Department of Health and Human Services

DEPARTMENTAL APPEALS BOARD

Civil Remedies Division

In the Case of:)
Lake City Extended Care Center,) Date: September 23, 1997
Petitioner,)
- v)) Docket No. C-96-206
Health Care Financing) Decision No. CR494
Administration.)

DECISION

I decide that the Health Care Financing Administration (HCFA) is not authorized to impose a civil money penalty of \$7,500 per day against Petitioner, Lake City Extended Care Center, for the period from November 21, 1995 until December 19, 1995. I decide also that I have no authority to order that a civil money penalty be imposed against Petitioner of less than the \$7,500 per day that HCFA determined to impose.

I. Procedural history, governing law, and background facts

The procedural history, governing law, and background facts which I recite in this portion of my decision are not disputed by the parties.

A. Procedural history

Petitioner is a 60-bed skilled nursing facility located in Lake City, Florida. Petitioner participates in the Medicare program. Petitioner's hearing request in this case is from a notice which HCFA sent to Petitioner on February 22, 1996. HCFA Ex. 11. In that notice, HCFA advised Petitioner that the State of Florida Agency for Health Care Administration (Florida State survey agency) had conducted a survey of Petitioner which ended on November 21, 1995. HCFA told Petitioner that the Florida State survey agency had ascertained that Petitioner was not in substantial compliance with federal Medicare and Medicaid participation requirements. HCFA asserted additionally that the Florida State survey agency had concluded that the level of Petitioner's noncompliance was so serious as to constitute immediate jeopardy to the health or safety of the residents of Petitioner.

HCFA informed Petitioner that, based on the findings of the Florida State survey agency, HCFA had determined to impose against Petitioner a civil money penalty of \$7,500 per day. The penalty was to begin to accrue on November 21, 1995, and continue until December 19, 1995, the date that HCFA determined that Petitioner had attained substantial compliance with participation requirements. HCFA stated that, in making its determination to impose a penalty of \$7,500 per day it had considered factors which included: the scope and severity of the asserted deficiencies; Petitioner's history of noncompliance with program participation requirements; its financial condition; and Petitioner's culpability for the asserted deficiencies.

Petitioner requested a hearing from HCFA's determination. The case was assigned to me for a hearing and a decision. On March 25 and 26, 1997, I held an in-person hearing in Atlanta, Georgia. At the hearing, I received the testimony of witnesses for HCFA and Petitioner. Both HCFA and Petitioner offered written exhibits in addition to the testimony of their witnesses. I received into evidence HCFA Ex. 1 - 18 and P. Ex. 1 - 15. At the close of the in-person hearing I established a schedule for the parties to submit posthearing briefs and reply briefs. The parties have complied with this briefing schedule.

Petitioner submitted an additional exhibit, P. Ex. 16, with its posthearing brief. Petitioner submitted yet an additional exhibit, which it designated as "Exhibit B", with its posthearing reply brief (Petitioner also submitted an "Exhibit A" with its reply brief which constitutes an appendix to the reply brief. Petitioner is not offering "Exhibit A" as evidence). For purposes of maintaining a consistent record I have redesignated Petitioner's Exhibit B as P. Ex. 17. HCFA objects to my receiving into evidence P. Ex. 16 and P. Ex. 17. HCFA filed a motion with its reply brief in which it requested that I exclude P. Ex. 16 from evidence. <u>The Respondent's Motion to Strike the Petitioner's Proposed</u> <u>Exhibit</u>. HCFA asserts that Petitioner submitted P. Ex. 16 untimely and that the exhibit is of questionable probative value. <u>Id</u>. HCFA did not file a motion to exclude P. Ex. 17 from evidence. However, in its reply brief, HCFA asserted that Petitioner offered P. Ex. 17 untimely and that the exhibit is of questionable probative value.

I am receiving P. Ex. 16 into evidence. The exhibit is an excerpt from a medical treatise and is offered by Petitioner to rebut an assertion of fact that one of HCFA's witnesses, Charles Fuller, R.N., testified to at the March 25 - 26, 1997 hearing, concerning the span of body temperatures that an individual might exhibit depending on the method used to take that individual's temperature. This assertion was not communicated by HCFA to Petitioner in any of the notices that HCFA or the Florida State survey agency gave to Petitioner or in any of the exhibits that were exchanged prior to the hearing.

There is nothing in the record to suggest that Petitioner knew of the assertion prior to the hearing. Receipt of P. Ex. 16 is consistent with the instructions I gave to the parties concerning the impact that the appellate panel's decision in <u>Hillman Rehabilitation Center</u> at DAB 1611 (1997) might have on my conduct of this case. Tr. at 6 - 10. I discuss the implications of the <u>Hillman</u> decision below, at Part B. of this section. I discuss Mr. Fuller's assertion, and Petitioner's rebuttal evidence below, at Finding 3.

I have decided not to admit P. Ex. 17 into evidence. In contrast to their purpose for offering P. Ex. 16, Petitioner offers P. Ex. 17 to rebut arguments that HCFA made in its posthearing brief. I find that these arguments are addressed adequately by the record that was created at the hearing, along with P. Ex. 16.

B. Governing law

Under both the Social Security Act (Act) and applicable regulations, Petitioner is classified as a long-term care facility. In order to participate in Medicare, a long-term care facility must comply with federal participation requirements. The statutory requirements for participation by a long-term care facility are contained in the Act, at sections 1819 and 1919. Regulations which govern the participation of a long-term care facility are published at 42 C.F.R. Part 483. A

principal aspect of this case is Petitioner's alleged noncompliance with the requirements of one of the regulations in Part 483, 42 C.F.R. § 483.25.

Sections 1819 and 1919 of the Act give the Secretary of the United States Department of Health and Human Services (Secretary) authority to impose against a long-term care facility a civil money penalty for failure by the facility to comply substantially with participation requirements. The Secretary has delegated to HCFA and the States the authority to impose remedies against a long-term care facility that is not complying substantially with federal participation requirements. 42 C.F.R. Part 488.

The Part 488 regulations provide that facilities which participate in Medicare may be surveyed on behalf of HCFA by State survey agencies in order to ascertain whether the facilities are complying with participation requirements. 42 C.F.R. §§ 488.10 - 488.28. The regulations contain special survey provisions for longterm care facilities. 42 C.F.R. §§ 488.300 - 488.325. Under the Part 488 regulations, a State or HCFA may impose a civil money penalty against a longterm care facility where a State survey agency ascertains that the facility is not complying substantially with participation requirements. 42 C.F.R. §§ 488.406, 488.408, 488.430. The penalty may be imposed for each day that the facility is out of compliance. Id.

The regulations specify that a civil money penalty that is imposed against a facility will fall into one of two broad ranges of penalties. 42 C.F.R. §§ 488.408, 488.438. The upper range of civil money penalties, of from \$3,050 per day to \$10,000 per day, is reserved for deficiencies that constitute immediate jeopardy to a facility's residents, and, in some circumstances, for repeated deficiencies. 42 C.F.R. §§ 488.438(a)(1), (d)(2). The lower range of civil money penalties, of from \$50 per day to \$3,000 per day, is reserved for deficiencies that do not constitute immediate jeopardy, but either cause actual harm to residents, or cause no actual harm, but have the potential for causing more than minimal harm to residents. 42 C.F.R. § 488.438(a)(2).

The terms "substantial compliance" and "immediate jeopardy" are defined terms in the regulations which govern participation of long-term care facilities in Medicare. "Substantial compliance" is defined to mean:

a level of compliance with the requirements of participation such that any identified deficiencies pose no greater risk to resident health or safety than the potential for causing minimal harm.

5

42 C.F.R. § 488.301. "Immediate jeopardy" is defined to mean:

a situation in which the provider's noncompliance with one or more requirements of participation has caused, or is likely to cause, serious injury, harm, impairment, or death to a resident.

<u>Id.</u>

There are additional factors which the State and HCFA consider in determining where within a range of penalties, a penalty should be determined once the range is established. These include the facility's: (1) history of noncompliance, including repeated deficiencies; (2) financial condition; and, (3) culpability for the deficiencies. 42 C.F.R. § 488.438(f). Additionally, the State and HCFA may consider factors specified in 42 C.F.R. § 488.404. These include the relationship that a deficiency may have to other deficiencies, and a facility's prior history of deficiencies.

A civil money penalty which falls within the lower range of penalties may not be increased to the upper range based on the presence or absence of factors described in 42 C.F.R. §§ 488.404 and 488.438(f), unless the deficiency at issue is a repeated deficiency. And, a civil money penalty which falls within the upper range of penalties may not be decreased to the lower range based on the presence or absence of factors described in 42 C.F.R. §§ 488.404 and 488.438(f).

A long-term care facility against whom HCFA has determined to impose a civil money penalty is entitled to a hearing before an administrative law judge at which the facility may contest HCFA's determination. 42 C.F.R. §§ 488.408(g); 498.3(b)(12),(13): <u>see</u> 42 C.F.R. § 488.438(e). The right to a hearing, and the authority of an administrative law judge to conduct a hearing, is only from a determination by HCFA to impose a remedy. 42 C.F.R. §§ 488.408(g), 498.3(b). Where HCFA has not determined to impose a remedy against a facility, that facility has no right to a hearing, and the administrative law judge is not authorized to conduct a hearing. <u>Rafael Convalescent Hospital</u>, DAB CR444 (1996), <u>aff'd</u> at DAB 1616 (1997).

There are potentially two issues to be heard and decided in a case where a longterm care facility requests a hearing before an administrative law judge from a determination by HCFA to impose a civil money penalty against the facility. The first issue is whether the facility was not complying substantially with federal participation requirements on the date or dates for which HCFA determined to impose a civil money penalty. The second issue is, assuming that noncompliance is established, whether the amount of the penalty imposed by HCFA is reasonable. 42 C.F.R. §§ 488.408(g); 498.3(b)(12), (13); see 42 C.F.R. § 488.438(e). The issue of reasonableness of the penalty is not reached unless there is a finding of substantial noncompliance on which a penalty may be predicated. Id.

In <u>Hillman</u>, an appellate panel of the Departmental Appeals Board held that, in a case involving a determination by HCFA based on the results of a survey of a provider, HCFA bears the burden of coming forward with evidence sufficient to establish a prima facie case that the provider is not complying with an applicable participation requirement or requirements. Once a prima facie case is established, the provider bears the burden of proving, by a preponderance of the evidence, that it was complying substantially with the participation requirements. Id.

This case was assigned to me before the appellate panel issued its decision in <u>Hillman</u>. Originally, I assigned to HCFA the burden of proving by a preponderance of the evidence that Petitioner was not complying substantially with the participation requirement which was the basis for HCFA's determination to impose a civil money penalty against Petitioner. At the beginning of the hearing of this case, I discussed with the parties the potential implications of <u>Hillman</u>. Tr. at 6 - 10. I advised Petitioner that I would consider permitting it to supplement its evidence, in light of the appellate panel's decision to impose on a facility the burden of proving by the preponderance in evidence that it complied with relevant participation requirements. <u>Id.</u>

A long-term care facility potentially bears an additional burden of proof in a case involving a determination by HCFA to impose a civil money penalty against the facility. The facility must prove that HCFA's determination of the level of noncompliance is clearly erroneous if the record of the case establishes that the facility is not complying substantially with a participation requirement that is the basis for HCFA's civil money penalty determination. 42 C.F.R. § 498.60(c)(2) (this regulation was formerly published as 42 C.F.R. § 498.61(b)). The facility would not have to meet this additional burden in a case where it was able to prove by a preponderance of the evidence that it was complying substantially with the participation requirement or requirements on which HCFA premised its civil money penalty determination.

C. Background facts

1. The September and November 1995 surveys of Petitioner

The Florida State survey agency surveyed Petitioner in September 1995. The surveyors found Petitioner to be deficient in complying with various participation requirements. HCFA Ex. 1. Petitioner does not contest the findings that were made by the Florida State survey agency in September 1995. Petitioner does not contest any determination to impose a remedy against it that may have been based solely on those findings or on events that predated the September 1995 survey. Tr. at 20 - 21.

Surveyors employed by the Florida State survey agency returned to Petitioner's facility in November 1995. It is the results of the November 1995 survey that are at issue in this case. HCFA Ex. 5. The November 1995 survey began on November 20, 1995 and was completed on November 21, 1995. Tr. at 52; HCFA Ex. 5. It consisted of an on-site visit to Petitioner's facility, and included a review of Petitioner's resident records and interviews with members of Petitioner's staff. Tr. at 52 - 53.

The report of the November 1995 survey identified four deficiencies in Petitioner's operation. These deficiencies are listed in the survey report under headings that are designated as "tags." HCFA Ex. 5, at 2, 5, 7, 12; Tr. at 53. Each of the tags states a requirement of participation that is contained in a regulation. <u>Id</u>. Under each tag are the facts, and an explanation of the facts, on which the surveyors based their finding of a deficiency.

The deficiencies that were identified by the surveyors at the November, 1995 survey are as follows (the facts and explanations that are cited in the survey report are omitted from this list of deficiencies):

<u>Tag 272</u> — failure to comply substantially with the requirements of 42 C.F.R. § 483.20(b). HCFA Ex. 5, at 2 - 5;

<u>Tag 279</u> — failure to comply substantially with the requirements of 42 C.F.R. § 483.20(d). HCFA Ex. 5, at 5 - 7;

<u>Tag 309</u> — failure to comply substantially with the requirements of 42 C.F.R. § 483.25. HCFA Ex. 5, at 7 - 11; and

Tag 385 failure to comply substantially with the requirements of 42 C.F.R § 483.40(a)(1) and (a)(2). HCFA Ex. 5, at 12 - 13.

In the left hand margin of the November 1995 survey report, under each one of the tags, is a scope and severity assessment of the deficiency described in the tag. The scope and severity assessment is the surveyors' findings of the scope and severity of each deficiency, and is intended to describe the seriousness of that deficiency. See Tr. at 50. "Scope and severity" is noted with the acronym "SS." After that acronym is a letter designating the scope and severity of the deficiency. For example, under the tag heading 272, at page 2 of HCFA Ex. 5, is the scope and severity notation "SS=F."

The letter designations of scope and severity in the survey report may be interpreted by referring to a guidance which HCFA issues to State survey agencies, known as the State Operations Manual (SOM). The SOM contains a chart which describes the letter characterizations of scope and severity. HCFA Ex. 15. That chart is significant also because it prescribes the category of remedies which may be imposed under each scope and severity designation. <u>Id.</u>

Although the scope and severity descriptions in HCFA Ex. 15 state the type of remedies which may be imposed for deficiencies of a given scope or severity, they do not direct that a particular remedy be imposed in a case. The State and HCFA have discretion to determine whether a civil money penalty, or other remedies described under a particular category, are imposed. 42 C.F.R. 488.408. Therefore, if the scope and severity description of a deficiency directs that a category 2 remedy be employed, that remedy *may*, but not *must*, include a civil money penalty in the \$50 - \$3000 per day range. The remedy may not include a civil money penalty in the \$3,050 - \$10,000 per day range.

The surveyors concluded that Tags 272 and 279 merited a scope and severity designation of "F". HCFA Ex. 5, at 2, 5. A scope and severity designation of "F" is described as comprising no actual harm to a resident with potential for more than minimal harm that is not immediate jeopardy. A scope and severity designation of "F" requires the imposition of category 2 remedies. Category 2 remedies may include: denial of payment for new admissions; denial of payment for individuals (to be imposed by HCFA); and a civil money penalty in the \$50 - \$3,000 per day range. HCFA Ex. 15. These remedies correspond with the category 2 remedies described at 42 C.F.R. § 488.408(d).

The surveyors concluded that Tag 385 merited a scope and severity designation of "I". HCFA Ex. 5, at 12 - 13. A scope and severity designation of "I" is described as comprising actual harm to a resident that is not immediate jeopardy. HCFA Ex. 15. This designation also requires the imposition of category 2 remedies. HCFA Ex. 15; 42 C.F.R. § 488.408.

Finally, the surveyors concluded that Tag 309 merited a scope and severity designation of "L". HCFA Ex. 5, at 7. A scope and severity designation of "L" is described as comprising immediate jeopardy to resident health and safety. HCFA Ex. 15. A scope and severity designation of "L" requires the imposition of category 3 remedies. HCFA Ex. 15; 42 C.F.R. § 488.408. These may include a civil money penalty in the \$3,050 - \$10,000 per day range.

There was initial uncertainty among the surveyors whether the deficiencies cited at Tag 309 merited a scope and severity of "L" and an immediate jeopardy designation. This survey was the first time that the surveyors encountered the possibility that an immediate jeopardy finding might be imposed. Tr. at 55. The concept of immediate jeopardy was something that was new to the surveyors. <u>Id</u>. The surveyors were unable to reach a conclusion while they were at Petitioner's facility whether the deficiency listed under Tag 309 comprised immediate jeopardy. <u>Id</u>. On the last day of the survey, the surveyors returned to their office and discussed their findings with their office supervisors, who in turn discussed the findings with the Florida State survey agency central office staff. <u>Id</u>. It was after these discussions that the immediate jeopardy designation was made. <u>Id</u>.

HCFA now asserts that the surveyors' finding of Level "I" scope and severity for the deficiency which they cited under Tag 385 was erroneous. HCFA's posthearing brief at 37. HCFA argues that this asserted deficiency should have been given an immediate jeopardy designation. Id. HCFA asserts that an immediate jeopardy designation for Tag 385 is reasonable inasmuch as the deficiency under that tag is predicated on many of the same facts as are the basis for the findings under Tag 309. Id. HCFA asserts, however, that it is not arguing now that the scope and severity finding under Tag 385 should be amended to include a finding of immediate jeopardy. Id. Thus, the immediate jeopardy finding which is at issue in this case consists only of the finding made under Tag 309, and not of any finding which the Florida State survey agency or HCFA might have made, but did not make, under Tag 385.

2. The findings which the surveyors made under Tag 309 at the November 1995 survey

As I explain below, at Finding 10, the only findings that the Florida State survey agency and HCFA made from the November 1995 survey which I conclude ultimately to be at issue in this case are the findings made under Tag 309, which are findings of a deficiency posing immediate jeopardy to Petitioner's residents. The findings under Tag 309 involve the asserted failure of Petitioner to comply with the requirements of 42 C.F.R. § 483.25. The regulation requires a longterm care facility to provide to each of its residents the care and services that are necessary for the resident to attain or maintain the highest practicable level physical, mental, or psychosocial well-being.

The surveyors found that Petitioner did not consistently monitor residents to identify changes in the residents' conditions which potentially could lead to harm or deterioration in their status. HCFA Ex. 5, at 8. Moreover, according to the surveyors, Petitioner did not react appropriately to the residents' conditions or changes in the residents' conditions which could have led to harm to the residents or to deterioration in their conditions. Id.

The surveyors made their findings principally from their review of resident treatment records. They reviewed ten resident records and found evidence to support their conclusions in the records of Resident 5 (P. Ex. 7; P. Ex. 8) and in the records of Resident 1 (P. Ex. 9; P. Ex. 12). The gravamen of the surveyors' findings concerning the care Petitioner provided to Resident 5 and to Resident 1 is that Petitioner failed to monitor fevers that these residents manifested, and failed to report the residents' fevers to the residents' treating physician on occasions when the residents' fevers exceeded 101 degrees. HCFA Ex. 5, at 7 - 11.

The surveyors found additional support for their conclusion that Petitioner had failed to report residents' fevers to the residents' treating physician in a conversation that the surveyors had with Petitioner's Director of Nursing and a unit charge nurse employed by Petitioner. HCFA Ex. 5, at 11. According to the surveyors, they were told by the Director of Nursing that a resident's physician would always be called when a resident's temperature exceeded 101 degrees. Id. The surveyors reported that the explanation for not calling the physician in the case of Resident 5, when that resident's fever exceeded 101 degrees, was that the resident had a viral condition and always ran a fever. Id. The surveyors stated that Petitioner was unable to explain why the physician who

treated Resident lowas not notified when the resident ran a fever in excess of 101 degrees. Id.

The initial review of records for the part of the November 1995 survey that involved Tag 309 comprised a review of ten resident records. HCFA Ex. 5, at 8. After the surveyors concluded that Petitioner had failed to monitor or report the temperatures of Residents 1 and 5, the surveyors expanded their survey to review the vital signs sheets that were maintained at the nursing station in Petitioner's facility. Tr. at 158 - 159. They did not find evidence in these documents of failure to monitor or report temperatures. The surveyors did not examine the treatment records of any residents other than the ten which they reviewed initially. <u>Id.</u>

All of the incidents which were the basis for the surveyors' findings under Tag 309 were reported by the surveyors as occurring between September 12, 1995 and November 14, 1995. HCFA Ex. 5, at 8 - 11. The surveyors did not document any failure by Petitioner to monitor a resident's temperature or to report a resident's fever that occurred after November 14, 1995.

3. Events which occurred after the November 1995 survey

On November 25, 1995, a surveyor returned to Petitioner's facility in order to ascertain whether any residents manifested elevated temperatures, and whether the facility was notifying the residents' treating physicians of residents' elevated temperatures. Tr. at 155 - 156. The surveyor found no evidence that a resident had an elevated temperature. Id.

On November 30, 1995, the Florida State survey agency sent a notice to Petitioner. HCFA Ex. 7. The notice first recited the results of the September 1995 survey of Petitioner. Petitioner was advised that one of the findings made as a consequence of the November 20 - 21 survey was that Petitioner had not attained substantial compliance with participation requirements. Petitioner was advised, therefore, that a civil money penalty of up to \$3,000 per day would be imposed on Petitioner retroactive to September 14, 1995. <u>Id.</u> at 1. As I note above, Petitioner is not contesting any remedy that might be imposed against it based solely on the noncompliance found at the September 1995 survey.

The November 30, 1995 notice then advised Petitioner that, at the November 1995 survey, the conditions in Petitioner's facility had deteriorated to the point that immediate jeopardy to residents existed at the facility. <u>Id.</u> at 2. Petitioner

was advised that, as a consequence, Petitioner would be subject to remedies that could include a civil money penalty of \$7,500 per day. <u>Id.</u>

HCFA wrote to Petitioner on December 5, 1995. HCFA Ex. 8. The notice directed Petitioner to file a plan of correction to address the deficiencies that were identified at the November 1995 survey. HCFA warned Petitioner that HCFA would terminate Petitioner's participation in Medicare on December 27, 1995 if the immediate jeopardy to resident health and safety was not removed by that date. HCFA also advised Petitioner that it might impose a civil money penalty against Petitioner in the amount of \$7,500 for each day that Petitioner was not in substantial compliance with federal participation requirements. Id. at 2. HCFA stated that the penalty might be decreased if it found that "immediate jeopardy has been removed but the non-compliance continues." Id.

Petitioner filed a plan of correction with the Florida State survey agency on December 12, 1995. HCFA Ex. 5, at 1; Attachment A. In filing its plan of correction, Petitioner averred that it was not admitting that HCFA or the Florida State survey agency were correct in finding deficiencies in Petitioner's operations. HCFA Ex. 5, at 3. Nonetheless, Petitioner stated that it would remedy the deficiencies that were identified in the report of the November 1995 survey by no later than December 14, 1995. <u>Id.</u> at 5 - 12.

On December 18 - 19, 1995, the Florida State survey agency conducted an additional survey of Petitioner. HCFA Ex. 10. The surveyors concluded that, as of those dates, Petitioner was complying substantially with all federal participation requirements. Id. Based on this survey, HCFA determined that Petitioner attained substantial compliance with federal participation requirements on December 19, 1995.

On February 22, 1996, HCFA sent Petitioner the notice letter which is the basis for Petitioner's hearing request. HCFA Ex. 11. The notice letter refers to HCFA's December 5, 1995 letter to Petitioner. It gives Petitioner official notice that HCFA had determined to impose a civil money penalty of \$7,500 per day against Petitioner, commencing on November 21, 1995 and continuing until December 19, 1995.

Petitioner requested that the civil money penalty determination be reviewed under an informal dispute resolution procedure. Informal dispute resolution procedures in cases of remedies imposed against long-term care facilities are provided for by 42 C.F.R. § 488.331. On May 22, 1996, the Florida State survey agency advised Petitioner that, as the result of the informal dispute resolution, it was sustaining the findings made by the surveyors. HCFA Ex. 12. On August 23, 1996, the Florida State survey agency advised Petitioner that it was affirming the results of the informal dispute resolution process. HCFA Ex. 17.

II. Issues, findings of fact and conclusions of law

A. Issues

This case involves the following issues:

1. During the period from November 21, 1995 until December 19, 1995, did Petitioner comply substantially with the federal participation requirements stated in 42 C.F.R. § 483.25?

2. Is there a basis to impose a civil money penalty against Petitioner, either in the upper or lower range of penalties, for Petitioner's alleged failure to comply substantially with the requirements of 42 C.F.R. § 483.25?

3. Am I authorized to order that a civil money penalty be imposed against Petitioner for findings of deficiency in the November 1995 survey from which HCFA did not make a determination to impose a civil money penalty?

I make findings of fact and conclusions of law (Findings) which address these issues. I set forth each Finding below as a separate italicized heading. I discuss each Finding in detail.

B. Summary of my Findings

At the center of this case is the treatment that Petitioner gave to two of its residents, Residents 1 and 5. Both of these residents are individuals who suffered from debilitating chronic illnesses.

HCFA alleges that Petitioner failed to monitor the fevers experienced by Residents 1 and 5 and failed to report these fevers to the residents' treating physician. In part, HCFA premises this allegation on assertions that Petitioner was obligated to monitor fevers experienced by its residents at regular intervals and that Petitioner was obligated to report to the residents' treating physician any fever in excess of 101 degrees Fahrenheit.

HCFA argues that Petitioner consistently failed to monitor and report the fevers experienced by Residents 1 and 5. HCFA asserts that this allegedly consistent failure to monitor and report residents' fevers evidenced a pervasive failure by Petitioner to follow professionally accepted standards of care in reporting and monitoring fevers. HCFA argues that these alleged systemic failures by Petitioner posed a threat, not only to the welfare of Residents 1 and 5, but to the welfare of all of Petitioners' residents.

HCFA asserts that there is no persuasive evidence that Petitioner changed its practices prior to December 19, 1995, when surveyors from the Florida State survey agency concluded that Petitioner was in substantial compliance with all participation requirements. From these assertions, HCFA argues that: (1) Petitioner failed to comply substantially with the participation requirement stated in 42 C.F.R. § 483.25; (2) Petitioner's failure to comply with that requirement posed immediate jeopardy to its residents; and (3) this alleged condition of immediate jeopardy persisted until December 19, 1995.

HCFA argues from the foregoing assertions that there exists a basis to impose a civil money penalty against Petitioner that falls within the upper range of civil money penalties, of from \$3,050 - \$10,000 per day for the period from November 20, 1995 until December 19, 1995. HCFA asserts that a civil money penalty of \$7,500 for each day during this period is justified, when Petitioner's alleged noncompliance with the requirements of 42 C.F.R. § 483.25 is considered in light of the other findings of deficiencies made by the surveyors at the November 1995 survey of Petitioner, under tags 272, 279, and 385.

I do not find HCFA's determination to impose the penalty to be justified, for the following reasons. First, HCFA has misstated the professionally accepted standards of care which apply to a long-term care facility's care of residents who experience fevers. There is no standard of care that a long-term care facility monitor a resident's fever at preset intervals. Rather, the standard of care is that a long-term care facility monitor a resident's fever as often as may be medically necessary to ensure that the fever is being assessed and treated. Nor do I agree with HCFA's allegation that professionally recognized standards of care require that a long-term care facility report to a resident's treating physician every temperature that a resident manifests in excess of 101 degrees. The standard of

care is that a long-term care facility should report a fever when the fever indicates a significant deterioration in the resident's condition.

Second, Petitioner's overall care of Residents 1 and 5 was not deficient when measured against the applicable standards of care. I conclude that, by and large, the professional staff of Petitioner was diligent in monitoring, treating, and reporting the fevers of these two residents. The staff's decisions to monitor and report the residents' fevers were motivated appropriately by the residents' medical conditions, and the instructions for care that were given for these residents.

That is not to say that Petitioner provided perfect care to its residents. I find that, in the case of Resident 5, Petitioner's staff erred in not reporting an episode of fever to the resident's treating physician. Although failure to inform the physician potentially harmed the welfare of the resident, I am not persuaded that the resident was harmed by this omission by Petitioner's staff.

Third, there is no evidence in this case of a pervasive failure by Petitioner to provide care to residents. There is no evidence that Petitioner was in any respect deficient in its compliance with 42 C.F.R. § 483.25 during the period from November 21, 1995 until December 19, 1995. Based on these conclusions, I find no basis to impose a civil money penalty against Petitioner, either in the amount of \$7,500 per day, or for a lower amount, predicated on Petitioner's alleged failure to comply with the requirements of 42 C.F.R. § 483.25.

I make no findings concerning whether Petitioner complied substantially with other participation requirements besides 42 C.F.R. § 483.25 during the period from November 21, 1995 until December 21, 1995. HCFA did not determine to impose any civil money penalty against Petitioner, based on the findings of deficiency made by the surveyors who conducted the November 1995 survey, under Tags 272, 279, and 385. I am without authority to decide whether a remedy is authorized or reasonable where HCFA has not determined to impose a remedy. Nor do I make any findings whether HCFA now could revisit the issue of whether to impose a civil money penalty against Petitioner based on the deficiencies identified under Tags 272, 279, and 385.

In their posthearing briefs and reply briefs, HCFA and Petitioner made numerous arguments as to the significance of individual elements of the record of this case. I have addressed the major arguments made by the parties in my Findings. The fact that I have not addressed in the body of this decision each argument made by

the parties concerning the significance of an item of evidence should not be taken to mean that I have ignored that argument. I have considered every argument that the parties made. However, I have elected not to discuss in detail each argument that the parties made on minor points, for purposes of efficiency.

C. Findings

1. It is reasonable to interpret 42 C.F.R. § 483.25 to require a long-term care facility to monitor adequately the temperatures of those residents who suffer from fevers and to report the elevated temperatures of residents to the residents' physicians when it is medically appropriate to do so.

The regulation on which HCFA predicates its determination that Petitioner failed to comply with a federal participation requirement to the extent that Petitioner's noncompliance posed immediate jeopardy to its residents is 42 C.F.R. § 483.25. The regulation states in its preamble that:

Each resident [of a long-term care facility] must receive and the facility must provide the necessary care and services to attain or maintain the highest practicable physical, mental, and psychosocial well-being, in accordance with the [resident's] comprehensive assessment and plan of care.

The regulation contains subsections (a) through (m) which describe specific types of care that a long-term facility must provide and which describe the manner in which the facility must provide such types of care.

The broad requirements of 42 C.F.R. § 483.25 implicitly include a requirement that a facility adhere to professionally recognized standards of care in providing care and treatment to its residents. As I discuss at Finding 2, the professionally recognized standards of care which apply to a long-term care facility include standards which govern the medically appropriate monitoring and reporting of residents' fevers.

The regulation does not specifically address, either in its preamble or in subsections (a) through (m), the circumstances under which a facility must monitor a resident's temperature or the circumstances under which a facility must report a resident's elevated temperature to the resident's treating physician. However, I find it to be evident that a resident's fever, if not treated adequately by a facility, may prevent the resident from attaining his or her highest practicable level of physical or mental well-being.

2. The implied requirement in 42 C.F.R. § 483.25 that a facility monitor and, when medically indicated, report a resident's fever to the resident's treating physician, does not generally require a facility to monitor every resident's fever at preset intervals, nor does it require a facility to report a resident's fever to the resident's physician whenever the fever exceeds 101 degrees Fahrenheit.

> a. The temperature monitoring requirement that is incorporated in 42 C.F.R. § 483.25 is the professionally recognized standard of care that a nursing home's professional staff monitor a resident's fever as often as the resident's medical condition warrants monitoring.

> b. The temperature reporting requirement that is incorporated in 42 C.F.R. § 483.25 is the professionally recognized standard of care that a nursing home's professional staff report to a resident's treating physician any change in the resident's temperature that indicates a medically significant deterioration in the resident's condition.

HCFA's case for asserting that Petitioner failed adequately to monitor and report the fevers manifested by its residents rests on two premises. First, HCFA argues that, when a resident of a long-term facility manifests a fever, it is the duty of the facility to monitor that fever by taking the resident's temperature at preset intervals. Second, HCFA asserts that a facility should report to a resident's treating physician every elevated temperature manifested by a resident which exceeds 101 degrees Fahrenheit.

a. The circumstances under which Petitioner has a duty to monitor a resident's fever

The report of the November 1995 survey did not state that the State survey agency surveyors expected Petitioner to monitor a resident's fever at preset intervals when a resident manifests a fever. The first notice that Petitioner received that this asserted requirement was a predicate for the surveyors' findings came in a notice dated May 22, 1996 that Petitioner received from the Florida State survey agency. HCFA Ex. 12. That notice reported to Petitioner the results of informal dispute resolution concerning the scope and severity findings of the surveyors, made at the November 1995 survey, on which HCFA based its determination to impose a \$7,500 per day civil money penalty against Petitioner. The notice recited, as part of the rationale for sustaining the findings of the surveyors, that:

According to our surveyors, the standard of [practice] is to monitor elevated temperatures every four hours. The record for Resident #5 indicates that there were greater than 12 hours between temperature checks during some of the occasions when this resident's temperature was high and therefore aggressive treatments were delayed.

<u>Id.</u> at 1.

It is reasonable to infer from this notice that one element of the Florida State survey agency's findings of deficiency under Tag 309 was that Petitioner was not complying with an asserted standard of practice that it monitor its residents' fevers at four-hour intervals. Petitioner devoted considerable effort at the hearing to rebut this assertion.

HCFA now argues, in its reply brief, that it is not asserting that there is a standard of care applicable to long-term care facilities which requires that a facility monitor a resident's fever at four-hour intervals. HCFA's reply brief at 10. I am puzzled by this argument, inasmuch as HCFA made no effort to correct the Florida State survey agency's assertion that such a standard existed and that Petitioner failed to comply with it. See P. Ex. 12. Petitioner presented substantial evidence at the March 25 - 26, 1997 hearing to refute the existence of an asserted once per four hours monitoring standard. At no time during the hearing did HCFA suggest that this evidence was not relevant or that is was unnecessary.

What makes HCFA's statement that it is not relying on an asserted once per four hours monitoring requirement even more puzzling is that HCFA has not made an affirmative assertion, other than the abandoned once per four hour assertion, as to what a facility's monitoring requirement is. Therefore, HCFA is arguing that Petitioner failed adequately to monitor its residents' fevers, but it is not asserting affirmatively, the standard of care that Petitioner was obligated to comply with in monitoring its residents' fevers.

I find that the professionally recognized standard of care for monitoring of a resident's fever in a long-term care facility is that the resident's temperature should be monitored as often as is warranted by that resident's condition. There is no professionally recognized standard of care which requires a long-term care facility to monitor a resident's temperature at standardized minimum time intervals except in the case of a resident who is receiving antibiotic therapy. In such a case, the standard is to monitor the resident's temperature once per eight hour nursing shift. These standards are incorporated impliedly into 42 C.F.R. § 483.25 as standards that should be followed by a long-term care facility in order to ensure that a resident achieve the highest practicable physical and mental well-being.

HCFA did not offer evidence at the hearing of this case that would support any monitoring standard. Petitioner offered evidence which proved that, in a long-term care facility, the general standard of care is to check the temperature of a resident once every eight-hour shift, where the resident is on antibiotics. Tr. at 264. This comports with the standard of care for nurses in acute care hospitals. There, the general standard of care for monitoring fevers is to check a patient's fever once every eight-hour shift when the patient is receiving antibiotics. Id. Only in a hospital intensive care unit is a once every four hours standard maintained for monitoring a patient's fever. Id. at 265. This evidence was supplied credibly, by Susan Watts, R.N., whose professional experience includes service as a director of nursing at an 180-bed long term care facility, and as a nurse in hospital intensive care units. Tr. at 242. It was not rebutted by HCFA.

Ms. Watts' testimony was corroborated by the testimony of Ralph Page, M.D. Tr. at 349. Dr. Page was retained by Petitioner as an expert physician. Dr. Page is board certified in internal medicine, with additional credentials in internal medicine. Tr. at 313. A major portion of Dr. Page's practice includes caring for elderly patients. <u>Id.</u> at 315. Dr. Page is the medical director of two nursing homes and the assistant medical director of a third nursing home. <u>Id.</u> at 315 -316. I find that his expert opinion on this issue and on other issues, as well, to be credible and essentially unrebutted by HCFA. It is the thrust of the testimony offered by Ms. Watts and Dr. Page that what is done for a resident in a long-term care facility ought to depend on the individual needs of that resident, and not on any predetermined or rigid criteria. See Tr. at 331 - 332; 337 - 340. This flexible standard of care incorporates a requirement that a long-term care facility should monitor a resident's temperature once per nursing shift, when the resident is on antibiotics. Tr. at 249; 264 - 266.

The treating physician for Resident 5 throughout her two stays at Petitioner's facility was Ernest deLeon, M.D. P. Ex. 10. Dr. deLeon is the medical director of Petitioner's facility. <u>Id.</u> at 1.

HCFA argues that an order given by Dr. deLeon for the administration of Tylenol to Resident 5 in order to control the resident's fever implicitly acknowledged a need to monitor the resident's fever at four-hour intervals. HCFA's posthearing brief at 28 - 29; <u>see</u> P. Ex. 8, at 13. I am not persuaded that the order at issue directed Petitioner's staff to monitor the resident's temperature at four-hour intervals. The order empowers the staff to administer Tylenol as needed by the resident at intervals as brief as once every four hours. P. Ex. 8, at 13; Tr. at 138. It is an order which gives the nursing staff an option to administer medication, not a directive. <u>Id</u>. It neither states nor suggests that monitoring at four-hour intervals was contemplated by Dr. deLeon.

b. The circumstances under which Petitioner has a duty to report a resident's fever to a resident's treating physician

The report of the November 1995 survey plainly suggests that the surveyors considered it to be mandatory that a resident temperature in excess of 101 degrees Fahrenheit be reported to a resident's treating physician. At several places in their description of Petitioner's alleged failure to comply with the requirements of 42 C.F.R. § 483.25, the surveyors assert that a resident manifested a temperature in excess of 101 degrees, but that Petitioner's professional staff failed to report the resident's temperature to the resident's treating physician. HCFA Ex. 5, at 8, 9, 10.

I do not find that professionally recognized standards of care, as they are incorporated into 42 C.F.R. § 483.25, require a long-term care facility to report every temperature of a resident in excess of 101 degrees. There is no specific temperature which triggers a reporting requirement. I find that the professionally recognized standard of care which is incorporated into 42 C.F.R. § 483.25 is that a long-term facility report a resident's temperature when that temperature indicates a medically significant deterioration in the resident's condition. What is significant depends on the unique circumstances which pertain to each individual resident.

HCFA's principal witness concerning the professionally recognized standards of care which govern long-term care facilities was Mr. Charles Fuller, R.N. Mr. Fuller was one of the surveyors who participated in the November 1995 survey of Petitioner. He has a nursing background, which includes working as a head nurse at a skilled nursing facility for a large hospital. Tr. at 47. Mr. Fuller testified that, in his experience as a nurse in long-term care facilities, such facilities had protocols which required that physicians be contacted routinely where residents' temperatures exceeded 101 degrees. Tr. at 69.

Petitioner rebutted Mr. Fuller's testimony by offering the professional opinion of Dr. Page. The credible testimony of Dr. Page is that the professionally recognized standard of care for physician notification by a long-term care facility of a resident's elevated temperature does not encompass a rigid requirement that a physician should be notified when a resident's temperature exceeds 101 degrees. Tr. at 330. Notification should be made where an elevated temperature is a sign of a significant decline in a resident's status. Tr. at 329 - 330. What is significant varies from resident to resident. In the case of a resident who has been experiencing normal temperatures, a spike in that resident's temperature might be a significant change in the resident's status which necessitates contacting the resident's physician. Tr. at 329. By contrast, frequent notification of a physician of temperature increases might not be appropriate where a resident chronically runs a fever. Tr. at 330.

I find the most persuasive evidence as to the standard of care which governs when a nursing facility should contact a resident's treating physician in the event of an elevated temperature in a resident to be the testimony given by Dr. Page. I find Dr. Page's explanation of the standard of care to be more persuasive than that given by Mr. Fuller, for two reasons. First, Dr. Page's qualifications as an expert are stronger than those of Mr. Fuller. Dr. Page is a physician who specializes in geriatric care and the medical director of two nursing homes. Second, and more important, Dr. Page gave a coherent explanation of the circumstances under which a nursing home should report a resident's elevated temperature. By contrast, Mr. Fuller merely recited the asserted requirement that every temperature in excess of 101 degrees must always be reported, without explaining why, as a matter of practice, a temperature in excess of 101 degrees should always be reported.

HCFA seeks to buttress its assertion that Petitioner was obligated under applicable standards of care to report every resident temperature in excess of 101 degrees with evidence that Petitioner maintained a protocol that required its staff to report temperatures in excess of 101 degrees. HCFA Ex. 5, at 11. Petitioner does not deny that, as of the November 1995 survey, it had a protocol which required its nurses to contact a resident's treating physician when the resident's temperature exceeded 101 degrees. Tr. at 293 - 294. Petitioner does not deny that its staff failed to follow this protocol. Nor does Petitioner dispute the possibility that Mr. Fuller's professional experience may have involved working at long-term care facilities which had similar protocols. However, Petitioner asserts that the protocol does not embody professionally recognized standards of care. Indeed, Petitioner discontinued the protocol after the November 1995 survey. Tr. at 297 - 299.

I do not find that Petitioner's failure to follow its protocol concerning physician notification in the event of an elevated temperature in a resident to be persuasive evidence that Petitioner did not follow a professionally recognized standard of care in its treatment of Residents 1 and 5. The protocol, which required Petitioner's staff to report a resident's temperature of more than 101 degrees, does not comport with a professionally recognized standard of care for reporting fevers.

As HCFA concedes, failure by a facility to comply with a protocol is not a failure to comply with a participation requirement where the protocol does not comport with a professionally recognized standard of care and where the participation requirement does not direct a facility to follow each of its internal protocols. HCFA's reply brief at 12 - 13. Failure by Petitioner to follow the protocol would be significant here only if the protocol contained a professionally recognized standard of care or if the protocol stated a federal participation requirement for a long-term care facility.

HCFA's assertion that there exists a professionally recognized standard of care which requires a facility to report to a resident's treating physician every temperature of that resident that exceeds 101 degrees is undercut by the fact that Petitioner's plan of correction, which it submitted in response to the November 1995 survey, did not represent that Petitioner would adhere to this asserted requirement. See HCFA Ex. 5. Petitioner proposed to implement an acute care charting system which gave explicit instructions to nurses concerning the care to be provided to residents who suffered from acute illnesses. See Id. at 8. Petitioner pledged to intensively monitor residents with acute illnesses. See Id. What Petitioner proposed to do, and HCFA accepted, is consistent with the kind of monitoring and reporting that Dr. Page testified would be appropriate. The fact that HCFA accepted a plan of correction which did not bind Petitioner to report every resident temperature in excess of 101 degrees at least suggests that HCFA did not consider the asserted reporting standard to be a mandatory requirement that long-term care facilities follow.

3. The method by which Petitioner measured residents' temperatures is not relevant to my decision.

In some respects, the surveyors premised their allegations concerning Petitioner's alleged failure to report residents' fevers to the residents' treating physician on an assertion that the fevers that Petitioner's staff recorded are actually lower than the true temperatures that the residents were running at the time. This assertion is in turn predicated on the allegedly different temperature readings that result from different methods of taking temperatures. Petitioner does not dispute that different methods of taking temperature may produce different readings at the same time in the same individual. However, Petitioner disagrees with the State survey agency and HCFA as to the span of temperatures that may be expected from different temperature recording methods.

There is no dispute that there are three generally accepted ways to take an individual's temperature. These are: orally; rectally; and axillary (recorded by placing a thermometer under the individual's arm). Tr. at 58 - 59. HCFA's witness, Mr. Fuller, testified that an oral temperature reading is usually one degree higher than is an axillary temperature reading taken at the same time, and a rectal temperature reading is usually one degree higher than is an oral temperature reading taken at the same time. Id. Thus, according to Mr. Fuller, one might expect a two-degree difference between an axillary and a rectal temperature.

Petitioner offered P. Ex. 16 to rebut this testimony. It is an excerpt from a medical treatise which states that an oral temperature is usually about one-half degree higher than is an axillary temperature that is taken at the same time, and that a rectal temperature is usually about one-half to one degree higher than is an oral temperature that is taken at the same time. P. Ex. 16, at 3. Therefore, according to Petitioner' treatise excerpt, an individual's temperature span will

vary between one and one and one-half degrees, depending on the method of taking the temperature, and not two degrees, as is averred by HCFA. <u>Id.</u>

I find this dispute largely to be irrelevant to my decision. The most accurate temperature of a resident might be important if I were to find that a facility was obligated to report automatically a resident's true temperature in excess of 101 degrees to the resident's treating physician. If that were the standard, then the method by which the resident's temperature is recorded might be significant in telling the facility whether the resident's actual body temperature of 99.5 degrees would translate to a rectal temperature of 101.5 degrees. Based on Petitioner's evidence, an axillary temperature to a rectal temperature of 99.5 degrees would translate to a rectal temperature of 101.5 degrees.

But, as I find above, at Finding 2, there is no standard of care that requires a facility automatically to report a temperature of more than 101 degrees to a resident's treating physician. Therefore, the fact that a resident's temperature might be above 101 degrees, depending on the method by which that temperature is taken, is not significant to my decision.

What is significant is whether a resident manifests a temperature change that establishes a significant deterioration in the resident's condition. No party disputes that such a change may be recorded by any of the accepted ways of taking an individual's temperature.

4. Petitioner followed professionally recognized standards of care in providing care to Resident 5.

The surveyors who conducted the November 1995 survey of Petitioner reviewed the records of two stays at Petitioner's facility by Resident 5. The first stay was from September 6, 1995 until September 27, 1995. P. Ex. 7, at 1 - 99. The second stay was from November 3, 1995 until November 14, 1995. P. Ex. 8, at 1 - 48.

Resident 5 began her first stay at Petitioner's facility with a discharge to the facility from a local hospital, Lake City Medical Center. P. Ex. 7, at 6. At the time of her first admission to Petitioner's facility, the resident was diagnosed to be suffering from a low grade fever. <u>Id.</u> The resident's other diagnoses included: urinary tract infection, viral syndrome, obs (which I infer to be

organic brain syndrome) status post CVA, decubitus ulcers, mild congestive heart failure, and diabetes mellitus. Id.

On September 27, 1995, Resident 5 was transferred from Petitioner's facility to Lake City Medical Center. Her diagnoses at the time of her transfer included left lower lobe pneumonitis. P. Ex. 8, at 7. On October 11, 1995, Resident 5 was transferred from Lake City Medical Center to Vencor Hospital. <u>Id</u>. The resident remained at Vencor Hospital until November 3, 1995, when she was transferred back to Petitioner's facility. The resident's diagnoses at the time of her transfer back to Petitioner's facility included: left lower lobe pneumonitis, resolved; urinary tract infection, yeast, resolved; decubitus ulcers, stage III - IV right hip, ongoing treatment; hypertension; adult onset diabetes mellitus; arteriosclerotic heart disease with congestive heart failure; anemia of chronic disease; dementia, status post cerebrovascular accident, remote; staph sepsis, resolved. <u>Id</u>.

The overall allegation of deficiency which the surveyors made and HCFA adopted concerning the care which Petitioner provided to Resident 5 during her two stays at Petitioner's facility is that Petitioner did not consistently monitor the resident's status to identify changes in her condition which could have resulted in harm to the resident or deterioration in the resident's condition. HCFA Ex. 5, at 8. The surveyors and HCFA allege that Petitioner did not react in response to the resident's identified conditions or to changes in the resident's conditions. Id. They assert that these alleged failures by Petitioner to react could have led to harm to the resident or deterioration in the resident's condition. Id.

HCFA implicitly adopted the surveyors' general and specific allegations in determining to impose a civil money penalty against Petitioner. In their report of the November 1995 survey, the surveyors amplify on these assertions by averring that on many occasions the resident was noted to have a fever in excess of 101 degrees and on one occasion was noted to be in respiratory distress. Id. The surveyors assert that Petitioner failed to notify the resident's treating physician of these allegedly potentially harmful changes in the resident's condition. Id. The surveyors' general statement of alleged failures by Petitioner to provide proper treatment to Resident 5 is followed by four specific examples, listed as examples a) through d).

The evidence which the parties offered concerning these allegations of noncompliance includes the report of the November 1995 survey, the testimony of Mr. Fuller, the surveyor who performed the review which led to the allegations about Resident 5, the resident's treatment records, the affidavit testimony of Dr. deLeon, and the opinions of Ms. Watts and Dr. Page. I conclude from all of this evidence that the preponderance of the evidence is that Petitioner complied with professionally recognized standards of care in providing care to Resident 5. Specifically, I conclude that Petitioner monitored adequately the fevers that the resident manifested on various occasions, and, with an exception that I shall discuss, reported significant changes in the resident's condition to Dr. deLeon. It is apparent also from the evidence that Petitioner's professional staff, under the direction of Dr deLeon, gave treatments to the resident that were appropriate, within the limitations of the treatment regime ordered for that resident.

As is apparent from the discussion which follows, I have relied heavily on the testimony of Dr. Page, not only for his description of the standards of care which apply to monitoring and reporting of a resident's temperature, but for his analysis of whether the care rendered by Petitioner's staff was within applicable standards. Dr. Page is the only expert physician who testified in person at the hearing which I conducted. HCFA did not rebut directly any of the testimony that Dr. Page offered.

At the in-person hearing, HCFA suggested that Dr. Page's testimony might be discounted by virtue of the fact that Dr. Page is a paid expert. I am not satisfied that the fact that Dr. Page was compensated for his testimony is a basis to discount that testimony. HCFA did nothing to impeach Dr. Page's credibility, aside from suggesting that his testimony was motivated by the compensation he received for it.

a. Example a)

The surveyors stated example a) of alleged failure by Petitioner to provide proper monitoring and reporting of the fevers manifested by Resident 5 as follows:

The resident was documented at 2:20 PM on 12-Sep-95 to have a fever of 99.5 axillary and at 12:10 AM on 13-Sep-95 was noted clammy, dusky with discoloration of the lower extremities and 3+ edema. The physician was notified eleven (11) hours later at 11:15 Am on 13-Sep-95 of the changes in the resident's condition.

HCFA Ex. 5, at 8 - 9.

Nowhere in the survey report do the surveyors explain what was inappropriate about the care in example a) that Petitioner provided to the resident. However, I am inferring from the example that the surveyors found that the fever of 99.5 axillary on September 12 should have been reported to Dr. deLeon. I am inferring also that the surveyors concluded that the medical signs of clamminess, duskiness, discoloration, and edema that the professional staff observed early on the morning of September 13, were signs of respiratory distress of which Dr. deLeon should have been notified immediately.

I conclude that the care that Petitioner provided to Resident 5 between September 12 and 14, 1995, comports with professionally recognized standards of care for monitoring and treating fevers and reporting to the resident's treating physician changes in a resident's condition. Example a) does not demonstrate a failure by Petitioner to provide care to Resident 5 which comports with professionally recognized standards of care.

The monitoring of the resident's fever that Petitioner's professional staff did is within the standard of care for monitoring of fevers. Resident 5 was suffering from an ongoing viral condition for which she was receiving antibiotics. P. Ex. 7, at 7; Tr. at 249. During the period beginning on September 12, and ending in the early morning hours of September 14, the resident ran a fever. P. Ex. 7, at 15 - 17. Petitioner's staff recorded the resident's temperature at least once per nursing shift. Id. This is consistent with that which would be done in an acute care facility for a patient who is suffering from a fever and who is receiving antibiotics. Tr. at 264.

Petitioner's staff recognized and treated appropriately the elevated temperatures manifested by Resident 5. In an effort to reduce the resident's fever, the staff administered Tylenol elixir to the resident at regular intervals. P. Ex. 7, at 15 - 16. HCFA has offered no evidence that the treatment provided for the resident's fever was inappropriate, nor has HCFA averred that there were other treatments that Petitioner ought to have administered, but which Petitioner did not administer. Mr. Fuller, who is HCFA's witness, agreed that administration of Tylenol is an appropriate way to reduce a fever. Tr. at 113. Dr. Page concluded that the treatment which Petitioner gave to the resident for her fever was appropriate. Tr. at 325 - 332.

Petitioner's staff treated the resident's respiratory distress diligently, appropriately, and successfully. There is no evidence that Petitioner was in any respect derelict in the care it gave for the respiratory distress of Resident 5. HCFA has not offered evidence to show that Petitioner's treatment of the resident's respiratory distress was inappropriate. By contrast, Petitioner offered unrebutted, persuasive evidence that Petitioner treated the resident's respiratory distress appropriately and effectively. That evidence consists of the results that Petitioner's staff obtained in treating Resident 5 along with the testimony of Ms. Watts and Dr. Page. P. Ex. 7, at 16; Tr. at 252; 325 - 332.

The resident manifested signs of respiratory distress at 12:10 am on September 13. These signs included the clamminess, duskiness, and edema that were reported by the surveyors. P. Ex. 7, at 16. They also included observations that rales could be heard at the bases of the resident's lungs. Id. The nursing staff suctioned the resident at 3:15 am on September 13. After suctioning, the resident's respiration was noted to be improved, without signs of further labored breathing. Id. A chest x-ray was taken of the resident as part of the care provided for the resident's respiratory distress. The results of the x-ray were received at 1:00 pm on September 13, 1995, and showed the patient to be without pneumonia and with reduced pleural effusion. Id.

Professionally recognized standards of care did not require that Petitioner notify Dr. deLeon of the resident's condition before 11:15 am on September 13, 1995. At no point during the episode which began on September 12, 1995, did the resident's status deteriorate to the extent that notification was mandated. The notification that was given to Dr. deLeon on September 13 was, in fact, a routine status update, and not a notification of a marked change in the resident's condition. Tr. at 254.

As I hold above, there is no professionally recognized standard of care that would require Petitioner to notify a physician of a resident's fever once that fever exceeded 101 degrees. The standard of care, either in the case of a fever or in the case of other problems, such as respiratory distress, is to notify a resident's physician of any change in the resident's condition which shows a significant deterioration in that resident's condition. Here, the evidence shows that the fever and the respiratory problems that the resident displayed between September 12 and September 13 were part of an ongoing, previously diagnosed condition for which Dr. deLeon had prescribed treatment. There were no changes in the resident's condition which mandated that Dr. deLeon be notified.

I draw this conclusion essentially from the unrebutted testimony of Dr. deLeon and Dr. Page. In his affidavit, Dr. deLeon avers that he would not have changed the treatment orders that he gave for Resident 5 had he been notified sooner by Petitioner's staff of elevations in the resident's temperature. P. Ex. 10, at 2. His testimony does not specifically address HCFA's example a), but I infer that it includes this example along with the other examples cited by HCFA.

Dr. Page reviewed the care that Petitioner provided to Resident 5 on the 12th and 13th of September 1995, and concluded that the care was appropriate, given the nature of the resident's condition. Tr. at 325 - 332. Dr. Page's opinion of the care provided by the facility was that the facility was doing all that could reasonably be expected for the resident, given the resident's state of health. Id. He concluded, additionally, that there was no particular reason why the facility would have been obligated to notify Dr. deLeon immediately of the increase in the resident's temperature, given the resident's condition. Tr. at 331 - 332.

HCFA asserts that Dr. deLeon has an interest in the outcome of this case which affects the credibility of his testimony. To be sure, Dr. deLeon, as the resident's treating physician, has an interest in defending the care that he provided to the resident. But Dr deLeon's self-interest does not disqualify his testimony. A witness may have an interest in the outcome of a proceeding and yet, deliver credible testimony. Here, there is nothing to show that Dr. deLeon's testimony is medically unsupported. Dr. deLeon's testimony is unrebutted. Moreover, it is supported by the testimony given by Dr. Page.

b. Example b)

The surveyors stated example b) as follows (for the sake of clarity, I am omitting a list of temperature readings and treatments that are part of the example):

The resident had multiple (10) temperature[s] checked between 8:30 PM on 23-Sep-95 (103 degrees rectal) and 1:30 AM on 25-Sep-95 (101 degrees) which were documented greater than 101 degrees. . . . The resident maintained a fever greater than 101 degrees for 42 hours during which there is no documentation that the resident's physician was notified of the resident's decline in physical well-being until 3:00 PM on 25-Sep-95. The resident's physical well-being continued to decline and the resident was transferred to the hospital at 2:15 PM on 27-Sep-95 with oxygen saturation level of 77% and fever of 105.9 R.

HCFA Ex. 5, at 8 - 10.

It is clear that the surveyors intended the example to show that Petitioner failed to report to Dr. deLeon a potentially dangerous change in the condition of Resident 5. It is not clear whether HCFA relies on the example also as evidence that Petitioner failed to monitor the resident's fever, or as an evidence that Petitioner failed adequately to treat the resident's fever. I have considered the evidence which is relevant to this example in terms of what it shows about how Petitioner monitored, treated, and reported the resident's fever to Dr. deLeon.

The surveyors' allegations in example b) contain errors of fact and a description of events which inflate the allegations by the surveyors that Petitioner was derelict in providing care to Resident 5. First, the surveyors assert, incorrectly, that Petitioner's temperature exceeded 101 degrees during a 42 hour period prior to 3:00 pm on September 25, 1995, during which Dr. deLeon allegedly was not notified of the resident's condition. HCFA Ex. 5, at 9. In fact, the period during which the resident's temperature exceeded 101 degrees, and during which there was no documented communication with Dr. deLeon, began at 2:45 pm on September 24 and ended at 7:25 am on September 25. P. Ex. 7, at 20 - 21.

Second, in asserting that the resident was transferred to the hospital on September 27, with an oxygen saturation level of 77% and a temperature of 105.9, measured rectally, the surveyors seem to link the patient's transfer, in part, to the resident's high fever. See HCFA Ex. 5, at 9 - 10. Although I am certain that the resident's continued fever contributed to Dr. deLeon's decision to order that the resident be transferred, the resident's fever was not the principal motivating reason for the transfer order. In the hours prior to Dr. deLeon's decision to transfer the resident, the resident's fever had, in fact, been reduced substantially. P. Ex. 7, at 22. The decision to transfer the resident was based on the decline in the resident's oxygen saturation level, coupled with evidence of blood clots in the resident's catheter. Id. The resident's fever rose to a high level after the decision had been made to transfer the resident. Id.

Indeed, the evidence shows that Petitioner's staff reacted swiftly to a final spike in the resident's temperature on September 27 which occurred after Dr. deLeon issued an order to transfer the resident. P. Ex. 7, at 23. In order to save time, Petitioner's staff contacted 911 and arranged for an expedited transfer of the resident. <u>Id.</u> My conclusions about example b) are that facts related to this example establish that, in general, Petitioner complied with professionally recognized standards of care in the monitoring and treatment that it provided for the fever and related problems manifested by Resident 5. Petitioner's staff adequately monitored and aggressively treated the resident's fever. I find that Dr. deLeon was in frequent contact with Petitioner's staff during the episode in question, and was well aware of the resident's general condition, including her persistently elevated fever.

Although I find a general compliance by Petitioner with standards of care, I find that Petitioner's staff must be faulted for not reporting to Dr. deLeon a serious elevation of the resident's temperature, which occurred on September 24, 1995. However, that is the only judgment error that I find concerning the course of treatment that Petitioner provided to the resident between the 23rd and 25th of September 1995. I do not find that this error in judgment resulted in harm to the resident. It is an isolated event, and does not typify the care that Petitioner provided to Resident 5.

The evidence does not show Petitioner's staff to have been derelict in communicating with Dr. deLeon concerning the condition of Resident 5. To the contrary, the record establishes frequent communications between Petitioner's staff and Dr. deLeon concerning the resident's condition. The communications concerning the resident's persistent fever began on September 18, 1995. P. Ex. 7, at 18. On that date, Petitioner's nursing staff notified Dr. deLeon of the resident's "repeatedly elevated temperature." Id. Dr. deLeon responded to this notification by ordering that blood cultures be taken of the resident. Id. The reason that Dr. deLeon ordered blood cultures of Resident 5 was to diagnose the cause of the resident's fever and to give Dr. deLeon evidence on which he could base a treatment plan. See Tr. at 115. Laboratory results were received on September 20, and Dr. deLeon was notified of these results. P. Ex. 7, at 19.

There was an additional communication between Petitioner's staff and Dr. deLeon concerning laboratory results on September 21, 1995. P. Ex. 7, at 19. On September 22, 1995, Petitioner's staff spoke again with Dr. deLeon concerning the resident's condition (the specific subject of this discussion was the resident's decubitus ulcers). <u>Id.</u> at 20.

Dr. deLeon visited the resident on September 23, 1995, and issued new treatment orders on that date. <u>Id.</u> Additional communications with Dr. deLeon were recorded on September 25, 1995, concerning the results of laboratory tests. <u>Id.</u> at 21. The nursing notes record another communication with Dr. deLeon, by

telephone, on September 26, 1995, to report the results of blood cultures. <u>Id</u>. On September 27, additional laboratory results were received. On that date, the nursing staff informed Dr. deLeon of a decline in the resident's condition. <u>Id</u>, at 22. Dr. deLeon ordered the resident be transferred to the hospital on that date, for evaluation. <u>Id</u>,

It is true that, during the days between September 18, and September 27, not every temperature reading of Resident 5 in excess of 101 degrees was communicated to Dr. deLeon. But, as I find above, there is no professionally recognized standard of care that would have required Petitioner to notify Dr. deLeon of every temperature manifested by the resident that exceeded 101 degrees. Rather, Petitioner's obligation was to make sure that Dr. deLeon was kept apprised of the resident's overall condition and of any changes in that condition that showed significant deterioration in the resident's status.

In general, this requirement was met by Petitioner's staff. There was no failure by Petitioner to keep Dr. deLeon apprised of the resident's ongoing and persistent fever, nor was there any failure by the facility to be diligent in communicating with Dr. deLeon concerning the treatment of the fever. Dr. deLeon was well aware of the resident's fever. P. Ex. 10, at 2. He addressed her fever by ordering blood cultures, prescribing antibiotic therapy, and issuing orders for the care of the resident.

There is evidence that, on one occasion, on September 24, 1995, the resident's fever was markedly elevated and Dr. deLeon was not notified of that event. On the evening of September 24, the resident's temperature rose to 105.1 degrees, measured rectally. P. Ex. 7, at 20. The nursing staff diligently treated the fever, with Tylenol and ice packs. Dr. deLeon was not notified of this specific event.

I conclude that the rise in the resident's temperature on September 24, 1995, was an event of which Dr. deLeon ought to have been notified by Petitioner's staff. Although the resident had run persistent fevers prior to that date, the temperature of 105.1 was markedly higher than any previously recorded temperature. Petitioner's own witness, Ms. Watts, agreed that Dr. deLeon should have been notified of this increase in temperature, because a temperature of that degree of elevation posed a risk for harm to the resident. Tr. at 258. Although failure to inform the physician potentially harmed the welfare of the resident, I do not find that the resident was harmed by this single failure of Petitioner's staff to notify Dr. deLeon of the resident's temperature. In its reply brief, HCFA asserts that the clinical signs manifested by the resident at midnight on September 24, 1995, were consistent with neurological damage produced by fever. HCFA's reply brief at 5. However, HCFA has offered no credible opinion evidence, nor has HCFA cited to findings in the resident's record, which show that the resident actually suffered harm from the episode of high fever that the resident sustained on September 24, 1995. The treatment that Petitioner gave for the elevated temperature, Tylenol and ice packs, was the medically indicated treatment. Tr. at 258; <u>see</u> Tr. at 113. The resident's fever was reduced. P. Ex. 7, at 20 - 21. HCFA has not asserted that there were other treatments that Petitioner might have given to the resident, which it failed to give to the resident.

I find to be appropriate the care that Petitioner gave to the resident through September 27, 1995. Petitioner's staff monitored the resident's temperature frequently. P. Ex. 7, at 20 - 23. When the resident's temperature was elevated, Petitioner's staff treated the fever aggressively. Treatments included frequent administration of Tylenol elixir and ice packs. <u>Id.</u> This was the medically appropriate course of care to address the resident's fever. Tr. at 258; <u>see</u> Tr. at 113. Dr. deLeon testified without rebuttal that he would not have changed the monitoring or the treatment provided to Resident 5 by Petitioner's nursing staff. P. Ex. 10, at 2. HCFA has not asserted that the resident should have been given treatments other than those which Petitioner's staff administered to the resident.

I find strong support in the testimony of Dr. Page for my conclusion that Petitioner's staff and Dr. deLeon cared for Resident 5 through September 27, 1995 consistent with that which was required by professionally recognized standards of care. Dr. Page concluded that the monitoring provided to the resident by Petitioner's nursing staff equaled or exceeded that which was required by applicable standards of care. Tr. at 338 - 339. Dr. Page noted that the purpose of antibiotics is to treat a possible source of the resident's fever. However, antibiotic therapy does not produce immediate results. Tr. at 333 -336. It would not have been realistic to expect an immediate reduction in the resident's fever after antibiotics were administered. Id. And, in light of the fact that Dr. deLeon was aware of the resident's persistent fever, notification of Dr. deLeon of every increase in the resident's temperature was unnecessary. Tr. at 337 - 338.

c. Example c)

The surveyors stated example c) as follows:

The resident was documented as having fever greater than 101 degrees on 05-Nov-95 (102.2 Ax and 101.9), 08-Nov-95 (101.5 Ax) and 09-Nov-95 (101.5 Ax). The resident was given Tylenol which was ordered PRN for fever. There is no documentation of physician notification for any of the four (4) documented temperature elevations which potentially could lead to resident harm and/or deterioration.

HCFA Ex. 5, at 10.

As with the other allegations, this allegation rests on the premise that Petitioner was obligated, under professionally recognized standards of care, to notify Dr. deLeon of every instance when a resident's temperature exceeded 101 degrees. I have discussed this premise under Finding 2. It is not necessary for me to repeat my discussion here, except to say that I do not find that the preponderance of the evidence substantiates the premise. The standard of care for reporting temperatures does not require a facility automatically to report to a resident's physician every temperature of the resident in excess of 101 degrees. Rather, the standard is that a temperature change should be reported when it evidences a significant deterioration in the resident's condition.

Petitioner complied with the applicable standard of care in the treatment that it provided to Resident 5 between November 5 and November 9, 1995. There was no need for the staff to have notified Dr. deLeon of fluctuations in the resident's temperature, inasmuch as the fluctuations were evidence of an underlying condition of which Dr. deLeon and Petitioner's staff were aware. P. Ex. 10, at 2. None of the temperatures recorded during the period from November 5 through November 9 suggested a significant deterioration in the resident's condition. See P. Ex. 10, at 2.

Although the surveyors did not allege specifically that Petitioner's staff failed to monitor or to treat adequately the resident's fever, I have examined the record of care provided to the resident in order to decide whether the staff complied with applicable standards of care which govern monitoring and treatment. Petitioner's staff monitored the resident's fever, and treated it appropriately. The care that was provided to the resident at this time is consistent with the resident's family's request that the resident be given comfort measures only. P. Ex. 8, at 8; Tr. at 347 - 349. It is the treatment that Dr. deLeon ordered be given to Resident 5. See P. Ex. 10, at 2.

Resident 5 was readmitted to Petitioner's facility from Vencor Hospital on November 3, 1995. P. Ex. 8, at 8. The Vencor Hospital discharge summary recited that:

The patient's son has requested no further antibiotic therapy [for the resident] or further intervention other than treatment for comfort measures only. The patient remains a full no-code.

<u>Id.</u>

I infer from this discharge summary that Petitioner's staff and Dr. deLeon knew as of November 3, 1995, that the care instructions for Resident 5 included a request that no further antibiotic therapy be given to the resident and that the resident was to be provided with comfort measures only. The care that Petitioner provided to the resident between November 5 and November 9, 1995 must be evaluated, not only in light of professionally recognized standards of care, but in light of these instructions.

The May 22, 1996 notice of results of informal dispute resolution which the Florida State survey agency sent to Petitioner suggests that Petitioner could have conditioned the care it provided to Resident 5 after November 3, 1995 on the instructions given by the resident's son, only in the presence of a living will signed by the resident, or a legal power of attorney. HCFA Ex. 12, at 2. HCFA has not offered any authority for this assertion. In fact, it is not clear that HCFA is arguing this assertion now. In any event, the preponderance of the evidence is that it is an acceptable standard of practice for a nursing home to predicate the care it gives to a resident on the instructions contained in a hospital discharge summary. Tr. at 343 - 346.

The evidence establishes that Petitioner's staff treated the resident consistent with the instructions contained in the Vencor Hospital discharge summary. There is no evidence that resident was either harmed or suffered the potential for harm from this care. HCFA has not offered any evidence to show that the resident was harmed or even potentially harmed by the care given to her. The staff monitored the resident's temperature frequently between November 5 and November 9, 1995. P. Ex. 8, at 18 - 22. The resident's temperature fluctuated

during this period. During this entire period, the nursing staff was attentive to the resident's needs, administering Tylenol elixir and ice packs to the resident, when necessary, to control the resident's fever. <u>Id.</u> Administration of these measures had the effect of reducing the resident's fever. <u>Id.</u>; Tr. at 270 - 272.

d. Example d)

The surveyors stated example d) as follows:

The resident was documented as having a fever in excess of 101 degrees (x5) from 12-Nov-95 through 14-Nov-95 [examples omitted]. The resident was given Tylenol which was ordered PRN for fever. There is no documentation that the facility monitored the resident's potentially harmful fever between 1 AM on 13-Nov-95 and 3:30 AM on 14-Nov-95. The resident maintained a fever in excess of 101 degrees for 35.5 hours and the physician was not notified until the resident's fever reached 104 degrees axillary at 3:30 AM on 14-Nov-95. The resident experienced harm and deterioration of physical well-being which resulted in admission to the hospital ordered by the physician at 3:45 AM on 14-Nov-95.

HCFA Ex. 5, at 10 - 11.

This example contains several allegations. First, the surveyors allege that were five instances between November 12 and November 14, 1995 in which Resident 5 was documented as having a fever in excess of 101 degrees. Implicit in this allegation is the conclusion that Dr. deLeon ought to have been informed of each of these fevers in excess of 101 degrees. Second, the surveyors allege that Petitioner failed to monitor the resident's fever for approximately 26 hours, between 1:00 am on November 13 and 3:30 am on November 14. Third, the surveyors allege a continuous period of more than 35 hours in which the resident maintained a fever in excess of 101 degrees. Finally, the surveyors suggest that dereliction of care by Petitioner's staff resulted in harm to the resident.

I find these allegations to be without merit. They are inaccurate in several key respects. As with the allegations in the examples a) through c), they depend on an asserted standard of care that a facility must notify a resident's physician each time the resident's temperature exceeds 101 degrees which I find not to be the applicable standard of care.

A close examination of the record of care provided by Petitioner to Resident 5 between November 12 and 14, 1995, shows that Petitioner's staff continued to provide care to the resident which was consistent with applicable standards of care and with the care that had been ordered for the resident. I do not find that Petitioner was derelict in the care it provided, nor do I find evidence that Petitioner's care caused harm to the resident.

The record establishes that, between November 12 and November 14, 1995, Resident 5 continued to manifest a fever that Petitioner's staff sought to control with the administration of Tylenol, ice packs, and cool towels. P. Ex. 8, at 23; 33. The record shows that the resident's fever was not continuous. There is no 35 hour period between November 12 and November 14 in which the resident ran a fever in excess of 101 degrees. Id. at 23 - 24. To the contrary, Petitioner's staff was successful in its efforts to reduce the fever, using the methods I have described. Id. At several points between November 12 and November 14, the resident's fever was reduced below 100 degrees. Id.

The surveyors also are incorrect in their assertion that the resident's fever went unmonitored for a period of about 26 hours between November 13 and November 14. It is true that the nursing notes for the resident do not record temperature readings continuously for this period. See P. Ex. 8, at 23. But, elsewhere in the resident's record, is a report of the administration of Tylenol to the resident and the effect of that medication on the resident's fever. It records several temperature readings of the resident on November 13, and at 6:00 am on November 14. Id. at 33. It shows also that the administration of Tylenol to the resident, coupled with the other treatments that Petitioner's staff administered to the resident, were effective in controlling the resident's fever.

The fever of 104 degrees that Resident 5 manifested on November 14, 1995, at about 3:30 am, constitutes a departure from the pattern of temperatures which the resident had manifested for the previous two days. The highest recorded temperature for the previous two days was 101.8 degrees (by axillary method) on November 13. The nursing staff's immediate response to the resident's temperature increase on November 14 was to call Dr. deLeon, who promptly ordered the resident transferred to a hospital. Id. at 23. I find the nursing staff's decision to contact Dr. deLeon when the resident's temperature rose to 104 degrees to be consistent with what is required by the applicable standard of care. Here, the nursing staff concluded that the resident's temperature, and called Dr. deLeon.

By contrast, the temperature increases which occurred on November 12 and 13 were not atypical of the resident's general condition, and were treated successfully by Petitioner's staff. There was nothing that the staff did that Dr. deLeon would have ordered be changed, had the staff contacted Dr. deLeon earlier. P. Ex. 10, at 2.

5. Petitioner followed professionally recognized standards of care in providing care to Resident 1.

The surveyors who conducted the November 1995 survey of Petitioner reviewed the records of a stays at Petitioner's facility by Resident 1. The record of this stay is documented in P. Ex. 9 and P. Ex. 12.

Resident 1 was admitted to Petitioner's facility suffering from decubitus ulcers. P. Ex. 9, at 1 - 3. The record of the resident's treatment establishes that at least one of these ulcers became infected. Dr. deLeon was notified by Petitioner's staff of the infection, and he directed care for the resident consisting of laboratory tests and the administration of antibiotics to the resident. P. Ex. 9, at 7. By November 7, 1995, the resident was receiving antibiotic therapy. <u>Id.</u>; P. Ex. 10, at 2 - 3. Dr. deLeon discussed this therapy with Petitioner's staff on that date. <u>Id.</u>

The surveyors stated their allegation concerning Petitioner's treatment of Resident 1 as follows:

Resident # 1 was documented as having a fever of 103.8 axillary at 2:30 AM on 08-Nov-95. The resident was given Tylenol, which was ordered PRN for fever, and cool wet towels were applied. There is no documentation that the physician was notified of this change in the resident's condition.

HCFA Ex. 5, at 11. As I read this allegation, it consists entirely of an assertion that Petitioner failed to discharge an asserted duty to notify Dr. deLeon of the resident's fever. There is no allegation that Petitioner failed to monitor the fever, that the treatment which Petitioner provided for the resident's fever was inappropriate, or that the resident was harmed, actually or potentially, by the care that Petitioner gave to the resident. The allegation thus can be characterized as an assertion that the failure of Petitioner to notify Dr. deLeon of the resident's temperature is, in and of itself, and without regard to the circumstances, a failure to comply with professionally recognized standards of care. In this instance, it was not necessary for Petitioner's staff to notify Dr. deLeon of the resident's temperature. As I have held above, there is no standard of care which would require a facility automatically to notify a resident's treating physician of a resident's fever. Thus, I cannot conclude that Petitioner is per se liable for not having notified Dr. deLeon of the episode of fever involving Resident 1.

Moreover, it is evident from the context of the care that Petitioner gave to Resident 1 that a fever was an expected development which did not signify a deterioration in the resident's condition requiring notification of Dr. deLeon. The resident was given the treatment necessary to control both the source of the fever and the fever.

The resident was experiencing an infection. A fever was a likely consequence of the infection. Tr. at 350 - 351. Only hours before the resident ran a fever, Dr. deLeon initiated antibiotic therapy for the resident. P. Ex. 9, at 7; P. Ex. 10, at 2 - 3. To expect immediate results from the therapy would be unrealistic. In the words of Dr. Page, it would have been "senseless" to notify Dr. deLeon of a fever that was expected, especially in light of the care that Dr. deLeon had prescribed for the resident. Tr. at 350 - 351.

The fever experienced by Resident 1 was an isolated episode which Petitioner's staff controlled quickly and efficiently. The staff treated the fever with Tylenol elixir and the application of cool wet towels to the resident. P. Ex. 9, at 8. Within hours, the resident's fever was reduced, and it remained that way. <u>Id.</u>

6. Petitioner complied substantially with the requirements of 42 C.F.R. § 483.25 between November 21, 1995 and December 19, 1995.

The preponderance of the evidence is that, between November 21, 1995 and December 19, 1995, Petitioner complied substantially with the requirements of 42 C.F.R. § 483.25. The evidence establishes Petitioner to have been out of compliance with the requirements of the regulation on one date, September 24, 1995. However, the evidence of noncompliance relates only to an isolated event, and not to the care that Petitioner gave to its residents on other dates.

As I find above, at Finding 2, 42 C.F.R. § 483.25 incorporates a requirement that a long-term care facility comply with applicable standards of care in its treatment of residents. The standards of care require a facility to notify a

resident's treating physician of a resident's fever that evidences a significant deterioration in the resident's condition. And, as I find at Finding 4, on September 24, 1995, Resident 5 experienced an increase in her temperature which evidenced a potential deterioration in the resident's condition. Under the applicable standard of care, Petitioner's staff was required to notify Dr. deLeon of that temperature increase.

Petitioner did not comply substantially with the requirements of 42 C.F.R. § 483.25 on September 24, 1995. The failure of Petitioner to notify Dr. deLeon of a sharp increase in the resident's temperature on that date contravened a standard of care that is incorporated within the regulation. That failure posed a risk of harm to the resident's health or safety that was more than minimal. 42 C.F.R. § 488.301.

However, I find that Petitioner complied substantially with the requirements of 42 C.F.R. § 483.25 on all other relevant dates. As I discuss above, at Findings 4 and 5, with the exception of the episode that occurred on September 24, 1995, Petitioner complied with applicable standards of care in the care that it provided to Residents 5 and 1.

HCFA's assertion that Petitioner was not complying substantially with the requirements of 42 C.F.R. § 483.25, between November 21 1995, and December 19, 1995, rests on two premises: (1) that the evidence of Petitioner's failure to comply with standards of care in providing care to Residents 5 and 1 establishes a generalized indifference by Petitioner and its staff to the obligation to comply with those standards; and (2) that this generalized indifference persisted until December 19, 1995, when Petitioner was re-surveyed and found to be in substantial compliance with participation requirements as of that date. The preponderance of the evidence does not substantiate either of these premises.

As to HCFA's first premise, there is no evidence of a generalized indifference by Petitioner to the requirements of professionally recognized standards of care. The evidence establishes only an isolated episode of Petitioner not complying with professionally recognized standards of care in providing care to Resident 5. Evidence relating to the other episodes relied on by HCFA shows that Petitioner's staff was attentive to the needs of the residents and diligent in providing care to them. The fact that Petitioner may not have complied substantially with the requirements of 42 C.F.R. § 483.25 in its treatment of one resident on one isolated date does not establish even a prima facie case of a generalized failure by Petitioner to comply with standards of care or with the requirements of the regulation.

Indeed, the evidence of noncompliance by Petitioner on one date is greatly outweighed by evidence that Petitioner complied with professionally recognized standards of care in caring for Residents 5 and 1 in all of the other episodes cited by the Florida State survey agency and relied on by HCFA. And, it is outweighed also by evidence that there were no derelictions of care in the treatment that Petitioner gave to any of its other residents.

As to HCFA's second premise, HCFA has offered no specific evidence that Petitioner failed to comply with the requirements of the regulation during the period beginning November 21, 1995 and ending on December 19, 1995. HCFA argues that I should infer that Petitioner was not complying on those dates from the evidence that HCFA offered concerning Petitioner's past practices.

I find that the sparse evidence of noncompliance prior to November 21, 1995 is insufficient for me to infer that Petitioner was not complying with the regulation on or after November 21. HCFA has not established a prima facie case that Petitioner was not complying with the requirements of 42 C.F.R. § 483.25 on or after November 21, 1995. Furthermore, there is affirmative evidence that Petitioner complied with the requirements of 42 C.F.R. § 483.25 after November 21, 1995. The Florida State survey agency surveyor who made a follow up visit to Petitioner on November 25 found no evidence on that date that Petitioner was failing to comply with the requirements of 42 C.F.R. § 483.25. Tr. at 155 - 156.

7. The alleged failure by the Florida State survey agency to follow applicable survey and remedial procedures is irrelevant to my decision.

Petitioner argues that the Florida State survey agency's finding that Petitioner's alleged deficiencies constituted immediate jeopardy to Petitioner's residents is vitiated by the agency's alleged failure to follow applicable survey procedures. HCFA asserts that I should not consider this argument, because Petitioner did not make it in its hearing request. HCFA asserts also that, under applicable regulations governing surveys, a failure by a State survey agency to follow applicable survey requirements is not a basis to invalidate the results of a survey. HCFA's reply brief at 14 - 16; see 42 C.F.R. § 488.305.

It is unnecessary that I resolve these arguments. I base my decision in this case on HCFA's failure to make a prima facie case on elements of its allegations, and on the preponderance of the evidence, which supports Petitioner's affirmative contentions of fact.

> 8. There is no basis for me to sustain a civil money penalty against Petitioner in the upper range of civil money penalties for the period beginning November 21, 1995 and ending on December 19, 1995 premised on Petitioner's alleged failure to comply substantially with the requirements of 42 C.F.R. § 483.25.

There are four necessary elements to HCFA's determination to impose an upper range civil money penalty of \$7,500 per day against Petitioner for the period from November 21, 1995 until December 19, 1995. These are that: (1) Petitioner failed to comply substantially with the requirements of 42 C.F.R. § 483.25; (2) Petitioner's failure to comply with the regulation was of a level of severity that posed immediate jeopardy to Petitioner's residents; (3) Petitioner's failure to comply with the regulation, at an immediate jeopardy level, persisted from November 21, 1995 until December 19, 1995; and (4) the presence of other deficiencies, cited at tags 272, 279, and 385 in HCFA Ex. 5, coupled with Petitioner's history of noncompliance with participation requirements, its culpability, and its financial status, justified a penalty of \$7500 per day.

The preponderance of the evidence is that the first of these four necessary elements is not established. Based on that, I conclude that I may not sustain an upper range civil money penalty against Petitioner for the period that is at issue in this case.

There is no need for me to consider whether HCFA established a prima facie case on the other three elements of its determination to impose an upper range penalty against Petitioner. I may not sustain a civil money penalty against Petitioner in the upper range of penalties (which includes a penalty of \$7,500 per day) *unless* I find that Petitioner failed to comply substantially with the requirements of 42 C.F.R. § 483.25 during the period from November 21, 1995 until December 19, 1995. That is because Petitioner's alleged failure to comply with the regulation, at the immediate jeopardy level, is an essential predicate to HCFA's determination to impose an upper range penalty against Petitioner. A determination by HCFA to impose a civil money penalty in the upper range against a long-term care facility may only be sustained if either: the facility is deficient in complying with a participation requirement at the immediate jeopardy level of noncompliance; or, if the facility is found to have engaged in repeat deficiencies. 42 C.F.R. § 488.438(a)(1) and (d)(2). Here, HCFA predicated its determination to impose a civil money penalty against Petitioner in the upper range solely on the presence of an alleged failure by Petitioner to comply with the participation requirement contained in 42 C.F.R. § 483.25 at the immediate jeopardy level of noncompliance. HCFA did not allege that an upper range penalty could be based on the presence of repeat deficiencies in Petitioner's operations.

I have found that Petitioner complied substantially with the requirements of 42 C.F.R. § 483.25 during the period from November 21, 1995 until December 19, 1995. For that reason, I conclude that there is no basis for me to sustain an upper range civil money penalty against Petitioner, including a penalty of \$7,500 per day, for the period from November 21, 1995 until December 19, 1995.

9. There is no basis for me to sustain a civil money penalty against Petitioner in the lower range of civil money penalties for the period beginning November 21, 1995 and ending on December 19, 1995 premised on Petitioner's alleged failure to comply substantially with the requirements of 42 C.F.R. § 483.25.

I may not sustain a civil money penalty against Petitioner in the lower range of \$50 - \$3,000 per day for the period beginning November 21, 1995 and ending December 19, 1995, premised on Petitioner's alleged failure to comply substantially with the requirements of 42 C.F.R. § 483.25. That is because I have concluded that, during the period at issue, Petitioner complied substantially with the requirements of the regulation.

In reaching this decision, I am mindful of the requirements of 42 C.F.R. § 488.438(e)(1). That regulation provides that, in reviewing a determination by HCFA to impose a civil money penalty, an administrative law judge may not set a penalty at zero or reduce a penalty to zero. I do not read this regulation as requiring me to sustain a penalty where there is no legal basis to impose one. Rather, the regulation instructs me not to absolve a facility from liability for a civil money penalty where there exists a basis to impose a penalty. I would have sustained a civil money penalty against Petitioner, albeit at a reduced amount, had I concluded that Petitioner was not complying substantially with the

requirements of 42 C.F.R. § 483.25, but that the level of noncompliance determined by HCFA (immediate jeopardy) was clearly erroneous.

10. I am without authority to impose a civil money penalty against Petitioner based on the allegations made at tags 272, 279, and 385 in the report of the November 1995 survey of Petitioner.

I have no authority to decide whether a civil money penalty would be reasonable predicated on the findings of deficiencies under tags 272, 279, and 385, absent a decision that Petitioner was deficient under tag 309. I may only hear and decide such issues as arise from a determination by HCFA to impose a remedy. HCFA made no determination to impose a civil money penalty against Petitioner based on the findings of deficiencies under tags 272, 279, and 385. The findings of deficiency under tags 272, 279, and 385 were used by HCFA only as ancillary evidence to justify fixing at \$7,500 per day the civil money penalty that HCFA imposed against Petitioner, premised on the alleged deficiency found under tag 309.

At the November 1995 survey, the surveyors found Petitioner to be deficient under four participation requirements. These alleged deficiencies included the asserted failure of Petitioner to comply substantially with the requirements of 42 C.F.R. § 483.25, cited at tag 309. HCFA Ex. 5, at 7 - 11. The alleged deficiency under tag 309 was the basis for HCFA's determination to impose a civil money penalty against Petitioner. I have discussed the evidence relating to this alleged deficiency in detail above, at Findings 3 - 5.

The other deficiencies cited by the surveyors are contained at tags 272, 279, and 385 of the November 1995 survey report. HCFA Ex. 5, at 2 - 7; 12 - 13. These alleged additional deficiencies were relied on by HCFA as a basis for determining that a civil money penalty of \$7,500 per day should be imposed against Petitioner. However, the necessary predicate for HCFA's determination was that the alleged deficiency under tag 309 be at the immediate jeopardy level. HCFA could not have imposed an upper range penalty against Petitioner, absent a finding of repeat deficiencies, *unless* it made a determination that there was a deficiency at the immediate jeopardy level. 42 C.F.R. § 488.438(a)(1). Once HCFA made the immediate jeopardy determination, predicated on the alleged deficiencies cited at tags 272, 279, and 385 as ancillary evidence to support a penalty within the upper range of \$7,500 per day. HCFA's posthearing brief at 41 - 42; <u>See</u> 42 C.F.R. § 488.438(f); 488.404.

What HCFA did *not* do was to make a determination whether any or all the deficiencies cited at tags 272, 279, and 385 merited the imposition of a civil money penalty against Petitioner, absent the deficiency cited at tag 309. The scope and severity of the deficiencies cited at tags 272, 279, and 385 were at the non-immediate jeopardy level (although HCFA now asserts that it erred in determining the deficiency at tag 385 to be of less than an immediate jeopardy level of severity). Presumably, HCFA might have determined to impose a civil money penalty against Petitioner in the lower range of penalties from \$50 - \$3,000 per day based on the alleged presence of the deficiencies cited at tags 272, 279, and 385. See 42 C.F.R. § 488.408(d). But, HCFA did not make such a determination.

I have no authority to decide whether a civil money penalty might be merited for Petitioner's alleged failure to comply with the requirements cited under tags 272, 279, and 385. My authority to hear and decide a case involving HCFA derives only from a determination by HCFA to impose a remedy. See 42 C.F.R. § 498.3. I have no authority to hear and decide an issue concerning which HCFA has not made a determination. Rafael Convalescent Hospital. I make no finding concerning whether HCFA established a prima facie case of deficiency under tags 272, 279, and 385, or whether Petitioner, by a preponderance of the evidence, overcame any prima facie case that HCFA might have made. The parties presented evidence and argument concerning these alleged deficiencies. However, that evidence and argument were not presented to support or rebut a determination by HCFA to impose a remedy based on these alleged deficiencies. Rather, they were presented in the context of HCFA's reliance on the alleged deficiencies cited under tags 272, 279, and 385 as ancillary evidence to support its determination to impose a civil money penalty against Petitioner predicated on the deficiency alleged under tag 309. The fact that the parties presented evidence concerning the deficiencies alleged under tags 272, 279, and 385 is, therefore, no basis for me to make findings concerning the alleged deficiencies.

It is tempting to decide whether the alleged deficiencies existed in light of the evidence offered by the parties. However, any decision that I might issue concerning the deficiencies found under tags 272, 279, and 385 would be dicta of no legal effect, inasmuch is there is no determination to impose a remedy based on these deficiencies.

I make no finding whether HCFA has the authority to make a new determination to impose a remedy against Petitioner predicated on the deficiencies that were found under tags 272, 279, and 385, but not on the deficiency that was found under tag 309. The issue of whether HCFA could do so would not be appropriate for a hearing and decision until and unless HCFA makes an additional determination. If Petitioner requested a hearing from that determination, then, presumably, the issue of HCFA's authority to make a new determination could be heard and decided in the context of that hearing.

/s/

Steven T. Kessel Administrative Law Judge