Department of Health and Human Services

DEPARTMENTAL APPEALS BOARD

Civil Remedies Division

In the Case of:	)	
	)	
South Valley Health Care Center,	)	Date: March 27, 1998
	)	
Petitioner,	)	
	)	
- v. -	)	Docket No. C-96-447
	)	Decision No. CR526
Health Care Financing	)	
Administration.	)	
	)	

DECISION

I decide that South Valley Health Care Center, Petitioner herein, was not in substantial compliance with 42 C.F.R. § 483.25(c) (pertaining to the prevention and treatment of pressure sores),[1] one of the requirements for participation in the Medicare program, during the period from February 29, 1996 to June 24, 1996. I decide also that the Health Care Financing Administration (HCFA) is authorized to impose a civil money penalty (CMP) against Petitioner in the amount of $400 per day for each day beginning February 29, 1996 through June 23, 1996. In so doing, I decide that the amount of the CMP previously imposed by HCFA, in the amount of $1300 per day, is not reasonable.

I. Background facts and procedural history.

Petitioner is a nursing facility and skilled nursing facility (SNF) located in West Jordan, Utah. It has at all times relevant hereto participated in the Medicare program as a provider of medical services, and, as such, is subject to the provisions of the Social Security Act (Act) and the regulations which govern participation in the Medicare program.

On February 29, 1996, the Utah Department of Health (State survey agency) conducted a survey of Petitioner on behalf of HCFA to determine whether Petitioner was complying substantially with Medicare participation requirements. Based on the

[1] In this decision, I may refer to pressure sores also as "wounds" or "decubitus ulcers."

findings of the surveyors, the State survey agency determined that Petitioner was not in substantial compliance with Medicare participation requirements, and it advised Petitioner that if the deficiencies were not corrected by May 29, 1996, it would recommend to HCFA that the following remedies be imposed:

- A CMP of $2720 per day, commencing February 29, 1996
- Termination (of the provider agreement), effective May 29, 1996
- A Directed Plan of Correction

HCFA Ex. 1.[2]

Petitioner submitted a plan of correction on April 1, 1996,[3] and, on April 18, 1996, it submitted a credible allegation of compliance, stating that Petitioner would be in compliance with Medicare participation requirements as of May 20, 1996. HCFA Ex. 3.

According to undisputed testimony adduced at the trial of this matter, the State survey agency advised Petitioner by telephone on April 17, 1996 that its plan of correction had been accepted. Tr. at 285. By letter dated May 20, 1996, the State survey agency sent a formal notice to Petitioner that its plan of correction had been accepted. HCFA Ex. 4. The notice advised Petitioner that, based on its allegation of compliance, it would be presumed that the facility had achieved substantial compliance with Medicare participation requirements as of May 20, 1996, unless a subsequent follow-up survey showed otherwise. Thus, only in the event that a subsequent survey showed otherwise, would penalties be imposed.

The record shows that the State survey agency actually conducted two follow-up (revisit) surveys in this case. The first revisit by State surveyors began on May 21, 1996 and concluded on June 10, 1996. Tr. at 293. The second revisit survey occurred on August 6, 1996. Tr. at 294.

Although Petitioner had been cited for numerous deficiencies following the initial survey in February 1996 (HCFA Ex. 1), the State surveyors reported only one deficiency following their first revisit concluding in June 1996. Specifically, on June 17, 1996, the State survey agency notified Petitioner that it was not in substantial

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[2] Throughout this decision the following abbreviations will be used for purposes of reference
Transcript - Tr. at (page);
Petitioner's Brief - P. Br. at (page);
HCFA's Brief - HCFA Br. at (page);
HCFA's Exhibits - HCFA Ex. (number) at (page);
Petitioner's Exhibits - P. Ex. (number) at (page).

[3] Amendments to the plan of correction were submitted on April 17, 1996. HCFA Ex. 2 at 87.

compliance with the participation requirement found at 42 C.F.R. § 483.25(c) (relating to the prevention and treatment of pressure sores), and that, as a result, the State survey agency would recommend that HCFA impose penalties. HCFA Ex. 5. Among the recommendations for penalties (and the only one at issue in this proceeding) was a recommendation that HCFA impose a CMP in the amount of $1290 per day, effective February 29, 1996. The State survey agency further advised Petitioner as follows:

> [t]his Civil Money Penalty is reduced from the amount proposed in our letter of March 20, 1996 based on the decrease in level of non-compliance and the number of residents who were effected by your non-compliance.

Id. at 1.

The State survey agency also recommended imposition of a Directed Plan of Correction.

On July 10, 1996, HCFA notified Petitioner that, based on the recommendations of the State survey agency and the survey findings, it was imposing a CMP in the amount of $1300 per day, effective February 29, 1996, for each day Petitioner was found not to be in compliance with Medicare participation requirements. HCFA Ex. 7.[4] HCFA also notified Petitioner that the remedy of a Directed Plan of Correction was imposed, effective July 2, 1996. Id.

On July 23, 1996, Petitioner filed its Credible Allegation of Compliance with the Directed Plan of Correction, alleging that it was in substantial compliance with Medicare participation requirements as of June 11, 1996 (the day following the first revisit survey), but at the same time maintaining that it was actually in substantial compliance as of May 20, 1996. HCFA Ex. 8.

On August 6, 1996, the State survey agency conducted its second revisit survey. On September 9, 1996, it notified Petitioner that, as a result of the second revisit survey, Petitioner had been found to be in substantial compliance with Medicare participation requirements as of June 24, 1996. HCFA Ex. 10.

On September 10, 1996, Petitioner filed a timely request for hearing, challenging the finding that it was not in substantial compliance with the participation requirements set forth in 42 C.F.R. § 483.25(c) and further challenging the reasonableness of the amount of the CMP imposed.

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[4] HCFA rounded off the State survey agency's recommendation for a CMP of $1290 per day to one of $1300 per day, as the State Operations Manual requires the imposition of penalties in $50 increments. Tr. at 449; HCFA Ex. 10 at 3.

On October 21, 1996, HCFA advised Petitioner that the amount of the CMP to be imposed in this case was $150,800, computed at $1300 per day for 116 days, beginning February 29, 1996 and extending to June 24, 1996. HCFA Ex. 11.

This case was ultimately assigned to me. Following a prehearing conference held in June 1997, I issued two rulings; the first, defining issues to be resolved at hearing and the second, ruling on certain objections raised by HCFA to Petitioner's prehearing submissions. Those rulings have heretofore been made a part of the record in this case, and are incorporated herein for reference.

A hearing was held in this case in Salt Lake City, Utah, from September 16 - 19, 1997. At that hearing, I admitted into evidence HCFA Ex. 1 - 42, which had been previously submitted and one additional exhibit, a document styled South Valley DQ Focus, as HCFA Ex. 43. Further, I admitted into evidence P. Ex. 1 - 3, consisting of: a letter from Dr. Dan Purser, dated May 29, 1996 (P. Ex. 1); a letter from Dr. Michael Jensen, dated May 29, 1996 (P. Ex. 2); and a page of Dr. Purser's physician's notes (P. Ex. 3).

I make my decision herein based upon the entire record before me, including prehearing and posthearing briefs submitted by the parties, the documentary evidence, and the testimony adduced at hearing.

II. Governing law and authority.

Under federal law, Petitioner is classified as a long-term care facility (and is a SNF under section 1819 of the Act and a nursing facility under section 1919 of the Act). 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 a CMP against a long-term care facility for failure by the facility to comply substantially with participation requirements. These sections state, in effect, that the Secretary's authority to impose a CMP against a long-term care facility is derived from the CMP authority that is conferred on the Secretary 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: "[t]he 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 - 488.335. Under the Part 488 regulations, a state or HCFA may impose a CMP 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.

A CMP may start accruing as early as the date that the facility was first out of compliance, as determined by HCFA or the state, and continues, as applicable in this case, until the facility achieves substantial compliance. 42 C.F.R. § 488.440(a) and (b).

Penalty amounts fall into two broad ranges. The lower range, $50 - $3000 per day, is imposed for deficiencies that do not constitute immediate jeopardy, but either caused actual harm, or caused no actual harm, but have the potential for causing more than minimal harm. 42 C.F.R. § 488.438(a)(2). The higher range, $3050 - $10,000 per day, is assessed where there is a finding of immediate jeopardy or, in some instances, of repeated deficiencies. 42 C.F.R. § 488.438(a)(1). In the present case, HCFA assessed a penalty falling within the lower range, based upon a finding that the facility's deficiency resulted in an isolated instance of actual harm to a resident. Tr. at 280.

Once HCFA or the state makes a determination as to the range of penalty applicable to the circumstances of a particular case, it must then make a determination as to the amount of a penalty to assess within that given range. In determining the amount of a penalty, the Secretary has directed that HCFA or the state must take into account the following factors: (1) the facility's history of noncompliance, including repeated deficiencies; (2) the facility's financial condition; (3) the scope and severity of the offense as set forth at 42 C.F.R. § 488.404; and (4) the facility's degree of culpability, including, but not limited to, neglect, indifference, or disregard for resident care, comfort, or safety. Absence of culpability is not a mitigating circumstance in reducing the amount of the penalty. 42 C.F.R. § 488.438(f).

A long-term care facility against whom HCFA has determined to impose a CMP is entitled to a hearing before an administrative law judge. Section 1128A of the Act provides that the Secretary shall not impose a CMP against an individual or entity until that individual or entity has been given written notice and an opportunity for a hearing. Act, section 1128A(c)(2). The right to a hearing has been interpreted uniformly to confer on a party against whom the Secretary has determined to impose

a CMP 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. Keszler, M.D., et al., DAB CR107 (1990). At such a hearing, the administrative law judge has jurisdiction to consider two issues: whether or not HCFA has established a basis for imposition of the penalty; and, whether or not the amount of the penalty is reasonable. 42 C.F.R. § 488.438(e). The regulations further provide that HCFA will establish a basis for imposition of a CMP when it is established that a facility is not in substantial compliance with one or more participation requirements. 42 C.F.R. § 488.430(a). Once it is determined that a basis exists for the imposition of a CMP, the administrative law judge may review the reasonableness of the penalty, taking into consideration the factors specified at 42 C.F.R. § 488.438(e)(3), and (f). Inasmuch as the facility is granted a de novo hearing, the administrative law judge has authority to impose a penalty for an amount which is less than that which HCFA determines to impose, where the amount that is determined by HCFA is not reasonable.

I previously ruled in this case that HCFA has the burden of going forward with evidence to establish a prima facie case that a basis exists for the imposition of a CMP, i.e., that the facility is/was not in substantial compliance with one or more participation requirements. I further ruled that, once HCFA establishes a prima facie case, the ultimate burden of proof rests with Petitioner to show that it was at all times relevant hereto in substantial compliance with Medicare participation requirements. In that ruling, I relied on a decision by an appellate panel of the Departmental Appeals Board in the case of Hillman Rehabilitation Center, DAB No. 1611 (1997). Although Petitioner objected and continues to object to that ruling, it has presented no convincing authority to the contrary. Accordingly, that ruling is maintained for purposes of this decision. In my prior ruling, I did not address the issue of the burden of proof with respect to the reasonableness of the CMP. However, I did rule that Petitioner has the burden of proving any affirmative defenses it might raise. With respect to the issue of the amount of the CMP, I hereby rule that, inasmuch as 42 C.F.R. § 488.438(f) provides that HCFA or the State must take into consideration the specific factors set forth in that regulation in establishing the reasonableness of the CMP, HCFA and/or the State have an affirmative duty to show that they complied with the regulation. In the event Petitioner believes HCFA considered the required factors erroneously, the burden of proof rests with Petitioner to prove the truth of its assertion.

I also previously ruled that, due to the specific language used by HCFA in its notice of imposition of the CMP in this case, the sole issue before me with respect to the establishment of a basis for imposing a CMP was whether or not Petitioner failed to comply with the participation requirements set forth at 42 C.F.R. § 483.25(c) relating to the prevention and treatment of pressure sores. HCFA has noted its objection to that ruling, citing Desert Hospital, DAB CR448 (1996), rev'd and remanded, DAB No. 1623 (1997). I believe my prior ruling in this matter is correct, and I maintain that ruling as the governing law for this proceeding. I have reviewed the appellate

decision in Desert Hospital, but find that the facts in that case are so dissimilar to the facts before me in this case as to make the decision in Desert Hospital inapplicable.

I will not attempt to repeat herein my previous ruling, as it speaks for itself. Briefly, however, the facts in this case are that there was an initial survey which found a number of deficiencies. The State advised Petitioner that if those deficiencies were not corrected by a date certain, a CMP would be imposed. After a resurvey, one deficiency remained uncorrected and HCFA imposed a CMP, reduced from the State survey agency's original recommendation because the scope and severity of the deficiencies previously found was reduced. HCFA contends that the basis for imposition of the CMP is that deficiencies were found on both surveys, not just the single deficiency found after the resurvey. I ruled otherwise, given that: the State survey agency advised that no penalty would be imposed if all the deficiencies were corrected; HCFA did not allege that more than one deficiency remained uncorrected; and HCFA reduced the amount of the penalty to reflect that there was but one remaining deficiency. I ruled then that the one remaining deficiency constituted the basis for the CMP.

The remedy in Desert Hospital did not involve a CMP, but, rather, was an action wherein HCFA sought to impose a denial of payment for new admissions. Unlike the present case, the facility was not given the opportunity to correct its deficiencies. Also unlike the present case, the facility admitted that it was not in substantial compliance with participation requirements. In Desert Hospital, HCFA's notice of imposition of remedies set forth two findings of substandard quality of care but also went on to say that HCFA was basing its action upon current **and past** (emphasis added) noncompliance with Medicare requirements. The appellate panel said that, read together, the plain implication of two sentences in HCFA's notice letter, one specifically referring to two findings of substandard quality of care, and the second referring to other findings of noncompliance, was that HCFA was basing its remedies on something more than the two enumerated findings of substandard quality of care, and that the notice of those findings is to be found in the statement of deficiencies. The language in the Desert Hospital notice is quite different from that in the present case. In addition, in the present case, if HCFA's notice incorporates the notice given by the State survey agency's statement of deficiencies, the said statement of deficiencies only gives notice of one deficiency at the time of the resurvey, following which HCFA imposed its penalty. Perhaps of greatest importance to my ruling in this matter is that if, at the time of the first revisit to South Valley, the surveyors had found no deficiencies, it is clear that no penalty would have been imposed. In Desert Hospital, however, HCFA made no such assurances. For the aforesaid reasons, I maintain my prior ruling with respect to the issues in this case.

Finally, with respect to the law governing this proceeding, I note that Petitioner contends, "[n]o definition has been provided, either by statute, regulation, or otherwise, and no attempt has been made to illuminate the Court as to what the term [substantial compliance] means in the context of deficiencies." P. Br. at 12. Counsel

for Petitioner then proceeds to provide the illumination he deems necessary, by defining substantial compliance to be compliance which is "largely but not wholly" met. P. Br. at 14. While I am appreciative of counsel's efforts to instruct, the regulations define the term "substantial compliance" 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.

By definition, if the government establishes in this case that Petitioner caused actual harm to a resident, even though it might be only one of more than a hundred residents, Petitioner is not in substantial compliance with participation requirements. A finding of actual harm is far more serious than a finding that there is "the potential" for causing minimal harm.

The regulations at 42 C.F.R. § 483.1 et. seq., "contain the requirements that an institution must meet in order to qualify to participate as a SNF in the Medicare program, and as a nursing facility in the Medicaid program. They serve as the basis for survey activities for the purpose of determining whether a facility meets the requirements for participation in Medicare and Medicaid."

42 C.F.R. § 483.25 provides in relevant part as follows:

> [e]ach resident must receive and the facility must provide the necessary care and services to attain or maintain the highest practicable physical, mental, and psychosocial well-being, in accordance with the comprehensive assessment and plan of care . . .
>
> > (c) **Pressure sores.** 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.

III. Issue.

The issue in this case is whether or not Petitioner was in substantial compliance with 42 C.F.R. § 483.25(c) as of the date of the initial survey, February 29, 1996, and, if

not, whether the facility was in substantial compliance with the said requirement of participation on or before May 20, 1996, the date the facility alleged it would be in substantial compliance. If it is established that the facility was not in substantial compliance with the above regulation on or before May 20, 1996, a further issue in this case is whether or not the amount of the CMP imposed by HCFA against the facility is reasonable.

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, and, thereafter, discuss each Finding in detail.

IV. Findings and Discussion.

Finding 1. Petitioner was not in substantial compliance with the requirements of 42 C.F.R. § 483.25(c) as of the date of the initial survey, February 29, 1996.

Deon Egbert testified that on February 29, 1996, and at all times relevant hereto, she was a Registered Nurse employed by the State of Utah as a team leader/health facility surveyor. On February 29, 1996, she was a member of the survey team that surveyed Petitioner's facility for compliance with Medicare participation requirements. Tr. at 23 - 24, 26. She testified that the survey team identified three residents who entered Petitioner's facility without pressure sores, but subsequently developed them. Tr. at 27. Those residents were identified as residents 71 (Tr. at 29, 32); 104 (Tr. at 36, 37); and 2 (Tr. at 42). See also HCFA Ex. 2 at 50 = 52.

The evidence offered by Ms. Egbert indicates that not only did these residents develop pressure sores while in Petitioner's facility, but Petitioner failed to provide the proper care and treatment of those wounds. With respect to Resident 71, Ms. Egbert testified that the resident's physician had ordered the application of a substance called duoderm for treatment of the resident's two pressure sores. She testified that the facility did not follow the doctor's orders in either instance. Tr. at 35.

With respect to Resident 104, Ms. Egbert testified that the physician had ordered application of duoderm to the wound, but the physician's order was not followed. She testified that the resident's physician had ordered a serum albumin test on February 16, 1996, but that as of February 20, 1996, the test had not been performed. Tr. at 39 - 41.

With respect to Resident 2, Ms. Egbert testified that the resident's physician had ordered application of duoderm to the resident's pressure sore. She observed the resident twice, on February 20, 1996 and again on February 21, 1996, and on both occasions the resident had "nothing" on the pressure sore. Tr. at 42.

While there was some evidence adduced at trial which tended to explain or rebut some of the other findings of the surveyors with respect to the above residents, Petitioner did not offer any evidence to rebut the surveyor's findings that the facility had failed to follow the physician's prescribed treatment with respect to each of the above residents. Thus, I find that these three residents did not receive the necessary treatment for their pressure sores, as ordered by their physicians, to promote healing, prevent infection, and prevent new pressure sores from developing.

Further, Petitioner did not present any evidence with respect to these three residents to rebut the surveyor's findings that these three residents were admitted to the facility without pressure sores, but later developed those sores while in the facility. Petitioner offers no evidence to show that the development of these pressure sores was unavoidable.

Accordingly, the evidence offered by HCFA clearly establishes that as of February 29, 1996, Petitioner was not in substantial compliance with the above Medicare participation requirement.

Ms. Egbert was also asked whether the facility had any quality assurance in place for resident skin checks. She testified that the facility was not consistently "looking through" the skin checks and that no consistent nurse was doing them. Tr. at 47. This evidence, too, was unrebutted by Petitioner.

Finding 2. Petitioner did not fully implement its plan of correction or come into substantial compliance with 42 C.F.R. § 483.25(c) as of May 20, 1996.

Following the February 1996 survey, the facility submitted a plan of correction to the State survey agency, which was accepted by the State, and the facility then advised the State survey agency that it had implemented its plan of correction and would be in substantial compliance by May 20, 1996. HCFA Ex. 2, 3.

The facility's plan of correction essentially stated it would take the following actions:

1. Counsel nurses to follow doctors' orders.

2. Do weekly skin checks and note any skin excoriation or beginning of breakdown.

3. Involve the dietary department, so that high risk residents can be provided with proper nutrition to promote healing and prevent skin breakdown.

4. Conduct a series of inservice training sessions for staff on skin care, wound prevention, and related matters.

5. Establish a wound care team consisting of the Physical Therapist, Risk Management Supervisor, Dietary Supervisor, Medical Director (when available), and the Director of Nursing (D.O.N.).

6. The Wound Care Team will develop treatment protocols and individual wound treatment plans for residents, notify physicians if treatment is not successful, and further intervene as indicated.

7. The Wound Care Team and Charge Nurses will monitor the program through observation and audits.

HCFA Ex. 2 at 50, 51.

Lycrisia Tone, team leader for the February survey, summarized the team's findings as follows: "[t]he team determined that the facility did not have in place a system for preventing pressure sores and a system for the residents who had pressure sores to promote healing of these pressure sores." Tr. at 276 - 279.

Based upon the plan of correction and the facility's credible allegation that it would be in substantial compliance by May 20, 1996, the State survey agency notified Petitioner that it would revisit the facility, and that if the revisit showed that the facility was in substantial compliance as of May 20, 1996, and that it had maintained substantial compliance, it would not recommend the imposition of remedies to HCFA. HCFA Ex. 4.

The State survey agency did conduct a follow-up survey of the facility on May 21, 1996, which was extended to June 10, 1996. HCFA Ex. 8; Tr. at 292. Ms. Tone testified that she continued to be the survey team leader at the time of the revisit and she testified that the team concluded that the facility had not followed its plan of correction. Tr. at 291. Specifically, Ms. Tone stated:

1. Skin checks were not being done on a weekly basis, and they were not accurate.

2. All of the inservices which the facility said it would conduct were not completed or done.

3. The skin care team was not a functioning team that assessed weekly skin checks.

4. The skin check program was not being monitored because the facility was unaware that skin checks were not being done weekly.

5. Resident 23 developed a new pressure sore between the time of the initial survey and the revisit.

Tr. at 291.

Since Petitioner contends that it was in substantial compliance with Medicare participation requirements, and that it had followed its plan of correction by May 20, 1997, I will discuss the evidence pertaining to each alleged deficiency.

Allegation 1. Skin checks were not being done on a weekly basis and they were not accurate.

> **Finding 2(A). The facility had a systemic pressure sore care and documentation problem which was not corrected, pursuant to the plan of correction, by May 20, 1996, and the facility did not fully correct the problem or come into substantial compliance until sometime in June 1996.**

In its plan of correction, Petitioner assured the State survey agency that "[t]he staff will do weekly skin checks, and will note any skin excoriation or beginning of breakdown." HCFA Ex. 2 at 50.

Linda Boulden, one of the members of the State survey team, testified regarding HCFA Ex. 16, a pressure sore record of Resident 23, taken from the facility's medical records. The pressure sore record indicates that the nurses noted what was described as a Stage II decubitus ulcer (pressure sore) on April 22, 1996, located on the inner knee area on the inside of the right leg. The wound is first described as 2 cm by 2.25 cm, and is described as having no granulation tissue, no drainage, and no odor.

The same document, on the same day, describes the wound as 4 cm by 2 cm, with a depth of .1, and describes the wound as a Stage III, a larger, more serious wound.

On April 30, 1996, the wound is described as Stage III, but the size is measured at 2 cm by 1 cm, which would indicate that the pressure sore was reducing in size.

The next note is May 21, 1996, wherein the findings are reported as the same as on April 30, 1996.

Ms. Boulden testified that when she observed the pressure sore on May 20, 1996, the pressure sore appeared to be bigger than that which was reported. She estimated that it was around 4 cm by 3.5 cm. She testified further that the accurate documentation of a pressure sore's size is important for treatment, as it serves as a gauge for the effectiveness of treatment. Tr. at 140 - 147.

Ms. Boulden pointed out that, at one point, the facility described the resident as having a pressure sore on the left buttock, but also described what appeared to be the same pressure sore on the right buttock. HCFA Ex 15, 16; Tr. at 148, 149.

Ms. Boulden also pointed out, as another example of the facility's problems with skin check accuracy, that nurse's notes of April 4, 1996, HCFA Ex. 20, documented a pressure sore on the inner left leg. No reference is made to such a pressure sore on HCFA Ex. 16, the pressure sore tracking report. She testified that when she saw the resident in May, there was no indication of a pressure sore on his inner left leg and she expressed the opinion that he never had a sore at that location. Tr. at 151, 152. Counsel for Petitioner argued that it might simply mean that between April 4, 1996 and May 21, 1996, when Ms. Boulden saw the resident, the pressure sore had been treated and resolved. However, Petitioner offered no evidence to support this argument.

HCFA Ex. 23 is Petitioner's skin assessment record for Resident 23. Ms. Boulden testified that between March 16, 1996 and May 27, 1996, this skin assessment record indicates that Resident 23 did not receive skin assessments on a weekly basis. Further, she testified that the record does not consistently reflect whether his pressure sores were healing, were changing in size, or were infected. Ms. Boulden was asked if she had a problem with the facility's weekly skin assessment forms, and she replied,

> [y]es, I did . . . It was hard to track even what pressure sores were actually there. There's a lot of discrepancy from week to week. On one of the forms toward the end it speaks to a left heel pressure sore at a Stage 3. I interviewed both the physical therapist and nursing staff, and there was never a heel pressure sore on this resident, nor was there a heel pressure sore on my observation of his heels. It's a very inconsistent tracking. Tr. at 162 - 163.[5]

Petitioner offered no evidence to rebut or explain the various inconsistencies set forth above. It does not appear from the record that Resident 23 was receiving regular weekly skin checks as of May 20, 1996, and, given the inconsistencies in the record, it appears the skin checks which were done were not accurate.

Counsel for HCFA notes that the skin assessment form used for Resident 23 on May 27, 1996, (HCFA Ex. 23), changed sometime in June 1996, when the facility adopted use of a form which required more specific assessment and documentation. HCFA Ex. 29 contains an example of the new form, and, while it is similar to that which was in use prior to June 1996, it does appear to be more complete than its predecessor. Cathy Caimi, the D.O.N. at Petitioner's facility, testified that the weekly skin check form changed in June 1996. Tr. at 625. Accordingly, I find that the facility had a systemic pressure sore care and documentation problem which was not corrected, pursuant to the plan of correction, by May 20, 1996, and that the facility did not come into substantial compliance until sometime in June 1996.

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[5] It appears from the record that Resident 23 never had ulcers on his heels, but that, instead, information regarding Resident 23's roommate was placed on the wrong chart. Tr. at 248.

Allegation 2. All of the inservices which the facility said it would conduct were not completed or done.

Finding 2(B). The inservice training requirement was not satisfactorily met until June 19, 1996.

In its plan of correction, which was accepted and approved by the State survey agency, Petitioner promised that it would conduct inservices "on skin care and wound prevention." Further, Petitioner promised that it would teach the requirements for pressure release mattresses, stress the importance of peri care with each diaper change, and follow doctor's orders for wound care. HCFA Ex. 2 at 51.

It is clear from the record that the facility did conduct some inservice training, beginning as early as April 3, 1996. HCFA Ex. 32. Inservice programs were conducted, according to the record, in pertinent part, as follows:

4/03/96 - State survey findings/plan of correction
4/16/96 - Numerous topics, but including peri care with diaper changes
4/23/96 - Night shift nursing assistant job description
4/24/96 - NuBasics (dealing with nutrition)
4/25/96 - Skilled documentation, protocol manual, risk management for wt loss and wound healing
4/29/96 - Bowel and Bladder documentation, A&D ointment use
5/28/96 - Miscellaneous
5/30/96 - How to obtain complete orders, proper documentation
6/17/96 - Prevention and treatment of pressure ulcers
6/20/96 - Prevention of pressure sores
6/25/96 - Turning and positioning of residents
- Skin Care
7/03/96 - New weekly skin assessment forms
- Prevention of skin breakdown, wound treatments and dressings.

Petitioner attempted to show that all of the inservice programs it had promised in its plan of correction were completed by May 20, 1996. Ms. Caimi testified that all of the required inservice sessions were held under her direction and were completed prior to May 20.

Ms. Tone testified on behalf of the State survey team that they were looking for a "series" of inservices conducted by the nursing staff. Tr. at 361. They determined that the training held in June and July fulfilled the requirements for inservice training contained in the plan of correction. The record contains a note dated August 6, 1996 that interviews with the facility staff indicated that they had a good working knowledge of skin care issues. HCFA Ex. 10 at 2.

Based upon the documentation and testimony adduced at the hearing, it is clear that Petitioner did conduct some inservice training on the relevant issues prior to May 20, 1996. The issue is whether or not that training was adequate to fulfill Petitioner's obligations under the plan of correction. The State survey agency wasn't convinced that it was sufficient, and, indeed, the inservice training conducted beginning on June 17, 1996, appears to be much more specific and focused on wound care and prevention than do those which preceded that date. Some discretion must be accorded the State survey agency in determining whether or not training which is offered by a facility is adequate to meet the needs of a plan of correction. They are, after all, the health care professionals in the best position to assess the training in relation to the plan of correction. The accepted plan of correction, however, did not require that the facility conduct a "series of inservice training." It appears to me that while the inservice training requirement was not satisfactorily met on May 20, 1996, it was so met beginning June 17, 1996, the date of the first inservice focused solely on wound care and prevention.

Allegation 3. The skin care team was not a functioning team that assessed weekly skin checks.

> **Finding 2(C). The facility did not implement its plan of correction with respect to establishing a wound care protocol until June 3, 1996 and did not establish a functioning wound team evaluation process under that protocol until July 19, 1996.**

The facility's plan of correction stated that the facility's wound care team "will be developing individual wound treatment plans for individual residents, treatment protocols, notification to Dr. if treatment is not successful and further intervention [a]s indicated." HCFA Ex. 2 at 51.

Ms. Caimi testified that a new wound care protocol was adopted by the facility on April 25, 1996 and that she personally conducted an inservice for the staff on that date. Tr. at 575, 576. A written wound care protocol bearing that date is not contained in the evidence of record.

Ms. Tone testified that the protocol is important because it identifies the system the facility staff will follow in the assessment, treatment, and prevention of pressure sores. Tr. at 300. She testified that the team determined that the facility did not have its wound care protocol in place until June 3, 1996, and, in making that determination, cited HCFA Ex. 29. Tr. at 299. HCFA Ex. 29 is a document dated June 3, 1996, which states, in pertinent part, "[t]he following protocol on 'wound care team with special emphasis for at risk residents' has been approved by the patient care committee and the quality assurance committee." HCFA Ex. 29 at 1.

On direct examination, Ms. Caimi testified, however, that essentially the same protocol was adopted by the facility on April 25, 1996 and that other than the cover

page bearing the date of June 3, 1996 the only difference in the later document was page 3 of HCFA Ex. 29. Tr. at 576. The new page explains that in April, May, and June 1996, the facility was using a "skin focus," whereby a list of residents was generated from the weekly skin checks and then the wound team evaluated and recommended a course of action which was added to the resident care plans. The document states, "[i]n July we eliminated the focus list and began using the 'Wound Team Evaluation.' This is specific to each resident." HCFA Ex. 29 at 3.

As further evidence that the facility did, in fact, have its wound care protocol in place in April, rather than June 1996, Ms. Caimi pointed out that the evidence of record does show that she conducted an inservice on the facility's protocol manual on April 25, 1996. HCFA Ex. 32 at 5.

Kellie Daugharty, Risk Manager at Petitioner's facility, testified that she began her employment with Petitioner on June 3, 1996 (Tr. at 522) and she signed the wound care protocol the same day. HCFA Ex. 29 at 1. She testified that as of June 3, 1996, the protocol was already in place, but she was not able to testify as to when the protocol was adopted, stating that she didn't know specifically when everything "was exactly in place." Tr. at 508.

When asked to provide an example of how the wound care team was functioning prior to May 20, 1996 (the date the facility alleged it would be in substantial compliance with Medicare participation requirements), Ms. Caimi referred to HCFA Ex. 25 at 1. On the middle of that page, there is a physician's telephone order dated April 2, 1996, signed by Dr. Jensen on April 10, 1996, pertaining to Resident 23. Ms. Caimi testified that the physician's order placed the resident on the facility's "focus" list in response to an existing pressure sore and that Dr. Jensen ordered "labs," treatment, and preventive measures. She testified that this action was a result of the development of the wound care team. Tr. at 594.

I find the evidence and argument presented by Petitioner as outlined above to be unconvincing and less than credible. First, with respect to Ms. Caimi's testimony that the physician's order contained in HCFA Ex. 25 is demonstrative of the facility's functioning wound care team, I note that, according to the testimony, Dr. Jensen was not a member of the wound care team. Tr. at 594, 595. He was the resident's treating physician. If the wound care team had, indeed, been functioning, they would have identified the pressure sore, placed the resident on the focus list, and made recommendations to the treating physician. There is no evidence that the wound care team met and evaluated this resident prior to Dr. Jensen's telephone order, and, indeed, under the system in place at the facility in April 1996, the wound care team would not have evaluated the resident until he was placed on the "focus" list. It was Dr. Jensen, not the facility, that directed that Resident 23 should be placed on the "focus" list. This is, in my opinion, strong evidence that the wound care team was not functioning.

Ms. Caimi further testified that the wound care protocol adopted on June 3, 1996, was the same as that adopted on April 25, 1996, with the exception that page 3 was new to the June 3rd edition. However, the alleged April protocol is conspicuous by its absence from the documentary evidence in this case. Further, if the said page 3 of HCFA Ex. 29 was adopted in June 1996, I am at a loss to understand how the document can say "[i]n July we eliminated the focus list . . . " HCFA Ex. 29 at 3. Obviously, page 3 was prepared sometime in late July or early August 1996. I note that the protocol was apparently faxed to HCFA on August 6, 1996. Ms. Caimi testified that the focus list was eliminated in July in favor of a wound team evaluation "because it was specific to the resident." Tr. at 598. As a part of its plan of correction, the facility promised that it would "be developing individual wound treatment plans for individual residents." HCFA Ex. 2 at 51. There is no evidence that the focus list resulted in any individual wound treatment plans.

With respect to Resident 23, the first documentary evidence that the wound team was functioning is found at HCFA Ex. 30, in a "Wound Team Evaluation" dated July 19, 1996. See also Tr. at 300.

The preponderance of the evidence supports a finding that the facility did not implement its plan of correction with respect to establishing a wound care protocol until June 3, 1996 and did not establish a functioning wound team evaluation process under that protocol until July 19, 1996.

Allegation 4. The skin check program was not being monitored because the facility was not aware that skin checks were not being done on a weekly basis.

Finding 2(D). The facility was monitoring its skin check program by May 20, 1996.

Ms. Boulden testified that with respect to Resident 23, the facility documented that it performed skin checks on March 16, March 23, April 8, April 22, May 6, May 20, and May 27, 1996. HCFA Ex. 23; Tr. at 161.

While it is clear that up until May 20, 1996, weekly skin checks were not being done, there is no evidence to show that the failure continued. The evidence shows that weekly skin checks were done on May 20 and May 27, 1996, and there is no evidence to show that these weekly skin checks did not continue thereafter.

The evidence supports a finding that the facility was monitoring its skin check program by May 20, 1996, the date it stated it would be in compliance with Medicare participation requirements.

Allegation 5. Resident 23 developed a new pressure sore between the time of the initial survey and the revisit.

Finding 2(E). Resident 23 did develop a new pressure sore between the time of the initial survey and the revisit.

The evidence shows that on February 25, 1996, Resident 23 was readmitted to Petitioner's facility following a stay in the hospital for a fractured right hip. On that date, the facility's nurse's notes establish that the resident had two pressure sores, the first on the left buttock and the second on the left hip ischium. HCFA Ex. 15 at 2.

HCFA Ex. 16, the facility's pressure sore record, on which the date April 22, 1996 is crossed out and the date February 25, 1996 is inserted, identifies the two above-mentioned pressure sores as located on the right buttock and the left hip.

From the very outset, the undersigned would note, it is difficult to ascertain from Petitioner's records what pressure sores the resident had, where they were, and their severity.

On March 13, 1996, Dr. Jensen examined the resident and his report makes no mention of any pressure sores, new or otherwise. In fact, he reports the condition of the resident's skin as normal. HCFA Ex. 22.

Nurse's notes from April 4, 1996, report that the resident had skin breakdown on two spots on his buttocks on the inner folds of his cheeks and one on the inner left leg. HCFA Ex. 20 at 4. The nurse felt that the areas required duoderm treatment. The pressure sore record does not reflect these areas of skin breakdown. HCFA Ex. 16.

Nurse's notes from April 15, 1996, describe a "new Decub [pressure sore] on inside of right knee." HCFA Ex. 20 at 5. The facility pressure sore record, HCFA Ex. 16, also documents what is described as a Stage II pressure sore on the inner side of the right knee, described as 2 cm by 2.25 cm, first observed on April 22, 1996.

On April 29, 1996, Dr. Purser issued a telephone order for Collagenese Santyl dressing to be applied to Resident 23's right medial knee pressure sore every day until eschar (dead skin) lifts off. Tr. at 169, 170; HCFA Ex. 25 at 3. The order was received and recorded by a physical therapist and signed by Dr. Purser on May 2, 1996.

Dr. Purser issued a letter to the State survey agency dated May 29, 1996, stating that, in his professional opinion, Resident 23 did not have a pressure sore, but that the wound was cellulitis that had abscessed. P. Ex. 1. When Dr. Purser was asked why his telephone order diagnosed the wound as a pressure sore, he testified:

> I have no idea. The nurses have written it in. They probably got my order right, but they look like they've added their own diagnosis to it, which they can't do, or misconstrued whatever I said.

Tr. at 720.

He further testified that the problem with telephone orders is that you can't change them. Id.

Dr. Purser testified that Resident 23 wore a brace covering his right knee and that it kept slipping down, causing an abrasion. Tr. at 710. He testified that this resident was receiving daily whirlpools for his other pressure sores, and that the physical therapist had mentioned to him, on more than one occasion, that the resident kept defecating into the whirlpool. Tr. at 711. The wound became infected, and he testified that the infection entered through the abrasion when the resident was in the whirlpool. Tr. at 712.

The evidence shows that, in fact, the wound, whether an abrasion or a pressure sore, did become infected. Dr. Purser testified that he ordered a culture of the wound on May 10, 1996 (Tr. at 711) and the culture showed e-coli and proteus mirabilis "both fecal bacteria." Tr. at 712. On May 14, 1996, Dr. Purser's progress notes diagnose the problem as cellulitis, right knee abscess, draining wound. He orders medication to treat the infection and whirlpool at the discretion of the physical therapist. HCFA Ex. 25 at 4; HCFA Ex. 26.

Dr. Purser further testified that there was no way a "pressure sore" could have developed on the resident's inner knee because, "[t]he splint, in no way, shape, or form touches the inner aspect or outer aspect of this patient's knee nor can basically anything else. It's going to protect the knee." Tr. at 712.

I find the testimony of Dr. Purser to be both disturbing and less than credible. On the one hand, he testified that because of the nature of the resident's brace, it was virtually impossible for anything to touch the resident's knee. At the same time, he testified that the brace kept slipping, which would mean that it was not always in place. Further, he testified that the brace itself caused what he termed an abrasion, while at the same time testifying that the brace, or splint, could in no way touch the knee. This testimony is inherently contradictory.

Further, Dr. Purser himself signed an order calling the wound a pressure sore. Although he blames this on nurse error (actually the physical therapist took the order), he does not explain why he didn't simply refuse to sign the order if it was in error. He testified that he didn't believe he could change a telephone order once given (which in itself is more than difficult to believe) but the fact is he wouldn't have had to change it if he had refused to sign it to begin with. If he believed the order was erroneous, but signed it anyway, serious questions are raised in my mind about the doctor's credibility and medical ethics.

Dr. Purser testified that it was his opinion that the resident's infection was caused by harmful bacteria in the whirlpool. If he truly believed that to be true, I find it difficult

to understand why his order of May 14, 1996, calls for continued whirlpool treatments.

Apparently because Petitioner's own records sometimes referred to Resident 23's wounds as a pressure sore, and at other times as cellulitis, the State survey agency requested an outside physician to look at the wound. The evidence shows that this resident was seen by Dr. John Hylen[6] on June 10, 1996. Dr. Hylen testified that:

> [f]or almost a month prior to [Dr. Purser's diagnosis that the wound was cellulitis that had abscessed] in the medical records, the area on his right knee was described as a pressure sore. And when I examined the patient on June 10, 1996, he did not have cellulitis or an abscess. It appeared to be a pressure sore to my examination.

Tr. at 401.

As to the question of whether or not Resident 23 had developed a new pressure sore while in Petitioner's facility, the record contains two distinctly different medical opinions. In weighing those opinions, I am cognizant of the fact that Dr. Purser was the resident's treating physician, and, as such, had more opportunity to see the resident than did Dr. Hylen. I am also cognizant of the fact that Dr. Purser is Medical Director of Petitioner's facility. In many instances, I would be inclined to give greater weight to the testimony of a treating physician over that of a one time medical consultant. In this case, however, I note that Dr. Hylen is better qualified to render an opinion, both by experience and education, than is Dr. Purser. Dr. Hylen testified that he is Board Certified in internal medicine, cardiovascular medicine, and geriatric medicine. He currently serves as staff physician for the Utah Department of Health and has held that position for seven years. He testified that over the past 25 years he has cared for residents in nursing homes, either as medical director of the facility or as a treating physician, treating residents with pressure sores or trying to prevent them. Tr. at 385 - 387. Dr. Purser testified that he has been practicing medicine for about 13 years, approximately seven of which have been involved with long-term care facilities, and that he holds no Board Certifications. Tr. at 701.

Given the qualifications of the two physicians, it is clear that Dr. Hylen's testimony should be accorded the greater weight, especially in light of the credibility problems with Dr. Purser's testimony that I have discussed above.

Accordingly, I find that Resident 23 did, indeed, develop a pressure sore on his medial right knee while he was a resident of the facility.

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[6] I note that the transcript spells Dr. Hylen's name as "Highland." Dr. Hylen did not spell his name for the record. However, I believe that the correct spelling of his name is "Hylen," as that is how it is spelled on HCFA's witness list. Thus, I am referring to him as Dr. Hylen.

Finding 3. The pressure sore which Resident 23 developed could have been avoided, i.e., it was not unavoidable. The facility did not provide the necessary services to promote healing and to prevent the development of infection. The facility failed to meet the requirements of 42 C.F.R. § 483.25(c)(1) and (2), as of May 20, 1996. HCFA has established a basis for imposition of a CMP.

The next issue, and one on which there was much testimony, was whether or not the development of that pressure sore was unavoidable. 42 C.F.R. § 483.25(c) clearly recognizes that there are occasions when the clinical condition of a resident is such that the development of pressure sores is unavoidable. In this case, Petitioner presented multiple witnesses who expressed the opinion that Resident 23 was one of those residents.

Ms. Daugharty testified that subsequent to the date of her employment, she had "hands-on" contact with Resident 23 until the time of his death. Tr. at 523. She testified that during this period his health continued to fail and he had problems maintaining his skin integrity, developing subsequent pressure sores, another abscess cellulitis, and skin sheers. Tr. at 525. She testified that Resident 23 was anemic, had muscle wasting, severe Alzheimer's disease, was combative, and refused care. She expressed the opinion that his pressure sores could not be avoided as the resident, who was 85, had multi-systems failure. Tr. at 524.

Ms. Caimi also expressed the opinion that Resident 23's pressure sores were unavoidable but did not elaborate upon what information she based her conclusion. Tr. at 605.

Dr. Jensen testified that he saw and treated this resident during the period from March 13, 1996 through April 1 or 2, 1996 (Tr. at 658, 667, 669), at which point daily physical therapy was instigated and the resident was moved to another site in the nursing home. At the time the resident left his care, he testified that the resident was wearing a brace on his right leg and "he thought it caused some irritation." Tr. at 668. He testified, however, "I noticed no specific lesion. If there was any redness, it was very minor." Tr. at 669. Despite the fact that the resident did not have a pressure sore or other lesion on his knee when he last saw him in early April, and despite the fact that he voiced no knowledge of the care and treatment the resident might have received or been receiving when the wound was first noted in mid-April 1996, Dr. Jensen expressed the opinion that development of pressure sores in this resident was unavoidable. Tr. at 661. He noted that the resident suffered from severe Alzheimer's Disease, chronic obstructive pulmonary disease, was incontinent of bladder and bowel, had muscle wasting, and was anemic. Tr. at 660, 661. Further, Resident 23 had a muscle contracture stemming from his right hip fracture, and he assumed a chronic position. Dr. Jensen explained, "[y]ou could move him anyway you want, but he had a certain position which did not hurt him." Tr. 663, 664. Dr Jensen indicated that if you moved the resident into a different position, he would

naturally rotate back into the chronic position. Tr. at 665. On cross-examination, however, Dr. Jensen admitted that the positioning and repositioning of Resident 23 was important to his care. Tr. at 681. In fact, on April 2, 1996, Dr. Jensen issued a telephone order directing the staff to "observe turning schedule" and on April 3, ordered physical therapy and "bed mobility training." HCFA Ex. 25 at 1. When he was asked on cross-examination what he meant by "observe turning schedule" he responded that this was "part of the protocol," but he testified that he did not recall specifically what the guidelines for turning a resident were. Tr. at 683.

The testimony of Dr Jensen is best characterized as evasive and non-responsive. He frequently answered questions by saying "that's part of the medical record." His inability to recall what he meant by the term "observe turning schedule," is simply further evidence of this witness's inclination to be less than candid or forthcoming. The credibility of this witness was severely undermined by his demeanor. Given that fact, coupled with the fact that at the time Dr. Jensen last saw the resident around April 1, 1996, at which time the resident did not have a pressure sore, and had, at most, minor redness, and given that Dr. Jensen had no personal knowledge of what measures, if any, were taken to prevent the development of pressure sores thereafter, I cannot assign the conclusion which Dr. Jensen reached (that Resident 23's pressure sore was unavoidable) any significant weight.

Finally, Dr. Purser, Resident 23's treating physician during the period of time the pressure sore developed and later became infected, testified that in his opinion the development of pressure sores in this resident was unavoidable. Tr. 705, 706. He cited the resident's long history of medical problems, the same history as recited by previous witnesses as discussed above. Tr. at 703. Since Dr. Purser was Resident 23's treating physician, one could not expect him to take a contrary position. For the reasons I set forth above, I find him to be a less than credible witness and accord his testimony little, if no, weight.

On the other hand, Dr. Hylen, HCFA's expert witness, testified that, in his opinion, this pressure sore could have been prevented. Tr at 398. Dr. Hylen expressed the opinion that the facility could have done three things to help prevent this pressure sore from developing:

> 1. Ensure proper nutrition. He noted that when the resident was first admitted to the facility, his ideal body weight was 139 pounds. When he returned from the hospital (the record shows that this was February 25, 1996) he weighed 112 pounds, and then over the next month he lost ten more pounds. The doctor testified that if he had gained weight and had been provided more protein it would have been helpful in the prevention of the pressure sore. Tr. at 398.
>
> 2. Earlier placement of pillows between his thighs. The doctor explained that because of the resident's hip contracture, more pressure was placed on the

resident's knees, and placement of pillows between his thighs would have prevented the knees from pressing together. Tr. at 398, 399.

3. Frequent (hourly) turning of residents. In this regard, the doctor testified on cross-examination that, in high-risk residents, turning a resident every hour is preferable to turning the resident every two hours, although he admitted this was a judgment call. Tr. at 399, 416.

With respect to nutrition, Dr. Hylen testified that approximately seven weeks before he saw the resident (June 10) the facility began to increase the resident's nutrition and he began to gain weight. Tr. at 398, 411. This would mean that in late April or very early May the facility made some effort to increase the resident's nutritional intake. In fact, the evidence contains a telephone order dated May 1, 1996, by Dr. Purser, directing a special nutrition focus on this resident. HCFA Ex. 25 at 3. Petitioner argues that this shows it was in substantial compliance on or before May 20, 1996. In fact, however, the findings regarding Resident 23 are only loosely related to the findings from the initial survey in February 1996 and to the facility's allegation that it would be in substantial compliance by May 20, 1996. Not only did the facility have an obligation to correct deficiencies that were found at the time of the initial survey but they had an obligation to maintain compliance at all times. That is to say, they had a continuing obligation to prevent new problems from developing. The fact that the facility began to increase the resident's nutritional intake on May 1, 1996, after the resident had already developed the pressure sore, and that the resident responded to the increased nutrition, is strong evidence that the facility did not do all that it could to prevent the pressure sore from developing.

With respect to Dr. Hylen's testimony that pillows should have been placed between the resident's thighs at an earlier date, Dr. Hylen clarified his testimony on cross-examination by saying that if an abductor pillow had been used from the time of Resident 23's admission to Petitioner's facility, the pressure sore would have been avoidable. Tr. at 414. It is clear that the facility did use an abductor pillow for this resident at some point in his care but the evidence is unclear as to exactly when. The file does contain an order from Dr. Purser issued on April 29, 1996, directing that an abductor pillow be on at all times. HCFA Ex. 25 at 2. This suggests to the undersigned that it may have been in sporadic use prior to that date. There is no evidence that such a pillow was in use in February, when the resident was readmitted to the facility.

There is no question that Resident 23 was a difficult resident. He was described by witnesses as combative. There is also no question that he was at high risk for developing pressure sores. Indeed, the record indicates that he had pressure sores when he was admitted to the facility and he developed pressure sores after the one in question here. However, the question here is whether this set of facts necessarily means that the pressure sore which he developed on his right medial knee could have

been avoided. The burden of proof is on the facility in asserting the affirmative, and, based upon the evidence before me, I conclude that it has not sustained that burden.

The preponderance of the evidence discussed at length above leads me to the inescapable conclusion that, with respect to this resident and this particular pressure sore, the facility could have, and should have, done more to prevent the pressure sore from developing. It is clear that the resident's weight and nutrition were not carefully monitored. It is clear that proper and simple steps were not taken to prevent his knees from pressing on one another. And, it is clear that, when the development of this pressure sore was first noted, on either April 15 or April 22, 1996 (HCFA Ex. 20 and 16), proper steps were not taken to assure adequate treatment and healing. The record shows that the pressure sore increased in severity and size, from a relatively small Stage II wound, to a larger, more serious Stage III wound. HCFA Ex. 16. The record further indicates that from the time Dr. Purser saw the resident in early April, until he saw him again on May 14, 1996, there had been a significant status change. Dr. Purser testified that the wound "had changed dramatically." Tr. at 758, 759. He admitted that a significant change in the status of the wound had occurred sometime well before May 14. Despite what Dr. Purser categorized as a "dramatic" change in the wound, the facility's own pressure sore record, HCFA Ex. 16, indicates that there was no change in the wound between April 30, 1996 and May 21, 1996. The record demonstrates that the facility did an extremely poor job of tracking and monitoring the development of this pressure sore. If there was a wound team functioning at this time, it was not functioning well. The wound went on to develop a serious infection, at least in part due to the facility's poor tracking and monitoring mechanism.

The record supports a finding that not only did Resident 23 develop a pressure sore which could have been avoided, but that, further, the facility did not provide the necessary services to promote healing and to prevent the development of infection. The facility failed to meet the requirements of 42 C.F.R. § 483.25(c)(1) and (2).

Finding 4. The facility's failure to turn Resident 23 on an hourly basis did not contribute to the development of his pressure sore and did not violate 42 C.F.R. § 483.25(c).

The issue of how often the resident needed to be turned in order to prevent the development of pressure sores is one which may have unduly preoccupied the State surveyors. Dr. Hylen thought it better practice to turn Resident 23 every hour but he admitted that this was a matter of judgment. He further admitted that the facility's records showed that the resident was turned/repositioned every two hours. HCFA Ex. 28; Tr. at 418. Dr. Hylen was then asked whether Dr. Jensen was in error in ordering that the resident only be turned every two hours, and responded, "I wouldn't think so." Tr. at 419. Given the fact that the facility's records do show that Resident 23 was turned every two hours, and that Dr Hylen could not state with certainty that this was deficient care with respect to Resident 23, I do not find that failure to turn the resident on an hourly basis contributed to the development of his pressure sore.

The above finding is of some importance, because it relates to HCFA's determination as to when the facility came into substantial compliance with Medicare participation requirements.

The record indicates that following the surveyors first revisit to the facility, which concluded on June 10, 1996, with the visit by Dr. Hylen, the State survey agency not only found that the facility had not complied with its plan of correction, but they imposed a Directed Plan of Correction. HCFA Ex. 8; Tr. at 292. Ms. Tone, survey team leader, explained that a Directed Plan of Correction is one written by an entity other than the facility but that the facility is directed to comply with it. Tr. at 292.

Ms. Tone testified that one of the elements of the Directed Plan of Correction was that the facility implement an hourly turning schedule for Resident 23. Tr. at 296. On cross-examination, she admitted that this was not an element of the original plan of correction. Tr. at 379. She further testified that with respect to fulfilling the requirements of 42 C.F.R. § 483.25(c), the only requirement the facility had not completed was "the one hour turning positioning that needed to be done." Tr. at 379. Again, at Tr. at 380, she testifies:

> Q. Okay. Well, then what requirements from the February 29 survey dealing with Tag 314 only (42 C.F.R. § 483.25(c)) were not satisfied.
>
> A. They did not have the flow sheet one hour turning in place.

The record shows that on August 6, 1996, the State survey agency conducted a second revisit to Petitioner's facility, following which it was determined that Petitioner was in substantial compliance with Medicare participation requirements as of June 24, 1996. HCFA Ex. 10. Ms. Tone testified that June 24 was selected because that was the date that the last element of the plan of correction was put into place. Tr. at 297, 298. The evidence further shows that the last element, the required hourly turning and positioning of Resident 23, was documented to be in place on June 24, 1996. HCFA Ex. 31.

The problem with the State survey agency's (and HCFA's) reliance on this date is that there is no requirement in the regulations that residents, even high-risk residents, be turned on an hourly basis, or that a specific form be used to document the position from which and to which a resident is turned. There was no evidence presented that the use of such a form, or, indeed, implementation of hourly turning, is standard medical practice. HCFA's own witness, Dr. Hylen, merely testified that in this case he felt it preferable, but at the same time he refused to say that turning a resident every two hours was inappropriate. The fact that the facility did not implement hourly turning of Resident 23 until June 24, 1996, has no bearing on whether or not the facility was in substantial compliance with the requirements of the regulation on that date.

Finding 5. HCFA's finding that Petitioner was in substantial compliance with 42 C.F.R. § 483.25(c) was in error, but, as the error was advantageous to Petitioner, the finding will not be disturbed.

Despite the testimony of the State surveyors to the effect that all of the elements of the plan of correction were in place, at least by June 10, 1996, (with the exception of the hourly turning schedule), as I have indicated previously herein, the evidence indicates that the facility did not have a functioning wound team evaluation process in place until July 19, 1996. The implementation of this team was a promise made by the facility as part of its initial plan of correction, and, indeed, it is a critical element to carrying out the regulatory directive that a facility take the steps necessary to both prevent and treat pressure sores. Because HCFA's erroneous finding that the facility was in substantial compliance as of June 24, 1996, is advantageous to Petitioner, and because, even though this is a de novo determination, I have grave due process concerns about extending the duration of a CMP over and above that which was the subject of this hearing, I will not disturb the ultimate finding of HCFA that the facility achieved substantial compliance with Medicare participation requirements as of June 24, 1996.

Finding 6. The CMP imposed by HCFA in the amount of $1300 per day is not reasonable.

Having determined that Petitioner was not in substantial compliance with 42 C.F.R. § 483.25(c) from February 29, 1996 through June 23, 1996, and that, therefore, HCFA has established a basis for the imposition of a CMP, the final issue to be resolved in this matter is whether the amount of the penalty imposed by HCFA is reasonable.

As noted previously, HCFA imposed a CMP on Petitioner in the amount of $1300 per day, effective February 29, 1996, and continuing to June 24, 1996. HCFA Ex. 7, 11 42 C.F.R. § 488.438(f) provides that--

> In determining the amount of penalty, HCFA does or the State must take into account the following factors:
>
> > (1) The facility's history of non-compliance, 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.

The factors set forth in 42 C.F.R. § 488.404 are those which deal with the severity and scope of a deficiency: the severity of a deficiency ranging from no actual harm with a potential for minimal harm, to immediate jeopardy to resident health or safety; and the scope of a deficiency ranging from isolated deficiencies to those which are widespread.

In the instant case, Ann E. Lee was called by HCFA to explain how the amount of the CMP was determined. Ms. Lee is the health program manager for the State survey agency and supervises the long-term care survey section. Tr. at 441. Ms. Lee testified that the State survey agency had established guidelines for the imposition of remedies which had been incorporated into a chart, HCFA Ex. 33. That chart was sent to the HCFA Regional Office in Denver and Ms. Lee testified that HCFA did not tell them to cease using the chart for purposes of establishing CMP amounts. Tr. at 452, 453. She explained that each State was compelled to establish its own guidelines for establishing CMP amounts because, to date, the State agencies have not received guidance from the federal government on what appropriate CMPs are. Tr. at 454. She testified further that HCFA has accepted all proposed CMP recommendations forwarded by the State survey agency. Tr. at 456.

Ms. Lee then explained how the chart, HCFA Ex. 33, was used by the State in making its recommendation to HCFA regarding the amount of the CMP in this case. She testified that the State surveyors had identified the scope and severity of the deficiency as "G," which she later defined as "a deficiency that was isolated that caused actual harm." Tr. at 449, 460. She testified further that the State policy, as set forth in HCFA Ex. 33, is to assess a base penalty of $100 per day, plus an occupied bed fine of $10 per day, plus an individual resident fine (in this case for Resident 23), in the amount of $100 per day. According to Ms. Lee, the facility census showed there were 109 occupied beds, and, accordingly, the occupied bed fine was $1090 per day. The total fine, including the base fine, the occupied bed fine, and the individual resident fine, using the chart, was $1290 per day, which was then "rounded" to $1300 per day. Tr. at 449. Ms. Lee testified that in considering the facility's financial ability to pay, the only thing which the State considered was the number of occupied beds. Tr. at 461.

During the course of the hearing in Salt Lake City, I expressed grave concerns regarding the methodology employed by the State in recommending the CMP in this case, and my concerns have not been alleviated. My concerns, briefly, are as follows:

> 1. The regulations at 42 C.F.R. § 488.408(d) call for a penalty ranging from $50 - $3000 per day where there is a finding of an isolated deficiency that causes actual harm, as in this case. There is no explanation offered by the State or by HCFA as to why a "base" fine of $100 per day is automatically

applied in all cases using HCFA Ex. 33, or what factors are considered by the State and HCFA in determining that "base" fine.

2. There was no evidence presented in this case from which one could reasonably conclude that consideration of the number of occupied beds in a facility necessarily takes into account a facility's financial condition as required by 42 C.F.R. § 488.438(f)(2). The mere fact that a facility is fully occupied does not give any indication of profit or loss. Further, it would appear to the undersigned that the formula used by the State may unfairly penalize larger facilities, as the more occupied beds, the larger the fine. A smaller facility, charged with the same deficiency, will pay a smaller fine, even though it could be operating more efficiently and have a greater profit than its larger counterpart.

3. The chart used by the State does not take into consideration a facility's history of non-compliance, including repeated deficiencies, as required by 42 C.F.R. § 488.438(f)(1), nor does it provide for an increased penalty based on a facility's degree of culpability, as required by 42 C.F.R. § 488.438(f)(4). In this case, the facility's past performance was not considered in determining the amount of the penalty (Tr. at 450), and there was no evidence that additional amounts were assessed as a result of a finding of culpability. Nevertheless, the problem here is that the chart used by the State makes no provision for consideration of these factors, and, accordingly, a small facility with repeated deficiencies, which had been shown to have disregard for resident care, could, under the formula used by the State, pay a smaller daily penalty than a larger facility which did care for its residents and which had no previous deficiencies.

4. There was no evidence offered to justify a separate $100 per day individual resident fine. Again, the flat fine appears to give no consideration to a facility's financial condition, and the amount of the penalty appears to be wholly arbitrary.

Of still greater concern, in this case, is that HCFA presented no independent evidence as to what factors, if any, it considered in determining the amount of the CMP in this case. The testimony firmly established that the State survey agency merely makes recommendations to HCFA, and, ultimately, it is the responsibility of HCFA to determine the amount of the penalty. Tr. at 450, 451. No representatives of HCFA were called to testify in this case, nor was any documentary evidence offered to show that HCFA considered the factors set forth in 42 C.F.R. § 488.438 with respect to determining the amount of the CMP.[7]

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[7] Ms. Lee was the only witness who gave any testimony with respect to what matters were considered in determining the amount of the CMP, and she is an employee of the State survey agency, not of HCFA.

Finding 7. A CMP in the amount of $400 per day, effective February 29, 1996, and continuing to and including June 23, 1996, is reasonable, and is in accordance with the evidence in this case, taking into consideration the factors subject to review pursuant to 42 C.F.R. § 488.438.

The undersigned has given serious thought to remanding this case to HCFA for purposes of determining the amount of the CMP in this case in accordance with the regulatory requirements. However, neither party has requested that I do so. HCFA argues that Petitioner has offered no evidence to show that the amount of the penalty imposed is unreasonable, and that, therefore, the penalty should be sustained. HCFA Br. at 38. Petitioner argues that HCFA did not establish a prima facie case that the amount of the penalty was reasonable, in that it did not show that it complied with the regulatory requirements. Petitioner urges that in the event I should find that a basis for the penalty exists, I set the amount of the penalty in accordance with the evidence. P. Br. at 41.

At the request of the parties, therefore, I have elected not to remand this case. After consideration of the entire record before me, I hereby impose a CMP against Petitioner in the amount of $400 per day, effective February 29, 1996 and continuing through and including June 23, 1996. In determining the amount of the CMP, I have considered the following factors:

1. The facility was in violation of 42 C.F.R. § 483.25(c) at the time of the initial survey, February 29, 1996, and the evidence establishes that three residents developed pressure sores while in the facility and suffered actual harm. Despite an opportunity to correct the deficiencies leading to that harm, the deficiency continued through June 23, 1996 and one additional resident was actually harmed. However, it is also noted that the facility made a sincere effort to correct its deficiencies, and that as of the first revisit concluding on June 10, 1996, only one of 113 residents had developed a pressure sore after the initial survey in February. HCFA Ex. 8 at 2.

2. Even though only one resident suffered actual harm after the February 1996 survey, that harm was significant, as the resident's pressure sore was allowed to become infected. This was a direct result of the facility's failure to do skin checks on a regular basis, to document the development and progression of pressure sores, and to implement a system-wide program for the prevention and treatment of pressure sores. Given the state of confusion and facility disarray in the pressure sore documentation of record in this case, it is truly amazing that only one additional resident developed pressure sores. Clearly there was the potential for more than minimal harm to a large number of residents. The deficiency in this case falls within category 2, 42 C.F.R. § 488.408(d), and, accordingly, a CMP in the amount of $50 to $3000 per day is authorized.

3. There is no evidence that the facility has a history of non-compliance or repeat deficiencies which would justify placing the amount of the penalty in the upper end of the penalty range.

4. There is no allegation of neglect, indifference, or disregard for resident care which would justify placing the amount of the penalty in the upper end of the penalty range.

5. Neither party has submitted any evidence with respect to the facility's financial condition. Petitioner has contended that the amount of the penalty previously imposed, $1300 per day, was unreasonable, but it has not contended that it is unable to pay. I am assuming, therefore, that the facility's financial condition is such that it has the ability to pay a lesser amount, more in keeping with the scope and severity of the offense.

6. HCFA has not established any national guidelines for setting CMPs, and, accordingly, wide discretion is left in the hands of the decision-maker. In this case, I believe a penalty in the amount of $400 is reasonable. The penalty in this case should be more than the minimal amount of $50 per day, as the deficiency is a serious one. A minimal penalty would not, in my judgment, convince the facility of the need to recognize its problems and correct them. At the same time, penalties should not be so excessive as to force facilities to close their doors or reduce resident services. Penalties should have a strong relationship to the gravity of the offense and should not be predicated solely on the size of the facility. I believe a penalty in the amount of $400 in this case recognizes the gravity of the offense and is sufficiently large so as to provide incentive to the facility to maintain compliance with the requirements of participation in the Medicare program.

V. Conclusion.

For the aforesaid reasons, and based upon the testimony and evidence of record in this case, I conclude that Petitioner was not in substantial compliance with a requirement of participation in the Medicare program, namely 42 C.F.R. § 483.25(c), from February 29, 1996 through and including June 23, 1996. I further conclude that the CMP previously imposed by HCFA against Petitioner, in the amount of $1300 per day, is unreasonable, and I impose, in lieu thereof, a CMP against Petitioner in the amount of $400 per day, effective February 29, 1996 and continuing through and including June 23, 1996.

/s/

Stephen J. Ahlgren

Administrative Law Judge