Department of Health and Human Services

DEPARTMENTAL APPEALS BOARD

Civil Remedies Division

In the Case of:

)
Hillman Rehabilitation Center,) DATE: May 22, 1996

Petitioner,)

- v. -) Docket No. C-95-159

Decision No. CR419

Health Care Financing)

Administration.

DECISION

In this decision I conclude that the Health Care Financing Administration (HCFA) did not establish a basis for terminating Petitioner's participation in the Medicare program. HCFA failed to prove by a preponderance of the evidence that Petitioner was not complying with a condition of participation in Medicare.

I. Background

The following background facts and law are not disputed by the parties. Petitioner is a provider of outpatient physical therapy and rehabilitation services. Its business office is in Lakewood, New Jersey. Petitioner treats a few patients at its Lakewood address. It provides the vast majority of its treatments to patients at eight long-term care facilities that are located throughout the State of New Jersey. Petitioner rents office space from these facilities. It employs therapists who provide treatment at the long-term care facilities. Petitioner maintains its original patient records at the long-term care facilities and not at its Lakewood address.

Petitioner's administrator is Dr. Benjamin Akinrolabu. Dr. Akinrolabu holds both master's and doctorate degrees in physical therapy.

The Medicare program reimburses a qualified entity for providing outpatient physical therapy services to an eligible beneficiary, if that entity is certified by HCFA as a provider of care, pursuant to the provisions of

section 1861(p) of the Social Security Act (Act) and implementing regulations. Petitioner was certified by HCFA in or about 1985 to participate in Medicare as a provider of outpatient physical therapy services.

The conditions of participation for entities who provide outpatient physical therapy services are stated in section 1861(p) of the Act and in 42 C.F.R. §§ 405.1701 - 405.1726. A provider may participate in Medicare only if the provider complies with applicable conditions of participation and other participation requirements. 42 C.F.R. § 489.13. HCFA may terminate a provider's participation in Medicare for failing to comply with an applicable condition of participation. See 42 C.F.R. § 488.24(a).

HCFA directs that a periodic compliance survey be conducted of a participating provider to assure that the provider is complying with applicable participation requirements. HCFA contracts with agencies of State governments (State Agencies) to perform compliance surveys. Act, section 1864(a); 42 C.F.R. §§ 488.10 - 488.12, 488.20 - 488.24. HCFA makes compliance determinations based on recommendations made by State Agency surveyors. Id. In New Jersey, the State Agency is the New Jersey Department of Health.

Petitioner was visited by a surveyor employed by the New Jersey State Agency on January 13, 1995, February 22, 1995, and April 5, 1995. On the occasion of each visit, the surveyor, Charles End, R.N., visited Petitioner's Lakewood, New Jersey business office. On none of these occasions did Mr. End or any other representative of the New Jersey State Agency visit Petitioner at any of the eight long-term care facilities at which Petitioner provides outpatient physical therapy and rehabilitation services.

The regulations governing survey, certification, and enforcement procedures were revised, effective July 1995. 59 Fed. Reg. 56116, 56237 (1994). My citations to survey, certification, and enforcement regulations in this decision, including regulations in 42 C.F.R. Part 488, are to regulations which were in effect before July 1995, inasmuch as the actions at issue occurred prior to that date. However, the revised regulations would not appear to direct a different outcome.

 $^{^2}$ Mr. End testified at the hearing of this case. Tr. at 41 - 159.

Using the surveyor's findings from the January 13, 1995 survey, HCFA determined that Petitioner was not complying with several conditions of participation. At the February 22, 1995 survey, Petitioner was found to be complying with all conditions of participation. However, after the April 5, 1995 visit by the surveyor, HCFA determined that Petitioner was not complying with two conditions of participation. These conditions of participation are stated in 42 C.F.R. § 405.1717 (plan of care and physician involvement) and in 42 C.F.R. § 405.1722 (clinical records). HCFA terminated Petitioner's participation in Medicare, effective July 5, 1995.

Petitioner requested a hearing. I held a hearing in Trenton, New Jersey, on February 13, 1996. I base my decision on the record of the hearing and on the applicable law.

II. Issues, findings of fact and conclusions of law

The issue in this case is whether HCFA proved that, on April 5, 1995, Petitioner was not complying with a condition of participation in Medicare. If I were to find that HCFA proved that Petitioner was not complying with a condition of participation, then I would sustain HCFA's determination to terminate Petitioner's participation in Medicare.

HCFA asserts that, as of April 5, 1995, Petitioner was not complying with two conditions of participation. These are the condition governing plans of care and physician involvement in the planning and delivery of care contained in 42 C.F.R. § 405.1717 and the condition governing clinical records contained in 42 C.F.R. § 405.1722.

In concluding that HCFA did not establish grounds for terminating Petitioner's participation in Medicare, I make the following findings of fact and conclusions of law (Findings). I discuss each of these findings in detail, below.

- 1. HCFA has the burden of proving that Petitioner failed to comply with a condition of participation in Medicare.
- 2. The Act and regulations require Petitioner to maintain clinical records that are completely and accurately documented, readily accessible, and systematically organized to facilitate retrieving and compiling information.

- 3. Petitioner is not obligated to maintain at its Lakewood, New Jersey, business office complete and contemporaneous copies of records of treatments that it provides at eight long-term care centers.
- 4. The account by the New Jersey State Agency surveyor of his April 5, 1995 visit to Petitioner is not credible.
- 5. HCFA did not prove that Petitioner failed to comply with the condition of participation governing plans of care and physician involvement in the planning and delivery of care contained in 42 C.F.R. § 405.1717.
- 6. HCFA did not prove that Petitioner failed to comply with the condition of participation governing clinical records contained in 42 C.F.R. § 405.1722.

III. Discussion

A. HCFA's burden of persuasion (Finding 1)

1. Allocation of the burden of persuasion to HCFA

I conclude here, as I have in other cases involving termination of a provider's participation in Medicare, that HCFA has the burden of proving that there is a basis for terminating Petitioner's participation in Medicare. Nazareno Medical Hospice Fajardo, Caquas, Cayey, DAB CR386, at 6 - 19 (1995); Hospicio en el Hogar de Utuado, DAB CR371, at 6 - 10 (1995); Hospicio en el Hogar de Lajas, DAB CR366, at 6 - 8 (1995); Arecibo Medical Hospice Care, DAB CR363, at 8 - 13 (1995). Neither the Act nor regulations state who has the burden of persuasion in a case involving termination of a provider's certification to participate in Medicare. regulations which govern a hearing in such a case give the administrative law judge discretion to allocate the burden of persuasion as is appropriate. 42 C.F.R. § 498.60(b)(1) and (3). It is both consistent with due process requirements and efficient to assign the burden to HCFA.

HCFA has obtained the evidence that it believes justifies its determination to terminate Petitioner's participation. Therefore, it is entirely reasonable to put HCFA to the test of proving that its determination is supported by the preponderance of the evidence.

In a case involving termination, it is generally not reasonable to require the provider to prove a negative proposition -- that it did not fail to comply with a

condition of participation -- in the absence of proof that it failed to comply with that condition of participation. As I found in Nazareno, to require a provider to prove the negative proposition in the absence of affirmative proof from HCFA would invite a massive and unfocused presentation of evidence by the provider.

Nazareno, at 8. In the absence of a prima facie case that the provider had failed to comply with a condition of participation, the provider might have to guess at the evidence necessary to prove that it had not failed to comply with the condition.

HCFA avers that it is willing to assume the burden of first coming forward with evidence of Petitioner's failure to comply with a condition of participation, thus giving Petitioner notice of what it needs to rebut. HCFA made the same offer in Nazareno. I did not understand the logic of that offer there, nor do I understand it here.

If HCFA has a burden of coming forward with evidence, but no burden of persuasion, then HCFA has neither an obligation nor an incentive to make even a prima facie case to justify its determination to terminate Petitioner's participation. Indeed, under HCFA's theory, Petitioner could offer evidence which might rebut completely whatever evidence HCFA opts to offer, but which would fail to overcome the presumption of validity which HCFA asserts attaches to its determination to terminate Petitioner's participation in Medicare.

My conclusion that the burden of persuasion should be assigned to HCFA in this case does not mean that it should be assigned to HCFA in every case. I will continue to evaluate the issue of burden of persuasion on a case-by-case basis, although, generally, and for the reasons I have stated above, I would be likely to assign it to HCFA in a case where HCFA terminates a provider's participation in Medicare.

In <u>Nazareno</u>, I noted that there may be circumstances where identical considerations of due process and efficiency as apply here support allocation of the burden of persuasion to the provider, and not to HCFA. A good example of such a case is the case where a provider challenges HCFA's determination of the effective date of that provider's participation in Medicare. In that case, the provider, and not HCFA, is most likely to be in possession of evidence proving that it qualified to participate in Medicare at an earlier date than the date determined by HCFA. <u>Nazareno</u>, at 7 n.5; <u>SRA</u>, <u>Inc.</u>, <u>D/B/A St. Mary Parish Dialysis Center</u>, DAB CR341, at 5 (1994).

In arguing that the burden of persuasion must be allocated to Petitioner, HCFA makes the same arguments here that it made in Nazareno, Utuado, Lajas, and Arecibo. In those decisions, I addressed these arguments at length. It is unnecessary for me to address them again here, in great detail. I summarize HCFA's arguments, along with my reasons for finding them to be without merit.

HCFA does not deny that I have discretion to allocate the burden of persuasion to a party, nor does HCFA assert that it is unreasonable for me to allocate the burden of persuasion to HCFA. Instead, HCFA asserts that, under various principles of administrative law, the burden of persuasion must be allocated to Petitioner.

First, HCFA asserts that Petitioner is a mere "applicant" for benefits with no right to due process. HCFA posthearing memorandum at 21. HCFA argues that, traditionally, an applicant has the burden of proving that it is eligible for the benefits that it seeks.

A participating provider is not merely an "applicant" for benefits. It is the recipient of a privilege. The law does not mandate that the burden of persuasion be imposed at all times on the recipient of a government benefit or privilege where the government seeks to terminate the benefit or privilege. In cases involving termination of Social Security benefits, and in exclusion cases brought under section 1128 of the Act, the burden of persuasion on ultimate issues has been allocated to the government, and not to the beneficiaries or recipients of privileges whose benefits or privileges the government seeks to terminate.

Second, HCFA argues that its termination of Petitioner's participation is a final agency action which must be presumed to be valid, even if challenged by a request for a hearing. HCFA misapplies the presumption of validity which attaches to a final government agency action that is challenged in a court of law. Nazareno, at 12.3 There is no presumption of validity which necessarily

³ HCFA cites my decision in <u>SRA</u>, <u>Inc.</u> as support for this argument. HCFA posthearing memorandum at 20. It does so, notwithstanding that the case is distinguishable from this case, and also notwithstanding that I noted the distinction in my <u>Nazareno</u> decision. In <u>SRA</u>, <u>Inc.</u>, an <u>applicant</u> to participate as a supplier of Medicare services challenged HCFA's determination of the effective date of its participation. The case did not involve termination of participation, as was the case in Nazareno, and is the case here.

attaches to determinations that are challenged in administrative hearings.

Under a number of regulations which govern determinations made by agencies of the United States Department of Health and Human Services, an agency determination becomes final unless a hearing is requested. Even so, the burden of persuasion often is assigned to the agency whose determination is challenged. For example, a determination by the Social Security Administration to terminate a beneficiary's Social Security disability benefits becomes final unless the beneficiary requests a hearing. However, if the beneficiary requests a hearing, then the burden is on the Social Security Administration to prove that the beneficiary's medical condition has improved.

In the case of an exclusion determination made by the Inspector General (I.G.) pursuant to section 1128 of the Act, the determination becomes final unless a hearing is requested. However, if a hearing is requested, the I.G. is assigned the burdens of proving that she has the authority to impose an exclusion and that the exclusion See 42 C.F.R. § 1005.15(c). Similarly, is reasonable. the burden of persuasion is assigned to the I.G. where a request for a hearing is made from a determination made by the I.G. pursuant to the Civil Money Penalty Act, section 1128A of the Act. 42 C.F.R. § 1005.15(b). same assignment of burden occurs where a hearing is requested from an I.G. determination to exclude pursuant to section 1156 of the Act. Id.

2. <u>The elements of HCFA's burden of persuasion</u>

In <u>Nazareno</u>, I identified the three elements of HCFA's burden of persuasion in a case involving termination of a provider's participation in Medicare. <u>Nazareno</u>, at 14 - 17. I restate them here, briefly.

First, HCFA must identify the legal criteria to which it seeks to hold the provider accountable. Nazareno, at 14 - 15. In doing so, HCFA must identify the specific language in the Act or regulations on which it is relying. HCFA must prove that its interpretation of the Act or a regulation is reasonable, where HCFA advocates an interpretation that is not apparent from the plain meaning of the Act or regulation. However, HCFA is entitled to deference if its interpretation of the Act or a regulation is one of more than one reasonable alternative interpretations. Where HCFA relies on an interpretation, albeit reasonable, that is not apparent from the plain meaning of the Act or of a regulation, it

must prove that it gave the provider notice of its interpretation before holding the provider accountable to it.

Second, HCFA must prove by a simple preponderance of the evidence that its assertions of fact are true. <u>Nazareno</u>, at 15. The evidence which HCFA might rely on to establish those facts may consist of the testimony of a surveyor or surveyors, or of exhibits.

Third, where HCFA alleges a failure by a provider to comply with a condition of participation as a basis for termination of that provider's participation in Medicare, HCFA must prove, by a preponderance of the evidence, that the provider's failure to comply with participation requirements meets the definition of a condition-level deficiency stated in 42 C.F.R. § 488.24(a). In order to be a condition-level deficiency, a failure to comply with participation requirements must be:

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

Id.

In establishing the degree of a deficiency, HCFA may rely on the qualified testimony of a surveyor. However, the surveyor's testimony will not be presumed to be true or authoritative. The testimony of the surveyor will be accorded the weight that it ought to receive, based on the experience and background of the surveyor, and the credibility of the surveyor's testimony.

B. <u>Petitioner's obligation to maintain records of the physical therapy it provides to patients</u>
(Findings 2-3)

HCFA premises its case against Petitioner on HCFA's assessment of the excerpts from patient treatment records that the New Jersey State Agency surveyor reviewed at Petitioner's Lakewood, New Jersey office on April 5, 1995. HCFA Ex. 12, 17 - 35; Tr. at 72 - 74. HCFA's allegations that Petitioner was not complying with conditions of participation result from the surveyor's and HCFA's conclusions that these records were incomplete or inadequate. HCFA Ex. 12. The surveyor never visited the eight facilities at which Petitioner provided outpatient physical therapy and rehabilitation services and made no effort to ascertain whether the patient records that Petitioner maintained at these facilities were incomplete or inadequate. Tr. at 122 - 124.

At the hearing, Petitioner produced records which it asserts to be complete copies of the original records that were maintained at the long-term care facilities. P. Ex. 9 - 28. Petitioner asserts that these exhibits rebut fully any inference that might be drawn from the records obtained by HCFA on April 5, 1995 that Petitioner was not complying with Medicare conditions of participation. The parties agree that these exhibits are not records that Petitioner had at its Lakewood office on April 5, 1995. HCFA argues that these records are irrelevant, because they were not present at Lakewood on April 5, 1995, nor were they provided to HCFA's surveyor on that date.

HCFA asserts that Petitioner had a duty to maintain complete and contemporaneous copies of patient treatment records at its Lakewood office. HCFA argues that Petitioner could not comply with Medicare participation requirements by maintaining such records only at the facilities at which Petitioner provided treatment to patients. HCFA asserts that because Petitioner was obligated to maintain contemporaneous copies of patient records at Lakewood, HCFA could draw dispositive inferences and conclusions about Petitioner's compliance with participation requirements from the records that the surveyor reviewed at the Lakewood office.

However, even as HCFA argues that it is essential that Petitioner maintain complete and contemporaneous copies of its treatment records at its headquarters, HCFA maintains that it is not really holding Petitioner to the asserted requirement in this case. HCFA states that the "entire question of whether . . . [Petitioner] was required to maintain copies of the clinical records at its certified location is just smoke and mirrors." HCFA posthearing memorandum at 16. According to HCFA, it did not terminate Petitioner's participation because Petitioner failed to keep copies of its records at the Lakewood office. HCFA argues that it terminated Petitioner's participation only because the records that Petitioner produced on April 5 at its Lakewood office proved that Petitioner was not complying with conditions of participation.

Contrary to HCFA's argument, HCFA's contentions about Petitioner's record-keeping obligations are central to HCFA's case against Petitioner. HCFA relies on its argument that Petitioner was required to maintain complete contemporaneous copies of its treatment records at its Lakewood office as a basis to assert that I should not find the treatment records that Petitioner introduced into evidence at the hearing to be relevant. HCFA posthearing memorandum at 24 - 25; see P. Ex. 9 - 28. Furthermore, HCFA argues that an aspect of Petitioner's

alleged failure to comply with the record-keeping requirements of 42 C.F.R. § 405.1722 is Petitioner's failure to maintain complete contemporaneous copies of all of its treatment records at its Lakewood office. HCFA posthearing memorandum at 25 - 29, 45 - 46, 53.

The Act and regulations require Petitioner to maintain complete records of the treatments it provides to patients. These records must be systematically organized and easily accessible. Petitioner is obliged to produce those records for HCFA's review and inspection, on reasonable notice by HCFA. However, there is no requirement in the Act or in the regulations that Petitioner retain either original treatment records or contemporaneous copies of those records at its business HCFA's argument that Petitioner is precluded office. from offering records obtained from the long-term care facilities as evidence that it complied with Medicare participation requirements, simply because those records were not present at Lakewood during the April 5, 1995 visit by the surveyor, is not persuasive.

The Act does not contain any requirement that would direct an outpatient physical therapy and rehabilitation provider which offers its services at more than one site, such as Petitioner, to centralize complete contemporaneous copies of all of its patient treatment records. It requires only that the provider maintain clinical records on all of its patients. Act, section 1861(p)(4)(A)(iii).

Nor do the regulations contain language which directs an outpatient physical therapy and rehabilitation provider to centralize its records at one address. There is no requirement in 42 C.F.R. § 405.1722 that directs an outpatient physical therapy and rehabilitation provider that furnishes care at multiple sites to maintain its original treatment records, or contemporaneous copies of those records, at a central repository. The regulation requires explicitly that records be: complete, accurate, systematically organized, conveniently located, and readily retrievable. The regulation leaves it to the provider to design a record-keeping system that satisfies these requirements. The regulation thus permits a provider, such as Petitioner, to maintain its treatment records at the sites where treatment is furnished, so long as the provider is able to access the records, and to retrieve information in those records, or copies of them, promptly when necessary.

My conclusion as to the meaning of the Act and regulations means that records produced by Petitioner of the treatments it provided to patients which were not available to the surveyor on April 5, 1995, are relevant

in deciding whether HCFA proved that Petitioner was in fact, deficient in complying with those conditions of participation that HCFA cited in its determination to terminate Petitioner's participation in Medicare. See P. Ex. 9 - 28. However, my conclusion that neither the Act nor regulations require Petitioner to retain contemporaneous copies of its treatment records at its Lakewood office is not a finding that Petitioner maintained its records pursuant to the requirements of the Act or regulations. HCFA did not determine, as a basis for terminating Petitioner's participation in Medicare, that Petitioner failed to maintain a system of records required by the Act or regulations. Therefore, it is not necessary for me to make a finding that Petitioner either maintained or did not maintain such a system.

HCFA acknowledges that the asserted requirement that an outpatient physical therapy and rehabilitation provider centralize contemporaneous copies of all records is not stated in either the Act or in regulations. HCFA's posthearing memorandum at 25. But, according to HCFA, the asserted requirement is "the only reasonable interpretation possible" of the Act and regulations. HCFA claims that to be so for several reasons. Id. at I am not persuaded by HCFA's arguments that the Act or regulations may be interpreted reasonably to require Petitioner to maintain contemporaneous copies of its treatment records at a centralized location. arguments do not overcome the fact that the Act and regulations do not contain the requirement asserted by HCFA. I find also that, individually, and collectively, HCFA's arguments are not persuasive.

First, HCFA argues that the regulations state requirements that must be met by providers and not by the therapists who are employed by providers. Therefore, according to HCFA, it makes sense to read the record-keeping requirements of the regulations as mandating Petitioner to maintain a centralized records system. I agree with HCFA that the regulations impose requirements on the provider of care and not on the therapists who are employed by the provider. But that begs the question of whether the regulations tell the provider that it must maintain a central records system of contemporaneous copies of all treatment records.

Second, HCFA cites language in the regulations which requires a provider to perform specific tasks, including performing research and administrative actions. See 42 C.F.R. § 405.1722(e). HCFA argues that a provider, such as Petitioner, that furnishes care at more than one site must centralize its records in order to perform these research and administrative actions. I do not agree that

this contention is, in fact, correct. HCFA has not persuaded me that a provider must centralize its records in order to perform the tasks mandated by the regulations. Nor do the regulations cited by HCFA contain any requirement that the records be centralized. The regulations provide only that the records be readily accessible and systematically organized. HCFA has not shown, nor do I otherwise have in this case any basis to find, that a provider could not perform the tasks mandated by the regulations so long as it maintains records accurately and systematically, in adequate facilities that are conveniently located, and is able to retrieve information from those records promptly.

Third, HCFA argues that the regulations require that all records must be readily accessible to a surveyor. According to HCFA, it is not acceptable for Petitioner to have treatment records only at the location where the patient is receiving physical therapy. Instead, HCFA maintains that Petitioner must have all records necessary for HCFA's review located at its headquarters location. HCFA asserts that the New Jersey State Agency surveyor had no obligation to visit any of the facilities at which Petitioner provided care in order to survey Petitioner's compliance with participation requirements. HCFA argues that, because Petitioner provides services in disparate locations, the only way in which Petitioner could have complied with the asserted requirement that it make records readily accessible to the surveyor was to have centralized contemporaneous copies of all records available to surveyors at Petitioner's central office location.

I agree with HCFA that there is an implied requirement in the regulations that a provider maintain records in a way that enables a surveyor to have access to them. However, HCFA did not prove that the requirement that a provider maintain its records in a way that enables a surveyor to have access to them means that a provider must maintain its records, or contemporaneous copies of those records, in a central location. I

⁴ HCFA asserts that Petitioner builds its case around the argument that HCFA's surveyor should have visited the eight long-term care facilities to review Petitioner's treatment records at those facilities. HCFA posthearing memorandum at 45. This does not characterize accurately Petitioner's argument. Petitioner is basing its evidentiary case on its allegation that HCFA's surveyor did not ask to review Petitioner's patient treatment records on April 5, 1995. Below, part III.C. of this decision, I discuss this issue and explain why I find Petitioner's allegation to be credible.

HCFA is not obligated to conduct surveys at multiple caregiving sites, where a provider has decentralized operations. 5 It would not be inappropriate for the New Jersey State Agency surveyor to visit Petitioner's business office in Lakewood, New Jersey, and to request that Petitioner produce its records at that location, for review by the surveyor. However, that does not mean that a provider must maintain complete, contemporaneous copies of its records in one location to facilitate a survey. The regulation requires only that the provider be able to produce its records if a surveyor requests to see them. Conceivably, a provider could fax or express mail copies of its records to a single site, if a surveyor requests to review them at that site.6

Fourth, HCFA argues that Petitioner was certified to be a provider only at its Lakewood, New Jersey business address. Therefore, according to HCFA, the only location at which Petitioner was certified to maintain treatment records was at the Lakewood address. I do not agree with this assertion. I do not read the regulations as requiring a provider to maintain its patient treatment records, or contemporaneous copies of its records, at the office at which it is certified. There is simply no such requirement in the regulations.

Fifth, according to HCFA, accepted professional standards and practices are that providers centralize their records. HCFA bases this argument on the testimony of Mr. End, that seems to indicate that he had performed hundreds of surveys and had never encountered a health care facility that did not maintain copies of its records at its main office. Tr. at 56.

⁵ However, the surveyor might have performed a more thorough survey of Petitioner had he visited at least one of the facilities at which Petitioner furnishes care. take notice of

the fact that one of the facilities at which Petitioner provides care, Mercer County Geriatric Center, is located in the same county in New Jersey as is the offices of the New Jersey

Department of Health.

At part III.C. of this decision, I discuss HCFA's allegation that, on April 5, 1995, the State Agency surveyor requested Petitioner to fax treatment records from the eight long-term care facilities to Petitioner's Lakewood office for review by the surveyor. I discuss also my reasons for concluding that the allegation is not credible.

I do not find that HCFA proved through the anecdotal testimony of Mr. End that professionally accepted standards of practice require an outpatient physical therapy and rehabilitation provider that furnishes care at multiple sites to maintain its treatment records, or contemporaneous copies of its records, centrally. End is not a physical therapist or a specialist in rehabilitation. He did not testify as to accepted standards of practice which apply to an outpatient physical therapy and rehabilitation provider. Mr. End did not testify explicitly that providers who furnished care at multiple sites adhered to a practice of maintaining records centrally. It is logical that a hospital or a laboratory or other provider housed under a single roof maintain its treatment records at that location. But, I am not convinced from Mr. End's testimony that what might be standard practice for such entities necessarily is followed by entities that are decentralized.

HCFA argues that Petitioner agreed to maintain contemporaneous copies of its treatment records at Lakewood. HCFA reply brief at 7. I am not persuaded by the evidence offered by HCFA that Petitioner made this asserted promise. HCFA bases its assertion in part on the contents of a plan of correction which Petitioner executed which allegedly contains the asserted promise. Tr. at 61 - 63. However, HCFA did not introduce the plan of correction into evidence. Tr. at 62. Instead, it asked Mr. End to paraphrase the plan in his testimony. Tr. at 61 - 63. As I advised the parties at the hearing, having a witness paraphrase a document which could have been introduced into evidence is not an acceptable substitute for introducing the document itself. I do not find Mr. End's paraphrasing of the plan of correction to be a credible statement of what the plan contains.

The credible evidence does not establish that Petitioner promised to maintain at its Lakewood office contemporaneous copies of its treatment records. To the contrary, it proves at most that Petitioner promised that it would maintain such records at its Lakewood office, updated at 30-day intervals. HCFA Ex. 10; P. Ex. 2.7

Finally, if HCFA thought it important that Petitioner maintain contemporaneous copies of its treatment records at Lakewood, it did not make that asserted requirement

⁷ HCFA does not contend that it reviewed Petitioner's treatment files in order to ascertain whether Petitioner complied with this promise.

plain to Petitioner. Mr. End testified that, although Petitioner was not complying with the asserted record-keeping requirement as of a February 22, 1995 survey, he concluded that Petitioner was complying with all conditions of participation. Tr. at 68 - 69. Furthermore, Petitioner expressly advised HCFA of its intent to update treatment records at Lakewood at 30-day intervals. HCFA Ex. 10; P. Ex. 2. There is no evidence that either the State agency or HCFA expressed any dissatisfaction to Petitioner about this proposed record-keeping system.

C. The credibility of HCFA's account of the April 5, 1995 survey of Petitioner (Finding 4)

In evidence are two different versions of the same patient records and two conflicting versions of how these records came to be made. HCFA asserts that the patient records it introduced as HCFA Ex. 17 - 35 comprise the documentation of Petitioner's patient treatments and record-keeping that Petitioner presented to HCFA's surveyor on April 5, 1995, in response to a request for a production of records made by the surveyor on that date. Petitioner avers that HCFA Ex. 17 - 35 consist only of excerpts of patient records from Petitioner's claims files that it provided on April 5, 1995 in response to a claims inquiry. It alleges that HCFA's surveyor did not ask Petitioner to produce treatment records on April 5, Petitioner asserts that P. Ex. 9 - 28, which are a different version of the records contained in HCFA Ex. 17 - 35, comprise Petitioner's actual patient treatment records.9 Petitioner asserts that it did not present the records contained in P. Ex. 9 - 28 to the surveyor on April 5, 1995, because the surveyor did not ask for them.

^{*} HCFA offers no explanation for the surveyor's finding.

The different versions of treatment records correspond as follows: HCFA Ex. 17 - P. Ex. 17; HCFA Ex. 18 - P. Ex. 27; HCFA Ex. 19 - P. Ex. 20; HCFA Ex. 20 - P. Ex. 28; HCFA Ex. 21 - P. Ex. 10; HCFA Ex. 22 - P. Ex. 21; HCFA Ex. 23 - P. Ex. 22; HCFA Ex. 24 - P. Ex. 15; HCFA Ex. 25 - P. Ex. 12; HCFA Ex. 26 - P. Ex. 9; HCFA Ex. 27 - P. Ex. 26; HCFA Ex. 28 - P. Ex. 25; HCFA Ex. 29 - P. Ex. 24; HCFA Ex. 30 - P. Ex. 18; HCFA Ex. 31 - P. Ex. 16; HCFA Ex. 32 - P. Ex. 23; HCFA Ex. 33 - P. Ex. 14; HCFA Ex. 34 - P. Ex. 13; and HCFA Ex. 35 - P. Ex. 19. Petitioner also introduced a treatment record for which there is no corresponding HCFA exhibit--P. Ex. 11.

The differences between HCFA Ex. 17 - 35 and P. Ex. 9 - 28 lie mainly in the completeness of the records. For example, HCFA Ex. 17 - 35 all contain plans of care for physical therapy for individual patients. These plans, by and large, are signed by the physical therapist who created them, but not by the physician who supervised the providing of care. By contrast, the same plans of care in P. Ex. 9 - 28 are signed by physical therapists, and also by physicians. HCFA Ex. 17 - 35 mostly lack physicians' orders for physical therapy, whereas P. Ex. 9 - 28 mostly contain those orders.

As I conclude at Part III.B. of this decision, Petitioner is not precluded from introducing patient treatment records from the eight long-term care facilities at which it furnished care to rebut HCFA's assertion that it was not complying with Medicare participation requirements. That conclusion does not resolve the question of the evidentiary weight that I should give to the records introduced by Petitioner.

HCFA asserts that the records contained in P. Ex. 9 - 28, to the extent that they contain documents or signatures not contained in HCFA Ex. 17 - 35, were fabricated by Petitioner after the April 5, 1995 surveyor's visit to Petitioner's Lakewood, New Jersey office, in order to make it look as if Petitioner was complying with participation requirements. HCFA argues that the only credible evidence of the state of Petitioner's records as of April 5, 1995 is in HCFA Ex. 17 - 35.

I would regard the records introduced by Petitioner as self-serving exhibits to which I would attach little or no probative value if I were to conclude that HCFA's version of what Petitioner produced on April 5, 1995 is credible. On the other hand, the exhibits introduced by Petitioner become potentially very significant to my evaluation of Petitioner's compliance with conditions of participation if I decide that Petitioner's version of what happened on April 5, 1995 is credible. Then, the exhibits must be regarded as the best evidence of the extent to which Petitioner complied with Medicare conditions of participation on that date.

Petitioner's account of the events that occurred on April 5, 1995 is the more credible account of those events. The most reliable evidence of the care provided by Petitioner and the way in which it kept treatment records as of April 5, 1995 consists of the medical records which are in evidence as P. Ex. 9 - 28. Therefore, I base my conclusions as to HCFA's allegations that Petitioner was not complying with conditions of participation on P. Ex 9 - 28, and not on the excerpts of medical records which HCFA introduced as HCFA Ex. 17 - 35.

HCFA asserts that, on April 5, 1995, Mr. End demanded Petitioner provide him with the complete records of 20 specified patients. According to HCFA, Petitioner represented to Mr. End that the documents that it furnished to him on that date comprised Petitioner's complete treatment records of the 20 patients. See HCFA Ex. 17 - 35.

Mr. End testified that, on April 5, 1995, he visited Petitioner's Lakewood office in the company of another individual, Jerry Livesay, a representative of Aetna Insurance Company, the Medicare intermediary. Tr. at 71.10

According to Mr. End, Mr. Livesay was performing an inquiry into some billing problems that the intermediary had with Petitioner. <u>Id.</u> Mr. End testified that Mr. Livesay brought with him a list of 20 patients about whom there were billing problems. <u>Id.</u> at 72. Mr. End asserted that he relied on this list to ask for Petitioner's treatment records. <u>Id.</u>

Mr. End testified that he met with Dr. Akinrolabu, and asked Dr. Akinrolabu to produce the treatment records for the 20 patients. Tr. at 72. Mr. End testified that he requested to be present when the records were taken from Petitioner's files. <u>Id.</u> According to Mr. End, he and Dr. Akinrolabu went to Petitioner's files, to discover that the records were not present there. <u>Id.</u> Mr. End asserted that the records which are in evidence as HCFA Ex. 17 - 35 were faxed into Petitioner's Lakewood office, piecemeal, over a period of two or three hours.

Dr. Akinrolabu testified that, on April 5, 1995, Mr. Livesay and Mr. End visited Petitioner's Lakewood office. Tr. at 211. According to Dr. Akinrolabu, all of the discussion that occurred on April 5, 1995 was between himself and Mr. Livesay. <u>Id.</u> at 212. Dr. Akinrolabu testified that Mr. Livesay informed him that he and Mr. End were doing a claims integrity check. Tr. at 212 - 213. Dr. Akinrolabu testified that Mr. Livesay informed him that he wanted to see specific claims-related documents which pertained to the patients on the list of patients that Mr. Livesay had brought to Petitioner's Lakewood office. <u>Id.</u> at 213.

¹⁰ Mr. Livesay did not testify in this case, nor did HCFA introduce into evidence a statement by Mr. Livesay. Therefore, Mr. End's testimony, and also the testimony of Dr. Akinrolabu, is not corroborated by that of any other witness.

Dr. Akinrolabu asserted that he complied with Mr. Livesay's request by having an employee obtain documents that Petitioner maintained for claims purposes. <u>Id.</u> Dr. Akinrolabu denied that he was asked by either Mr. Livesay or Mr. End to obtain documents from the long-term care facilities at which Petitioner provided treatments. <u>Id.</u> at 214. He denied that documents were faxed to the Lakewood office on April 5, 1995 to be provided to Mr. Livesay or to Mr. End. <u>Id.</u> at 213, 216 - 217.

Dr. Akinrolabu explained the differences between HCFA Ex. 17 - 35 and P. Ex. 9 - 28 by asserting that Petitioner would obtain partially executed treatment records from the long-term care facilities in order to create a record for claims purposes. Frequently, those records had not been completed when they were submitted, because Petitioner viewed it as unnecessary to have them fully executed in order to memorialize for claims purposes the services that Petitioners' employees provided. Tr. at 228 - 232.

On its face, the testimony of Mr. End and that of Dr. Akinrolabu is credible. I do not find from the demeanor of either witness that the witness was not credible. Yet, obviously, the testimony of the two witnesses is directly contradictory on major points. There is no witness who corroborates the testimony of either Mr. End or Dr. Akinrolabu. Thus, I cannot make credibility conclusions concerning these witnesses' conflicting testimony from corroborating testimony or impeachment testimony by a third party witness. I must evaluate the relative credibility of the witnesses' testimony by measuring that testimony against whatever facts are in evidence that supports it or contradicts it.

Dr. Akinrolabu's version of what happened on April 5, 1995 is the more credible version. I base my conclusion on the following: (1) the primary purpose of the April 5, 1995 visit to Petitioner's Lakewood office was not to conduct a Medicare compliance survey, but to review Petitioner's billing records to satisfy questions raised by the Medicare intermediary, and Petitioner's assertion that it produced only billing records on that date is consistent with that purpose; (2) Mr. End's testimony that Petitioner faxed documents to its Lakewood office on April 5, 1995 is not credible; and (3) on their face, the records which Petitioner introduced at the hearing are consistent with what Petitioner purports them to be, which is complete treatment records of the 20 patients whose records are at issue here.

Mr. End and Dr. Akinrolabu agree on one point, that being that the primary purpose of the April 5, 1995 visit to Petitioner's Lakewood office was for the intermediary's

representative, Mr. Livesay, to conduct an inquiry related to Petitioner's claims. It was Mr. Livesay who brought the list of patients whose records were to be reviewed. I am persuaded that the most likely records to be sought on that date would have been records related to Petitioner's reimbursement claims. This substantiates Dr. Akinrolabu's assertion that the documents which were requested on April 5 were claims documents. It also provides some support for Dr. Akinrolabu's assertion that his interactions on that date were with Mr. Livesay, and not Mr. End.

Mr. End's assertion that, on April 5, 1995, Petitioner had records faxed to its Lakewood office from the long-term care facilities is not supported by any credible evidence, and is in key respects, contradicted by the evidence of record. Mr. End admitted that he did not personally witness any document being faxed to Petitioner's Lakewood office. Tr. at 119 - 120. More telling, none of the documents that comprise HCFA Ex. 17 - 35 have the appearance of documents that were faxed to Petitioner. Dr. Akinrolabu testified, without contradiction, that Petitioner's fax machine at Lakewood would have left an imprint on each document that was faxed to that machine. Tr. at 217. None of the pages of HCFA Ex. 17 - 35 contain fax imprints.

The exhibits which comprise P. Ex. 9 - 28 have the appearance of patient records. They contain plans of care, physicians' order forms, and records of treatment. They are signed by the individuals who provided care to the patients, including physicians and physical therapists. There are numerous individuals whose signatures appear on the exhibits. The exhibits have every appearance of being what they are offered as --genuine treatment records of patients -- and not of self-serving or fabricated documents.

D. HCFA's allegation that Petitioner did not comply with the condition of participation governing plans of care contained in 42 C.F.R. § 405.1717 (Finding 5)

I have evaluated HCFA's allegation that Petitioner did not comply with the condition of participation governing plans of care contained in 42 C.F.R. § 405.1717 by measuring the credible evidence and the arguments offered by HCFA against the three elements of HCFA's burden of persuasion which I outlined at part III.A.2. of this decision. I conclude that HCFA failed in several respects to prove that Petitioner did not comply with the condition of participation stated in the regulation. First, HCFA's asserted interpretation of the regulation is not consistent with the language of either the

regulation or of the Act, and is not reasonable. Second, even if I accept HCFA's interpretation of the regulation, and use that interpretation as a basis for evaluating Petitioner's compliance, the weight of the evidence fails to substantiate HCFA's assertion that Petitioner did not comply with the requirements of the regulation. Third, HCFA has not proven that Petitioner's asserted failure to comply with the regulation is a condition level deficiency.

1. The requirements of the plan of care regulation

HCFA would read the plan of care regulation to require the physician to approve the details of physical therapy before therapy is initiated by the physical therapist. I find this asserted interpretation is inconsistent with the requirements of section 1861(p) of the Act and exceeds the plain meaning of the plan of care regulation. Although a physician must order physical therapy as a prerequisite to initiation of therapy, both the Act and the plan of care regulation plainly permit a physical therapist to prepare a plan of care and to initiate the therapy pursuant to a physician's order without first having the details of that therapy approved by a physician. Administration of physical therapy must be reviewed by a physician no less than 30 days from initiation of therapy.

Section 1861(p)(2) of the Act permits either a physician or a physical therapist to establish the care that is provided to a patient. It requires that the therapy be periodically reviewed by a physician. The Act provides for coverage for physical therapy for a Medicare beneficiary:

with respect to whom a plan prescribing the type, amount and duration of physical therapy services that are to be furnished . . . has been established by a physician . . . or by a qualified physical therapist and is periodically reviewed by a physician . . .

Act, section 1861(p)(2) (emphasis added).

Although there is no explicit requirement in section 1861(p) of the Act or regulation that physical therapy not be administered unless first ordered by a physician, the conditions of coverage under Part B of the Medicare program would not permit reimbursement for physical therapy that is not certified as necessary by a physician. Act, section 1814(a)(2). When section 1814(a)(2) is read together with section 1861(p), it is apparent that the Act mandates that physical therapy be

ordered by a physician, although the physician does not have to participate in the planning of the details of the therapy and in the initial administration of the therapy.11

The plan of care regulation, 42 C.F.R. § 405.1717, is consistent with section 1861(p) of the Act. It permits either a physician or a physical therapist to prepare a plan of care and to initiate care. It requires that a physician review the administration of care, at least once every 30 days. The regulation states the following general condition of participation:

For each patient in need of outpatient physical therapy or speech pathology services there is a written plan of care established and periodically reviewed by a physician, or by a physical therapist or speech pathologist, respectively. . . .

42 C.F.R. § 405.1717. A standard contained in the regulation provides, in relevant part that:

The plan of care and results of treatment are reviewed by the physician or by the individual who established the plan at least as often as the patient's condition requires, and the indicated action is taken. (For Medicare patients, the plan must be reviewed by a physician in accordance with § 424.25(e) of this chapter.)

42 C.F.R. § 405.1717(b)(3).

The reference to 42 C.F.R. § 424.25(e) is inaccurate. The section has been superseded by 42 C.F.R. § 410.61(e). This section states as follows:

- (e) Review of the plan:
 - (1) The physician reviews the plan [of care] as often as the individual's condition requires, but at least every 30 days.
 - (2) Each review is signed and dated by the physician who performs it.

HCFA asserts that 42 C.F.R. \S 405.1717, read with 42 C.F.R. \S 410.61(e), must be interpreted to require that each plan of care that is created by an outpatient

HCFA did not discuss the implications of section 1814(a) of the Act.

physical therapy and rehabilitation provider must be approved and signed and dated at the inception of the plan of care, by the physician on whose orders the plan is made. HCFA asserts also that 42 C.F.R. § 405.1717 requires an outpatient physical therapy and rehabilitation provider obtain a written order by a physician, in addition to having the plan of care reviewed and approved and signed and dated by the physician, before providing physical therapy to a patient. HCFA posthearing memorandum at 34 - 35.

The regulation contains no language which suggests that a physician must review, approve, sign and date a plan of care prior to the initiation of therapy. The regulation explicitly authorizes a physical therapist to implement treatment pursuant to a plan of care prepared by the physical therapist. The plain meaning of the regulation is that, in the case of a Medicare beneficiary, a physician must review the plan of care at some point, but no later than 30 days, after inception of treatment. This reading is entirely consistent with the regulation's language permitting a physical therapist to establish a plan of care. It is consistent also with the requirements of section 1861(p) of the Act.

Furthermore, I do not agree with HCFA's contention that the patient's record must contain <u>both</u> an order for physical therapy signed by a physician <u>and</u> an initial plan of care signed by the physician and by the physical therapist. The physician's signature on a plan of care alone is ample evidence that the physician ordered and approved that care. Thus, a physician's approval of the administration of physical therapy to a patient would be evidenced either by a physician's order for physical therapy, or by a physician's signature on the initial plan of care for physical therapy.

2. The evidence of Petitioner's compliance with the plan of care regulation

Although I do not agree with HCFA's interpretation of 42 C.F.R. § 405.1717, I have used that interpretation to weigh the credible evidence of Petitioner's conduct. HCFA has not proved that Petitioner failed to comply with HCFA's interpretation of the regulation.

HCFA contends that evidence, consisting of HCFA Ex. 17 - 35, proves that Petitioner did not comply with HCFA's interpretation of the plan of care regulation. It alleges that in 19 of the 20 records reviewed by Mr. End, the initial plan of care was not signed by a physician. It alleges also that in 10 of the 20 records reviewed by Mr. End there was no physician order for physical therapy predating the inception of treatment.

That may be so. However, as I conclude at part III.C. of this decision, the more credible evidence of Petitioner's performance under the conditions of participation is P. These exhibits are the best evidence of the Ex. 9 - 28. care that was provided to Petitioner's patients. prove that Petitioner was complying with HCFA's interpretation of the plan of care regulation. Every one of these exhibits contains a plan of care signed by a physician. P. Ex. 9 at 3; P. Ex. 10 at 3; P. Ex. 11 at 4; P. Ex. 12 at 3; P. Ex. 13 at 3; P. Ex. 14 at 3; P. Ex. 15 at 3; P. Ex. 16 at 3; P. Ex. 17 at 2; P. Ex. 18 at 2; P. Ex. 19 at 2; P. Ex. 20 at 3; P. Ex. 21 at 3; P. Ex. 22 at 3; P. Ex. 23 at 3; P. Ex. 24 at 3; P. Ex. 25 at 3 - 4; P. Ex. 26 at 2; P. Ex. 27 at 2; P. Ex. 28 at 3. explain below, there is no requirement that there be both a physician's approval of the initial plan of care and a physician's order for physical therapy. However, nearly all of these exhibits also contain a written order for physical therapy.

I conclude from P. Ex. 9 - 28 that Petitioner was providing physical therapy to its patients pursuant to the approval and direction of physicians. I conclude also that the plans of care for physical therapy that were developed by therapists employed by Petitioner were reviewed and approved by physicians.

3. Evidence as to the level of deficiency

As I find at part III.A.2. of this decision, in order to prove a condition level deficiency, HCFA must prove that a deficiency is of such character as to substantially limit the Petitioner's capacity to render adequate care or that it adversely affects the health and safety of patients. 42 C.F.R. § 488.24(a). However, there can be no finding of a condition level deficiency where the evidence does not prove any deficiency. Inasmuch as HCFA did not prove that Petitioner failed to comply with the plan of care regulation, it follows that HCFA failed to prove that Petitioner did not comply with the condition of participation that is stated in that regulation.

I would note, however, that HCFA's assertion of a condition level deficiency is premised on Mr. End's conclusion that Petitioner was not providing physical therapy to its patients under the direction of a physician. Tr. at 118. I agree with HCFA that the Act and regulations contemplate that a physician will exercise control over the physical therapy that is provided to a beneficiary. However, the evidence in this case does not prove that Petitioner failed to assure physician direction and control over the physical therapy that it provided to beneficiaries.

E. HCFA's allegation that Petitioner did not comply with the condition of participation governing clinical records contained in 42 C.F.R. § 405.1722 (Finding 6)

I have evaluated HCFA's allegation that Petitioner did not comply with the condition of participation governing clinical records contained in 42 C.F.R. § 405.1722 pursuant to the three elements of HCFA's burden of persuasion. HCFA proved that, in some respects, Petitioner did not comply with a standard in the regulation which requires that medical records be completed promptly. However, HCFA did not prove that the failure by Petitioner to comply with this standard was so egregious as to contravene a condition of participation. 42 C.F.R. § 488.24(a).

1. The requirements of the clinical records regulation

HCFA argues that the clinical records regulation contains two requirements that are relevant here. First, HCFA argues that the regulation implicitly requires an outpatient physical therapy and rehabilitation provider to maintain its treatment records, or at least contemporaneous copies of those records, at a central location. HCFA asserts that, in this case, the central location is Petitioner's Lakewood, New Jersey office. I addressed HCFA's argument that Petitioner must centralize copies of its records at part III.B. of this decision and found it not to be persuasive.

Second, HCFA argues that the regulation requires an outpatient physical therapy and rehabilitation provider to complete its patient records promptly. I agree with HCFA that there is a standard in the regulation which requires a provider to complete all clinical records promptly.

The Act does not set forth detailed clinical records requirements for outpatient physical therapy and rehabilitation providers. It provides only that such providers must maintain clinical records. Act, section 1861(p)(4)(A)(iii). The clinical records regulation is intended to implement this statutory requirement. It provides, as a condition of participation, that an outpatient physical therapy and rehabilitation provider must maintain:

clinical records on all patients in accordance with accepted professional standards, and practices. The clinical records are completely and accurately documented, readily accessible,

and systematically organized to facilitate retrieving and compiling information.

42 C.F.R. § 405.1722.

A standard of this regulation requires that an outpatient physical therapy and rehabilitation provider must assure that clinical records are "completed promptly." 42 C.F.R. § 405.1722(c).

HCFA interprets the prompt completion requirement of 42 C.F.R. § 405.1722(c) to mean that a clinical record must be signed by a physician, where a physician's signature is required, within 14 days from generation of the record. HCFA posthearing memorandum at 32. HCFA bases this argument on Mr. End's experience, both as a nurse and as a surveyor, and on New Jersey regulations which govern physical therapy. Tr. at 88; N.J. Admin. Code tit. 13, § 39A-2.1. Petitioner has not offered evidence to contradict that on which HCFA relies. I find that HCFA proved that the accepted practice is to complete a clinical record within 14 days of its generation. completion means a signature, then the record must be signed within 14 days of its generation. Therefore, I agree with HCFA's interpretation of the prompt completion requirement of 42 C.F.R. § 405.1722(c).

HCFA argues that the regulation requires that, where a physician's signature appears in a clinical record, that signature must be dated. I do not read this general requirement into the regulation. There is a requirement that a progress review of a plan of care be signed and dated by the physician who performs the review. 42 C.F.R. § 405.1717(b)(3), incorporating 42 C.F.R. § 410.61(e)(2). But that requirement does not attach to other records that are signed by a physician. The regulation states only that: "Each physician's entries into the clinical record are signed by the appropriate physician." 42 C.F.R. § 405.1722(c)

2. <u>Petitioner's records</u>

HCFA asserts that Petitioner failed, systematically, to comply with the prompt completion requirement of 42 C.F.R. § 405.1722(c). HCFA bases its assertion on its analysis of HCFA Ex. 17 - 35. HCFA contends that these exhibits establish a general failure by physicians to sign plans of care or orders for physical therapy.

As I hold above, the more credible evidence of Petitioner's records is in P. Ex. 9 - 28. I have examined these records in light of the requirements of 42 C.F.R. § 405.1722(c). These records establish that: (1) in some instances, physicians signed records more than 14

days after their creation; (2) in many instances, physicians signed records and dated their signatures; and (3) in many other instances, physicians signed records without dating their signatures. There also are records in some exhibits which appear not to have been signed by physicians, although they should have been. However, in no exhibit do I find a pattern of failure by the treating physician to sign requisite records.

For example, in P. Ex. 9 (the corresponding HCFA exhibit is HCFA Ex. 26), the physician signed and dated an order for physical therapy. P. Ex. 9 at 2 (the date of the signature is illegible). The physician signed and dated the initial plan of care for physical therapy. Id. at 3. However, the plan is dated January 25, 1995, and the physician signed it on March 7, 1995. Id. physician signed and dated a transfer for the patient from a hospital to a nursing home. Id. at 5. This document includes directions for administration of physical therapy to the patient. Id. The physician also signed and dated various physician's orders. Id. at 6. Finally, the physician signed and dated a plan of treatment for outpatient rehabilitation. Id. at 7 - 8. The date of the physician's signature on this document is not clear, but it appears to be April 20, 1995. The plan of treatment was executed by the physical therapist on January 25, 1995. Id.

The other exhibits introduced by Petitioner as examples of its records contain a similar pattern of signatures. P. Ex. 10 - 28. I conclude from my review of these exhibits that Petitioner failed to comply with the standard of participation contained in 42 C.F.R. § 405.1722(c), in that there are a substantial number of instances in which physicians signed documents more than 14 days after their creation. That is evident from the dates of the physicians' signatures, to the extent that the signatures are dated. P. Ex. 9 at 3. I do not conclude, however, that these exhibits prove a wholesale failure by physicians to sign their orders or to review the treatments provided by physical therapists. contrary, the records demonstrate physician involvement in the physical therapy provided to the patients treated by Petitioner.

Evidence as to the level of deficiency

HCFA proved that Petitioner did not comply with the standard of participation in 42 C.F.R. § 405.1722(c). It does not follow, necessarily, that Petitioner's failure to comply with a standard of participation is also a failure by Petitioner to comply with the condition of participation which includes the standard. Where HCFA proves that a provider fails to comply with a standard of

participation, HCFA must prove that the deficiency is so serious as to comprise a condition level deficiency, within the meaning of 42 C.F.R. § 488.24(a). Nazareno Medical Hospice Fajardo, Caguas, Cayey, DAB CR386, at 15 - 16 (1995); Hospicio en el Hogar de Utuado, DAB CR371, at 12 (1995).

HCFA asserts that it is reasonable to infer from Petitioner's failure to assure that its records were completed promptly, that physicians were derelict in their responsibility to oversee and monitor the physical therapy that Petitioner was providing to beneficiaries. HCFA posthearing memorandum at 44 - 45. From this, it argues that beneficiaries were being provided physical therapy that either might not be beneficial to them, or which placed them at risk. <u>Id.</u>

I agree with HCFA that, if the evidence in this case proved a failure by Petitioner to assure that physicians oversee and monitor the physical therapy that Petitioner was providing to beneficiaries, that failure would be a condition-level deficiency. In enacting section 1861(p) of the Act, Congress thought it necessary that the administration of physical therapy be monitored by a physician. However, I do not find that HCFA proved the premise of its assertion that Petitioner failed to comply with a condition of participation. As I conclude at Part III.E.2. of this decision, the failures of physicians to sign or date all clinical records in some instances do not establish a pattern of dereliction of responsibility by physicians. To the contrary, the clinical records in evidence as P. Ex. 9 - 28 show a substantial degree of involvement by a physician in each case.

IV. Conclusion

I conclude that HCFA did not prove that Petitioner failed to comply with a condition of participation. Therefore, HCFA did not establish a basis for terminating Petitioner's participation in Medicare.

/s/

Steven T. Kessel Administrative Law Judge