Department of Health and Human Services

DEPARTMENTAL APPEALS BOARD

Civil Remedies Division

In the Case of:	)	
	)	
Cross Creek Health Care Center,	)	Date: November 18, 1997
	)	
Petitioner,	)	
	)	
- v. -	)	Docket No. C-96-112
	)	Decision No. CR504
Health Care Financing	)	
Administration.	)	
	)	

DECISION

I decide that the Health Care Financing Administration (HCFA) is authorized to impose a civil money penalty against Petitioner, Cross Creek Health Care Center, in the amount of $1,000 per day for each day beginning on July 21, 1995 and running through September 8, 1995. I decide also that HCFA is not authorized to impose a civil money penalty against Petitioner of $7,500 per day beginning on July 21, 1995 and ending on August 18, 1995. Additionally, I decide that HCFA is not authorized to impose a civil money penalty against Petitioner of $2,000 per day beginning on August 19, 1995 and ending on September 8, 1995.

In summary, my decision is as follows:

- HCFA bases its case for imposing a civil money penalty of $7,500 per day against Petitioner in part on allegations of which Petitioner had no notice prior to the hearing of this case. It would not be consistent with the requirements of due process for me to hear and decide HCFA's untimely allegations of noncompliance.

- The allegations of which HCFA gave Petitioner timely notice, and which are part of the basis for HCFA's determination to impose a civil money penalty against Petitioner in the amount of $7,500 per day, are unsubstantiated. The evidence which HCFA offered to support these allegations in large measure constitutes unfounded opinions by witnesses who did not establish the expertise needed to offer the medical

opinions that they made about Petitioner's compliance with Medicare participation requirements.

- Petitioner is not required to rebut allegations which HCFA made untimely. Petitioner is not required to offer affirmative evidence to rebut allegations by HCFA which are unsubstantiated and as to which HCFA failed to establish a prima facie case. Nonetheless, Petitioner proved by a preponderance of the evidence that, in many instances of alleged noncompliance by it with Medicare participation requirements, it was in fact complying substantially with the applicable participation requirements. Petitioner proved that it did not commit any derelictions of care which placed any of its residents in immediate jeopardy.

- HCFA established that Petitioner was deficient in providing care to residents, although Petitioner's deficiencies were not so severe as to pose immediate jeopardy to Petitioner's residents. The deficiencies manifested by Petitioner include Petitioner's failure to comply substantially with Medicare participation requirements governing the use of chemical restraints and effective administration of long-term care facilities. Other deficiencies established by HCFA include failures by Petitioner to: attend to the needs of and to respect the dignity of its residents; provide all of the care that had been ordered for its residents; and, comply with requisite sanitation requirements.

- Petitioner manifested no deficiencies which would justify imposition against it of a civil money penalty in a range which is reserved for instances of immediate jeopardy ($3,050 to $10,000 per day).

- Petitioner proved that it attained substantial compliance with Medicare participation requirements on September 8, 1995.

- The civil money penalty of $1,000 per day which I find HCFA to be authorized to impose against Petitioner is within the range of civil money penalties which HCFA may impose for deficiencies that do not constitute immediate jeopardy ($50 to $3,000 per day). I base my decision that a $1,000 per day civil money penalty is authorized on those factors which applicable regulations require me to consider, and the evidence of record which is relevant to those factors. I conclude, based on the entire record of this case, that Petitioner was generally not diligent in providing its residents with the care required by applicable participation standards. Residents of Petitioner did not receive the attention or the care that the standards are designed to assure that they receive. Although Petitioner's derelictions of care did not pose immediate jeopardy to the residents of Petitioner, they placed the residents at risk for more than minimal harm.

I. Background

The facts and law which I recite here are not disputed by the parties.

A. Background facts and procedural history

Petitioner is a long-term care facility that is located in Pensacola, Florida. Petitioner is a participating provider in the Medicare program. It is subject to provisions of the Social Security Act (Act) and regulations which govern the participation in Medicare of long-term care facilities.

On July 17 - 21, 1995, the State of Florida Agency for Health Care Administration (Florida State survey agency) conducted a survey of Petitioner on behalf of HCFA in order to determine whether Petitioner was complying substantially with Medicare participation requirements. The surveyors who conducted the survey issued a report in which they concluded that Petitioner was not complying substantially with Medicare participation requirements. HCFA Ex. 5.

The surveyors cited 17 deficiencies in Petitioner's compliance with participation requirements. Of these alleged deficiencies, three were found to be at a degree of severity such as to pose immediate jeopardy to residents of Petitioner.

The surveyors organized their findings of deficiencies under headings known as "tags." HCFA Ex. 5. Each tag, which is set forth in the left-hand margin of the report of the July 17 - 21 survey, incorporates a specific participation requirement that is stated in a regulation. E.g., HCFA Ex. 5, at 1.

The three immediate jeopardy tags are set forth in the survey report as tags 221 (HCFA Ex. 5, at 1 - 5), 222 (HCFA Ex. 5, at 6 - 7), and 490 (HCFA Ex. 5, at 30). Tag 221 addresses Petitioner's use of physical restraints. Tag 222 addresses Petitioner's use of chemical restraints (medications). Tag 490 addresses the manner in which Petitioner was administered.

Under both tags 221 and 222, the surveyors cited examples of the way in which Petitioner provided care to specified residents as evidence of Petitioner's alleged failure to comply with participation requirements. Although not clear from the survey report, it is now evident that the surveyors concluded that Petitioner's care of only certain of these residents evidenced failures by Petitioner to comply with participation requirements such as to pose immediate jeopardy to residents. HCFA's posthearing brief at 17 - 30. The surveyors' immediate jeopardy findings under tag 221 are based on the care that Petitioner allegedly provided to residents who are designated in the survey report as Residents 3 (HCFA Ex. 5, at 3), 8 (HCFA Ex. 5, at 4 - 5), and 18

(HCFA Ex. 5, at 1 - 2). The surveyors' immediate jeopardy findings under tag 222 are based on the care that Petitioner allegedly provided to Residents 8 (HCFA Ex. 5, at 6) and 29 (Id.).

On August 8, 1995, Petitioner submitted a plan of correction to the Florida State survey agency. HCFA Ex. 5. Petitioner did not admit that it had failed to comply substantially with participation requirements. Id. at 1. However, Petitioner offered specific corrective actions to address each of the findings of noncompliance made by the Florida State survey agency surveyors.

On August 18, 1995, surveyors returned to Petitioner's facility in order to resurvey Petitioner. HCFA Ex. 2; 6. At this survey, the surveyors made no findings that Petitioner manifested deficiencies that constituted immediate jeopardy to Petitioner's residents.

Under tag 221, the surveyors stated that the Petitioner was taking action to reduce the use of physical restraints and to make more thorough assessments concerning the use of restraints. The surveyors concluded that Petitioner was making progress to reduce its use of restraints so that Petitioner's deficiency under the tag no longer constituted immediate jeopardy to residents. HCFA Ex. 6, at 1. The surveyors concluded, however, that "although progress is being made, there are still a number of residents who need assessment and reduction efforts." Id. The surveyors made no findings under tag 222. See Id. Under tag 490, the surveyors concluded that Petitioner was taking corrective action sufficient to remove findings of immediate jeopardy. HCFA Ex. 6, at 24. However, the surveyors found that Petitioner's efforts had "not cleared the deficiencies . . . ." Id.

As to the remaining 14 deficiency tags, the surveyors reiterated the findings that they made in their report of the July 17 - 21, 1995 survey. HCFA Ex. 6. It is not entirely clear from the face of the report of the August 18, 1995 resurvey whether the surveyors made new deficiency findings under the remaining 14 tags or were simply reiterating the findings that they had made in the report of the July 17 - 21, 1995 survey.

In fact, on August 18, 1995, the surveyors did not survey Petitioner to determine anything other than whether the immediate jeopardy circumstances that the surveyors had found previously persisted. The surveyors did not survey Petitioner on August 18, 1995 to determine whether Petitioner had attained substantial compliance with participation requirements as of that date.

On September 8, 1995, Petitioner was resurveyed for a second time by the Florida State survey agency. The surveyors concluded that, as of September 8, 1995, Petitioner had attained substantial compliance with Medicare participation requirements and that Petitioner had corrected all outstanding deficiencies. HCFA Ex. 4.

On October 27, 1995, HCFA advised Petitioner that HCFA had determined to impose civil money penalties against Petitioner. HCFA Ex. 3. HCFA announced that it would impose a penalty of $7,500 per day against Petitioner, with this penalty beginning to accrue on July 21, 1995 and continuing until August 18, 1995. Id. at 1. HCFA announced that it would impose an additional penalty of $2,000 per day against Petitioner, with this additional penalty beginning to accrue on August 19, 1995. Id.

HCFA's October 27, 1995 notice to Petitioner is confusing in two respects. First, the notice incorrectly advises Petitioner that HCFA had determined that Petitioner had attained substantial compliance with participation requirements as of August 18, 1995. It recites that the end date for the $7,500 per day penalty of August 18, 1995 was the date "when . . . [Petitioner] was found to have corrected the deficiencies and to have achieved substantial compliance with Medicare and Medicaid program participation requirements." HCFA Ex. 3, at 1. As is apparent from the remainder of the notice, the quoted language is incorrect. HCFA determined that Petitioner remained deficient on dates beginning with August 19, 1995. Otherwise HCFA would not have determined to impose a civil money penalty of $2,000 per day against Petitioner beginning on August 19, 1995.

Second, the notice suggests, incorrectly, that as of October 27, 1995, HCFA had determined that Petitioner remained noncompliant with participation requirements. The notice states no end date for the $2,000 per day civil money penalty which HCFA determined to impose beginning with August 19, 1995. It recites that the $2,000 per day penalty "will accrue beginning August 19, 1995 until the deficiencies are corrected." HCFA Ex. 3, at 1. In fact, the Florida State survey agency had determined that Petitioner had attained substantial compliance with all participation requirements on September 8, 1995.

It is apparent that HCFA meant to tell Petitioner that HCFA was adopting the findings that the Florida State survey agency surveyors made at the July 17 - 21, August 18, and September 8, 1995 surveys. What HCFA determined to impose against Petitioner was: a civil money penalty of $7,500 per day which began to accrue on July 21, 1995 and which continued to accrue through August 18, 1995; and, a civil money penalty of $2,000 per day which began to accrue on August 19, 1995 and which continued to accrue through September 8, 1995.

HCFA advised Petitioner that it had a right to a hearing to contest HCFA's determination to impose civil money penalties against it. Petitioner timely requested a hearing, and the case was assigned to me for a hearing and a decision. I held a hearing in Pensacola, Florida, on January 7 - 8, 1997.

At the hearing, I received into evidence from HCFA 15 exhibits (HCFA Ex. 1 - 15). I heard the testimony of six witnesses who testified on behalf of HCFA. These witnesses are: Gloria Gonzalez (Tr. at 46 - 177); Paula Faulkner (Tr. at 178 - 253); Christene Denson, R.N. (Tr. at 253 - 268); Paul Pineau (Tr. at 268 - 276); and Richard James (Tr. at 276 - 297). I received into evidence from Petitioner a single exhibit (P. Ex. 1). I heard the testimony of three witnesses who testified on behalf of Petitioner. These witnesses are: Billie Brock, R.N. (Tr. at 311 - 343); Lee Ann Jensen, R.N. (Tr. at 344 - 444); and Patricia Merrill, R.N. (Tr. at 445 - 513).

After completion of the January 7 - 8, 1997 hearing, an appellate panel of the Departmental Appeals Board issued its decision in Hillman Rehabilitation Center, DAB 1611 (1997). In Hillman, the appellate panel found that, where HCFA determines that a provider has not complied substantially with Medicare participation requirements, the provider bears the burden of proving, by a preponderance of the evidence, that it was in compliance with such requirements.

I assumed that the appellate panel decision in Hillman meant that in this case Petitioner bore the burden of proving that it was complying with participation requirements. I afforded Petitioner the opportunity to supplement its evidence, in light of the appellate panel decision in Hillman. Petitioner offered additional documents as an addendum to P. Ex. 1. HCFA did not object to my receiving into evidence this additional evidence, and I have received it into evidence.

HCFA and Petitioner each submitted posthearing briefs and reply briefs. Additionally, prior to the hearing, Petitioner made numerous motions in which Petitioner asserted that the specific findings made by the surveyors at the July 21, 1995 survey of Petitioner did not state failures by Petitioner to comply with participation requirements. I have considered these motions to be part of the arguments made by Petitioner. I address these motions in my decision.

I base my decision in this case on the governing law, the evidence, and the parties' arguments.

B. Summary of the governing law

Under both the 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.

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. These sections state, in effect, that the Secretary's authority to impose a civil money penalty against a long-term care facility is derived from the civil money penalty authority that is conferred under Section 1128A of the Act. Act, sections 1819(h)(2)(B)(ii); 1919(h)(3)(C)(ii). Both sections 1819 and 1919 state that: "The provisions of section 1128A (other than subsections (a) and (b) shall apply to a civil money penalty . . . [imposed under either section 1819 or 1919] in the same manner as such provisions apply to a penalty or proceeding under section 1128A(a)." Id.

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 long-term 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 long-term 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.

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.

Id.

There are additional factors which the State and HCFA consider in determining where, within a range of penalties, the amount of 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). However, once the range of a penalty is fixed (either upper or lower) the factors described in 42 C.F.R. §§ 488.404 and 488.438(f) become important in determining where within that range the penalty will be established. Those factors and only those factors must be considered by an administrative law judge in any case where the amount of a civil money penalty is challenged. 42 C.F.R. § 488.438(e).

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. Act, section 1128A(c)(2); 42 C.F.R. §§

488.408(g); 498.3(b)(12),(13); see 42 C.F.R. § 488.438(e). A relevant part of section 1128A of the Act provides that the Secretary shall not impose a civil money penalty against an individual or entity until that individual or entity has been given written notice and an opportunity for the Secretary's determination to be made on the record after a hearing at which the individual or entity is entitled to be represented by counsel, to present witnesses, and to cross-examine adverse witnesses. Act, section 1128A(c)(2). This right to a hearing under section 1128A has been interpreted uniformly to confer on a party against whom the Secretary has determined to impose a civil money penalty a right to a de novo hearing. Anesthesiologists Affiliated, et al. DAB CR65 (1990), aff'd 941 F.2d 678 (8th Cir. 1991); Tommy G. Frazier DAB CR79 (1990), aff'd 940 F.2d 659 (6th Cir. 1991); Berney R. Kezler, M.D., et al. DAB CR107 (1990).

In a de novo hearing in a case involving a determination to impose a civil money penalty against a party, the party against whom a civil money penalty determination is made is afforded the right to contest both the determination of misconduct which is the basis for the penalty and the amount of the proposed penalty. In such a case the administrative law judge has authority to impose a penalty for an amount which is less than that which the agency determines to impose where the amount that is determined by the agency is not reasonable.

There are potentially two issues to be heard and decided in a case where a long-term 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.

As I discuss above, I am assuming that the appellate panel's decision in Hillman means that, in a civil money penalty case, a long-term care facility has the burden of overcoming, by a preponderance of the evidence, any prima facie case that HCFA might make that the facility is not complying substantially with federal participation requirements. I make this assumption out of an abundance of caution, and in order to ensure that this case does not become entangled in collateral issues.

However, as a matter of law and logic, it may be inappropriate in a civil money penalty case to impose on a provider the burden of proving that it complied with participation requirements. The issues in a civil money penalty case are somewhat different from the issues that were heard and decided in Hillman.

In Hillman, the appellate panel emphasized that it was appropriate to impose on the provider the burden of proof inasmuch as the provider was the proponent of an order to invalidate HCFA's determination to terminate its participation. Here, termination of Petitioner's participation in Medicare is not at issue. What is at issue is a proposed penalty which may not go into effect until after a decision by an administrative law judge. HCFA plainly is the proponent of an order to authorize it to impose a civil money penalty.

Furthermore, in cases in which the Inspector General (I.G.) has sought to impose civil money penalties pursuant to section 1128A, the burden of proof has been imposed on the I.G. There would not seem to be any meaningful distinction between a civil money penalty case brought by the I.G. pursuant to section 1128A and a civil money penalty case brought by HCFA pursuant to section 1128A such as to impose the burden of proof on the I.G. in a case brought by the I.G. and on the provider in a case brought by HCFA.

In a civil money penalty case, a long-term care facility potentially bears an additional burden of proof where it challenges the level of the deficiency determined by HCFA. 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.

II. Issues

This case involves the following issues:

1. Between July 21, 1995 and August 19, 1995, did Petitioner fail to comply with Medicare participation requirements to the extent that Petitioner's failure to comply with those requirements posed immediate jeopardy to residents of Petitioner?

2. Between July 21, 1995 and September 8, 1995, did Petitioner fail to comply substantially with Medicare participation requirements, albeit without posing immediate jeopardy to residents of Petitioner?

3. Did HCFA establish a basis to impose a civil money penalty against Petitioner, and if so, for what amount and on what dates?

I make findings of fact and conclusions of law (Findings) which address both the factual and legal aspects of these issues. I state each Finding below, as an italicized heading. I discuss each Finding in detail.

III. Findings and discussion

1. A long-term care facility may restrain a resident only in the circumstance where the restraint is used for a medically necessary purpose. A long-term care facility may not restrain a resident for the purposes of convenience to the facility or as a means of disciplining the resident.

At the center of this case is the question of whether Petitioner restrained residents for proper purposes. The most serious allegations of deficiencies in Petitioner's operations made by the Florida State survey agency surveyors in their report of the July 17 - 21, 1995 survey are at tags 221 and 222. These allegations refer to the participation requirement which governs use of physical and chemical restraints by a long-term care facility stated in 42 C.F.R. § 483.13(a). Indirectly, the findings that the surveyors made under tag 490 also relate to the foregoing participation requirement. The restraints requirement states:

> The resident has the right to be free from any physical or chemical restraints imposed for purposes of discipline or convenience, and not required to treat the resident's medical symptoms.

The restraints requirement is a subpart of a broader regulation, 42 C.F.R. § 483.13, which governs resident behavior and facility practices. Other subparts of the regulation: prohibit a long-term care facility from abusing or secluding residents (42 C.F.R. § 483.13(b)); and, require a long-term care facility to develop policies to prohibit abuse, neglect or mistreatment of residents (42 C.F.R. § 483.13(c)).

It is evident, both from the plain language of 42 C.F.R. § 483.13(a), and from the location of this subpart within 42 C.F.R. § 483.13, that the critical question which must be decided in concluding whether a facility is acting consistent with the restraints requirement is the facility's purpose in applying a restraint to a resident. A facility complies with the requirements of the regulation only when it is applying a restraint for

a reason that is medically necessary. A facility contravenes the regulation whenever it applies a restraint for reasons of convenience or discipline.

The regulation is not, strictly speaking, a regulation which governs the quality of care that a facility may provide in applying restraints, so much as it is a regulation which establishes the very limited purposes for which restraints may be applied. In any case where HCFA alleges under 42 C.F.R. § 483.13(a) that a facility has applied a restraint improperly, the dispositive evidence will be evidence which establishes the facility's purpose in applying the restraint. The quality of care involved in applying a restraint only is relevant to the issue of compliance with 42 C.F.R. § 483.13(a) where the facility's purpose for applying a restraint can be inferred from the way in which it applies the restraint.

There is another regulation which governs quality of care. 42 C.F.R. § 483.25. Under this regulation, a facility might be found noncompliant in the circumstance where it had applied a restraint incorrectly albeit for a proper purpose. The surveyors who conducted the July 17 - 21, 1995 survey concluded in their survey report at tags 309, 314, 316, 319, and 324, that Petitioner manifested deficiencies in the quality of care that it gave to its residents. HCFA Ex. 5, at 15 - 24. However, neither the surveyors nor HCFA alleged that Petitioner was deficient under the quality of care regulation in the manner in which it applied restraints to residents.

The regulation which governs a facility's application of restraints does not contain any definition of the word "restraint," nor is that word defined elsewhere in regulations which govern the participation in Medicare of long-term care facilities. HCFA asserts that the definition of "restraint" may be found in interpretive guidelines that HCFA published to provide guidance to State survey agency surveyors in surveying a facility for compliance with the regulation. HCFA's posthearing brief at 13 - 16; HCFA Ex. 7.

The guidelines define a "physical restraint" to be:

> any manual method or physical or mechanical device, material, or equipment attached or adjacent to the resident's body that the individual cannot remove easily which restricts freedom of movement or normal access to one's body.

HCFA Ex. 7, at 1. The definition provides a working statement as to the kind of device which might constitute a physical restraint. It is silent, however, as to the critical question of purpose. For example, under the definition of "physical restraint" contained in the interpretive guidelines, a plaster cast that is applied to a resident's wrist to help mend a fracture would be a "physical restraint," because it: is adjacent to

the resident's body, is not easily removable by the resident, and restricts the resident's freedom of movement and access to his or her body. But, plainly, no one would question the legitimacy of the cast if a physician prescribed it in order to heal a fracture that had been diagnosed by a medically accepted test such as an x-ray.

The guidelines define a "chemical restraint" to be "a psychopharmacologic drug that is used for discipline or convenience and not required to treat medical symptoms." HCFA Ex. 7, at 1. The interpretive guidelines link the definition of a "chemical restraint" to the purpose for which a drug is administered.

> ***2. HCFA did not give Petitioner timely notice of its assertions that: Petitioner was obligated to perform comprehensive assessments of its residents to determine the residents' need for restraints; and Petitioner failed to perform comprehensive assessments.***

HCFA argues that a long-term care facility must perform a comprehensive and detailed assessment of the proposed use of a restraint, as is described in the interpretive guidelines, at any time it applies a restraint to the resident. HCFA asserts that the purpose of a restraint is per se improper where a long-term care facility has not performed a comprehensive restraint assessment. According to HCFA: "[t]he test of whether a facility has met . . . its obligation [under 42 C.F.R. § 483.13(a)] is whether the facility has used a systematic process of evaluation that addresses the issues discussed in the interpretive Guidelines." HCFA's reply brief at 4. HCFA asserts that Petitioner must be found to be deficient under tags 221 and 222 because Petitioner allegedly failed to perform comprehensive assessments. These arguments capture testimony at the hearing of this case by surveyors who participated in the July 17 - 21, 1995 survey of Petitioner. See, e.g., Tr. at 79 - 81; 190; 199 - 203; 210.

It was at the in-person hearing of this case that HCFA raised for the first time the allegation that Petitioner failed to make mandatory comprehensive assessments. HCFA never gave Petitioner notice prior to the hearing that it intended to assert that Petitioner was deficient because Petitioner had failed to assess comprehensively its residents for restraints. The surveyors who performed the July 17 - 21, 1995 survey of Petitioner did not state in their report of the survey that Petitioner was deficient because it failed to assess comprehensively its residents for the use of restraints. See HCFA Ex. 5.

The surveyors made only minimal findings in their report of the July 17 - 21, 1995 survey concerning Petitioner's alleged failure, under tag 221, to conduct assessments in the cases of two residents, Residents 3 and 8. Id. at 3 - 5. Furthermore, even with respect to the two residents at issue, the surveyors did not assert that Petitioner failed to conduct the comprehensive assessment that HCFA now asserts is required as a prerequisite to applying a restraint. With respect to Resident 3, the surveyors stated

only that: "[r]ecord review showed the facility's siderail assessment form had not been completed . . . ." HCFA Ex. 5, at 3. With respect to Resident 8, the surveyors stated only that: "[n]o assessment was done for restraint use." HCFA Ex. 5, at 5. This laconic assertion, which is at the very end of the findings that the surveyors made about Resident 8 under tag 221, contains no elaboration or discussion of what type of assessment the surveyors believed Petitioner was supposed to have made of Resident 8.

I have imposed on Petitioner the burden of proving, by a preponderance of the evidence, that it complied with any participation requirement about which HCFA established a prima facie case of noncompliance by Petitioner. That is based on my understanding of the appellate panel's decision in Hillman. Petitioner must have reasonable notice of HCFA's allegations in order to have an opportunity to attempt to construct a meaningful defense to them.

The time and place for HCFA to notify a provider of its allegations is prior to the hearing and not at the hearing. In a case involving HCFA, a provider has no opportunity for pre-hearing discovery. See 42 C.F.R. Part 498. It cannot serve interrogatories on HCFA or take the depositions of HCFA's employees or of State survey agency surveyors in order to flesh out the details of HCFA's allegations of noncompliance. It would be a fundamental denial of due process to a provider for the provider to be mousetrapped at an in-person hearing by substantive allegations of noncompliance about which it received no prior notice, particularly in light of the decision of the appellate panel in Hillman that the provider must disprove allegations of noncompliance.

HCFA's allegation that Petitioner is deficient per se under the restraint requirement because it failed to perform comprehensive assessments is an allegation of noncompliance of which Petitioner received no notice prior to the hearing. I make no Findings about this allegation because to do so would deny Petitioner due process. I do decide below, consistent with the surveyors' allegations of which Petitioner received notice, whether Petitioner performed assessments of the need for restraints of Residents 3 and 8. However, with respect to Residents 3 and 8, my review of that issue is limited to considering the allegations made by the surveyors in their report of the July 17 - 21, 1995 survey.

3. A decision about a long-term care facility's purpose for applying a restraint must be based on competent and credible evidence.

Any allegation that a long-term care facility applied a restraint improperly must be supported by competent and credible evidence that establishes the facility's purpose in using the restraint. Such evidence may consist of evidence which explicitly describes

the purpose of a restraint, or it may consist of evidence from which a facility's purpose may be inferred.

In this case, the parties relied on several categories of evidence. HCFA relied heavily on the observations and opinions of the surveyors who participated in the July 17 - 21, 1995 survey to support its allegations. Petitioner relied on the treatment records of the residents whose care is at issue, which, in many instances, included orders by physicians that restraints be applied to these residents. Petitioner relied also on the testimony of the nurses who were in charge of the care that was provided to the residents during the relevant periods of time.

> ***a. The opinion testimony of a surveyor concerning whether a restraint has been applied for a medically necessary purpose is credible and competent evidence only if it is founded on evidence establishing that the surveyor possesses the training or the experience which would enable the surveyor to make such an opinion.***

Ultimately, the issue of whether a facility applied a restraint properly in a given instance may turn on medical considerations. The restraint regulation distinguishes between a permissible restraint which is applied for a medically necessary reason, and an impermissible restraint which is applied for a non-medically necessary reason, consisting of discipline or convenience to the facility. Where a surveyor offers an opinion as to whether a restraint is for a permissible purpose, that opinion may involve a judgment as to the medical necessity for application of the restraint. Where the surveyor's opinion rests on a judgment of medical necessity, the surveyor's opinion is in the nature of expert medical opinion. Such an opinion is credible and competent only where it is supported by evidence which establishes that the surveyor is qualified to give the opinion.

HCFA is governed by the same requirements of evidence that apply in any proceeding where a party relies on expert opinion testimony to make its case. HCFA must establish, as part of its prima facie case, that the surveyor has the training or the experience requisite to make his or her opinion competent and credible. It will not be presumed that a surveyor possesses the requisite training or experience.

There is nothing in the Act or regulations which deems a State survey agency surveyor to be an expert in any subject matter about which the surveyor testifies. The regulation which governs the performance of surveys provides that "[s]urveyors are professionals who use their judgment, in concert with Federal forms and procedures, to determine compliance; . . . ." 42 C.F.R. § 488.26(c)(3). This section is written as part of a broader regulation which is intended to ensure that compliance surveys are conducted

by State survey agency surveyors who follow prescribed procedures and use approved forms. 42 C.F.R. § 488.26. The regulation neither states nor suggests that a surveyor is presumed to be vested with the training and the experience requisite to make an expert judgment, or to render an expert opinion, concerning the need for care or the quality of care that a long-term care facility delivers to a resident.

A State survey agency may compose its survey teams of medical professionals and other professionals. 42 C.F.R. §488.314(a)(2). That does not mean that each member of a survey team is vested with the expertise to make findings about, or to provide expert opinion testimony about, every issue that the team may investigate at a survey of a long-term care facility. Id.

Stating that a State agency surveyor is a "professional" does not mean that the surveyor is vested with the training or expertise to testify in a particular area of medicine. An attorney or an administrative law judge is a "professional" in that each has professional training and skills. But neither an attorney nor an administrative law judge has the expertise to make medical judgments based on his or her professional training in law.

In a case where the issue is whether a facility applied a restraint for medically necessary reasons, even the observation of a surveyor which is not offered as an opinion may have to be supported by expert testimony in order to be found to be probative. For example, a surveyor might testify that he or she observed a restrained resident to be manifesting signs of distress. But, it does not necessarily follow from this observation that the restraint was applied for an improper purpose.

By definition, a restraint is something that restricts a resident's freedom of movement or choice. A restraint is something that impinges on the resident's right to take voluntary actions. That is why the prohibition on using a restraint for an improper purpose is an important part of a regulation which governs the rights of residents to be free from unnecessary restraints. But, given that a restraint may be medically necessary even though it restricts a resident's freedom of movement or choice, an observation that a restraint is causing a resident to experience distress may beg the question of whether the restraint was applied for a proper purpose.

b. A physician's order that a restraint be applied to a resident may be persuasive evidence that the restraint is being applied for reasons that are medically necessary.

A physician's order for the application of a restraint to a resident is highly relevant to deciding whether the restraint was applied for a medically necessary purpose. A physician is a medical professional whose license and training qualifies him or her to

order the application of a physical or a chemical restraint where the application of the restraint is medically necessary. A physician's order that a restraint be applied to a resident embodies an expert opinion that the restraint is medically necessary. And, evidence which establishes that the facility is applying the restraint consistent with a physician's order is evidence that the facility is using the restraint for a medically necessary purpose.

A physician's order for a restraint is not necessarily conclusive proof that a facility is applying a restraint for a medically necessary purpose. Conceivably, expert testimony could establish that there was no medical necessity for a restraint despite the fact that a physician ordered the application of a restraint. And, the possibility exists in any case that a facility might apply a restraint for a purpose that is different than what the physician envisioned when the physician ordered the restraint. However, a physician's order for a restraint is evidence from which a legitimate purpose may be inferred, especially in the absence of evidence which counters that order.

HCFA asserts that a physician's order does not constitute persuasive evidence that a restraint is for a legitimate purpose. According to HCFA, a physician's order for a restraint has at best minor relevance to deciding whether a facility has applied a restraint for a proper purpose. It argues that a facility may not rely on a physician's order as justification for employing a restraint. HCFA's posthearing brief at 24 - 25. HCFA is asserting, in effect, that a long-term care facility has an independent duty to decide whether application of a restraint is appropriate in a particular instance, irrespective of any orders that may have been issued by a resident's physician. Id. Under HCFA's analysis, a facility should ignore a physician's order to apply a restraint, if, in the judgment of the facility, the restraint is unnecessary.

I do not find this argument to have merit. HCFA's argument ignores the reality that, where medical necessity is the *only* appropriate purpose for imposing a restraint, the person who is likely to be the best judge of whether a restraint ought to be applied is the resident's physician. As I have discussed, a physician's order for a restraint does not allow a facility to use a restraint for an improper purpose that is inconsistent with the order. And, conceivably, there may be some circumstances where a restraint is not medically justified despite a physician's order for the restraint. But, that is not to say that a physician's order is not relevant — and in some cases dispositive — evidence that the purpose of a restraint is appropriate.

HCFA cites to a comment to the preamble of the long-term care regulations of which 42 C.F.R. § 483.13(a) is a part as authority for its assertion that a facility may not rely on a physician's order as a basis to apply a restraint. 59 Fed. Reg. 56,116, at 56,227 (1994); HCFA's posthearing brief at 24 - 25. HCFA's reliance on the comment is misplaced. The comment addresses the circumstance where "noncompliance occurred

because the facility was following a physician's orders." 59 Fed. Reg. 56,116, at 56,227. (Emphasis added). It articulates the Secretary's conclusion that a facility may not justify improper conduct towards a resident premised on the assertion that the facility was merely carrying out the incorrect or inappropriate order of a physician. What the comment does not address is what is at issue in this case, which is whether a facility's purpose in applying a restraint to a resident is for a medically necessary reason when it is premised on a *correct or appropriate* order by a physician.

As I observe above, conceivably, a physician might order inappropriately that a restraint be applied to a resident. HCFA has the option to rebut any physician's order for a restraint with credible expert evidence to show that the order is inappropriate. But, a physician's order for a restraint is, given the physician's expertise and training, entitled to some presumption of legitimacy, absent any other credible evidence showing that the application of the restraint is for an improper purpose. A facility is entitled to rely in good faith on a legitimate physician's order to restrain a resident.

4. The opinions which Florida State survey agency surveyors offered as to whether Petitioner applied restraints for medically necessary reasons are largely unfounded and, therefore, are not competent or credible evidence that Petitioner applied restraints improperly.

HCFA failed to establish that two of the surveyors, Ms. Gonzalez and Ms. Faulkner, on whose testimony it relied to show that Petitioner applied restraints for improper purposes, were qualified to offer expert medical opinions as to whether restraints were applied for a proper purpose. As a consequence, much of the evidence on which HCFA relies to establish a prima facie case that Petitioner did not comply with the restraints requirement is not competent or credible evidence that Petitioner applied restraints for an improper purpose.

The opinions of the surveyors concerning whether Petitioner applied restraints for a proper purpose are critical to HCFA's assertions that Petitioner did not comply with the restraints requirement. HCFA relied on the testimony of surveyors, both to establish the care that they observed Petitioner giving to residents, and to show that Petitioner was applying restraints for improper purposes. And, although the surveyors based their impressions and testimony in part on the treatment records that they reviewed during the July 17 - 21, 1995 survey, HCFA did not offer any of these records as evidence in its case against Petitioner. That omission by HCFA underscores the importance of the surveyors' testimony to its case.

I am not suggesting that the testimony of Ms. Gonzalez or Ms. Faulkner was insincere or dishonest. These witnesses testified in good faith and believed strongly in the truth of their testimony. But, it is apparent from the transcript of this case that these two

surveyors were asked to render expert opinions on subjects about which they did not demonstrate they were qualified to testify.

a. HCFA did not establish that Ms. Gonzalez is competent to render expert medical opinions as to medical issues.

Ms. Gonzalez is, by training and experience, an expert in dietetics and nutrition. Tr. at 46 - 47. She has a B.S. degree in dietetics, a Master's degree in nutrition, and has worked towards attaining a Ph. D. in nutrition. Tr. at 46. Ms. Gonzalez has worked as a public health nutrition consultant. Id. Her nursing home experience includes working as a food service manager in a nursing home, and as a consultant. Id. at 48 - 49; 133. Ms. Gonzalez has no formal training, either in nursing or in medicine. See Tr. at 132 - 133.

HCFA offered no evidence to show that Ms. Gonzalez has any training in medicine, nursing, or pharmacology. HCFA offered no evidence to establish that Ms. Gonzalez possesses skills or training in assessing the medical purpose of physical or chemical restraints, the physical or psychological state or condition of residents, or the quality of nursing care provided by a facility. Nor did HCFA present any evidence to establish that Ms. Gonzalez is qualified to read and to interpret medical records.

Ms. Gonzalez testified that she was trained to look at all aspects of a nursing home. Tr. at 49. She averred that she had taken training courses offered by HCFA and by the State of Florida. Id. She testified that her training concerning the use of restraints by a long-term care facility consisted of "hours of training" provided by the State of Florida "for us as surveyors to recognize what is considered a restraint and what ways restraints can be used and what can't be used as a restraint in conditions that was in nursing homes." Id. at 62 - 63. Aside from this summary, Ms. Gonzalez provided no details as to what this training consisted of.

I do not question the fact that Ms. Gonzalez is a trained surveyor. However, I am not satisfied by the evidence that HCFA presented about Ms. Gonzalez' education, experience, or training, that Ms. Gonzalez is qualified to offer the *medical* opinions that she offered at the hearing of this case. HCFA offered no evidence to show that any of the training Ms. Gonzalez received as a surveyor addressed the medical questions in sufficient depth so as to make Ms. Gonzalez' opinions credible.

Ms. Gonzalez was asked at the hearing of this case to offer expert medical opinions on numerous medical questions. The opinions she gave directly involved or touched on issues of: medicine, psychology, pharmacology, and nursing. I find that the opinions

she gave lack foundation, and therefore, are not credible. These opinions include the following:

- It is uncertain whether there ever are any medical benefits resulting from the use of restraints. Tr. at 65.

- In any instance where a restraint is applied to a resident, there are medical risks to the resident ranging from death to decreased abilities. Tr. at 71.

- With respect to Resident 8, who was restrained with a roll belt, the roll belt was applied incorrectly. Tr. at 83; 135.

- During the five-day period from July 17 - 21, 1995, the personality of Resident 8 changed from being very vocal to being almost comatose. Tr. at 87.

- Resident 8 manifested a "complete personality change from one day to the next. . . ." Tr. at 89.

- The perceived personality changes in Resident 8 may have resulted from the application of restraints to the resident and from neglect of the resident by Petitioner's staff. Tr. at 87.

- The combative behavior that Resident 8 manifested while a resident at Petitioner's facility may have been due to an adjustment disorder that Petitioner's staff failed to recognize or to address appropriately. Tr. at 93 - 96.

- The combative behavior that Resident 8 manifested while a resident at Petitioner's facility may have been, from the resident's point of view, reasonable, in light of the facility's perceived inattentiveness to the resident's needs. Tr. at 96.

- A possible prior history of combative behavior by Resident 8 was irrelevant to determining whether the combative behavior that the resident manifested during the July 17 - 21, 1995 survey was due to improper application of restraints to the resident. See Tr. at 137.

- Resident 8 was restrained by Petitioner for reasons of convenience or discipline. Tr. at 98.

- The allegedly improper application of physical restraints by Petitioner to Resident 8 constituted immediate jeopardy to the resident, because the restraints precipitated a drastic personality change in the resident which caused the resident to suffer irreparable harm. Tr. at 99; 101; 104.

• Improper administration of a chemical restraint by Petitioner to Resident 8 may have been responsible for the resident experiencing "a big personality change overnight." Tr. at 103.

b. HCFA did not establish that Ms. Faulkner is competent to render expert medical opinions as to medical issues.

Ms. Faulkner has a Bachelor's degree in social work Tr. at 179. She has some additional education in the field of social work, directed at attaining a Master's degree. Id. Ms. Faulkner has nearly nine years' experience as a social service director at a 155-bed long term care facility. Id. Prior to that experience, Ms. Faulkner worked for about seven years as an out-placement coordinator at another long-term care facility. Id. Ms. Faulkner has extensive experience at nursing facilities, which includes many direct interactions with residents. Id. at 179 - 183. Her experiences include involvement as part of interdisciplinary teams that planned the care of residents. Id.

Ms. Faulkner's work experiences included helping to perform assessments of residents and assisting in preparing residents' care plans. Id. She served as an advocate for residents, with the responsibility of bringing to the attention of a facility's staff problems that the residents might be experiencing. Tr. at 181.

I am satisfied from Ms. Faulkner's training and work history that she is knowledgeable in the operations of nursing homes, including the activities that are involved in the planning of care and the delivery of care to residents. However, there is no evidence of record in this case to show that Ms. Faulkner possesses the training or experience requisite for making *medical* judgments about the need for, or the appropriateness of, medical care that is administered to residents of a long-term care facility.

There is no evidence that Ms. Faulkner has received any training in medicine or nursing or has any work experience in these fields. Ms. Faulkner did not aver that she had any training in medical issues, or in psychology, or in pharmacology. Ms. Faulkner asserted that she had taken training courses offered by HCFA and the State of Florida concerning the conduct of surveys. Tr. at 185. But, Ms. Faulkner provided no evidence as to what was taught in these courses.

it is apparent from Ms. Faulkner's testimony that her opinions of the need for restraints for certain residents involved her judgment as to whether restraints were medically appropriate. I find these judgments to be without foundation, and not credible. They include the following opinions:

- Bed rails did not appear to be a necessary physical restraint in the case of Resident 3, because the resident was capable of getting out of bed and ambulating. Tr. at 203 - 204.

- Resident 3 suffered harm because of improper use of restraints consisting of the development of pressure sores by the resident, and the failure of Petitioner to timely remove a catheter. Tr. at 207.

- Resident 3 was at a high risk of decline due to Petitioner's improper application of physical restraints to the resident. Tr. at 208.

- There was no legitimate medical purpose for Petitioner to apply physical restraints to Resident 18. See Tr. at 209.

- Petitioner restrained Resident 18 for reasons of safety, and not for medical reasons. Tr. at 213 - 215.

- Resident 18 experienced actual harm due to Petitioner's asserted improper application of restraints to the resident. Tr. at 209. "The harm that I saw is tying down a human being who should be allowed to freely walk about." Id.

- Restraints were applied to Resident 18 by Petitioner as a punishment and not for medical reasons. Tr. at 211.

> ***5. The assertions made under tag 221 in the report of the July 17 - 21, 1995 survey that Petitioner did not apply physical restraints to Residents 3, 8, and 18 for a proper purpose, thereby placing the residents in immediate jeopardy, either are unsubstantiated or are rebutted by the preponderance of the evidence.***

The findings of immediate jeopardy made under tag 221 by the surveyors who conducted the July 17 - 21, 1995 survey relate solely to the allegedly improper application by Petitioner of physical restraints to Residents 3, 8, and 18. I conclude that HCFA failed largely to establish even a prima facie case of noncompliance on the issue of application of physical restraints to these residents. I conclude further that Petitioner rebutted by a preponderance of the evidence any prima facie evidence of noncompliance introduced by HCFA.

The surveyors made a general allegation under tag 221 that Petitioner failed to comply with the restraints requirement. They stated that:

> 9 of 29 sampled residents (including 3 closed records) were physically restrained without medical indication of need.

HCFA Ex. 5, at 1. These nine allegedly improperly restrained residents included the three residents whose restraining by Petitioner was cited as the basis for the immediate jeopardy finding under tag 221. The surveyors supplemented their general assertion of noncompliance with a somewhat more specific allegation:

> During the initial tour on 7/17/95 and throughout the survey until 7/21/95, these sampled residents and numerous others, were observed restrained with lap restraints tied in the back, velcro lap belts (considered restraints as the residents were unable to remove them upon request) lap buddies and siderail usage. **There was no medical reason given or documented for these restraints**, nor were they used as positioning devices. These residents included, #2, 3, 6, 8, 16, 17, 18, 26, and 29.

Id. (Emphasis added). As I read this allegation of noncompliance, the gravamen of the allegation is that Petitioner failed to give or to document a medical reason for its use of restraints in the cases of the enumerated residents.

The surveyors then made specific assertions concerning their observations of the way in which Petitioner cared for each of the cited residents. The surveyors offered their observations as evidence to support their allegations of noncompliance under tag 221.

My analysis here of the allegations made under tag 221 addresses the specific immediate jeopardy allegations made by the surveyors, inasmuch as it is these allegations, in part, on which HCFA relied to impose an upper-range civil money penalty against Petitioner. I discuss other specific assertions of deficiencies that the surveyors made under tag 221, at an alleged level of noncompliance that is less than the immediate jeopardy level, at Finding 12, in my analysis of the amount of the civil money penalty that is reasonable in this case. These other assertions of deficiencies were not relied on by HCFA as a basis for imposing a civil money penalty against Petitioner in the upper range that is reserved for instances where a long-term care provider places its residents in immediate jeopardy.

a. Resident 3.

The surveyors' allegations concerning Petitioner's application of physical restraints to Resident 3 are:

> Resident #03, was admitted on 6/23/95. On admission she was ambulatory with walker, was able to wheel self in wheelchair and had a bedside commode. Interview with staff and family on 7/17/95 and 7/18/95 revealed resident was able to use her bedside commode. Record review revealed she was found on the floor on 6/25/95. CNA said the bedrails were "probably" up when she was found on floor on 6/25/95. Record review showed the facility's siderail assessment form had not been completed and the MDS done 7/2/95 does say bedrails are used. Record review and observation reveals this resident also had decline in several areas of capability.

HCFA Ex. 5, at 3. Petitioner argues that the allegations concerning Resident 3 do not state a failure by Petitioner to comply with the participation requirement governing use of restraints. I agree with Petitioner that the allegations are vaguely worded. However, when read with the general assertions of noncompliance by Petitioner with the restraints requirement, it is reasonable to find that the surveyors asserted that Petitioner: did not restrain Resident 3 for a medically necessary purpose and failed to complete a siderail assessment form of the resident. It is reasonable also to find that the surveyors concluded that the allegedly unjustified use of siderails caused the resident to experience a fall on June 25, 1995, and that the resident experienced a decline in her overall functioning due to allegedly improper restraint use.

HCFA largely did not establish even a prima facie case that Petitioner improperly applied restraints to Resident 3. HCFA's assertions of noncompliance rest in part on untimely allegations that Petitioner failed to make a comprehensive assessment of Resident 3 for the use of restraints. They rest also on the unfounded medical opinions offered by Ms. Faulkner.

At the hearing of this case, Ms. Faulkner expanded greatly on the allegations that are stated in the report of the July 17 - 21, 1995 survey by asserting that the main deficiency in Petitioner's care of Resident 3 was the failure by Petitioner to conduct a *comprehensive assessment* of the resident for use of restraints. Tr. at 190; 200 - 203. As I discuss at Finding 2, HCFA made the allegation that Petitioner failed to perform comprehensive assessments of its residents for the use of restraints for the first time at the hearing of this case. I make no Findings about the allegation due to HCFA's failure to give Petitioner timely notice of it.

Ms. Faulkner additionally made unfounded medical judgments about Petitioner's application of restraints to Resident 3. Ms. Faulkner's medical judgments are necessary elements of the surveyors' conclusion that Petitioner applied restraints improperly to the resident and caused the resident to suffer harm. As I find above, at Finding 4, Ms. Faulkner is not qualified to make judgments about the medical propriety of Petitioner's application of restraints to residents or about the harm occasioned to residents from the improper use of restraints. For that reason, I find the surveyors' allegations about Petitioner's alleged improper use of restraints in the case of Resident 3 to be unfounded.

The medical judgments which Ms. Faulkner made, without foundation, include the assertion that restraints were not medically necessary for Resident 3. They include also assertions that Resident 3 probably developed a pressure sore from improper application of restraints, and that the resident's functioning declined as a result of Petitioner's allegedly improper application of restraints. Tr. at 203; 207; 209.

Allegations about Petitioner's use of physical restraints in the case of Resident 3 which, if true, might have been a basis for finding Petitioner to be deficient, are rebutted by the preponderance of the evidence. These allegations are inaccurate in key respects.

The surveyors were wrong in concluding that Petitioner failed to complete a bed siderail assessment form for Resident 3. See HCFA Ex. 5, at 3. In fact, on June 24, 1995, 23 days prior to the beginning of the July 17 - 21, 1995 survey, Petitioner completed a siderail assessment form of Resident 3. P. Ex. 1, at 175. Not only was the form completed, but it establishes that bed siderails were *requested* by Resident 3 and were not imposed on the resident by Petitioner as an involuntary restraint. Id.

The surveyors were incorrect in concluding that the resident experienced a fall on June 25, 1995 which was caused by an improper application of a restraint (bed siderails) to the resident. See HCFA Ex. 5, at 3. Resident 3 did sustain a fall on June 25, 1995. However, the fall was from the resident's wheelchair, and not from the resident's bed, and was due to the resident's failure to lock her wheelchair brakes. P. Ex. 1, at 177. The use of siderails had nothing to do with the resident's fall.

b. Resident 8.

The surveyors' allegations concerning Petitioner's application of physical restraints to Resident 8 are:

> Resident #8, admitted 7/7/95, observed on 7/17/95 in bed with side rails up and roll belt on. Physical therapy notes on 7/11/95 state resident is independent in bed and standing, ambulation with assist, and can propel

> wheelchair with feet. At 1:50 pm on 7/18/95 resident was struggling in bed, pulling at belt restraint that was tied across abdomen to each side of bed. On 7/19/95 at 8 a.m. resident observed attempting to eat breakfast with restraint around chest and tray at bed side. After ambulation by therapy on 7/19/95, resident was back in bed at 10:30 a.m. and remained in bed with roll belt on and side rails on until 5:00 p.m. During five days of survey, resident was observed being ambulated by physical therapy on 3 occasions and to the dining room on one occasion. No attempt was made to use less restrictive restraints before use of roll belt. Resident continued to be increasingly agitated during survey, soiling the bed and combative with staff, until chemical restraints were given. No assessment was done for restraint use.

HCFA Ex. 5, at 4 - 5. Petitioner argues that the specific statements which the surveyors made about the way in which Resident 8 was restrained by Petitioner fail to state a deficiency under tag 221. I agree with Petitioner that these statements are vaguely worded. However, as with the allegations that the surveyors made concerning Resident 3, the allegations that the surveyors made about Resident 8 do contain examples of noncompliance by Petitioner which put Petitioner on reasonable notice of that which it had to defend against at the in-person hearing.

The allegations that the surveyors made about Petitioner's use of physical restraints are intended to be examples of Petitioner's deficiencies in complying with the restraints requirements. The surveyors' report gives Petitioner notice of these assertions about the care that Petitioner gave to Resident 8: the resident was not restrained for reasons of medical necessity; even assuming restraints to have been medically necessary, the resident may have benefitted from less restrictive physical restraints than were employed by Petitioner; Petitioner failed to assess Resident 8 for the use of restraints; and, the improper use of restraints in the case of Resident 8 caused the resident to become increasingly combative, thereby harming the resident.

However, Petitioner is not obligated to rebut assertions of which it was not given reasonable notice. At the in-person hearing, Ms. Gonzalez, who was the surveyor who made direct observations of the care Petitioner gave to Resident 8, made assertions about the care which Petitioner provided to the resident which greatly exceeded the allegations contained in the surveyors' report. I find that Petitioner was not obligated to respond to these assertions, because it did not receive reasonable notice of them. These assertions of which Petitioner did not receive notice include Ms. Gonzalez' allegations that: Petitioner's staff ignored Resident 8 and restrained the resident because they did not want to be in the resident's presence; the resident experienced a psychological decline as a result of Petitioner's alleged improper application of restraints to the resident; and, Petitioner fastened a roll belt incorrectly to the resident.

Furthermore, it is evident from Ms. Gonzalez' testimony, as I describe above at Finding 4, that she bases her allegations that Petitioner applied physical restraints to Resident 8 for improper purposes, and that Resident 8 was harmed by Petitioner's improper application of restraints to the resident, on her judgment of what would have been medically appropriate care for the resident. I have concluded that Ms. Gonzalez is not qualified to offer this judgment as expert opinion. For that reason, I conclude that HCFA failed to establish even a prima facie case that: Petitioner applied physical restraints to Resident 8 for an improper purpose; Resident 8 would have benefitted from less severe restraints than those which were employed by Petitioner; and, Resident 8 was harmed by Petitioner's application of restraints to the resident.

It is not necessary for Petitioner to rebut the unsubstantiated allegations made by the Florida State survey agency and HCFA concerning Petitioner's use of physical restraints in the case of Resident 8. Nor is it necessary for Petitioner to rebut the allegations of which Petitioner did not receive timely notice. Nevertheless, Petitioner offered persuasive evidence which rebutted the allegations which the surveyors made about its use of restraints in the case of Resident 8. Petitioner proved by the preponderance of the evidence that it applied restraints to Resident 8 for medically necessary reasons.

The treatment records of Resident 8 which Petitioner introduced to rebut Ms. Gonzalez' testimony establish that Resident 8 had suffered from severe progressive dementia of about four to five years' duration. P. Ex. 1, at 549. Even prior to his stay at Petitioner, Resident 8 was a severely demented individual, given to outbursts of agitated and violent behavior. Id. at 538, 547. He had been restrained both physically and chemically, while hospitalized for treatment of a broken hip, immediately prior to the commencement of his stay at Petitioner's facility. Id. at 538. The restraints that were applied to the resident during his stay at Petitioner's facility were prescribed by a physician and were a continuation of the restraints that had been applied to the resident while he was hospitalized. Id. at 546. The restraints were prescribed because of the resident's demented state, which affected his judgment and his behavior, and his physical problems, which included a gait that was so impaired that the resident required the assistance of two people to walk. Id. at 347.

The physician's orders for restraints for Resident 8 are justified in part by the behavior the resident exhibited while he resided at Petitioner's facility. The resident posed a threat to harm both himself and others. The resident manifested irrational behavior while he resided at Petitioner's facility which included spitting medicines at nurses. The resident was extremely disoriented to time, place, and person, and displayed severe mood swings. P. Ex. 1, at 529. He exhibited signs of aggressiveness and combativeness from the day he arrived at Petitioner's facility. Tr. at 360. The resident became violent and combative without warning and he attempted to assault members of

Petitioner's staff. P. Ex. 1, at 543. On July 18, 1995, the second day of the July 17 - 21, 1995 survey of Petitioner, Resident 8 assaulted Ms. Jensen, one of Petitioner's nursing supervisors, by head-butting her. Tr. at 363.

Although quality of care in the application of restraints to Resident 8 is not an issue here, the weight of the evidence does not show that Petitioner attached restraints to the resident in a way that evidenced poor quality of care. Petitioner proved that the displacement of restraints on the resident's body frequently were the product of the resident's own irrational movements. Resident 8's irrational behaviors included thrashing constantly while he was in bed. Tr. at 367. The resident's thrashing caused restraints to become dislodged. Id.

Petitioner established that it assessed Resident 8 for the use of restraints and rebutted HCFA's assertion that Petitioner did not assess Resident 8 for the use of restraints. On July 10, 1995, Petitioner's restraint committee discussed Resident 8's situation. P. Ex. 1, at 529. It concluded that the resident would be safer at that time with a grey belt while in a wheel chair and roll belt while in bed. Id. It decided that Resident 8 should be observed for possible restraint reduction at a later date. Id.

As I find above, at Finding 2, HCFA's assertion that Petitioner was deficient because Petitioner did not conduct a comprehensive assessment of Resident 8 and other residents consistent with the requirements of interpretive guidelines, is untimely, and Petitioner did not receive adequate notice of it. I do not evaluate the assessment that Petitioner performed of Resident 8 pursuant to HCFA's asserted comprehensive assessment requirement. The evidence offered by Petitioner establishes that its staff reviewed the use of restraints in the case of Resident 8 and considered whether it would be appropriate to reduce the use of those restraints. That evidence is sufficient to rebut the surveyors' bare allegations that Petitioner failed to assess Resident 8 for restraint use.

Moreover, the assessment that Petitioner performed of Resident 8 complies with the requirements of applicable regulations. The time period for performing a full assessment of Resident 8 for use of restraints, as opposed to the preliminary assessment that Petitioner performed, had not expired as of the July 17 - 21, 1995 survey of Petitioner. Under applicable regulations, Petitioner was obligated to perform a comprehensive assessment of Resident 8 within 14 days of the commencement of his stay at Petitioner's facility. 42 C.F.R. § 483.20. In the case of Resident 8, that period ended on July 22, 1995, the day after the completion of the July 17 - 21, 1995 survey.

c. Resident 18.

The surveyors' allegations concerning Petitioner's application of physical restraints to Resident 18 are:

> Resident #18 was observed on 7/18/95 at 9:45 am ambulating without assistance behind her wheelchair. When the CNA stopped her and put her back in the chair she put a lap belt on. When the surveyor asked the CNA to have the resident remove the belt the resident was unable to do so. When the CNA was asked why she would place a lap belt on a resident who was observed walking so well she stated "so she won't get up and wander. We don't have enough staff to watch her.["] This resident also has a roll belt when in bed and siderails up. The resident has had these restraints as written orders since 9/29/94.

HCFA Ex. 5, at 1 - 2. As with Residents 3 and 8, Petitioner asserts that the surveyors' statement does not allege any deficiency by Petitioner. I conclude that the statement is reasonably clear. The surveyors concluded that the ability of Resident 18 to ambulate demonstrated that a restraint was unnecessary. However, it is not clear from the statement in the survey report what harm, either actual or potential, was caused to Resident 18 by Petitioner's alleged improper use of restraints.

The allegations that the surveyors made in the report of the July 17 - 21, 1995 survey about Petitioner's restraining of Resident 18 are sufficient to make out a prima facie case that Petitioner did not comply with participation requirements in its care of the resident. Absent credible and probative rebuttal evidence from Petitioner, I would find that Petitioner restrained Resident 18, an individual who was capable of ambulation without assistance, because Petitioner did not have sufficient staff to keep track of the resident when she wandered. This is an allegation that Petitioner restrained the resident for purposes of convenience.

However, the preponderance of the evidence rebuts HCFA's assertions of noncompliance with respect to Resident 18. The evidence establishes that this resident suffered from severe osteoporosis. Tr. at 347. There was a medically justified purpose for the restraints. A physician issued an order to restrain the resident in order to protect the resident from injuring herself. Tr. at 346 - 347. I note that Petitioner removed restraints from the resident after the July 17 - 21, 1995 survey, in order to address the allegations of noncompliance that the surveyors had made concerning Resident 18. Shortly thereafter, the resident sustained a fall, resulting in irreversible injury to the resident from a fractured hip. Id.

I am not persuaded that HCFA established a basis for finding that Petitioner's use of restraints placed Resident 18 in immediate jeopardy, even assuming that Petitioner was deficient in its application of restraints to the resident. In its posthearing brief, HCFA asserts that: "[t]he harm to this resident was the harm any human being who can walk freely suffers from being restrained." HCFA's posthearing brief at 29; see Tr. at 209. This argument is an assertion that prima facie evidence of an improper restraint of a resident establishes a prima facie case that a facility has placed the resident in immediate jeopardy.

There is nothing in the record of this case which supports this sweeping contention. The question in deciding whether an improper restraint places a resident in immediate jeopardy is whether the restraint caused or would be likely to cause the resident, serious injury, harm, impairment, or death. 42 C.F.R. § 488.301. HCFA introduced no evidence aside from Ms. Faulkner's unfounded assertion to support its argument that Petitioner's restraining Resident 3 caused the resident to experience actual or potential harm at the level of immediate jeopardy.

In her testimony, Ms. Faulkner made an allegation about Petitioner's care of Resident 18 that was not made in the report of the July 17 - 21, 1995 survey, and of which Petitioner had no notice prior to the hearing of the case. The allegation is that, in the year which preceded the July 17 - 21, 1995 survey, Petitioner made no effort at restraint assessment or reduction in the case of Resident 18. Tr. at 205; 236; 238. I conclude that Petitioner is not obligated to respond to this allegation, inasmuch as it was not given reasonable notice of it. Additionally, I conclude that this allegation does not on its face state that Petitioner was using restraints in the case of Resident 18 for an improper purpose.

> ***6. The assertions made under tag 222 in the report of the July 17 - 21, 1995 survey that Petitioner did not apply chemical restraints to Residents 8 and 29 for a proper purpose, thereby placing the residents in immediate jeopardy, either are unsubstantiated or are clearly erroneous.***

The Florida State survey agency surveyors predicated their conclusions in their report of the July 17 - 21, 1995 survey that Petitioner employed chemical restraints for improper purposes on Petitioner's use of chemical restraints in the cases of two residents, Residents 8 and 29. HCFA Ex. 5, at 6 - 7. The surveyors concluded further that the failure by Petitioner to employ chemical restraints for proper purposes in the cases of these two residents placed these residents in immediate jeopardy. HCFA adopted the surveyors' conclusions.

I conclude that, in the case of Resident 8, Petitioner proved that it was administering chemical restraints to the resident for a medically necessary purpose. Petitioner was not deficient under tag 222 in the care that it gave to Resident 8. In the case of Resident 29, HCFA established that Petitioner administered a chemical restraint to Resident 29 for an improper purpose. However, HCFA's determination that Petitioner's administration of Ativan to Resident 29 placed the resident in immediate jeopardy is clearly erroneous.

In their report of the July 17 - 21, 1995 survey, the surveyors averred that:

> 2 of 29 sampled residents (including 3 closed records) were found to have chemical restraints not required to treat medical symptoms.

HCFA Ex. 5, at 6. They elaborated on this assertion with specific statements concerning the care that Petitioner gave to Residents 8 and 29.

a. Resident 8.

The surveyors made the following assertions concerning the care Petitioner gave to resident 8:

> Resident #8 had a long standing medication order for Ativan 0.5 mg every 4 hours PRN, until changed 7/19/95 to Ativan 0.5 mg every 8 hours, Loxitane 15 mg every am, 20 mg every pm, and Haldol 5 mg IM every 6 hours PRN for severe agitation. This was a telephone order after nursing note "took 6 CNA's to manage while changing bed linens soiled from urine and stool" on 3-11 shift on 7/18/95. Therapy notes 7/11/95 state "should be taken to bathroom, gets agitated when needs to use bathroom." Physical therapy could not ambulate resident on 7/20 and 7/21 due to drowsiness. Staff ambulated to dining room on 7/20 with assistance of two and resident had to be fed. Interview with family members on 7/21 indicated drowsiness and lack of response was not usual behavior and staff had responded to family questioning about medication with answer "Ativan, I've only given him Ativan."

HCFA Ex. 5, at 6. Petitioner asserts that this statement does not allege any specific improper conduct by Petitioner. I infer that the statement was written to document that the resident was being overmedicated by Petitioner. This seems to be the import of the references to the resident's drowsiness. Beyond that, however, it is, indeed unclear what the statement is intended to communicate. I conclude that, when the statement is read with the surveyors' overall assertion of noncompliance under tag 222, the surveyors found that: Petitioner administered chemical restraints to Resident 8 without

a medically necessary basis for doing so; and Resident 8 was harmed to the extent that he was overmedicated and became drowsy.

I do not find that HCFA made even a prima facie case to show that Petitioner administered chemical restraints improperly to Resident 8. The evidence which HCFA offered to support this assertion consisted exclusively of the testimony of Ms. Gonzalez. Ms. Gonzalez opined that the resident manifested an "overnight" personality change due to the administration of chemical restraints to him. Tr. at 103. Ms. Gonzalez cited nothing to show that the administration of a chemical restraint to Resident 8 by Petitioner was improper, even assuming that it produced the personality change in the resident to which Ms. Gonzalez attested. Furthermore, as I hold above at Finding 4, HCFA did not establish that Ms. Gonzalez has any qualifications to opine as to the psychological effects of medication.

Petitioner introduced evidence that rebuts HCFA's allegations that chemical restraints were applied for improper purposes to Resident 8. As HCFA concedes, there were orders by a physician that the medications at issue be administered to the resident. P. Ex. 1, at 546; see HCFA Ex. 5, at 6. As is attested to by the resident's physician, the administration of chemical restraints was warranted by the unprovoked episodes of aggressive behavior manifested by the resident, which I describe above at Finding 5.b. P. Ex. 1, at 347.

b. Resident 29.

The surveyors made the following assertions concerning the care Petitioner gave to Resident 29:

> Resident #29 observed walking the hall with the nursing staff assisting her. The staff had to leave. The med-nurse told the resident it was okay to walk with her. Resident walking along making sounds and statements that could and sometimes could not be understood. As the resident began to walk away from the med-cart, the staff member stated "I'm going to give her the Ativan." Surveyor questioned why? The reply was "sometimes she goes out the door" pointing toward the door. Documentation in the resident's record stated the son has asked the facility not to give his mother any more Ativan, because he thought she was getting too much.

HCFA Ex. 5, at 7.

The unrebutted evidence that HCFA offered concerning the care that Petitioner gave to Resident 29 is that Petitioner's staff administered Ativan to the resident in order to control the resident's movement. This is an improper purpose, related to the convenience of Petitioner, rather than to the medically necessary care of the resident. Petitioner was deficient in its use of chemical restraints with respect to Resident 29.

The surveyors' allegation concerning Petitioner's administration of chemical restraints to Resident 29 is supported by the testimony of one of the surveyors who participated in the July 17 - 21, 1995 survey of Petitioner, Ms. Christine Denson, R.N. Tr. at 257 - 258. Ms. Denson's testimony establishes a prima facie case that Petitioner administered Ativan to resident 29 for reasons of convenience and not for a medically necessary reason.

Petitioner did not rebut Ms. Denson's testimony. Resident 29 had a prescription for Ativan. P. Ex. 1, at 1162. However, the prescription was for the medication to be administered in order to control the resident's aggressive behavior, and not to control the resident's tendency to wander. Id. Petitioner concedes that Ativan may have been administered to the resident for a purpose that was not medically necessary — to control the resident's movement — rather than for a medically necessary reason. See Tr. at 369.

HCFA's allegation that Petitioner's improper administration of Ativan to Resident 29 placed the resident in immediate jeopardy is clearly erroneous. HCFA offered no evidence to show that the resident was either harmed, or even potentially harmed, by the improper administration of Ativan.

Ms. Denson is a registered nurse, with experience both in a hospital setting, and in a long-term care facility as a director of nursing. Tr. at 254 - 255. Unlike Ms. Gonzalez or Ms. Faulkner, Ms. Denson is qualified to testify about medical issues related to the nursing care given by Petitioner to its residents. I presume Ms. Denson's nursing experience includes some training in the effects of prescription drugs. Had HCFA asked Ms. Denson to opine about the potentially deleterious effects of improper administration of Ativan to a resident, Ms. Denson might have expressed a credible opinion.

However, HCFA never asked Ms. Denson to opine whether administration of Ativan to Resident 29 even potentially harmed the resident. Ms. Denson was asked no questions concerning the pharmacologic effects of Ativan, the side effects of Ativan, or the potential consequences of misuse of Ativan. Ms. Denson's only testimony about the possible effects that Ativan may have had on Resident 29 came in response to questions that Petitioner's counsel asked her on cross-examination. In response to these

questions, Ms. Denson opined that Resident 29 experienced no harm from Petitioner's administration of Ativan to the resident. Tr. at 268.

Ativan is a prescription medication. I take notice that there is some possibility that improper administration of Ativan — as would likely be the case with improper administration of any prescription medication — to an individual might cause more than minimal harm to that person. Beyond that, however, I make no Finding concerning the potential for harm which might have resulted from improper administration of Ativan to Resident 29. There simply is no evidence of record which would support any additional Finding.

> ***7. The assertions made under tag 490 in the report of the July 17 - 21, 1995 survey that Petitioner was not administered effectively, thereby placing Petitioner's residents in immediate jeopardy, either are unsubstantiated or are clearly erroneous.***

The surveyors who conducted the July 17 - 21, 1995 survey of Petitioner concluded at tag 490 that Petitioner was not complying with a Medicare participation requirement governing the administration of long-term care facilities, to the extent that it was placing its residents in immediate jeopardy. HCFA Ex. 5, at 30. The surveyors asserted that Petitioner was deficient under a requirement that is stated at 42 C.F.R. § 483.75, which provides that:

> A facility must be administered in a manner that enables it to use its resources effectively and efficiently to attain or maintain the highest practicable physical, mental, and psychosocial well-being of each resident.

The deficiency which the surveyors found at tag 490 emanated from deficiencies which the surveyors found in Petitioner's compliance with requirements governing the use of restraints, abuse and neglect, quality of life, quality of care, and nursing services staffing. HCFA Ex. 5, at 30. The premise for the finding of deficiency under tag 490 is that a facility that is deficient under the other requirements that are cited under the tag must be deficient in the manner in which it is administered.

However, the surveyors' finding that Petitioner was deficient in its administration at a level that posed immediate jeopardy to its residents is premised *only* on their assertions that Petitioner was deficient in its application of restraints to residents to an extent that the alleged misapplication of restraints posed immediate jeopardy to residents. But for the immediate jeopardy findings under tags 221 and 222, the surveyors, and HCFA, would not have found Petitioner deficient under tag 490 to the extent that the deficiency

under tag 490 posed immediate jeopardy to Petitioner's residents. See HCFA's posthearing brief at 30.

Petitioner was deficient in its administration to the extent that it permitted its staff to engage in acts that were deficient under other participation requirements. As I discuss at Finding 6.b., Petitioner's staff was deficient in its administration of chemical restraints to Resident 29, although not to the extent that the administration of chemical restraints to the resident posed immediate jeopardy to the resident.

However, there is no credible evidence to show that Petitioner was deficient in its overall administration to the extent that its administration posed immediate jeopardy to its residents. I have concluded that the allegations of immediate jeopardy under tags 221 and 222 on which the surveyors' and HCFA's assertion of an immediate jeopardy level deficiency under tag 490 rest are without substance. Therefore, the allegation of an immediate level deficiency under tag 490 is unsubstantiated and is clearly erroneous.

In its posthearing brief, HCFA embellishes on the allegations of the Florida State survey agency surveyors of a deficiency under tag 490 by asserting that Petitioner's employment of "two nurses inexperienced in performing long term care resident assessments, especially restraint evaluations," contributed to Petitioner's other alleged deficiencies. HCFA's posthearing brief at 30. This is an allegation that HCFA raises for the first time in its posthearing brief, and of which HCFA never gave Petitioner notice prior to the hearing. Moreover, there is no credible evidence to support the allegation. To the contrary, the evidence establishes that Ms. Jensen and Ms. Merrill, the two nurses who were in charge of the care given to Petitioner's residents as of the July 17 - 21, 1995 survey, are qualified and competent registered nurses.

8. HCFA established a basis for imposing a civil money penalty against Petitioner.

HCFA determined to impose a civil money penalty against Petitioner commencing on July 21, 1995, based on its determinations that Petitioner had failed to comply with the restraints requirement, both in its application of physical and chemical restraints to residents, and with the effective administration requirement. 42 C.F.R. §§ 483.13(a), 483.75. The additional 14 findings of deficiencies made by the surveyors at the July 17 - 21, 1995 survey of Petitioner were not the basis for HCFA's determination to impose a civil money penalty against Petitioner, but were relied on by HCFA as ancillary evidence of noncompliance by Petitioner with participation requirements. This ancillary evidence was used to determine the amount of the penalty. I discuss these additional findings of deficiency below, at Finding 12, in my discussion of the amount of the civil money penalty that I sustain in this case.

HCFA established a basis for imposing a civil money penalty against Petitioner. Petitioner failed to comply with both the restraints requirement and the effective administration requirement.

HCFA established that Petitioner failed to comply substantially with the restraints requirement. In the case of Resident 29, Petitioner applied a chemical restraint to the resident for an impermissible purpose consisting of convenience to the facility. 42 C.F.R. § 483.13(a). I conclude that the improper administration of Ativan to the resident evidenced a belief on the part of at least one member of Petitioner's staff that Ativan could be used for purposes of convenience. From this, I infer that at least one member of Petitioner's staff, potentially, might administer Ativan improperly to any resident who had a tendency to wander.

HCFA established also that Petitioner failed to comply with the administration requirement. The failure by Petitioner to ensure that all of its employees respected the rights of Petitioner's residents establishes that Petitioner was not administered effectively. 42 C.F.R. § 483.75.

9. HCFA did not establish a basis for imposing an upper range civil money penalty against Petitioner of from $3,050 - $10,000 per day.

HCFA bases its determination to impose an upper range civil money penalty of $7,500 per day against Petitioner from July 21, 1995 until August 18, 1995 on the conclusions of the Florida State survey agency surveyors that, during this period, Petitioner was deficient to the extent that its deficiencies caused immediate jeopardy to residents. See 42 C.F.R. §§ 488.408(e); 488.438(a)(1). HCFA did not establish a basis for imposing an upper range civil money penalty against Petitioner. As I discuss in Findings 5 - 7, Petitioner manifested no deficiencies in the immediate jeopardy range.

10. HCFA established a basis for imposing a lower range civil money penalty against Petitioner of from $50 - $3,000 per day.

Petitioner's failure to comply with the participation requirements that are the basis for HCFA's determination to impose a civil money penalty did not place Petitioner's residents in immediate jeopardy. However, Petitioner's failure to comply with the requirements had the potential of causing residents more than minimal harm. Petitioner's deficiencies at a level that had the potential of causing residents more than minimal harm is a basis for imposing a civil money penalty against Petitioner of from $50 to $3,000 per day for each day that Petitioner manifested these deficiencies. 42 C.F.R. §§ 488.408(d); 488.438(a)(2).

11. HCFA is authorized to impose a civil money penalty against Petitioner beginning on July 21, 1995 and for each day thereafter through September 8, 1995.

HCFA is authorized to impose a lower range civil money penalty of between $50 and $3,000 per day against Petitioner for each day that Petitioner was not in substantial compliance with participation requirements. 42 C.F.R. §§ 488.408(d); 488.430; 488.438(a)(2). HCFA is authorized to impose a civil money penalty against Petitioner beginning with the first date on which HCFA established that Petitioner was not complying substantially with participation requirements and ending with the date on which Petitioner attained substantial compliance with participation requirements.

HCFA determined that Petitioner attained substantial compliance with all participation requirements on September 8, 1995. That date is the date of the second resurvey of Petitioner. I conclude that the preponderance of the evidence establishes that Petitioner attained substantial compliance with participation requirements on that date.

It is Petitioner's burden to establish that it attained compliance with all participation requirements with which it had been found to be deficient. HCFA argues that compliance may only be assured by surveyors' findings that all deficiencies had been cleared. I disagree with this assertion. The regulations which govern civil money penalties do not require a long-term care facility to be resurveyed as a prerequisite to establishing that the facility has attained compliance with participation requirements. See 42 C.F.R. § 488.454. The date of compliance may be established by credible evidence of compliance other than the report of State survey agency surveyors. Id.

However, Petitioner did not offer credible evidence that it complied with participation requirements earlier than September 8, 1995. Petitioner offered as evidence of its compliance a plan of correction which shows the corrective actions that Petitioner took to correct any deficiencies which the surveyors identified at the July 17 - 21, 1995 survey. The plan recites various dates when Petitioner implemented its corrective actions. HCFA Ex. 5. Several of these corrective actions have completion dates which occurred after the first resurvey of Petitioner, on August 18, 1995. Id. Several of the corrective actions are listed as being "ongoing," which I infer means that the corrective actions were in the process of being implemented. Petitioner did not explain when any of these "ongoing" corrective actions would be completed.

HCFA had no credible assurances from Petitioner that Petitioner had completed all of its corrective actions prior to the September 8, 1995. Nor do I find from the evidence of Petitioner's corrective actions that, in fact, Petitioner completed its corrective actions prior to September 8, 1995. For that reason, I conclude that Petitioner has not proven

that it attained substantial compliance with participation requirements earlier than September 8, 1995.

12. A civil money penalty of $1,000 per day for each day that Petitioner was not complying substantially with participation requirements is reasonable.

There exists a basis to impose a civil money penalty against Petitioner in the lower range of civil money penalties of from $50 to $3,000 per day. The period during which any penalty may accrue begins on July 21, 1995 and ends on September 8, 1995. What remains to be decided is the amount of the penalty that HCFA is authorized to collect from Petitioner. I decide, based on the entire record of this case, that a penalty of $1,000 per day is reasonable.

The regulations which govern imposition of civil money penalties establish the factors which must be used in determining the amount of a civil money penalty once the permissible range (upper or lower) of the penalty is established. 42 C.F.R. § 488.438(f). The regulations additionally make it clear that an administrative law judge may consider only the enumerated factors in deciding the amount of a civil money penalty. 42 C.F.R. § 488.438(e)(3). The factors which may be considered in deciding the amount of a civil money penalty are stated as follows:

> (1) The facility's history of noncompliance, including repeated deficiencies.
>
> (2) The facility's financial condition.
>
> (3) The factors specified in [42 C.F.R.] § 488.404.
>
> (4) *The facility's degree of culpability. Culpability* for purposes of this paragraph includes, but is not limited to, neglect, indifference, or disregard for resident care, comfort, or safety. The absence of culpability is not a mitigating circumstance in reducing the amount of the penalty.

42 C.F.R. § 488.438(f)(1) - (4). The factors that are specified in 42 C.F.R. § 488.404 include the level of harm associated with deficiencies manifested by a facility. 42 C.F.R. § 488.404(b)(1). They include also whether the deficiencies are isolated, constitute a pattern, or are widespread. 42 C.F.R. § 488.404(b)(2). They include the relationship of one deficiency to other deficiencies resulting in findings of noncompliance. 42 C.F.R. § 488.404(c)(1). Finally, they include a facility's prior

history of noncompliance in general and specifically with reference to the cited deficiencies. 42 C.F.R. § 488.404(c)(2).

There are some redundancies in these factors. A facility's history of noncompliance is mentioned as a factor, both in 42 C.F.R. § 488.404(c)(2) and in 42 C.F.R. § 488.438(f)(1). Notwithstanding, I have considered all of the factors identified in 42 C.F.R. §§ 488.404 and 488.438 in determining that a civil money penalty of $1,000 per day is reasonable in this case.

There is some arguable ambiguity in the regulations concerning an administrative law judge's authority to review a civil money penalty and to make an independent decision as to what is reasonable in a given case. Under 42 C.F.R. § 498.3(b)(13), a long-term care facility's appeal rights of a civil money penalty determination by HCFA are described as being an appeal of: "The level of noncompliance found by HCFA . . . only if a successful challenge on this issue would affect the range of civil money penalty amounts that HCFA could collect." When read in isolation, this regulation arguably suggests that a long-term care facility has no right to request a hearing to challenge the *amount* of a civil money penalty determination by HCFA. Arguably, the appeal rights of the facility would be limited to challenging HCFA's determination of the *level* of its noncompliance, where a successful challenge might reduce the range of a penalty from the upper to the lower range.

I do not find this regulation limits my authority to decide the reasonable amount of a civil money penalty in a case where a provider challenges whether the amount of the penalty is reasonable. A conclusion that a facility may challenge only the level of its deficiencies and not the amount of a penalty would render meaningless the express authority that is conferred on an administrative law judge under 42 C.F.R. § 488.438(e) to decide the appropriate amount of a civil money penalty. Furthermore, a reading of 42 C.F.R. § 498.3(b)(13) to preclude a long-term care facility from appealing the amount of a civil money penalty would contradict the requirement of Section 1128A of the Act that a party against whom a civil money penalty determination is made has a right to a de novo hearing.

In its October 27, 1995 notice to Petitioner, HCFA advised Petitioner that it had determined to impose a civil money penalty against it of $2,000 per day, beginning with August 19, 1995. The notice did not advise Petitioner how HCFA had determined this amount to be reasonable. From the record of this case, it is apparent that the $2,000 per day determination was based on a conclusion by the Florida State survey agency that, as of August 18, 1995, Petitioner no longer was deficient in complying with participation requirements to the extent that residents of Petitioner were in immediate jeopardy, but that Petitioner remained out of compliance with participation requirements as of that date. See Tr. at 111 - 113. The reduced civil money penalty,

of from $7,500 per day to $2,000 per day, evidently, was intended to reward Petitioner for eliminating alleged immediate jeopardy deficiencies, but also as an incentive to induce Petitioner to eliminate remaining deficiencies completely.

I have found that Petitioner did not manifest deficiencies to the extent that its residents were placed in immediate jeopardy. There is no basis in law or in the evidence to impose a civil money penalty of $7,500 per day against Petitioner, beginning with July 21, 1995. An essential predicate for the $2,000 per day penalty which HCFA determined to impose beginning on August 19, 1995, is missing. The $2,000 per day penalty plainly was viewed by HCFA as a *reduction* from a higher penalty amount. But, as I have found, there is no basis in this case for imposing the higher amount.

Nevertheless, as a starting point for my analysis of the amount of the penalty, I have considered whether a penalty of $2,000 per day would be reasonable in this case. I conclude that a penalty in that amount would not be reasonable. A penalty of $2,000 per day approaches the upper reach of the non-immediate jeopardy penalty range of from $50 to $3,000 per day. That suggests that a penalty in that amount should be reserved for instances in which a facility manifests extreme derelictions of care which begin to approach the immediate jeopardy level. I do not find such a degree of noncompliance to be established in this case.

Furthermore, HCFA has not offered any evidence to show that *it* predicated the $2,000 per day penalty determination on the factors which are described in 42 C.F.R. § 488.438(f). Richard James, who is chief of the survey and certifications operations office of HCFA's Atlanta region, testified that HCFA made no independent determination of what would be reasonable in this case. Tr. at 277; 284. Rather, HCFA relied entirely on the recommendation sent to it by the Florida State survey agency. There is no evidence in the record of this case that the Florida State survey agency considered the factors described in 42 C.F.R. § 488.438(f) in making a penalty recommendation to HCFA.

In its posthearing reply brief, HCFA stated that: "The administrative law judge in this case stated that . . . he would consider agency officials' testimony, concerning how they decided upon the per day amount of the . . . [civil money penalty] to be irrelevant." HCFA's posthearing reply brief at 6. I am surprised by this statement. I can only assume that it represents a misunderstanding by HCFA of the scope of the evidence that I permitted in this case, because it contradicts directly my instructions to the parties. At the beginning of the hearing of this case I advised the parties, and especially HCFA, explicitly that I would expect them to produce evidence concerning HCFA's basis for its determinations to impose penalties of particular amounts. Tr. at 23. Plainly, that evidence might include evidence about the deliberations by HCFA's employees. I permitted HCFA to offer precisely the evidence that it now contends I

held to be irrelevant. That is made evident by the fact that I permitted Mr. James to testify about the agency's determinations.

Of course, the hearing in this case is a de novo hearing, and not an appellate review of the determinations made by HCFA's employees. HCFA may misunderstand my statements, made in other contexts, that I do not consider to be especially relevant in a de novo hearing the opinions of HCFA's employees that their determinations are *correct*. I plainly am not bound by the opinions of HCFA's employees concerning the correctness of their determinations. On the other hand, objective evidence from these employees concerning the factors on which a penalty determination may be based may be highly relevant to my de novo decision concerning whether a penalty is reasonable.

I base my determination to impose a civil money penalty of $1,000 per day on Petitioner on my analysis of the evidence as it relates to the factors which govern the determination of the amount of an exclusion. The penalty which I impose is substantial. Petitioner was not diligent in ensuring that its employees respected the rights of residents of Petitioner. I base this conclusion on the following:

- Petitioner allowed at least one of its employees to administer chemical restraints to a resident for reasons of convenience.

- Petitioner has a history of compliance problems. Past deficiencies in Petitioner's operations include deficiencies which suggest a failure by Petitioner to respect the welfare and dignity of its residents.

- As of July 17 - 21, 1995, Petitioner manifested deficiencies in addition to the deficiencies under tags 222 and 490 which are the basis for the civil money penalty. These additional deficiencies establish a general lack of diligence by Petitioner's staff to ensure that the rights and welfare of residents of Petitioner were respected. These deficiencies include instances where Petitioner's staff: left residents in need of care and attention alone and ignored for extended periods; failed to give residents the care that the residents' physicians had prescribed for them; failed to respect the dignity or privacy of residents; and, did not employ proper sanitation procedures.

- Petitioner bears a relatively high degree of culpability for its deficient care. The evidence, in total, establishes a lack of diligence by Petitioner in ensuring that all of the needs of its residents were met.

- Petitioner's derelictions of care did not place its residents in immediate jeopardy. There is no evidence that a resident was harmed irreparably by Petitioner or its staff. However, the weight of the evidence is that Petitioner's lack of diligence posed the potential for more than minimal harm to residents. Moreover, the evidence

establishes a significant disregard by Petitioner for its obligation as a participant in the Medicare program to comply with the standards and requirements of the program and to assure beneficiaries that they receive care which comports with these standards and requirements.

My analysis of each of the factors is as follows:

a. Petitioner's history of compliance with participation requirements (42 C.F.R. §§ 488.404(c)(2) and 488.438(f)(1)).

Petitioner had a history of compliance problems which predated the July 17 - 21, 1995 survey of Petitioner. Tr. at 131 - 132. Previously identified problems at Petitioner's facility included: a lack of sanitation; poor quality of daily care of residents; and, staffing problems. Id. In the year which preceded the July 17 - 21, 1995 survey of Petitioner, residents of Petitioner complained about the conditions in Petitioner's facility. Id. at 131. In the year previous to the survey, the State of Florida placed a moratorium on new admissions by Petitioner so that Petitioner could correct various problems. Id. at 131 - 132.

b. Petitioner's financial condition (42 C.F.R. § 488.438(f)(2)).

Neither HCFA nor Petitioner introduced evidence which addressed Petitioner's financial condition. Therefore, I make no Finding concerning Petitioner's financial condition. Specifically, I do not make a Finding that Petitioner would be unable to pay the civil money penalty that I have decided to impose.

c. The level of harm that is associated with the deficiencies that are the basis for the civil money penalty (42 C.F.R. §§ 488.404(b)(1) and 488.438(f)(3)).

The evidence in this case is that Petitioner's improper administration of chemical restraints and its failures in administration caused no actual harm, but had a potential for more than minimal harm that did not place its residents in immediate jeopardy. Findings 6.b.; 7; 42 C.F.R. § 488.404(b)(1)(ii).

d. Whether the deficiencies that are the basis for the civil money penalty are isolated, form a pattern, or are widespread (42 C.F.R. §§ 488.404(b)(2); 488.438(f)(3)).

The terms "isolated," "form a pattern," and "widespread" are not defined in the regulation which establishes the relative pervasiveness of deficiencies as a basis for remedies under the regulations which govern long-term care facilities. See 42 C.F.R. § 488.404(b)(2). I conclude that, in the absence of any definition, these terms ought to be applied consistent with their common and ordinary meanings.

The deficiencies which Petitioner manifested under tags 222 and 490 were widespread. By "widespread" I mean that the problems that were established by the examples identified by the surveyors were pervasive, and were not confined to a single, isolated incident of dereliction of care. I base this conclusion on the essential nature of the deficiencies. While it is true that the improper administration of a chemical restraint by Petitioner was established in the case of only one resident (Resident 29), the improper administration of the restraint to the resident emanated from the belief held by an employee that the restraint could be administered for purposes of convenience. From that, I infer that other residents of Petitioner who might wander were at risk for the same type of improper application of restraints.

e. The relationship of the deficiencies that are the basis for the civil money penalty with other deficiencies that were identified at the July 17 - 21, 1995 survey of Petitioner (42 C.F.R. §§ 488.404(c)(1); 488.438(f)(3)).

As I have discussed above, HCFA based its determination to impose a civil money penalty against Petitioner only on those deficiencies that the surveyors identified as being at the immediate jeopardy level. These were alleged deficiencies identified under tags 221, 222, and 490 in the report of the July 17 - 21, 1995 survey of Petitioner. However, the surveyors identified numerous other deficiencies at the July 17 - 21, 1995 survey which they did not find to be at the immediate jeopardy level. All of these additional alleged deficiencies were found by the surveyors to be lower range deficiencies.

These additional alleged deficiencies, to the extent that they are established, are relevant to deciding the amount of the civil money penalty to be imposed against Petitioner. To the extent that they are established, additional deficiencies shed light on whether Petitioner was derelict only in specific ways in which it provided care or was derelict in its overall treatment of residents.

In this section, I discuss the additional alleged deficiencies and make conclusions about which of them are established. I conclude that, although many of the alleged deficiencies are not established, enough of them are established to support my overall conclusion that Petitioner failed to ensure that its employees respected the rights of residents.

What these additional deficiencies establish is a pattern of neglect of residents' welfare by Petitioner's staff. Residents who needed attention were left on their own for extended periods of time. Residents were not given all of the care that had been ordered for them by their physicians. Petitioner's staff failed to protect the dignity and privacy of residents. The staff did not always observe proper sanitation requirements.

I do not discuss these additional alleged deficiencies in the same degree of detail with which I have discussed the deficiencies that are the basis for HCFA's determination to impose a civil money penalty against Petitioner. I do not cite to every exhibit which is in evidence concerning each of these additional alleged deficiencies, nor do I discuss in detail all of the testimony that was offered concerning them. However, I have reviewed all of the evidence that relates to these additional alleged deficiencies, and have considered each of the parties' arguments about the alleged deficiencies.

i. Additional alleged deficiencies under tag 221 (HCFA Ex. 5, at 1 - 5).

The surveyors made allegations of improper use by Petitioner of restraints under tag 221 in addition to those which they made concerning Residents 3, 8, and 18. These additional allegations of deficiency relate to Residents 16, 2, 6, 17, and 26 (the report of the July 17 - 21, 1995 survey also alludes to Resident 29, however, HCFA has not asserted that Petitioner was deficient under tag 221 with respect to this resident). HCFA Ex. 1, at 1 - 5.

I do not find that these additional allegations of improper use of physical restraints by Petitioner are substantiated. With respect to each resident whose care is at issue, HCFA either failed to establish a prima facie case of improper purpose, or Petitioner rebutted the evidence which HCFA presented.

I find no credible evidence to support the allegation that restraints were applied to Resident 16 for an improper purpose. Indeed, the surveyors did not even allege an improper purpose for the application of restraints to the resident. The surveyors' allegation as stated in the report of the July 17 - 21, 1995 survey is, essentially, that the application of restraints to the resident was not checked regularly by Petitioner's staff pursuant to orders issued by the resident's physician. HCFA Ex. 5, at 2 - 3. This is an allegation of incorrect use of restraints rather than an allegation of application of

restraints for an improper purpose. It raises a quality of care issue. However, what is at issue under tag 221 is not quality of care, but Petitioner's purpose in applying restraints. As HCFA concedes, the resident had a physician's order for the restraints that were employed. Id.

In its posthearing brief, HCFA asserts that Resident 16 was not assessed by Petitioner for the use of restraints. HCFA's posthearing brief at 32. This is an allegation of which Petitioner did not receive timely notice. It is stated nowhere in the report of the July 17 - 21, 1995 survey of Petitioner. Moreover, HCFA's new allegation is, in some respects, contradicted by the testimony of one of the surveyors, Ms. Faulkner. Tr. at 197.

HCFA failed to establish a prima facie case that Petitioner applied restraints to Resident 2 for an improper purpose. The report of the July 17 - 21, 1995 survey does not specifically allege any improper purpose for applying restraints to the resident. HCFA Ex. 5, at 3 - 4. In its posthearing brief, HCFA makes a new allegation that Petitioner failed to assess Resident 2 for the use of restraints. This is an allegation that was not stated in the report of the July 17 - 21, 1995 survey, and of which Petitioner did not receive timely notice.

The treatment records of Resident 2 establish that there was a medically necessary reason for applying restraints to the resident. The resident's physician had ordered restraints be applied to the resident. P. Ex. 1, at 284 - 286. A nursing assessment of the resident, completed on May 24, 1995, showed that the resident suffered from a left hip fracture, a compression fracture of her lower spine, osteoporosis, and an increased risk of falls. It was noted that the resident required extensive assistance for bed mobility and total assistance for transfers and locomotion. P. Ex. 1, at 294.

I do not find that Petitioner restrained Resident 6 for an improper purpose. The report of the July 17 - 21, 1995 survey does not specifically allege that the resident was restrained for an improper purpose. HCFA Ex. 5, at 4. In its posthearing brief, HCFA alleges for the first time that Petitioner's deficiency in providing care to the resident lay in its alleged failure to assess the resident for the use of restraints. I find the allegation to be untimely.

Moreover, allegations of improper use of restraints by Petitioner in the case of Resident 6 are unfounded. The restraints were ordered by the resident's physician. P. Ex. 1, at 325. Petitioner completed at least some assessments of the resident for the use of restraints, notwithstanding HCFA's allegation to the contrary. P. Ex. 1, at 340.

Finally, some of the allegations that the surveyors made concerning Petitioner's care of Resident 6 do not support any conclusion that Petitioner's use of restraints was injurious to the resident. The surveyors asserted that the resident sustained a fall on February 21, 1995 "when side rails were up." HCFA Ex. 5, at 4. There is nothing in the record to show that this fall had anything to do with Petitioner's use of side rails. The surveyors alleged also that the resident sustained a fall on June 30, 1995, while in the shower. Id. There is no evidence that the resident was restrained on this occasion.

I do not find that HCFA established a prima facie case that Petitioner applied restraints for improper purposes, either in the case of Resident 17, or in the case of Resident 26. The report of the July 17 - 21, 1995 survey does not allege that Petitioner applied restraints to these residents for improper purposes. HCFA Ex. 5, at 5. Petitioner did not receive timely notice of HCFA's assertion that Petitioner failed to assess the residents for use of restraints.

ii. Tag 223 (HCFA Ex. 5, at 7 - 9).

The allegations which the surveyors made under this tag relate to the requirement of 42 C.F.R. § 483.13(b), which states that a resident has the right to be free from verbal, sexual, physical, and mental abuse, corporal punishment, and involuntary seclusion. The surveyors who participated in the July 17 - 21, 1995 survey alleged that four of 29 sampled residents were being neglected, as was evidenced by Petitioner's alleged failure to provide services to avoid physical harm or mental anguish. HCFA Ex. 5, at 7.

The allegation is somewhat awkwardly phrased. The regulation does not prohibit mere neglect (neglect is addressed elsewhere in regulations that govern quality of life and quality of care). However, it is evident that where a facility systematically neglects the needs and care of a resident, that neglect may rise to the level of abuse. I conclude that this is what the surveyors meant when they used the word "neglected" in their survey report.

The evidence establishes that Petitioner failed to comply with this requirement as respects the care that it provided to one resident, Resident 6. I am not persuaded that the other allegations of abuse made by the surveyors are substantiated.

I do not find that the preponderance of the evidence establishes that Petitioner abused Resident 2. The gravamen of the surveyors' allegations concerning the care that Petitioner gave to this resident is that it, in effect, secluded the resident. HCFA Ex. 5, at 7 - 8. The evidence establishes that the resident preferred to remain in her room and preferred the use of a bedpan to using the bathroom. Tr. at 164; 348 - 349. There is nothing to suggest that Petitioner forced these choices on the resident. Arguably,

Petitioner might have encouraged the resident to function at a higher level. However, I do not find its failure to have done so constitutes abuse of the resident.

I find that Petitioner failed to give requisite attention to the needs of Resident 6, to the extent that Petitioner, in effect, secluded the resident. The credible testimony of Ms. Gonzalez is that the resident was allowed to stay by herself in her room for a three-hour period. Tr. at 166. Petitioner challenges this testimony as being unlikely, but has not come forward with persuasive evidence which rebuts it.

I do not find that Petitioner failed to give requisite attention to the needs of Resident 8, to the extent that Resident 8 was abused. The surveyors' allegations of abuse of Resident 8 are premised on Ms. Gonzalez' testimony that a tray of food was left at the resident's bedside while the resident was restrained and that the resident was observed to be uncovered. Although I agree that this is not an appropriate practice for a facility to engage in with a resident who is restrained, I am not persuaded that it rises to the level of abuse of a resident. As for the resident becoming uncovered, the credible evidence is that the resident often would uncover himself, due to his irrational movements and thrashing. Tr. at 367.

I do not find that HCFA established a prima facie case of abuse with respect to Resident 20. The surveyors' allegations of abuse seem to be that the resident was not provided with proper nutrition by Petitioner. HCFA Ex. 5, at 8 - 9. To be sure, deprivation of nutrition, if demonstrated, would constitute abuse. However, HCFA has offered no evidence to establish the cause of the resident's malnutrition. Id.

iii. Tag 225 (HCFA Ex. 5, at 9 - 10).

Under tag 225, the surveyors alleged noncompliance by Petitioner with the requirements of 42 C.F.R. § 483.13(c)(1)(ii). This regulation prohibits a long-term care facility from employing an individual who has been found guilty of abusing, neglecting, or mistreating a resident by a court of law, or has had a finding entered against him or her in a State nurse aide registry concerning neglect, abuse, or mistreatment of a resident, or misappropriation of a resident's property.

I do not find that HCFA established a prima facie case that Petitioner failed to comply with this requirement. The surveyors based their allegation of noncompliance on the fact that Petitioner had hired nurse's aides without performing required background checks of these aides. Petitioner has not denied this fact. However, a failure by a facility to perform a required check of an employee's background is not tantamount to saying that the facility has employed an individual with a tainted past. The regulation does not, on its face, state that a facility will be found to be in violation where it fails to perform background checks of its employees. While interpreting the regulation to

require such checks might not be unreasonable, HCFA has not shown that it gave Petitioner notice of this interpretation prior to holding Petitioner accountable to it.

iv. Tag 241 (HCFA Ex. 5, at 10 - 14).

The surveyors who conducted the July 17 - 21, 1995 survey of Petitioner made their allegations of deficiencies under tag 241 in relation to a participation requirement that is stated in 42 C.F.R. § 483.15(a). The section is a subpart of a regulation which governs the quality of life that a facility must give to its residents. The section provides that a facility must promote care for residents in a manner and in an environment that maintains or enhances each resident's dignity and respect in full recognition of the resident's individuality.

The surveyors alleged that nine of 29 residents whose care the surveyors reviewed did not receive care in a manner which promoted dignity and respect. I find that HCFA established that in some instances, but not in all of the instances that were alleged by the surveyors, Petitioner failed to respect adequately the dignity of its residents.

I sustain certain of the allegations of failure to respect residents' dignity that the surveyors made concerning Residents 11, 16, 22, 8, 9, and 7. HCFA established prima facie cases of derelictions of care concerning these residents which Petitioner did not rebut by the preponderance of the evidence. I am persuaded by the surveyors' report and the testimony of surveyors that Residents 11, 16, and 22 were left essentially unattended by Petitioner's staff for long periods of time. HCFA Ex. 5, at 11 - 12. Petitioner has not effectively refuted these allegations. I am persuaded also that Petitioner's staff tolerated Residents 8 and 9 being exposed to the view of staff and other residents in states of undress. Finally, I am persuaded that Petitioner's staff did not make adequate efforts to communicate with Resident 7.

I do not sustain allegations that Petitioner was derelict in its care of Resident 2. As I have described above, the isolation that this resident experienced appears largely to have been self-imposed. Nor do I sustain allegations that Residents 18 and 9 were improperly dressed by Petitioner's staff. The preponderance of the evidence is that these residents' dress, while arguably inappropriate, was dictated by members of the residents' families.

v. Tag 248 (HCFA Ex. 5, at 14 - 15).

The allegations which the surveyors made under tag 248 are based on the requirement stated in 42 C.F.R. § 483.15(f)(1). This section provides that a long-term care facility must provide for each resident an ongoing program of activities designed to meet the

interests and the physical, mental, and psychosocial well-being of the resident in accordance with the resident's comprehensive assessment.

The surveyors alleged that, for nine of the 29 residents that were surveyed, Petitioner did not provide ongoing activities involving staff other that Petitioner's activities director. HCFA Ex 5, at 14.

I sustain the allegations that the surveyors made with respect to Residents 6, 12, 13, 20, 22, and 26. The allegations which the surveyors made, which Petitioner did not rebut credibly, essentially are that these residents either were left alone for long periods or were not exposed to suitable group activities. HCFA Ex. 5, at 14 - 15.

I do not sustain similar allegations by the surveyors concerning Residents 2, 3, and 8. It is apparent from the record that each of these residents manifested conditions which made the resident unsuitable for the kinds of activities programs that surveyors asserted they should be involved in.

vi. Tag 309 (HCFA Ex. 5, at 15 - 18).

The allegations which the surveyors made under tag 309 are based on the requirements of 42 C.F.R. § 483.25. This regulation states that each resident must receive, and a long-term care facility must provide, the necessary care and services for the resident 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 surveyors who conducted the July 17 - 21, 1995 survey of Petitioner alleged that seven of 29 residents whose treatment was reviewed did not receive the care necessary to maintain or reach their highest practicable level of physical well-being. HCFA Ex. 5, at 16.

I sustain these allegations. The credible allegations of the surveyors are that none of the seven residents whose care is discussed under this tag received assistive devices or other supports that were prescribed in their plans of care. Petitioner has not expressly denied these allegations.

vii. Tag 314 (HCFA Ex. 5, at 18 - 20).

The surveyors' allegations under tag 314 are based on the requirements of 42 C.F.R. § 483.25(c). This requirement states that:

> Based on the comprehensive assessment of a resident, the facility must ensure that --
>
> (1) a resident who enters the facility without pressure sores does not develop pressure sores unless the individual's clinical condition demonstrates that they were unavoidable; and
>
> (2) a resident having pressure sores receives necessary treatment and services to promote healing, prevent infection and prevent new sores from developing.

The surveyors alleged that four of 29 residents whose care the surveyors reviewed developed pressure sores in Petitioner's facility under circumstances where the was no clinical condition manifested by each of these residents that demonstrated that the development of a pressure sore was unavoidable. HCFA Ex. 5, at 19. The surveyors made these allegations with respect to Residents 3, 21, 13, and 20.

The plain language of the regulation imposes on a facility the burden to do whatever is reasonably necessary to avoid the development of pressure sores in its residents. And, the regulation imposes on a facility the burden of establishing that the development of a sore by a resident is unavoidable.

I sustain the surveyors' allegations. The weight of the evidence is that each of the four residents in question developed a pressure sore while residing at Petitioner's facility. Petitioner had not adduced credible evidence to show that the development of pressure sores by these residents was unavoidable.

The surveyors found that Resident 3 developed a Stage II pressure sore about 10 days after becoming a resident at Petitioner's facility. HCFA Ex. 5, at 19. Petitioner asserts that the sore did not develop due to improper care by Petitioner. Specifically, Petitioner asserts that the sore was not a consequence of improper use of restraints in the case of Resident 3. That may be true, but it begs the question of whether the sore that Resident 3 developed was unavoidable.

Resident 21 developed a pressure sore on May 19, 1995, several years after becoming a resident at Petitioner's facility. HCFA Ex. 5, at 19. Petitioner asserts that the development of the sore was unavoidable. I have considered the evidence cited by

Petitioner to support this assertion and I find it not to be persuasive. See P. Ex. 1, at 644 - 645; 649; Tr. at 465 - 466.

Additionally, I sustain the surveyors' allegations concerning Residents 13 and 20. In neither case did Petitioner establish why the pressure sores these residents developed were unavoidable.

viii. Tag 316 (HCFA Ex. 5, at 20 - 22).

Under this tag, the surveyors cited to the requirement stated at 42 C.F.R. § 483.25(d)(2). This requirement is that a resident who suffers from bladder incontinence must receive appropriate treatment and services to prevent urinary tract infections and to restore as much normal bladder function as possible.

The surveyors who conducted the July 17 - 21, 1995 survey of Petitioner found that Petitioner was derelict in the care it provided under this requirement with respect to the care it provided to four of the 29 residents whose care the surveyors reviewed. I do not sustain these allegations.

The surveyors alleged that the Resident 3 was to have had a Foley catheter removed on July 11, 1995, but that the resident was still wearing the catheter as of July 17, 1995. HCFA Ex. 5, at 21. This allegation is not supported by the evidence. The credible testimony offered by Petitioner was that the catheter was removed as of July 11, but was reinserted at a later date for medical reasons. Tr. at 466 - 467.

The allegations that the surveyors made concerning Resident 6 are, essentially, that the resident was not toileted as often as the resident should have been. HCFA Ex. 5, at 21. Assuming the allegations to be true, they do not address the requirements under which the allegations are made.

With respect to Resident 27, the surveyors merely assert that the reasons for the resident's development of incontinence while a resident at Petitioner's facility were not documented. HCFA Ex. 5, at 21. I do not understand how this asserted failure, even if true, establishes a prima facie case of a deficiency under tag 316. Finally, with respect to Resident 8, the surveyors merely repeat excerpts from the resident's record which document the resident's incontinence. These statements do not, on their face, establish a deficiency in the care that Petitioner gave to the resident.

ix. Tag 319 (HCFA Ex. 5, at 22 - 24).

This tag addresses the requirements stated in 42 C.F.R. § 483.25(f)(1). The requirement is a subsection of 42 C.F.R. § 483.25(f). It provides that:

> Based on the comprehensive assessment of a resident, the facility must ensure that —
>
> (1) A resident who displays mental or psychosocial adjustment difficulty, receives appropriate treatment and services to correct the assessed problem, ...

The surveyors who conducted the July 17 - 21, 1995 survey alleged that seven of 29 residents whose care they reviewed did not receive appropriate treatment and services to correct assessed problems. HCFA Ex. 5, at 22.

I sustain the surveyors' allegations made under tag 319 with respect to residents 16, 11, 27, 22, and 26. With respect to each of these residents, the surveyors documented that care had been recommended for the resident which the resident did not receive. I do not sustain the surveyors' allegations made concerning residents 2 and 8. The record does not establish that Petitioner failed to provide care to Resident 2. As far as Resident 8 is concerned, the surveyors' allegations are incorrect. The allegations concerning Resident 8 hinge on the surveyors' conclusions that between July 7 and July 18, 1995 there was no documentation of behavior problems in the resident's record. HCFA Ex. 5, at 23 - 24. In fact, the record contains ample documentation of erratic and irrational behavior by Resident 8 which predated his stay at Petitioner's facility and which continued during the resident's stay at Petitioner's facility.

x. Tag 324 (HCFA Ex. 5, at 24 - 25).

The allegations made under tag 324 are based on the participation requirement that is contained in 42 C.F.R. § 483.25(h)(2). This requirement states that a facility must ensure that each resident receives adequate supervision and assistance devices to prevent accidents. The surveyors alleged that four of the 29 residents whose care they reviewed did not receive adequate supervision, which resulted in the residents having accidents. HCFA Ex. 5, at 25.

I do not find Petitioner to have been deficient under this requirement. The surveyors did not offer prima facie evidence that failures by Petitioner caused any of the four residents in question to sustain accidents. It is simply speculation on the part of the surveyors to attribute the accidents that these residents suffered to derelictions in care by Petitioner.

xi. Tag 353 (HCFA Ex. 5, at 25 - 26).

The surveyors alleged under tag 353 that Petitioner maintained inadequate staff to discharge its functions. I do not sustain this allegation. Although I agree with HCFA that Petitioner's staff was deficient in delivering services to residents of Petitioner, there is not sufficient credible evidence of record to support a conclusion that Petitioner's derelictions of care were due to a staffing shortage. From the record of this case, the derelictions of care could as easily be attributed to inadequate training or supervision of staff as they could be attributed to staffing shortages.

xii. Tag 364 (HCFA Ex. 5, at 27).

Under this tag, the surveyors alleged that Petitioner was deficient in the care that it gave to Resident 27. The surveyors asserted that the resident was served food that was cold to the touch. I sustain this allegation. Petitioner has not denied it, except to assert that any harm occasioned by the failure of Petitioner to serve warm food to the resident caused the resident to experience minimal harm.

xiii. Tag 441 (HCFA Ex. 5, at 28 - 29).

Under tag 441, the surveyors alleged that Petitioner utilized poor infection control techniques in its handling of residents' linens, and in its general adherence to aseptic techniques. The surveyors made allegations that did not relate to specific residents. They alleged that, in changing residents' bed linens, Petitioner's staff placed pillows that had been used by a resident on another resident's bed. The surveyors also made specific allegations which addressed the care that Petitioner gave to Residents 28 and 29. HCFA Ex. 5, at 28 - 29.

I sustain the surveyors' allegations concerning the manner in which Petitioner's staff changed bed linens. Petitioner did not deny these allegations. I also sustain the allegations made concerning the care given to Resident 29. I do not sustain the allegations made concerning the care given to Resident 28. The gravamen of these allegations is that Petitioner had not implemented infection control procedures with respect to this resident. The allegation is refuted by the resident's treatment record. P. Ex. 1, at 400 - 411.

xiv. Tag 464 (HCFA Ex. 5, at 29 - 30).

The surveyors alleged that Petitioner did not provide sufficient space in its dining room to accommodate its residents during meal times. The surveyors alleged also that the handling of meals in the dining facility was coordinated poorly by Petitioner's staff. Petitioner did not dispute the surveyors' allegations. I note, however, that the severity

level attached to these allegations by the surveyors is so low that the allegations, if sustained, would not support the imposition of a civil money penalty against Petitioner. HCFA Ex. 5, at 29. For that reason, I make no Finding concerning these allegations.

xv. Tag 514 (HCFA Ex. 5, at 30 - 31).

Under tag 514, the surveyors alleged that the treatment records of five of the residents whose records they reviewed were not complete, accurately documented, or systematically organized. HCFA Ex. 5, at 30 - 31. The surveyors made these allegations pursuant to the clinical records maintenance requirement that is stated at 42 C.F.R. § 483.75(l)(1).

I do not sustain these allegations. I find that Petitioner offered clinical records for its residents adequate to meet the requirements of the regulation. Alternatively, I find that Petitioner gave satisfactory explanations for the absence of clinical records in certain cases. For example, in the case of Resident 11, the surveyors charged Petitioner with failure to maintain records of the resident's visits with a physician. As Petitioner explained, the resident was taken by a family member to see a private physician, and Petitioner was unable to obtain copies of the physician's records.

f. Petitioner's degree of culpability (42 C.F.R. § 488.438(f)(4)).

Petitioner manifests a high degree of culpability for the deficiencies that were established at the July 17 - 21, 1995 survey of Petitioner. The deficiencies are not simply isolated derelictions of care. Taken together, they show that Petitioner and its staff were not diligent in meeting their fundamental responsibility to residents that the residents be treated compassionately and with dignity.

/s/

Steven T. Kessel
Administrative Law Judge