposed to advise its patients of their rights and obligations under 42 C.F.R. § 418.62. C-94-383, HCFA Ex. 17 at 3. I discuss the issue of Petitioner Fajardo's alleged failure to comply with the informed consent condition of participation below, at section III.C. of these decisions.

offer the document as an exhibit. HCFA did attach a purported English translation of the document to its posthearing brief. Petitioner Fajardo objected to my receiving this document into evidence.

I do not admit the medical director manual into evidence, and I do not rely on it as part of my analysis. HCFA did not justify offering the document untimely, nor did it prove an absence of prejudice to Petitioner.

At the hearing, I commented that HCFA's case might be deficient without the medical director manual being in evidence. Tr. at 498 - 500. HCFA did not offer the document. Also, HCFA did not elicit testimony from the surveyors concerning whether any of them had reviewed the performance of Petitioner Fajardo pursuant to the medical director manual. HCFA rested its case without suggesting that it wished to offer the manual at a later date.

Not only has HCFA not shown good cause for my considering the medical director manual at this point, but it would be prejudicial to Petitioner. HCFA has not proven the purported translation to be accurate, and the parties have not stipulated to its accuracy. Furthermore, Petitioner would be deprived of the opportunity to cross-examine the surveyors concerning whether they reviewed Petitioner's performance pursuant to the manual.

HCFA's failure to offer timely into evidence the remedial plan which governed the performance of Petitioner Fajardo's medical director after June 23, 1994, constitutes a fatal gap in HCFA's proof. Having accepted a corrective action plan from Petitioner Fajardo, HCFA has the burden of proving that Petitioner Fajardo failed to comply with it. It is not possible for me to evaluate Petitioner Fajardo's compliance with the medical director condition of participation after June 23, 1994, given that the part of the corrective action plan which addresses this condition of participation is not in evidence.

Not only did HCFA not offer as evidence the part of the corrective action plan that related to the medical director condition, but also it is not apparent from the record that the State survey agency surveyors even considered whether Petitioner Fajardo was complying with it in conducting their July 6, 1994 resurvey of Petitioner. None of the testimony of these individuals relates in any respect to whether or not Petitioner Fajardo complied with the corrective action plan. See Tr. at 184 - 218, 496 - 537.

Furthermore, it is unclear from the evidence offered by HCFA that the evidence would prove that Petitioner Fajardo failed to comply with the corrective action plan after June 23, 1994, assuming that the part of the plan relating to the medical director was in evidence. That is so because the evidence does not prove that it relates to events after June 23, 1994.

HCFA bases its assertion that the medical director was not properly supervising the certification of patients for hospice services on its finding that, in seven of eight patient records reviewed on July 6, 1994, the recertification documents lacked statements as to the patient's present health status, prognosis, and life expectancy. C-93-383, HCFA Ex. 21 at 3. The statement of deficiencies prepared by the State agency surveyors after the July 6, 1994 resurvey does not note the dates of any of these records. Id. Testimony offered by HCFA at the hearing relates to recertifications of two patients, patient # 2 and # 9. Tr. at 214 - 215, 507 - 508. However, the patient records relied on by HCFA show that the recertification of patient # 2 was made on May 9, 1994, and the recertification of patient # 9 was made on May 18, 1994. C-94-383, HCFA Ex. 36 at 20 - 21; C-94-383, HCFA Ex. 43 at 10 - 14. Both of these recertifications were made prior to June 23, 1994.

Finally, I am not persuaded that Petitioner Fajardo failed to comply with the medical director condition of participation because it discharged 66 patients between May 27 and July 6, 1994. HCFA asserts that this is proof that Petitioner Fajardo was treating patients who were not eligible to receive hospice care, and that its medical director was deficient in allowing Petitioner Fajardo to provide such treatment. The record is devoid of meaningful evidence pertaining to the circumstances under which these patients were discharged. Furthermore, assuming for the sake of argument that HCFA correctly asserts that these patients were not eligible to receive hospice care, then, by discharging these patients, Petitioner Fajardo was attaining compliance with the criteria for providing hospice care. That can hardly be a basis for finding Petitioner Fajardo to be deficient as of the July 6, 1994 resurvey.

D. The alleged failure of Petitioner Fajardo to comply with the informed consent condition of participation contained in 42 C.F.R. § 418.62

HCFA asserts that, as of July 6, 1994, Petitioner Fajardo was not complying with the condition of participation governing informed consent of patients, contained in 42

C.F.R. § 418.62. HCFA bases this assertion on the findings of the State agency surveyors who conducted the July 6, 1994 resurvey of Petitioner Fajardo. The surveyors examined ten patient records and concluded that none of them contained the informed consent form that Petitioner Fajardo developed as part of its corrective action plan. C-94-383, HCFA Ex. 21 at 6 - 7.

Petitioner Fajardo does not dispute this evidence. It argues, however, that the evidence does not prove that it failed to comply with the informed consent condition of participation. It asserts that its obligations under the corrective action plan are prospective only. According to Petitioner Fajardo, insofar as the corrective action plan pertained to the issue of informed consent, it required Petitioner Fajardo to obtain patient consent on the newly developed form from any patient admitted after June 23, 1994. Petitioner Fajardo argues that HCFA failed to prove that Petitioner Fajardo did not live up to this obligation, inasmuch as the ten patients whose records were examined by the surveyors had all been admitted to hospice care prior to June 23, 1994.

HCFA responds to this argument by asserting that the obligation to obtain informed consent from a patient is a continuing obligation. It argues that the corrective action plan did not excuse Petitioner Fajardo from obtaining executed consents from all of its patients on the newly developed form, including those who were admitted prior to June 23, 1994.

Petitioner Fajardo could have concluded reasonably from its communications with HCFA that HCFA intended that it use the new informed consent prospectively, to advise patients admitted after June 23, 1994 of the services available to them. HCFA did not tell Petitioner Fajardo that it was to have the new form executed by both existing and future patients.

Petitioner Fajardo sent its first proposed corrective action plan to HCFA on May 16, 1994. C-94-383, HCFA Ex. 16. In that document, Petitioner Fajardo took issue with HCFA's assertion that an informed consent form must recite all of the services that Petitioner Fajardo would supply to its patients. Id. at 12 - 13. Petitioner Fajardo asserted that, in fact, all of its patients had been informed of the services to be provided to them in other forms which Petitioner Fajardo had supplied to these patients. Id. Notwithstanding, Petitioner Fajardo proposed to correct deficiencies in the manner in which it obtained informed consent by creating a manual to be

provided to patients which detailed the services that would be offered to them. Id.

HCFA found this proposal to be unacceptable. Id.; C-94-383, HCFA Ex. 17 at 3. It advised Petitioner Fajardo that Petitioner Fajardo was obligated to obtain informed consent on a single form which addressed all services to be provided to patients under its care. Id. On June 14, 1994, Petitioner Fajardo responded to HCFA by providing HCFA with a proposed new informed consent form. C-94-383, HCFA Ex. 18.[15] On June 23, 1994, HCFA accepted the new form. C-94-383, HCFA Ex. 19.

There is nothing in the correspondence between HCFA and Petitioner Fajardo concerning the corrective action plan in which HCFA states its intent concerning how Petitioner Fajardo was to use the new informed consent form. HCFA never told Petitioner Fajardo that it assumed that Petitioner Fajardo would have the new form executed by patients who had been admitted previously to its care.

I do not find it unreasonable that Petitioner Fajardo would have concluded that the form was to be utilized prospectively, with patients admitted after the date the form was found to be acceptable by HCFA. I find this to be so, particularly, because Petitioner Fajardo was contending that it had complied with the spirit, if not the letter, of the informed consent requirement. Petitioner Fajardo told HCFA that it had advised its patients of all of the services it would be providing to them, albeit in a format that was different from the one insisted on by HCFA. HCFA did not take issue with this statement.

Thus, the evidence presented by HCFA does not prove that Petitioner Fajardo was failing to comply with the informed consent condition after June 23, 1994. At most, it proves a misunderstanding between HCFA and Petitioner Fajardo concerning Petitioner Fajardo's obligations.

E. The alleged failure of Petitioner Fajardo to comply with the physician services condition of participation contained in 42 C.F.R. § 418.86

At the July 6, 1994 resurvey of Petitioner Fajardo, the State survey agency surveyors identified seven

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[15] As with the medical director manual, the new informed consent form, part of the corrective action plan, was not made an exhibit by HCFA and is not in evidence.

deficiencies which they concluded established that Petitioner Fajardo was not complying with the physician services condition of participation contained in 42 C.F.R. § 418.86. C-94-383, HCFA Ex. 21 at 12 - 14. I have examined carefully the evidence that HCFA offered pertaining to these alleged deficiencies. I conclude that this evidence does not prove that, as of July 6, 1994, Petitioner Fajardo had failed to comply with the physician services condition of participation.

The regulation which governs physician services provided by a hospice states:

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

42 C.F.R. § 418.86.

The meaning of this regulation is plain. It requires physicians who are employed by a hospice to provide palliation and management of patients' terminal illnesses and related conditions. It requires also that physicians who are employed by a hospice provide care to meet the general medical needs of hospice patients <u>if</u> those needs are not met by the patients' attending physicians.

The term "attending physician" is defined elsewhere in the regulations. Under 42 C.F.R. § 418.3, an attending physician is a doctor of medicine or osteopathy who is identified by the patient at the time he or she seeks hospice care "as having the most significant role in the determination and delivery of the . . . [patient's] medical care."

At the hearing, I questioned whether HCFA had shown that the physicians whose services HCFA had found to be deficient were employed by Petitioner Fajardo. My preliminary assessment was that HCFA's burden of persuasion under 42 C.F.R. § 418.86 included the duty to prove that any deficiency under the regulation was the direct consequence of a failure by a physician employed by the hospice to provide that service personally.

On further reflection, however, I conclude that, in expressing these concerns I missed a broader and more fundamental point. Under 42 C.F.R. § 418.86, the hospice

(and its physician employees) assume the burden of providing physician services to a patient only to the extent that the services are not being provided by the patient's attending physician. The necessary predicate to establishing deficient care by the hospice physician is to first prove that the care is not being provided by the patient's attending physician. Guaynabo at 30.

Therefore, in order to prove that a hospice is deficient under 42 C.F.R. § 418.86, HCFA must prove that a patient's attending physician has not provided a service required by the regulation and that the hospice physician also has not provided that service. Guaynabo at 30. HCFA does not meet its burden of persuasion under 42 C.F.R. § 418.86 by proving only that a hospice physician failed to provide necessary care to a patient. Such evidence is not meaningful unless HCFA first proves that the service that was not being provided by the hospice physician was also not provided by the patient's attending physician.

HCFA appears to concede that it must prove that a patient's needs are not being met, both by that patient's attending physician and by the hospice physician, in order to prove a deficiency under 42 C.F.R. § 418.86. HCFA reply brief at 11. However, HCFA seems to argue, without explanation, that it has accomplished this task simply by offering excerpts of hospice records which show that a necessary service was not provided by an individual whom HCFA asserts to be the hospice physician. Id. HCFA argues also that it would be unreasonable to expect it to prove that a patient's attending physician did not provide required services as a prerequisite to proving that a hospice is deficient under the physician services regulation. According to HCFA, it would be faced with the unreasonable requirement of having the attending physician admit against his or her self-interest that he or she had not provided required services. Id. at 10 - 11.

I am not persuaded that it would be unreasonable to require HCFA to prove that a patient's attending physician had not provided required services as a prerequisite to proving that the hospice had not complied with 42 C.F.R. § 418.86. First, that is what is required by the regulation. Second, the burden is not difficult for HCFA to meet.

In any case where State agency surveyors find that necessary physician services are not documented in a hospice record for a patient, the surveyors could ask the hospice personnel or the patient's family whether that

patient had an attending physician other than the hospice physician. If the surveyors established that the patient had no physician other than the hospice physician, a deficiency in providing physician services would be a deficiency under 42 C.F.R. § 418.86. If the surveyors established that the patient did have an attending physician, they could then ask that physician whether he or she had records to document that necessary services which were not documented in the hospice record had been provided to the patient. If that physician did not produce such records, an inference could be drawn that the physician had not provided the necessary services. HCFA has not offered any evidence regarding whether the patient's attending physician failed to provide necessary services. Therefore, HCFA has not established a necessary element to proving a deficiency pursuant to 42 C.F.R. § 418.86.

HCFA failed to meet its burden of proving that the hospice physician failed to provide necessary medical services that had not been provided by an attending physician. The patient records it offered consist of fragments of the hospice records. It does not appear that the State agency surveyors made any effort to determine whether the patients had attending physicians, other than the hospice physician, and whether records existed elsewhere for services provided by the attending physicians.[16]

Furthermore, I am not persuaded by the evidence offered by HCFA that in fact it proved that the services which it asserts to be deficient are deficient. My analysis of the evidence relating to the seven alleged deficiencies cited by the surveyors follows.[17]

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[16] It is possible that a patient's attending physician could be a physician employed by a hospice. The regulations plainly contemplate that, in some cases, a patient could designate the hospice physician as his or her attending physician. In that event, HCFA would meet its burden of persuasion under 42 C.F.R. § 418.86 by proving a deficiency in the treatment afforded by the hospice physician. However, HCFA did not prove that the hospice physician served as the attending physician for the patients of Petitioner Fajardo.

[17] Petitioner Fajardo's compliance with a plan of correction is not at issue here. That is so because the alleged deficiencies in physician services which the surveyors identified at the July 6, 1994 resurvey of Petitioner Fajardo were not addressed in the plan of

1. Patient # 2

The surveyors found that, on May 10, 1994, the physician who treated patient # 2 ordered that the patient be administered the medication Prozac in the amount of 20 mg, but failed to indicate the frequency of administration and the route of administration. C-94-383, HCFA Ex. 21 at 12. HCFA asserts from these findings that the physician's order was incomplete and, consequently, Petitioner Fajardo was deficient under 42 C.F.R. § 418.86. I am not satisfied that HCFA proved that the service provided by the physician to patient # 2 was substantially deficient.

The evidence HCFA offered at the hearing to support the surveyors' findings concerning the order to administer Prozac to patient # 2 consisted of the testimony of Alba N. Muñoz, a surveyor who participated in the July 6, 1994 resurvey of Petitioner Fajardo. Tr. at 186 - 188. Ms. Muñoz is a nurse, and it is apparent, both from her resume and from her testimony, that she has extensive training and work experience in the nursing profession. C-94-383, HCFA Ex. 61; Tr. at 179 - 183. HCFA offered the testimony of Ms. Muñoz as expert testimony to prove that the services she reviewed did not comport with the standards of care which governed the physicians who provided services to the patients cared for by Petitioner Fajardo.

I accept as credible Ms. Muñoz' testimony that the failure of the physician to specify the route and frequency of administration of Prozac to patient # 2 is a failure to comply with a generally accepted requirement that a physician's order specify the route and frequency of administration of medications that are prescribed in that order. Tr. at 187. Ms Muñoz' experience as a nurse qualifies her to attest to what is usually contained in a physician's order. Furthermore, her testimony was supported on this point by the testimony of Alma V. Rivera, M.D., a physician. Tr. at 655.

However, Ms. Muñoz did not testify as to the possible adverse consequences that might have resulted to patient # 2 from the failure of the physician to specify the route and frequency of administration of Prozac to that patient. Neither did Dr. Rivera. Indeed, Dr. Rivera did not review the treatment records of patient # 2, or of

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correction accepted by HCFA. See C-94-383, HCFA Ex. 15 at 22 - 26; C-94-383, HCFA Ex. 16 at 21 - 23; C-94-383, HCFA Ex. 17; C-94-383, HCFA Ex. 18.

any of the patients whose records are in evidence in these cases. Tr. at 659.

HCFA offered no evidence, either through Ms. Muñoz or Dr. Rivera, as to the medical purpose of Prozac, or of the usual route and frequency of administration of that medication. HCFA did not offer evidence to show that misinterpretation of a physician's order to administer Prozac to a patient might produce harmful consequences to that patient. Thus, there is no evidence of record to prove that the incomplete order to administer Prozac to patient # 2 might have adversely affected the health and safety of that patient. Absent such evidence, I cannot fairly conclude that the failure to specify the route and frequency of administration of Prozac to patient # 2 is a substantial deficiency in the providing of physician services to that patient.

HCFA did not argue that the failure to properly document the order to administer Prozac to patient # 2 was a failure by Petitioner Fajardo to comply with the clinical records condition of participation contained in 42 C.F.R. § 418.74. Nor did it argue that other alleged failures by Petitioner Fajardo or of the other Petitioners in these cases to maintain accurate records of medical treatments ordered for and provided to patients were failures to comply with that condition. I might have found that such alleged failures constituted failures to comply with the clinical records condition, had HCFA alleged that and provided the Petitioners with notice of its allegations.

2. Patient # 3

The surveyors found that, as of June 13, 1994, the plan of care for patient # 3 indicated that the patient's breathing problems had been solved. However, nursing documentation recorded on June 19 and 29, 1994 showed that the patient was again experiencing breathing problems and was receiving respiratory therapy for these problems. C-94-383, HCFA Ex. 21 at 12. HCFA asserts that these findings demonstrate that Petitioner Fajardo was not documenting properly the services it was providing to the patient, nor was it planning that patient's care. According to HCFA, this comprises a failure to comply with 42 C.F.R. § 418.86.

HCFA did not prove that Petitioner Fajardo was deficient in providing physician services to patient # 3. There is nothing in the surveyors' statement to suggest or show that inadequate or improper services were supplied to this patient. There is no suggestion that the patient's

physician failed to diagnose or to treat the patient's breathing problems. Ms. Muñoz offered nothing in her testimony that would support the conclusion that the physician who treated patient # 3 provided inadequate care to that patient. See Tr. at 188 - 197.

At the hearing, HCFA asserted that the deficiency with respect to patient # 3 was a failure by Petitioner Fajardo to amend its plan of care for that patient to reflect breathing problems that developed after June 13, 1994. If so, that is not a deficiency in the services provided by a physician, so much as it is a deficiency in recording the plan of care of the patient. There is a regulation which governs the requirement for a hospice to plan a patient's care and to document that care. 42 C.F.R. § 418.58. I do not find that regulation to be incorporated by reference into 42 C.F.R. § 418.86. Thus, an alleged failure by a hospice to properly plan the care it provides to a patient cannot automatically be attributed to a deficiency in the services provided by a hospice physician.

At the hearing, I observed that HCFA seemed to be arguing that most of the regulations governing hospices are incorporated by reference into most of the other regulations governing hospices. Thus, HCFA asserts that: deficiencies under other regulations are automatically deficiencies under 42 C.F.R. § 418.50; virtually any failure by a hospice to provide care to a patient consistent with the requirement of some regulation is a deficiency in the performance of the hospice medical director under 42 C.F.R. § 418.54; and a deficiency in planning a patient's care may be construed to be a deficiency in the performance of a hospice physician employee under 42 C.F.R. § 418.86. I observed then, and I reiterate, that the Secretary did not intend the regulations governing hospices to be interpreted so loosely. And, even if that is the Secretary's intent, HCFA has not established that it has communicated that intent to hospices in a manner which would put them on notice of their obligation to comply.. Tr. at 194 - 197.

3. Patient # 4

The surveyors found that patient # 4 was first admitted to the care of Petitioner Fajardo on June 29, 1992. On May 23, 1994, this patient was hospitalized with chest pain. The hospice records for this patient document visits to the patient during the patient's hospitalization by various professionals, but not by the hospice physician. On June 2, 1994, the hospice physician noted that the patient was not terminally ill

and that the hospice planned to transfer the patient to the services of home care. C-94-383, HCFA Ex. 21 at 13; Tr. at 198.[18] HCFA argues from these findings that Petitioner Fajardo failed to comply with the requirements of 42 C.F.R. § 418.86 in that a physician or physicians in its employ should not have been providing services to a patient who was not terminally ill. Tr. at 200 - 201.

I am not persuaded, either by the evidence or by HCFA's argument as it relates to patient # 4, that HCFA proved that Petitioner Fajardo did not comply with the physician services condition in its treatment of this patient. First, 42 C.F.R. § 418.86 does not address the allegations raised by HCFA with respect to this patient. The regulation was intended to insure that hospice patients received physician services. It cannot be read to state that hospice physicians who treat hospice patients who may not be terminally ill are somehow deficient in providing services to these patients.

That is not to say that a hospice may accept and treat patients whom it knows not to be terminally ill. Both the Act and the regulations limit coverage for hospice care to patients who are terminally ill and impose requirements on hospices to certify that their patients are terminally ill. But those requirements are not incorporated implicitly into 42 C.F.R. § 418.86.

Second, HCFA offered no qualified evidence to prove that Petitioner Fajardo misjudged the medical condition of patient # 4. It offered the testimony of Ms. Muñoz, who is a nurse and not a physician, to demonstrate that the patient's treatment records did not establish the patient to be terminally ill. Tr. at 205 - 210. I do not find her opinion to be credible on this issue. Indeed, under regulations governing hospices, the Secretary has determined that only a physician is qualified to adjudge whether a patient is terminally ill. 42 C.F.R. §§ 418.20 - 418.22.

4. Whirlpool treatment for Patient # 2

The surveyors found that, on June 26, 1994, the physician who treated patient # 2 ordered a consultation with a "physical medicine physician" for whirlpool treatment. C-

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[18] The statement of deficiencies contains an obvious error in that it recites that "on June 2, 1994, the physician documented that the patient was terminally."

94-383, HCFA Ex. 21 at 13.[19] As of the July 6, 1994 resurvey, the patient had not yet been evaluated nor had the patient received whirlpool treatment. HCFA argues from this that the patient had not received services ordered by a physician and that, therefore, Petitioner Fajardo was not complying with the physician services condition of participation.

I am not persuaded that these findings document a failure by Petitioner Fajardo or by a physician employed by it to provide a service that is covered under 42 C.F.R. § 418.86. There is proof that the patient did not receive services that the physician had ordered. However, the evidence offered by HCFA does not establish that the physician had it within his or her ability to control whether the services were delivered. The evidence establishes only that the physician directed that there be a consultation with another individual. The evidence does not establish whether that individual is an employee of the hospice, or whether the physician who ordered the consultation had it within his or her ability to assure that the consultation took place.

Under the regulation, a physician who is employed by a hospice has a duty to order that necessary services be provided to a patient, to the extent that those services are not provided by the patient's attending physician. The hospice physician has the additional obligation to assure that services which are under his or her control are delivered to the patient. But the regulation does not impose on a hospice physician the duty to assure that third parties, who may not be under the physician's control, deliver services that have been ordered. Thus, a failure to supply a service to a patient that has been ordered by a hospice physician is not automatically a failure to deliver a physician service under 42 C.F.R. § 418.86.

Arguably, Petitioner Fajardo may have had an obligation under some regulation other than 42 C.F.R. § 418.86 to assure that services provided by a third party, but ordered by a hospice physician, actually are provided to a patient. However, HCFA did not make that assertion here. I find only that HCFA cannot attribute the

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[19] The surveyors' findings and the testimony offered at the hearing do not establish whether the physician ordered that the patient be seen by a physician who specialized in physical medicine or by a physical therapist.

deficiency in providing a service to a hospice physician who ordered that service, where it is unclear from the record that the physician had the power to assure that the service was delivered to the patient.

Furthermore, HCFA did not offer any credible evidence to show that a 10-day delay in providing whirlpool treatments to patient # 2 constituted a substantial deficiency, if indeed it is a deficiency. HCFA offered no evidence as to what adverse consequences this patient might suffer from a failure to provide whirlpool treatments to the patient.

5. Patient # 7

The surveyors found that patient # 7 was admitted to the care of Petitioner Fajardo on June 23, 1993, with a diagnosis of "COPD." C-94-383, HCFA Ex. 21 at 13.[20] On June 21, 1994, a physician issued a statement that patient # 7 was terminally ill. This patient was discharged on July 5, 1994 with a finding that her medical condition was stable. C-94-383, HCFA Ex. 45 at 10. The surveyors found no evidence in that patient's record that the patient had been reevaluated between June 23, 1994 and July 1, 1994. From this, HCFA asserts that the patient was deprived of necessary physician services.

HCFA argues that "the absence of medical evidence showing that
. . . [the patient] was reevaluated prior to being discharged suggests that her medical needs were not being met." HCFA posthearing brief (Fajardo) at 22. In effect, HCFA is saying that there must have been deficient services to this patient because the reasons for her discharge were not explained fully in her treatment records. I conclude that this argument is speculative, and not supported by any credible evidence. HCFA has simply not identified a deficiency in the care provided to this patient.

6. Patient # 10

The surveyors found that patient # 10, who was diagnosed to be suffering from "COPD," was receiving the medication Theodur in a dose of 200 mg, at 12-hour intervals, beginning March 24, 1994. C-94-383, HCFA Ex. 21 at 14.

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[20] There is an error in the statement of deficiencies prepared by the surveyors. It states incorrectly that the patient was admitted to hospice care on June 23, 1994. Id.

They found that the patient's records showed that, on June 3, 1994: "Theophyllin levels were o.2 mcg/ml (normal range 10.0-20.0 mg)." Id. The surveyors concluded that: "Eventhough [sic] the result was below normal range, no intervention was indicated."

HCFA has not explained what it intends these findings to signify. Ms. Muñoz offered no testimony concerning alleged deficiencies in the treatment provided to patient # 10. HCFA made no argument in its posthearing brief concerning alleged deficiencies in the treatment provided to patient # 10. There is no evidence in the record defining or explaining any of the technical language contained in the surveyors' findings. I can find no deficiency in the services provided to patient # 10 by Petitioner Fajardo in the absence of a credible explanation from HCFA as to why the findings by the State agency surveyors establish a deficiency.

7. Discharge of 66 patients

The surveyors found that Petitioner Fajardo had discharged 66 patients between May 27, 1994 and July 5, 1994, with findings that these patients were medically stable. C-94-383, HCFA Ex. 21 at 14. The surveyors concluded that these discharges showed that Petitioner Fajardo was not complying with admission criteria for terminally ill patients.

I do not conclude that these findings, assuming them to be true, support a determination that Petitioner Fajardo was not complying with the physician services condition of participation. First, HCFA has not shown how admission criteria relate to the services which Petitioner Fajardo must provide pursuant to 42 C.F.R. § 418.86. The fact that Petitioner Fajardo discharged many of its patients in a short period of time does not prove that its physician employees were not providing the patients with required medical services. Second, as I find above, the fact that Petitioner Fajardo discharged many of its patients between the first survey, conducted on April 19, 1994, and the resurvey of July 6, 1994 may show an attempt by Petitioner Fajardo to bring its operations into compliance with HCFA conditions of participation.

At the hearing, I noted that a persistent theme in HCFA's cases against all of the Petitioners appeared to be that these Petitioners had treated many patients who were not, in fact, eligible to receive hospice care. That may be so. But HCFA made no specific allegation that these alleged practices by the Petitioners constituted a

failure by them to comply with participation requirements. Nor am I convinced that HCFA may use generalized allegations of improprieties by the Petitioners as a technique to strengthen less-than-probative evidence relating to allegations of failures by the Petitioners to comply with specific conditions of participation.

F. Conclusion as to Petitioner Fajardo

HCFA did not establish a prima facie case that Petitioner Fajardo failed to comply with conditions of participation. Therefore, HCFA did not prove a basis for terminating the participation in Medicare of Petitioner Fajardo.

IV. Analysis of the issues and evidence relating to Petitioner Caguas (Docket No. C-94-384)

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

At the July 8, 1994 resurvey of Petitioner Caguas, the State survey agency surveyors found that Petitioner Caguas failed to comply with conditions of participation stated in the following regulations: general provisions, 42 C.F.R. § 418.50 and medical director, 42 C.F.R. § 418.54. The issue in this case is whether Petitioner Caguas failed to comply with either of these conditions of participation.

I make the following findings of fact and conclusions of law with respect to Petitioner Caguas:

1. HCFA did not prove that Petitioner Caguas failed to comply with the condition of participation contained in 42 C.F.R. § 418.50. Page 42.

2. HCFA did not prove that Petitioner Caguas failed to comply with the condition of participation contained in 42 C.F.R. § 418.54. Pages 42 - 44.

3. HCFA did not prove a basis for terminating the participation in Medicare of Petitioner Caguas. Page 44.

B. The alleged failure of Petitioner Caguas to comply with the general provisions condition of participation contained in 42 C.F.R. § 418.50

HCFA makes the same argument concerning the alleged failure of Petitioner Caguas to comply with the general provisions condition of participation as it makes with respect to Petitioner Fajardo. Here, as it did with respect to Petitioner Fajardo, HCFA asserts that a failure by a hospice to comply with a condition of participation stated elsewhere in the regulations also is a failure to comply with the general provisions condition.

I do not find that HCFA proved that Petitioner Caguas failed to comply with the requirements of 42 C.F.R. § 418.50, for the same reasons that I found that HCFA failed to meet its burden with respect to Petitioner Fajardo. HCFA's argument is moot, because HCFA failed to prove that Petitioner Caguas did not comply with other conditions of participation. Furthermore, I do not agree with HCFA's assertion that the Secretary intended that 42 C.F.R. § 418.50 be read to mandate a finding that a hospice be found not to have complied with the condition of participation stated in the regulation if it is found not to have complied with a condition of participation stated elsewhere.

C. The alleged failure of Petitioner Caguas to comply with the medical director condition of participation contained in 42 C.F.R. § 418.54

HCFA argues that the findings of the surveyors at the July 8, 1994 resurvey of Petitioner Caguas establish that the Petitioner was not complying with the medical director condition of participation as of that date. The gravamen of HCFA's argument was that the medical director was failing to exercise his supervisory responsibility over the medical component of Petitioner Caguas' operations to assure that only patients who were terminally ill were being treated by Petitioner Caguas.

I conclude that HCFA did not prove that Petitioner Caguas was not complying with the medical director condition of participation. I base this conclusion on the following:

- As was the case with Petitioner Fajardo, the duties of the medical director of Petitioner Caguas were the subject of a corrective action plan that HCFA accepted on June 23, 1994. C-94-383, HCFA Ex. 18. However, HCFA failed to offer as evidence the portion of the corrective action plan that described

the duties of the medical director.[21] The critical compliance issue related to the medical director condition is whether Petitioner Caguas was complying with the plan that HCFA accepted. I cannot find that Petitioner Caguas was failing to comply with its obligations, given HCFA's failure to offer as evidence the document which describes those obligations.

- As was also the case with Petitioner Fajardo, the witnesses whose testimony HCFA offered concerning the compliance of Petitioner Caguas with conditions of participation made no attempt in their testimony to explain whether Petitioner Caguas was complying with the medical director portion of its corrective action plan. Tr. at 218 - 235, 496 - 515. It is unclear whether these witnesses even reviewed that part of the plan as an element of their resurvey of Petitioner Caguas.

- I do not find that HCFA proved that any of the patients whose records are at issue were not terminally ill. The two witnesses whom HCFA called to testify about the alleged failure of Petitioner Caguas to comply with the medical director condition were Alba Muñoz and Mirta Fernandez. Both Ms. Muñoz and Ms. Fernandez are nurses (I discussed Ms. Muñoz' qualifications in Part III of this decision). HCFA offered both of these witnesses as experts. These witnesses opined that the various patient records they reviewed at the July 8, 1994 resurvey failed to establish that the patients were terminally ill. C-94-384, HCFA Ex. 19 at 2 - 4; Tr. at 221, 530. From this, HCFA asserts that the medical director was failing to exercise his supervisory responsibility to assure that Petitioner Caguas treated only terminally ill patients.

HCFA did not establish that either Ms. Muñoz or Ms. Fernandez possesses the necessary qualifications to opine whether a patient's treatment record establishes that patient to be terminally ill. Nothing in these

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[21] As was the case with Petitioner Fajardo, HCFA also attempted to offer a purported English translation of the medical director portion of the corrective action plan as an appendix to its posthearing brief. HCFA posthearing brief (Caguas), Appendix. Petitioner Caguas objected to my admitting this document into evidence. I do not accept it for the same reasons that I refused to accept HCFA's offer concerning Petitioner Fajardo.

witnesses' backgrounds, including their education and training as nurses, would suggest that they possess the medical training and expertise to make such judgments. Neither witness gave testimony at the hearing to suggest that she possessed the experience to offer such a judgment.

HCFA argues that the testimony of Ms. Muñoz and Ms. Fernandez is expert testimony that must be accorded "immense weight." HCFA posthearing brief (Caguas) at 17. As I conclude at Part II.A.3. of this decision, State survey agency surveyors may qualify as experts and their testimony may constitute important expert opinion. However, an expert witness' opinion as to an issue is probative only insofar as it is supported by the credentials of that expert to render an opinion. Here, I find that HCFA failed to prove that Ms. Muñoz and Ms. Fernandez have the training, skills, or knowledge to make medical judgments from patients' treatment records as to whether the patients are terminally ill.

As I observed in the case of Petitioner Fajardo, the Secretary has determined that only a physician is qualified to decide whether an individual is terminally ill, and thus eligible for hospice care. 42 C.F.R. §§ 418.20 - 418.22. HCFA had available at the hearing a physician, Dr. Rivera, who might have offered persuasive evidence as to whether the records of the patients in question showed these patients to be terminally ill. However, HCFA did not ask Dr. Rivera any questions about these records.

D. Conclusion as to Petitioner Caguas

HCFA did not establish a prima facie case that Petitioner Caguas failed to comply with conditions of participation. Therefore, HCFA did not prove a basis for terminating the participation in Medicare of Petitioner Caguas.

V. Analysis of the issues and evidence relating to Petitioner Cayey (C-94-386)

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

At the July 20, 1994 resurvey of Petitioner Cayey, the State survey agency surveyors found that Petitioner Cayey failed to comply with conditions of participation stated in the following regulations: general provisions, 42 C.F.R. § 418.50; medical director, 42 C.F.R. § 418.54;

and physician services, 42 C.F.R. § 418.86.[22] C-94-386, HCFA Ex. 21. The issue in this case is whether Petitioner Cayey failed to comply with any of these conditions of participation.

I make the following findings of fact and conclusions of law with respect to Petitioner Cayey:

1. HCFA did not prove that Petitioner Cayey failed to comply with the condition of participation contained in 42 C.F.R. § 418.50. Page 45.

2. HCFA did not prove that Petitioner Cayey failed to comply with the condition of participation contained in 42 C.F.R. § 418.54. Page 46.

3. HCFA did not prove that Petitioner Cayey failed to comply with the condition of participation contained in 42 C.F.R. § 418.86. Page 47 - 50.

4. HCFA did not prove a basis for terminating the participation in Medicare of Petitioner Cayey. Page 50.

B. The alleged failure of Petitioner Cayey to comply with the general provisions condition of participation contained in 42 C.F.R. § 418.50

HCFA makes the same argument concerning the alleged failure of Petitioner Cayey to comply with 42 C.F.R. § 418.50 as it did with Petitioners Fajardo and Caguas. I do not find that HCFA proved that Petitioner Cayey failed to comply with this regulation for the same reasons that I concluded that HCFA did not prove that Petitioners Fajardo and Caguas failed to comply with the regulation.

C. The alleged failure of Petitioner Cayey to comply with the medical director condition of participation contained in 42 C.F.R. § 418.54

The medical director of a hospice is required to supervise the delivery of the medical component of hospice care. This includes assuring that physicians employed by the hospice provide care in accord with the

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[22] The statement of deficiencies states incorrectly that Petitioner Cayey was noncompliant with physician services, 42 C.F.R. § 418.85.

requirements of 42 C.F.R. § 418.86. HCFA asserts that Petitioner Cayey failed to comply with the medical director condition of participation. HCFA bases this argument on its assertion that, as of the July 20, 1994 resurvey, Petitioner Cayey was not complying with the physician services condition. Therefore, according to HCFA, the hospice medical director was deficient in supervising the delivery of physician services.

The statement of deficiencies which the State survey agency surveyors prepared after the July 20, 1994 resurvey of Petitioner Cayey asserted several alleged specific failures by the medical director to supervise the delivery of care. C-94-386, HCFA Ex. 21 at 2 - 3. However, in its posthearing brief, HCFA did not assert that any of these alleged specific failures constituted proof that Petitioner Cayey had failed to meet the medical director condition of participation. HCFA posthearing brief (Cayey) at 15. Rather, HCFA argues only that the alleged failure of Petitioner Cayey to comply with the medical director condition derives from its alleged failure to comply with the physician services condition.

I do not find that HCFA proved that Petitioner Cayey failed to comply with the medical director condition of participation. First, as I discuss below at Part V.D. of these decisions, HCFA did not prove that Petitioner Cayey had failed to comply with the physician services condition of participation. HCFA's argument concerning Petitioner Cayey's alleged noncompliance with the medical director condition thus fails.

Furthermore, I do not find that HCFA proved a condition-level failure of Petitioner Cayey to comply with the medical director condition of participation, even assuming that HCFA proved some failures by Petitioner Cayey to meet the physician services requirement of participation. I am not persuaded by the evidence, of a few possible failures to deliver physician services in accord with Medicare participation requirements, that there was an overall failure by the medical director to supervise the delivery of medical services.

D. The alleged failure of Petitioner Cayey to comply with the physician services condition of participation contained in 42 C.F.R. § 418.86

HCFA asserts that Petitioner Cayey was deficient in providing physician services. The evidence on which HCFA relies to prove this assertion is the findings of the State survey agency surveyors. At the July 20, 1994

resurvey of Petitioner Cayey, State agency surveyors found that, in two patient records that they reviewed, there were missing orders for physician services. C-94-386, HCFA Ex. 21 at 5 - 6. Additionally, they found that, in one of the two records, there was evidence that services had been provided for which no written justification by a physician existed. Id. at 6.

I am not persuaded by this evidence that Petitioner Cayey failed to comply with the physician services condition of participation.

I find this evidence not to be persuasive, for the following reasons:

- As with Petitioner Fajardo, HCFA did not offer proof that there exists any deficiency in the services provided by the attending physicians of the patients. HCFA's argument thus assumes facts which it did not prove, that there exist underlying deficiencies in the services provided by the patients' attending physicians which the hospice physician became responsible for providing.

- HCFA did not prove that physicians failed to provide necessary services to patients of Petitioner Cayey. The fact that written orders may not exist for all services that were provided to a patient does not mean necessarily that the services that were ordered by the physicians were not provided. For example, with respect to patient # 1, the State agency surveyors found that there were no orders in the patient's record for a nasogastric tube, a "Foley" (apparently, a Foley catheter), and "Osmolite 60 cc/hr." C-94-386, HCFA Ex. 21 at 5 - 6. However, the treatment record for patient # 1 establishes that this patient was in fact receiving all of these items or services. C-94-386, HCFA Ex. 25 at 4, 16, 18, 20, 26. The State agency surveyors did not find that these services were unnecessary or that they were not being provided correctly to the patient.

- HCFA did not prove that failure to document the ordering of a service is necessarily a failure to provide a service, within the meaning of 42 C.F.R. § 418.86. The regulation does not contain specific record-keeping requirements. It does not state or suggest that a hospice is deficient in meeting patient needs if it provides medical care for patients, but fails to document that care with complete accuracy.

Arguably, the evidence which HCFA offered concerning the alleged failure of Petitioner Cayey to record orders for physician services or treatment delivered pursuant to those orders might prove a failure by Petitioner Cayey to comply with the record-keeping requirements of 42 C.F.R. § 418.74. That regulation requires a hospice to maintain complete and detailed records of all services that are provided to a patient. However, HCFA has not argued that the alleged failures by Petitioner Cayey to maintain records of orders for treatment or of treatments provided constitute deficiencies under 42 C.F.R. § 418.74. Therefore, I make no findings as to whether Petitioner Cayey was deficient under 42 C.F.R. § 418.74.

It is certainly possible that, in a given circumstance, a failure by a physician to document adequately the reason why he or she orders or provides care to a patient, or to explain the treatments that he or she provides, may constitute a deficiency in the providing of care to that patient. But I am not satisfied that it follows automatically that a failure to record accurately a treatment order or the failure to explain a treatment constitutes a failure to meet the medical needs of a patient. HCFA has the burden of proving why that is so in a particular instance.

Here, HCFA did establish a prima facie case that failure to provide a written order for the changing of a Foley catheter is a deficiency in the underlying service (the administration of the catheter to the patient). I am persuaded by Dr. Rivera's testimony that, in the case of patient # 1, failure to provide written instructions for the changing of the patient's catheter might impair the appropriate use of the catheter. Tr. at 653 - 654.[23]

However, HCFA did not prove that failure to document other services is a deficiency. HCFA did offer the testimony of one of the surveyors, Delia Fortis, to show that a written physician's order is a necessary prerequisite for obtaining laboratory tests. Tr. at 394. This testimony was offered to prove that failure to

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[23] Again, HCFA did not prove that the patient's attending physician failed to issue written orders for the administration and management of the Foley catheter. It proved only that a physician whom HCFA asserts to be the hospice physician did not issue such orders. However, a failure by the hospice physician to issue such orders would be a deficiency only if HCFA proved that such orders had not been made by the patient's attending physician.

maintain a written order by a physician for laboratory tests supplied to patient # 2 constituted a deficiency in providing physician services to that patient. C-94-386, HCFA Ex. 21 at 6. However, the fact is that, in the case of patient # 2, tests were obtained for that patient. Thus, even if a written order signed by a physician usually is a prerequisite for obtaining test results, the evidence in this case offered by HCFA proves that the results were obtained without a written order. HCFA has offered nothing to show how this would have adversely affected the health of patient # 2.

> ○ HCFA did not prove that a single deficiency in the providing of physician services by Petitioner Cayey, assuming that these services had not been provided by the patient's attending physician, is so substantial as to constitute a failure to comply with the condition of participation contained in 42 C.F.R. § 418.86. As I conclude at Part II.A.2. of these decisions, HCFA's burden is to prove that a deficiency constitutes a substantial failure to comply with participation requirements. The test for substantial noncompliance is stated in 42 C.F.R. § 488.24. In order to be substantial, a deficiency or deficiencies must be "of such character as to substantially limit the provider's . . . capacity to render adequate care or which adversely affect the health and safety of patients." 42 C.F.R. § 488.24.

I am not satisfied that this test has been met here. In this case, the only deficiency in the providing of physician services that HCFA arguably proved was the failure of a physician to provide written instructions for maintenance of one patient's Foley catheter. I am not satisfied that this one possible deficiency proves an overall inability by Petitioner Cayey to provide adequate care to its patients.

Furthermore, I am not convinced that one deficiency in management of a patient's Foley catheter proves that Petitioner Cayey engaged in practices which adversely affected the health and safety of its patients in a manner which is so substantial as to constitute a failure under 42 C.F.R. § 488.24. At most, the evidence proves a potential to adversely affect the health and safety of one patient.

Dr. Rivera testified that, where a Foley catheter is not changed regularly, there exists an increased risk that a patient may suffer from an infection. Tr. at 654 - 655. However, Dr. Rivera did not review the specific patient record at issue. She did not testify that the patient

was put at risk. There is no evidence of record to show that the patient suffered from an infection as the result of improper management of the Foley catheter.

VI. Conclusions

I conclude that HCFA did not prove, by a preponderance of the evidence, that Petitioners Fajardo, Caguas, and Cayey were not complying with conditions of participation in Medicare as of the dates of the resurveys that were conducted of these Petitioners in July 1994. HCFA has not proven a basis for terminating the participation in Medicare of these Petitioners.

/s/

Steven T. Kessel
Administrative Law Judge