Department of Health and Human Services

DEPARTMENTAL APPEALS BOARD

Civil Remedies Division

In the Case of:	)	
	)	
Antelope Valley Convalescent Hospital,	)	Date: December 19, 1997
	)	
Petitioner,	)	
	)	
- v. -	)	Docket No. C-96-411
	)	Decision No. CR511
Health Care Financing Administration.	)	
	)	

DECISION

For the reasons stated below, I conclude that Petitioner, Antelope Valley Convalescent Hospital, a skilled nursing facility (SNF), was not in substantial compliance with Medicare participation requirements governing SNFs. Accordingly, the Health Care Financing Administration (HCFA) was authorized to deny Petitioner payment for new admissions.

I. Background

A. Applicable law and regulations

Title XVIII of the Social Security Act (Act) establishes a federally subsidized health insurance program for the elderly and disabled, commonly referred to as Medicare. Medicare provides reimbursement for certain services rendered by providers, such as SNFs, who participate in the Medicare program under "provider agreements" with the Department of Health and Human Services (DHHS). In order to enter into such an agreement, SNFs must meet certain requirements imposed by applicable statute and regulations. 42 U.S.C. § 1395i-3 and 42 C.F.R. Parts 483, 488, and 489. Golden State Manor and Rehabilitation Center, DAB No. 1597 at 3 (1996). The requirements for participation in Medicare by SNFs are set forth in 42 C.F.R. Part 483. A SNF is subject to the survey, certification, and remedies provisions of 42 C.F.R. Part 488, and to the provisions governing provider agreements in 42 C.F.R. Part 489.

The survey process is the means by which DHHS (through HCFA) assesses providers' compliance with these requirements. State survey agencies, under agreements with HCFA, perform the surveys

of SNFs and make recommendations to HCFA as to whether such facilities meet federal requirements for participation in the Medicare program. Act, section 1864(a); 42 C.F.R. § 488.10, 488.11, 488.20. The results of these surveys are used by HCFA as the basis for its decisions regarding a SNF's initial or continued participation in Medicare. HCFA, not a State survey agency, makes the determination as to whether a facility is eligible to participate or remain in Medicare. Id.

Following a survey, HCFA may deny payment for all new admissions if it determines that a SNF is not in substantial compliance with Medicare participation requirements. 42 C.F.R. § 488.417(a). "Substantial compliance" is defined as "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. The regulations require HCFA to deny payment for all new admissions when a facility is not in substantial compliance three months after the last day of a survey identifying the noncompliance.[1] 42 C.F.R. § 488.417(b).

The regulations provide that, with respect to SNFs, I am authorized to adjudicate a petitioner's challenge to HCFA's finding of noncompliance that results in the imposition of a remedy specified in 42 C.F.R. § 488.406. However, the regulations preclude me from hearing a petitioner's challenge to its loss of approval for a nurse-aide training program. 42 C.F.R. § 498.3(b)(12).

The burden of proof in this case is governed by the decision of an appellate panel of the Departmental Appeals Board in Hillman Rehabilitation Center, DAB No. 1611 (1997). Under Hillman, HCFA bears the burden of coming forward with evidence sufficient to establish a prima facie case that Petitioner failed to comply with participation requirements. Petitioner has the burden of proving, by a preponderance of the evidence, that it complied substantially with participation requirements. In determining whether HCFA has met its burden of establishing a prima facie case, I may consider rebuttal evidence offered by Petitioner that HCFA's evidence is neither credible or relevant to the issue of Petitioner's compliance with participation requirements, or that the weight of the evidence establishes that the regulatory deficiency alleged by HCFA did not occur. Hillman Rehabilitation Center, DAB CR500 (1997), at 3-8. If I conclude that the preponderance of the evidence establishes that such circumstances exist, then I will find that HCFA has not met its burden of establishing a prima facie case (but rather its case is based on

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[1] I note that 42 C.F.R. § 488.417(b)(1) states that section 488.401 defines the term "substantial compliance." However, that section defines "new admission" and "plan of correction." "Substantial compliance" is defined, instead, at section 488.301.

unsubstantiated allegations) and Petitioner will not be obligated to prove that it was substantially complying with participation requirements.[2]

B. History of this case

Petitioner is a 299-bed SNF located in Lancaster, California. HCFA Ex. 11. Petitioner was initially found out of compliance with participation requirements following a certification survey conducted by the California Department of Health Services (DHS or State survey agency), which was completed on April 4, 1996 (April survey). HCFA Ex. 1. Petitioner was again found out of compliance during a revisit survey completed on June 1, 1996 (June survey). HCFA Ex. 4. Petitioner admits that it was out of compliance with participation requirements during the April and June surveys and that it submitted a plan of correction in response to a third revisit survey completed on August 12, 1996 (August survey).[3] Tr. 28, 54; Petitioner's Trial Brief 3; HCFA Ex. 7. Petitioner is contesting only the conclusions of a second revisit survey, completed on July 16, 1996 (July survey), which also found Petitioner to be out of compliance with participation requirements and resulted in HCFA imposing a denial of payment for new admissions against Petitioner, for the period July 12, 1996 through August 21, 1996.[4]

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[2] In a recent decision, an appellate panel of the Departmental Appeals Board reiterated that the burden of persuasion set forth in Hillman applies only where the evidence proffered by both sides is "in equipoise." Oak Lawn Pavilion, Inc., DAB 1638 at 16-17 (1997). In such cases, the burden of persuasion would be on Petitioner.

[3] Petitioner was not deemed to be in substantial compliance with participation requirements until August 21, 1996.

[4] HCFA asserts that the July survey was completed on July 16, 1996. HCFA Response Brief (HCFA Resp. Br.) at 1, n. 1. HCFA asserts also that, after July 16, 1996, it continued the denial of payment for new admissions which it imposed by notice letter of July 27, 1996, effective July 12, 1996, as a result of HCFA's certification of noncompliance based upon deficiencies documented during the June survey. Id.; HCFA Ex. 7. Petitioner asserts that the July survey was completed on July 11, 1996. Petitioner argues, in effect, that if it was in compliance with participation requirements on July 11, 1996 (as opposed to July 16, 1996), the July 12, 1996 denial of payment for new admissions would not have gone into effect. See Petitioner's First Supplemental Brief (P. Br.) at 74-75. As I have found that Petitioner was not in substantial compliance with participation requirements during the July survey, this issue does not now affect the denial of payment which went into effect on July 12, 1996. However, I agree with HCFA that the survey process, which

(continued...)

I held a hearing in this case from January 27-31, 1997. Following the hearing, both parties submitted written briefs. On March 20, 1997, I ruled that I did not have authority to grant Petitioner's request to stay the effect of DHS' action withdrawing approval for Petitioner's nurse aide training and competency evaluation (NATCEP) program. I base my decision in this case on the governing law, the evidence I received at hearing, and on the parties' arguments as expressed in their briefs.[5] I use the following format for my decision. The numbered paragraphs set out in boldface, and any subheadings thereunder, are my findings of fact and conclusions of law (Finding(s)). The descriptive text under each heading is my rationale for such determinations.

C. Evidentiary Issue

During the hearing, both HCFA and Petitioner introduced exhibits into evidence which had not been submitted with the prehearing exchange and which, in Petitioner's case, included documents that were extant at the time of the survey, but which apparently were not shared with or specifically requested by the State surveyors. During the hearing, both parties objected to the admission into evidence of these exhibits. I admitted these exhibits into evidence. At that time, I discussed with the parties my reluctance to exclude evidence if a remedy is to be imposed against a party where there is documentation to show that, before the survey was completed, the deficiency did not occur and was cited only because the State surveyor was not in possession of or did not note that documentation. See Tr. 878-879. The dispositive date for assessing whether a facility is out of compliance is the date of the survey from which its termination resulted. Carmel Convalescent Hospital, DAB No. 1584, at 12 (1996). Following the hearing, HCFA continued to object to those exhibits of Petitioner's that were at the facility at the time of the survey, but were not provided to HCFA (HCFA stated that its own exhibits were, for the most part, the fruit of the survey process completed on July 16, 1996). HCFA argues that the survey

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[4](...continued)
began at Petitioner's facility on July 10 and 11, 1996, did not conclude until July 16, 1996, when the State surveyors finished their fact-finding. Tr. 82, 281. This was the last day the State surveyors gathered evidence or were provided with information. Tr. 83, 282. The fact-finding part of the survey is not limited to what the surveyors do on-site; their investigation may continue off-site. In this case, the fact-finding continued. Specifically, on July 16, 1996, one of the State surveyors interviewed a physician with regard to resident 3. Tr. 281-282; HCFA Ex. 20 at 4.

[5] I have evaluated carefully all arguments made by the parties in their briefs. If I do not specifically refer to such argument in my Decision, I have rejected it.

process is the means to assess compliance with federal health, safety and quality standards (42 C.F.R. § 488.26(c)) and, thus, only exhibits which derive from this process are relevant. The only exception, according to HCFA (asserting reliance on Hillman Rehabilitation Center, DAB No. 1611 (1997) at FFCL 16), is where the provider has alleged prior to hearing that the records it produced were incomplete because of the inadequacy of the surveyors' document requests, and the provider is able to carry the burden of proving, by a preponderance of the evidence, that the records were readily accessible at the time of hearing, would have demonstrated substantial compliance, and were not produced because the surveyors' document request was too limited. HCFA's Letter of June 6, 1997. HCFA's argument is not persuasive, as it mischaracterizes FFCL 16. In Hillman, a controversy existed as to the probative value of certain documents provided to HCFA by the petitioner during a survey of its facility to demonstrate compliance with the regulatory requirements. The petitioner argued that it provided billing records (incomplete patient records) during the survey based on its misunderstanding of the State surveyor's document request. Specifically, the petitioner alleged that it did not understand that the State surveyor was requesting complete clinical records. At the hearing, the petitioner submitted complete patient clinical records for the purpose of demonstrating compliance. HCFA argued that the patient records were irrelevant, because they were not the documents produced at the survey and could not be a measure of Petitioner's compliance at the time of the survey. Id. at 28. The FFCL cited by HCFA pertains to this narrow issue and not to the broader issue of whether Petitioner here can offer at hearing documents that were made available to the State surveyor during the survey, or at the time of HCFA's determination, but never specifically requested by the State surveyors. As to the latter issue, the appellate panel acknowledged in Hillman that HCFA did not argue for such a limitation on Petitioner's right to present relevant evidence, but, to the contrary, recognized that "any evidence proffered by Petitioner at the hearing should bear on the facts of its compliance as of the relevant time and not simply reflect later events." Id. at 27-28. In short, at the hearing, Petitioner may not rely on evidence: 1) it generated after the survey was completed; or, 2) was not available at the time of the survey to demonstrate compliance. Neither of these circumstances pertain to the documents I admitted into evidence in this case. I did admit documentary evidence relevant to issues identified in the HCFA form 2567 which was not provided by Petitioner during the survey, as part of the informal dispute resolution (IDR) process, or as part of the prehearing exchange of proposed exhibits. It appears, however, that the State surveyors had access to all of Petitioner's clinical records and were never denied access to any clinical records. See Tr. 298, 907. HCFA has never argued that the State surveyors advised Petitioner to produce all of the clinical records in its possession relative to each issue raised by the State surveyors during the survey process, or that the failure to present such evidence at the time of the survey would preclude Petitioner from

offering it at a later date. For example, it appears Petitioner was allowed by HCFA to offer further evidence of its compliance at the time of the IDR. Even as to such evidence, HCFA never argued that it represented Petitioner's full submission of relevant evidence. The State Operations Manual requires surveyors to ask facility staff to assist them in finding information that the surveyor is unable to find on his or her own or that requires validation. P. Br. at attached Ex. D, page P-23. It appears here that Petitioner was not informed during the survey with regard to the specific regulations it was alleged to have violated, and that it provided documentary information based on concerns brought to Petitioner's attention by the State surveyors. Tr. 787, 900-902, 907. However, it was not until the exit conference that Petitioner was informed of the deficiencies against it, and then only generally under quality of care or life. Tr. 911-914. While Petitioner could have produced these documents more timely (at the IDR or as a part of the prehearing exchange), this is a de novo hearing. I am reluctant to exclude documents which were available at the site, and relevant to the period covered during the survey and the issues raised by the deficiency citations. It is common that the specifics of the cited deficiencies become focused in the context of a hearing. It is also not unusual that the parties will discover evidence at that time that is necessary to the presentation of their cases to respond to or to clarify testimony of witnesses presented at the hearing. In my judgement, due process and fairness dictate that such evidence should be received at the hearing, unless a party can establish extraordinary prejudice. HCFA's counsel was given the opportunity to review the newly submitted evidence and discuss it with his technical expert prior to presentation of such evidence. The requisite prejudice was never demonstrated. Under similar circumstances, HCFA was allowed to offer documents at the hearing which were not included in its exchange.

II. Discussion

A. Basis for evaluation of deficiencies

Below, I evaluate each of the deficiencies identified by DHS and adopted by HCFA. In my analysis of each deficiency, I must determine whether, for each deficiency, HCFA has put forward a prima facie case that a deficiency existed. If HCFA has put forward this prima facie case, I must then determine whether Petitioner has successfully rebutted HCFA's prima facie case and proved, by a preponderance of the evidence, that no deficiencies existed causing it to be out of substantial compliance with participation requirements. Finally, if, after evaluating all the evidence, I find that a deficiency existed, I must determine whether the deficiency demonstrates substantial compliance, i.e., whether the deficiency posed no greater risk to resident health

or safety than the potential for causing minimal harm.[6] I address each deficiency in the order in which it appears in DHS' statement of deficiencies (HCFA Form 2567) prepared following the completion of the July survey. HCFA Ex. 15.[7]

1. Petitioner was not in substantial compliance with the participation requirement at 42 C.F.R. § 483.10(b)(2)(i) during the July survey, with respect to HCFA's finding of a deficiency at F Tag 153, and the deficiency constituted a potential for more than minimal harm to the resident.

This regulation states, in pertinent part, that a resident or his or her legal representative has the right, upon either an oral or written request (emphasis added), to access all records pertaining to him or herself, including current clinical records, within 24 hours (excluding weekends and holidays). 42 C.F.R. § 483.10(b)(2)(i).

During the July survey, HCFA found that Petitioner was not in substantial compliance with this requirement. HCFA Ex. 15 at 1, F Tag 153. HCFA asserts, based on interviews and record reviews conducted by State surveyors, that Petitioner failed to ensure that, upon an oral request, the legal representative of a resident was able to access all records within 24 hours.

Specifically, based on the State surveyors' interview and record review, HCFA alleges the following facts: a family member of a resident stated that when she requested access to her grandmother's clinical record, the licensed nursing staff member

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[6] I note here Petitioner's argument that if it is found noncompliant, the failure must have a serious negative impact on a resident, such as harm or a strong potential for harm, before it can be found out of compliance and a denial of payment for new admissions is imposed. Further, Petitioner argues that the noncompliance has to be of such a character as to substantially affect the health and safety of patients. I do not agree. The regulations define noncompliance as any deficiency that causes a facility to not be in substantial compliance, and substantial compliance to be a level of compliance such that any identified deficiency poses no greater risk to resident health or safety than the potential for causing minimal harm. 42 C.F.R. § 488.301. I find nothing in the current statute or regulations to suggest that either of the standards Petitioner asserts exists.

[7] On August 1, 1996, Petitioner requested an IDR with DHS concerning the July survey. HCFA Ex. 12 at 1. On August 28, 1996, DHS notified Petitioner of its findings, agreeing to delete some of the deficiencies listed in its first statement of deficiencies. HCFA Ex. 9. Subsequently, DHS clarified its written IDR decision (HCFA Ex. 14) and a new statement of deficiencies was prepared for the July survey, in conformity with DHS' written IDR decision. HCFA Ex. 15.

she talked to told her that facility policy required her to provide the facility 72 hours notice in advance; on July 11, 1996, a licensed nursing staff member stated that the family member grabbed the clinical record from another licensed nurse and read the record without permission; the staff member stated that she was not aware whether family members were allowed access to the clinical record; the family member stated she has a durable power of attorney to make health care decisions for the resident; however, this durable power of attorney was not included in the resident's clinical record until after this incident occurred. HCFA Ex. 15 at 1-3, F Tag 153.

Both parties now agree that the family member who requested and then grabbed the resident's chart was a granddaughter. HCFA's Initial Post-hearing Memorandum (HCFA Br.) at 29; P. Br. at 2-3. The evidence indicates that the granddaughter was told by the facility that she needed to make a written request (HCFA Ex. 31 at 8; P. Ex. 4) and that the State surveyor was also informed by Petitioner's staff of the 72-hour advance notice requirement. Tr. 296; HCFA Ex. 44 at 4. At the time of this incident, Petitioner's written policy was that it would provide records to a resident or a resident's representative within 24 hours of a written request.[8] Tr. 284-85; HCFA Ex. 31 at 9.

Petitioner primarily argues that this incident did not constitute a deficiency, because the granddaughter, who was an alternate agent, had no legal right to review her grandmother's records. P. Br. at 6. However, Petitioner's argument misses the point. The thrust of this regulatory requirement is to provide residents and family members access to records. Here, the granddaughter was in the facility ready to act, and it appears that the mother, the agent, was not. Arguing that the granddaughter, as an alternate agent, should not have access to the records unless her mother, the agent, could be shown under strict rules of evidence not to be available, would render the regulation meaningless. Most importantly, however, this incident is a reflection of Petitioner's policy regarding access to records. Even if I assume that the granddaughter had no authority to see the records, this does not overcome the fact that Petitioner had a policy regarding access to records which contravened the regulations and which applied to <u>all</u> residents and residents' representatives with a legal right to examine records. Specifically, the policy in effect at the time of this incident stated that a record request had to be in writing. P. Ex. 4 at 1, P. Ex. 5 at 5; HCFA Ex. 31 at 9; Tr. 824. This is in direct contravention of the regulations, which allow for a written or oral request.

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[8] Although a copy of a document entitled "Resident Rights Under Federal Regulations," given to Petitioner's residents as an attachment to Petitioner's Complete Resident Admission Agreement, tracks the language of the regulation. P. Ex. 3 at 9.

Petitioner argues that it is standard in the nursing home industry to require that an oral request be reduced to writing. P. Br. at 7. However, while a facility may have a policy to reduce oral requests to writing after the fact in order to maintain a record of a request, this practice cannot be used to impose a written requirement on a resident or a resident's agent before access to a record is granted where the regulation clearly requires access upon either a "written or oral" request. See HCFA Ex. 31 at 9.

Petitioner argues also that the discrepancy in what the nurse said (that a resident or resident's representative had to give 72 hours written notice before receiving the record), and the 24 hours required by the regulations, is unimportant, because the discrepancy would have been corrected through the chain-of-command at the facility, as the resident or the resident's representative was supposed to direct such requests to Petitioner's administrator or the administrator's designee. P. Br. at 7. This argument is not persuasive. There is no evidence to support Petitioner's assertion that requests were scrutinized by others before being granted. There is no evidence that a requestor would be aware that a request had to be made to an administrator or designee. The notice of resident's rights cited by Petitioner fails to describe the in-house process claimed by Petitioner. P. Ex. 3. Moreover, Petitioner's written policy, as set forth in HCFA Ex. 31 at 9, does not impose such a requirement on requestors, nor does it track the regulatory requirements. The record strongly suggests that Petitioner's staff (at least the staff dealing directly with residents) were, at best, confused about the requirements of Petitioner's policy. Such misinformation regarding how long it might take a resident or a resident's representative to gain access to a resident's records might have a chilling effect on a resident or representative who wants to see the records.

Petitioner argues further that the allegations in the HCFA Form 2567 prove that the family member requesting the chart read it within 24 hours of making the request. P. Br. at 7. However, self-help by a requestor does not excuse a policy that contravenes the regulations. Further, the argument that 24 hours had to elapse before a violation occurs is without merit. The violation here is that Petitioner's policy requires written acknowledgment of oral requests before any access is granted. It is also irrelevant that the request was made on a Saturday. While weekends, by regulation, are not included within the 24-hour requirement, this access requirement is separate from Petitioner's policy with regard to oral requests.

Petitioner's Director of Nursing (DON), testified that, despite Petitioner's policy of requiring written requests (acknowledged by the DON at Tr. 824), if a resident or resident's representative refused to sign a written acknowledgment of a request, the request would be granted. Tr. 827-829. I do not find this testimony credible, as it specifically contradicts

Petitioner's written policy. Further, Petitioner revised its policy two weeks after the July survey (compare P. Ex. 6 at 3 with P. Ex. 3 at 9) to remove the requirement that a request be in writing, further suggesting that this requirement was imposed on residents or their representatives at the time of the survey.

Thus, I determine that HCFA put forth a prima facie case which Petitioner has not rebutted. Further, I determine that the potential inability of residents or their representatives to gain timely access to their records, as reflected in Petitioner's policy, has the potential for causing more than minimal harm to the health or safety of residents and had the potential to cause such harm to the resident in question here. While I have no information on actual harm, it is apparent that the resident's granddaughter had to go to extraordinary lengths of self-help to obtain a copy of the resident's records. This suggests to me that the granddaughter had a significant need to see those records. Residents' representatives may have information to contribute with regard to the care of a resident. Timely access to records may result in a resident or resident's representative discovering inappropriate rendering of care by a facility or provide a check on the quality of care provided to a resident. Without timely access, a valuable restraint on facilities' practices may be limited, which may negatively impact on residents' health and safety.

2. Petitioner was not in substantial compliance with the participation requirement at 42 C.F.R. § 483.10(b)(11) during the July survey, with respect to HCFA's finding of a deficiency at F Tag 157, and the deficiency constituted a potential for more than minimal harm to the resident.

This regulation states, in pertinent part, that a facility must immediately inform a resident's physician when there is a significant change in the resident's physical, mental, or psychosocial status (i.e., a deterioration in health, mental, or psychosocial status in either life-threatening conditions or clinical complications).

During the July survey, State surveyors found that Petitioner was not in substantial compliance with this requirement. Based on the State surveyors' record review, interviews, and observation, HCFA asserts that Petitioner failed to immediately consult with resident 3's physician when there was a significant change in this resident's physical condition or complications in the clinical condition. HCFA Ex. 15 at 7, F Tag 157. To support its assertion, HCFA alleges that resident 3 had a Stage IV decubitus ulcer (a decubitus ulcer or a pressure ulcer will be referred to hereinafter as a pressure sore) on her left hip. On June 17, 1996, licensed nurses notes taken at 3:30 p.m. indicate that resident 3's left hip had a large amount of brownish red drainage with an odor, and that a message was left for resident 3's physician. Documentation on the Decubitus Report of June 19, 1996, indicates that the pressure sore measured 1.3 x 1.5 x 2.5

centimeters, with undermining at 4 centimeters at 6-7 o'clock and 3.5 centimeters at 9 o'clock with pink yellow drainage with a slight odor, slow to respond to healing. On June 26, 1996, the pressure sore measured 2 x 1.5 x 2.5 centimeters with undermining at 6-7 o'clock at 4 centimeters and at 9 o'clock at 3.5 centimeters, with a large amount of brown drainage and a slight odor. According to the licensed nurses notes, a message was again left for the physician. On June 29, 1996, the physician responded and gave orders for treatment. HCFA contends that there was no documentation that the facility contacted a physician regarding the "infected" wound for 12 days. By July 3, 1996, the pressure sore measured 2 x 1.5 x 3 centimeters, with undermining at 6-7 o'clock and 9 o'clock at 4 centimeters, still with brown drainage with an odor. Additionally, resident 3's white blood count increased from 10.5 on May 28, 1996 to 16.2 on June 17, 1996 (where a normal white blood cell count is 4-10). HCFA Ex. 15 at 7-8, F Tag 157.

I find that HCFA has sustained its position that there was a significant change in this resident's physical condition which should have caused Petitioner to immediately consult with the resident's physician. Resident 3 was an 87 year old diabetic with multiple medical problems, including seizure disorders, urosepsis, incontinence, dementia, and the Stage IV pressure sore on the back of her left hip, which exposed bone and muscle. She was totally dependent on Petitioner. Tr. 91, 120. The record reflects that resident 3's pressure sore started to show signs of deterioration on June 17, with an increase in her white blood count, which continued on June 19 with the added symptoms of increased drainage with an odor. P. Ex. 8 at 5b. This combination of the increase in the white blood count and the odor should have indicated to Petitioner a need to consult with resident 3's physician to determine whether treatment needed to be altered.[9] Tr. 94, 118-119.

A second significant change in the pressure sore occurred on June 26, when the size increased and there was a significant amount of brown, as opposed to serosanguinous, drainage, as well as odor.

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[9] Petitioner argues that the drainage alone was not a significant change in the status of the pressure sore. Further, Petitioner argues that the State surveyor who testified with regard to this deficiency, contradicted herself by stating that the conditions present on June 19 did not reflect signs of infection. Tr. 107-108. However, this mischaracterizes the testimony of the surveyor. The surveyor did state that the drainage alone was not necessarily a sign of infection. However, the surveyor then said that combining the drainage with a slight odor indicated "the beginning of something starting." Tr. 108. The surveyor testified further that the elevated white blood count of June 17, combined with the discharge and odor of June 19, constituted a significant change in resident 3's condition. Tr. 94, 117-118.

P. Ex. 8 at 5b; HCFA Ex. 42 at 19. At this point, the licensed personnel weekly progress notes reflect that there was a change in condition prompting Petitioner to call resident 3's physician and request that he return the call. HCFA Ex. 42 at 19. The physician's progress notes for June 29 indicate that resident 3's physician examined the pressure sore and then ordered the antibiotic Keflex to treat it. P. Ex. 11 at 2; Tr. 1066.[10]

Petitioner asserts that the ordering of antibiotics was not a significant change in this pressure sore. I disagree. Even if resident 3 had been treated in the past for this pressure sore, and even if in the past the pressure sore varied in size and condition, and even if her physician was informed of resident 3's status and his orders were followed (see P. Ex. 12), the issue is not the pressure sore's history, but the timeliness of the notification and the import of any delay.

The precise reason for the regulation is that when there is a significant change in condition, a physician should be notified so that appropriate treatment can be timely initiated. In this case, the potential for harm began on June 19, when the change in the white blood count was followed by an odor emanating from the pressure sore. Tr. 118-119, 139-140, 149.[11] Here, there is both a potential for more than minimal harm to the resident and possible actual harm, in that the pressure sore on June 26 (as compared to June 19 when odor was identified) increased in size and arguably became more infected (as exemplified by the amount

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[10] In a physician's note dated July 30, 1996 (P. Ex. 11 at 2) resident 3's physician notes that he saw resident 3 on May 31, 1996, and, as of that date, she had a stable pressure sore, with no evidence of infection or worsening. The physician's note may have been in response to a June 17, 1996 note on the same page, indicating that he did not see resident 3 in May. However, the status of the pressure sore on May 31, 1996, is irrelevant as to whether there was a significant change in the pressure sore on the dates in question.

[11] I note here Petitioner's argument that the elevated white blood count of June 17 could have been caused by resident 3's urosepsis. P. Br. at 14. While this may be true, it is at least as likely that the elevated white blood count was caused by an infected pressure sore. By June 19, the elevated white blood count, combined with the odor in the pressure sore, should have alerted the facility to contact the physician with regard to the pressure sore. The controlling factor in determining compliance with this regulation is whether the facility had sufficient information regarding a potential change in condition which might adversely affect the resident. It is the physician's prerogative to decide whether the information supplied warrants a change in treatment. The purpose of the regulation is to create an avenue of communication between the caregiver presently treating the patient and the physician who is directing such treatment.

and type of drainage identified) due to the delay in the administration of antibiotics until June 29.

Even if I accept Petitioner's argument that there is no change other than the increase in drainage reflected by resident 3's physician's report (P. Br. at 13), this change alone indicates a significant change in condition. As reflected in HCFA Ex. 42 at 19, the licensed nurse's progress notes indicate the nature of the condition, reciting resident 3's physician's order for the antibiotic Keflex: "new orders rec'd for infected decub."

I find that the evidence demonstrates a deterioration in the condition of this pressure sore from June 19 to June 26. Moreover, there was sufficient indication as of June 19 to alert Petitioner that the pressure sore was becoming infected, such that Petitioner should have notified resident 3's physician on June 19. Petitioner did not notify resident 3's physician until June 26, when it telephoned him and asked him to return the call. At the least, HCFA proved that there was a potential for more than minimal harm here. By delaying treatment of an infected pressure sore, Petitioner put the resident at risk of sepsis (a condition in which bacteria invades the bloodstream, can impact all other major organisms, and can lead to septic shock and death if not treated). Tr. 124-125, 134.

3. Petitioner was in substantial compliance with the participation requirement at 42 C.F.R. § 483.15(a) during the July survey, with respect to HCFA's findings a and b of F Tag 241.

This regulation states, in pertinent part, 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 his or her individuality. Based on the State surveyors' record review, observations, and interviews, HCFA alleges that Petitioner failed to promote such care in four of 18 sample residents and one non-sample resident. In two of the instances, as set forth below, I find that HCFA has not made its prima facie case. Thus, Petitioner prevails.

F Tag 241 a. Based on the observations of a State surveyor, HCFA alleges that on July 11, 1996, at approximately 4:20 p.m., three residents were observed sitting in their wheelchairs lined up against the wall of a hallway in front of the facility's main dining room. Resident 19 was standing in front of the other residents talking to them. A certified nursing assistant (CNA) approached the dining room, opened the door, and the door hit resident 19's back. The resident fell forward from the force, towards the residents sitting in wheelchairs. The surveyor alleged that resident 19 stated "She (the CNA) almost knocked me down." The CNA indicated to the surveyor that she was aware what had occurred, but she did not acknowledge this by checking resident 19 for injuries, nor did she apologize to resident 19. HCFA Ex. 15 at 10-11. In P. Ex.

17, Petitioner appears to admit that its investigation of this matter established that the incident occurred in the manner stated by the surveyor.[12]

The allegation that the CNA struck resident 19 with the door (even if true), does not constitute an intentional act on the part of the CNA. It was accidental. Any failure to meet the regulatory requirement allegedly violated here would be the CNA's alleged failure to examine and apologize to the resident. However, there is no evidence that the conduct of the CNA was prompted by any facility policy.

The regulatory requirement in question here calls for action by the facility, not a single incident by an employee where there is no showing that the employee's action was taken consistent with facility policy or with approval from the facility after the incident occurred. In fact, in this case, once the facility learned of and then investigated the incident, the CNA was fired. Tr. 835-838, 1059-1061; P. Ex. 14, 17. This action on behalf of the facility to determine the circumstances of the incident, examine the resident for injuries and, finding none, discipline the employee, meets the regulatory requirement.

F Tag 241 b. Based on the observation of a State surveyor, HCFA alleges that on July 11, 1996, at approximately 4:00 p.m., an alert resident 11 stated that a CNA told her how demanding she is and then stated, "Just looking at your face makes me sick." Allegedly, resident 11 further stated that she realized that she constantly demanded assistance; however, what the CNA said really hurt her. The surveyor alleged that resident 11 had a diagnosis of cerebral vascular accident with left-sided hemiplegia and requires total assistance in all areas of activities of daily living. HCFA Ex. 15 at 11.

The record reflects that resident 11 is a 59-year-old woman who was admitted to the facility with a right mid-cerebral aneurysm with subarachnoid hemorrhage. This means that the resident had ruptured a blood vessel in her brain and then underwent a craniotomy which left her left side paralyzed and nonfunctional. This resident became totally dependent on staff for her activities of daily living. Tr. 327-328; HCFA Ex. 29 at 1. Resident 11 was also being treated for anxiety and depression. P. Ex. 18 at 2, 19, 20 at 4. Medical records indicate that resident 11 had periods and episodes of confusion and forgetfulness. P. Ex. 22. Resident 11's physician stated in a

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[12] However, I note that another witness to the incident states that when the CNA opened the door, the CNA may not have seen resident 19. This witness also states that he "stopped the door a little," and that the door touched resident 19 a little, but did not push resident 19. P. Ex. 14.

declaration[13] in lieu of testimony that resident 11 had negative, despairing feelings related to her loss of functionality and severe physical deformity, and that her feelings were likely to be projected by her onto others. Resident 11's physician states further that resident 11 might have believed that others found her as unattractive, frightening, or burdensome as she herself thought she was. P. Ex. 18, 19.

The mere allegation by resident 11 that this statement was made, without further proof, and where resident 11 was suffering from a mental impairment, including confusion, impairs the credibility of her statement and is not enough, standing alone, to support HCFA's allegation. However, even if I assume that this incident occurred, there is no showing that the incident was condoned by the facility. The facility cannot be held accountable for every comment made by a staff member to a resident which may hurt a resident's feelings, in the absence of evidence showing that the facility knew about and tolerated such remarks. HCFA here has not met its prima facie case that the regulation was violated.

4. Petitioner was not in substantial compliance with participation requirements at 42 C.F.R. § 483.15(a) during the July survey, with respect to HCFA's finding of deficiencies at paragraphs c and d of F Tag 241, and the deficiencies constituted a potential for more than minimal harm to the residents.

F Tag 241 c. HCFA alleges that a family member of resident 13 stated to a State surveyor that resident 13's call light was on for 10 minutes before the CNA came. Allegedly, the resident requested a special type of bedpan, which the CNA was not able to immediately provide. When the CNA came back, the resident had wet her bed and the CNA allegedly stated, "Look what you did, you wet your bed, now I have to change the whole bed." HCFA asserts that Resident 13 has a diagnosis of right hip replacement and requires total assistance in all areas of activities of daily living. HCFA Ex. 15 at 11.

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[13] HCFA argues that resident 11's physician's declaration should be discounted, since it was prepared for litigation and occurred after July 11. I do not agree. There is ample evidence in the medical record to corroborate the existence of resident 11's mental condition as of July 11. P. Ex. 20, 22. Further, this exhibit is a good example of where some latitude must be allowed an administrative law judge in determining whether an exhibit should be received where it did not exist at the time of the survey. A rigid standard favoring exclusion in such cases gives HCFA an unfair advantage and prevents petitioners from presenting relevant information that was available, but not produced, at the time of the survey.

The record reflects that resident 13 was an elderly woman with osteoarthritis and status post right hip replacement who required care in all activities of daily living and a special bedpan due to her hip surgery. Tr. 348-351; HCFA Ex. 31 at 1.

With regard to these allegations, the only evidence presented that the CNA made this comment to the resident is the statement of resident 13's family member to the State surveyor. The CNA, in a written declaration and in interdisciplinary team notes of July 2, 1996, stated that she does not recall having a conversation. P. Ex. 29, 31. Another CNA, who testified in a written declaration that she was in the room at the time, does not recall any conversation taking place. P. Ex. 28, 32. HCFA did not call the family member to testify, nor did it supply a declaration of the family member in question. Here, I find that the preponderance of the evidence shows that the statement was not made. However, this does not mean, in this instance, that a violation of this requirement did not take place.

Of particular importance here is the failure of the facility to have the special bed pan near the resident for her use. Whatever the timing of the CNA's response to resident 13, the CNA herself confirms that she had to go to "another station to obtain the right bed pan." P. Ex. 29 at 2. By the time she returned, resident 13 had become incontinent. P. Ex. 29 at 2. The facility should have been aware of the type of bedpan this resident needed and should have had it located where it could be obtained promptly by a CNA. The failure to have this necessary piece of equipment available, especially where its use should have been anticipated given resident 13's medical status, led to resident 13's unnecessarily wetting the bed in the presence of others. I find that such inaction on the part of the facility resulted in the potential for more than minimal harm to this resident's dignity, in that she likely suffered the unnecessary embarrassment of incontinency in front of others. I have no information from this record as to whether the resident suffered actual harm. The resident in question was never interviewed by the State surveyor, so I am unable to determine her reaction to this situation.

F Tag 241 d. Based on the observations of a State surveyor, HCFA alleges that, on July 11, 1996, the surveyor observed resident 9 sitting in a wheelchair in a corridor among other residents wearing boots with heavy black smudges and brown food stains. HCFA alleges further that the hat resident 9 wore had dried yellow, brown, and red liquid stains. HCFA notes also that resident 9 has a severe visual impairment and requires assistance with the activities of daily living. HCFA Ex. 15 at 11, 14. Resident 9's patient records reflect that resident 9 had highly impaired vision and hearing. P. Ex. 36, 39, 40, 41, 42, 99.

Under the regulatory requirement, the facility has an obligation to maintain a resident's dignity, which includes ensuring that a resident wear clean clothing. Here, the resident's clinical record indicates that his care plan required Petitioner to assure that he be dressed daily with proper attire. P. Ex. 38 at 2. It also identified inappropriate behavior on resident 9's part, such as spitting and throwing food on the floor. P. Ex. 38 at 1, 39. Consequently, Petitioner was on notice from the resident's own records that he would need constant monitoring to preserve cleanliness. However, resident 9's patient records and the observations of the State surveyor do not reflect adequate attention by Petitioner to this problem. I find credible the testimony of the State surveyor as to the soiled condition of Petitioner's boots and hat. Tr. 485-487; HCFA Ex. 27 at 1.

Petitioner argues that the facility respected resident 9's dignity by allowing him to wear preferred items of clothing. P. Br. at 26-27. Petitioner's social service's designee testified that resident 9 resisted all efforts Petitioner made to dress and groom him, including efforts to clean resident 9's boots and hat. P. Br. at 26-27; Tr. 944-945. I agree with HCFA, however, that Petitioner had an obligation to take alternative action if resident 9 resisted having his hat and boots cleaned. I note that nowhere in the record is such attempt reflected. Tr. 508. Moreover, I note that documentary evidence of record does not reflect that resident 9 refused to have his clothing cleaned. See P. Ex. 36 (where resident 9 is assessed as "friendly upon approach," "alert," and "appears oriented during conversation)." In fact, it appears that resident 9 may have been receptive to such changes, since, following the State survey, resident 9's hat was cleaned without documentation of problems on his part. Petitioner's Second Supplemental Brief (P. Resp. Br.) at 18; Tr. 490-491.

Petitioner asserts that its practice was to wipe off resident 9's boots daily and argues that the hat was merely minimally stained. P. Br. at 26. To support the assertion that Petitioner's boots were wiped off daily, Petitioner offered the testimony of the facility's social services designee. However, her testimony is not credible because she spoke in general terms about the care for resident 9. She did not personally care for the resident on a daily basis; nurse's aides did. She never observed this activity, but merely recited that this "would be the routine for him in the morning." Tr. 943.

Petitioner asserts also that resident 9's son stated, under oath, that he believed Petitioner was providing quality care, in a caring environment, for his father, and that he never stated his father was in soiled clothes, boots, or hat. P. Resp. Br. at 18. However, there is no evidence that the son observed the condition of the resident's hat and boots on July 11, 1996. There is no credible evidence to corroborate that Petitioner did the best it could, under the circumstances, to respond to resident 9's soiling of his boots and hat.

In sum, although resident 9's care plan identified that he was to be dressed daily in proper attire (which, arguably, would cover a clean hat and boots) the record does not support that the facility kept him in proper attire. Resident 9's hat and boots were soiled. Petitioner took no documented steps to correct the situation. If, for example, Petitioner had an established procedure for cleaning the boots at a particular time and the surveyor had observed stains prior to cleaning, I would not necessarily conclude that a violation of the regulation had occurred. However, I do not find that the record supports such a conclusion.

I conclude also that there was the potential for more than minimal harm to resident 9's dignity. Petitioner argues that it allowed resident 9 to wear preferred items of clothing, which maintained and enhanced his dignity and respect in full recognition of his individuality. I agree with HCFA, however, that the issue here is different. This issue is whether leaving a resident, who needs assistance in choosing clean clothing, in soiled hat and boots, comports with the regulatory requirement. I agree with HCFA's conclusion that, due to the condition of resident 9's hat and boots, resident 9 suffered potential humiliation in front of his peers.[14] See Tr. 496. Further, I agree with HCFA's conclusion that resident 9 also suffered an insult due to the fact that, given his infirmities, he may not even have been aware of the cleanliness status of his hat and boots. See Tr. 493.

5. Petitioner was in substantial compliance with the participation requirement at 42 C.F.R. § 483.20(b) during the July survey, with respect to HCFA's finding of a deficiency pertaining to F Tag 272 relating to resident 9's ability to communicate, but was not in substantial compliance with such participation requirement as it pertains to resident 9's ability to independently dress, and the deficiency pertaining to independent dressing constitutes a potential for more than minimal harm to resident 9.

This regulation states that a facility must make a comprehensive assessment of a resident's needs, based on a uniform data set specified by the Secretary, using an instrument specified by the State and approved by the Secretary, which describes the resident's capability to perform daily life functions and

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[14] I have insufficient information to determine actual harm, particularly if I use as a gauge for such harm the impact of such action on the resident. The record is somewhat equivocal as to his desires regarding the need for clean clothing. If I applied a reasonable person standard (what a resident would likely desire in such circumstances), I would have to conclude that a resident would not want to wear soiled clothing which might make the resident subject to the ridicule of others. In such circumstances, actual harm could be shown.

significant impairments in functional capacity. The regulation lists 13 different areas of information which the comprehensive assessment must include, one of which is sensory and physical impairments.

Based on the State surveyors' record review and observation, HCFA determined that Petitioner failed to make a comprehensive assessment of resident 9's needs regarding sensory and physical impairments. Specifically, HCFA argues that resident 9's Minimum Data Set (MDS), dated July 8, 1996, indicates that he is independent in dressing. However, resident 9 was observed sitting in a wheelchair in the corridor, fully dressed, on July 10, 1996, wearing soiled clothing. HCFA asserts that resident 9 has severe visual and hearing deficits and was not observed with a hearing device on July 10 or 11, 1996. The facility staff members were unable to communicate with the resident. HCFA Ex. 15 at 17-18, F Tag 272.

I find that HCFA has not put forth a prima facie case that Petitioner failed to make this assessment as it pertains to resident 9's ability to communicate. However, HCFA has put forth a prima facie case relating to resident 9's ability to engage in independent dressing. While Petitioner adequately assessed resident 9's sensory and physical impairments regarding the resident's ability to communicate, it did not do so regarding his ability to independently dress. It is reasonable to conclude that the ability to independently dress subsumes the ability to dress in appropriate clothing.

With regard to resident 9's ability to communicate, his full annual MDS, from January 10, 1996, indicates that he is highly impaired in both vision and hearing, but notes that he is usually understood when he communicates. P. Ex. 99 at 1-2. Resident 9's quarterly MDS, from July 8, 1996, indicates that he exhibited behavioral symptoms of socially inappropriate or disruptive behavior, but that he is "usually understood" and "sometimes understands" others (P. Ex. 37 at 1), and interdisciplinary team quarterly conference notes of July 6, 1996, indicate no significant change in his activity status. These notes indicate also that resident 9 appears alert and oriented during conversation and, that while his hearing and vision are impaired, he is able to get around. P. Ex. 36. I find no record evidence to support the State surveyor's statement that facility staff was unable to communicate with the resident. To the contrary, there is contemporaneous documentation in the January 10, 1996 interdisciplinary team notes which indicate that the resident is usually understood and understands with appropriate voice elevation, and that the resident's family did not want him to wear a hearing aide, as the resident is usually able to understand without one (P. Ex. 41), which is consistent with the interdisciplinary team assessment of July 6, 1996. P. Ex. 36. In fact, the State surveyor's testimony indicated that she was able to communicate with the resident and that he was able to communicate with facility staff. Tr. 526, 545.

With regard to resident 9's ability to independently dress, HCFA noted that the resident was wearing soiled clothing, despite his MDS indicating that he was independent in dressing. Thus, HCFA is contending by implication that the MDS was invalid because the soiled wearing apparel establishes that the resident was not capable of independent dressing. Consequently, the MDS did not accurately describe this resident's capability to perform daily life functions. I note that I upheld a deficiency regarding this resident's soiled clothing, at Finding 4, F Tag 241 d, concerning 42 C.F.R. § 483.15(a), which relates to maintaining or enhancing a resident's dignity and respect in full recognition of his or her individuality. HCFA's counsel did not discuss this part of the deficiency cited under F Tag 272 in his briefing, nor was there specific testimony by the State surveyor relating to this issue. At the hearing, there was testimony referring to the resident's need to use vaseline to insert his hearing aid into his ear.[15] HCFA's counsel raises this point in discussing this deficiency. HCFA Br. at 47. I reject such evidence as being unrelated to the cited deficiency. It was not cited by HCFA in the HCFA Form 2567 pertaining to F Tag 272. However, despite HCFA's failure to specifically reference evidence relating to this F Tag, I do consider the evidence introduced regarding F Tag 241, since it pertains to the deficiency cited under F Tag 272. Petitioner knew or should have known that the evidence for F Tag 241 also applies to F Tag 272, even where HCFA does not specifically raise the point in its briefing. A similar factual deficiency was cited under two separate regulatory provisions. In essence, the same facts violate the requirements pertaining to quality of life and resident assessment.

For purposes of F Tag 272 relating to resident 9's ability to engage in independent dressing, I will incorporate my discussion in Finding 4 regarding F Tag 241 d. This resident's appearance in soiled clothing suggests that he was not independent in dressing, in that he either was not cognizant of his appearance or did not have sufficient mental acuity to realize that his appearance could affect his ability to interact with other residents in the facility who might be react negatively to his appearance. The MDS is the instrument that the facility is required to use to ensure that the resident's clothing appearance is appropriate and, if it is not, the facility must take steps to correct it. The comprehensive assessment for this resident did not adequately deal with his propensity to wear soiled clothing to his detriment. Such failure by Petitioner, as I found above in Finding 4 at F Tag 241 d, has the potential for more than minimal harm to resident 9's dignity, and may have subjected him to be held in ridicule by other residents of the facility.

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[15] There was a specific deficiency cited under F Tag 246 relating to resident 9's hearing aid, and to the resident's need to use vaseline to apply the hearing aid. HCFA Ex. 15 at 15-16. This deficiency was deleted as a result of the informal dispute resolution process.

6. Petitioner was in substantial compliance with the participation requirement at 42 C.F.R. § 483.20(b)(4)(iv) during the July survey, with respect to HCFA's findings a and b of F Tag 274.

This regulation states, in pertinent part, that resident assessments must be conducted promptly after a significant change in the resident's physical or mental condition.[16]

F Tag 274 a. Based on the July survey, HCFA concluded that Petitioner failed to conduct an assessment promptly for resident 1. HCFA alleges the following: Resident 1 was readmitted to Petitioner's facility on January 9, 1996, weighing 114.3 pounds. Her usual weight range is 100-110 pounds and her ideal body weight range is 90-110 pounds. Documentation on the vital signs and weight record of April 1, 1996, indicated that resident 1 weighed 115 pounds, and on May 22, 1996, documentation indicated that resident 1 weighed 123.8 pounds, showing an increase of 8.8 pounds from the previous month. There is no documentation to indicate that the resident's physician was immediately notified of this weight gain. The resident's physician was finally notified on May 31, 1996, nine days after the assessment of the 8.8 pound weight gain. On June 21, 1996, documentation in the vital signs and weight record indicates that resident 1 weighed 129 pounds, showing a 5.2 pound weight gain. There is no documentation that the physician was immediately notified of this weight change; in fact, documentation indicates that notification of the physician was not indicated and that resident 1 would be reweighed. However, resident 1 was not reweighed until June 24, 1996, three days later, and the weight indicated was 128.2 pounds. Again, the facility did not notify the physician. On June 29, 1996, documentation in the Nutritional Assessment notes indicates a 4.4 pound weight gain over the past month. The concern reflected there is that the resident had been on tube feeding at 70 cubic centimeters per hour and was taking 35-40% of a pureed diet and 100% of an Ensure drink three times a day. Further investigation revealed a recommendation to reduce tube feeding to 40 cubic centimeters per

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[16] Petitioner argues that the dates referred to in Findings 6 at F Tag 274 a and b and 7 below, for the July survey, were prior to the June 21, 1996 completion date for Petitioner's plan of correction for correcting deficiencies identified during the June survey under F Tag 157, 42 C.F.R. § 483.10(b)(11), regarding physician notification. Thus, Petitioner asserts, HCFA should be precluded from citing them as deficiencies pursuant to the July survey. I agree with HCFA that it is not precluded from citing these deficiencies here, as the deficiencies are cited under a different F Tag in the June survey. I note also that HCFA has not asserted in its briefing that these incidents violate 42 C.F.R. § 483.10(b)(11) with regard to the July survey, and I am not considering that section with regard to the deficiencies cited here.

hour. HCFA asserts that a review of the clinical record revealed that Petitioner failed to notify the physician of the recommendation. Upon inquiry, facility staff were unclear as to why the recommendation had not been forwarded to resident 1's physician for consideration. HCFA. Ex. 15 at 19-20.

In sum, HCFA asserts that resident 1 gained approximately 14 pounds in 5 months. She is above her usual weight range and ideal body weight range. Resident 1 is totally dependent on facility staff, and has many medical problems, including chronic renal failure. HCFA Ex. 15 at 20.

The regulatory section cited here refers to significant changes in a resident's physical or mental condition which mandate a prompt assessment, not to whether or not a physician has been notified of a change in a resident's condition.[17] Thus, whether or not resident 1's physician was advised as to her weight gain is irrelevant in and of itself. The question here is whether resident 1's weight gain should have necessitated a prompt assessment by Petitioner.

The record reflects that resident 1's weight gain resulted from a physician's order to increase her tube feeding as of April 28, 1996, due to poor oral intake of food. P. Ex. 46. Thus, resident 1's weight gain appears to have been a planned event under the scrutiny of her physician. Resident 1's weight was monitored during the period in question and her physician was notified at various times. P. Ex. 46, 47 at 2-4, 113 at 3-4. Once the weight gain goal was achieved, the amount of the tube feeding was adjusted downward, pursuant to her physician's order. P. Ex. 47 at 4.

Arguably, the only time an assessment may have been appropriate was in April 1996, when the decision was made to increase resident 1's rate of tube feeding. At this point, it appears that her poor oral food intake could have compromised her health and necessitated a change in her manner of nutrition. While there may have been times when her physician was not promptly notified of a weight gain (as on May 22, 1996, where resident 1 showed an 8.8 pound gain from the previous month and the physician was not notified until May 31, 1996 (P. Ex. 45, 47 at 2)), there is no allegation in the deficiency cited that her weight gain led to a significant change in her health warranting reassessment. Furthermore, HCFA's "Guidance to Surveyors - Long Term Care Facilities" notes that reassessment promptly after a change in a resident's physical or mental condition is to be done if there is a "significant change" such as a resident's "unplanned weight loss." HCFA Ex. 39 at 10-12. The trigger for

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[17] HCFA concedes this point in its Reply to Petitioner's Second Supplemental Brief (HCFA Reply at 16).

an assessment is an "unplanned weight loss." Neither situation applies here, where there is a planned weight gain.[18]

F Tag 274 b. Based on the July survey, HCFA concluded that Petitioner failed to conduct an assessment promptly for resident 3. HCFA alleges that: Resident 3 was readmitted to Petitioner on January 19, 1996, weighing 122 pounds. Her usual weight range is 103-135 pounds and her ideal body weight is 103-127 pounds. Nutritional Assessment notes indicate that resident 3 lost five pounds from February to March 1996 (while the vital signs and weight record notes a 4.8 pound loss). There was no documentation that her physician was immediately notified of the weight change. On April 8, 1996, resident 3 weighed 115 pounds. On April 28, 1996, documentation in the vital signs and weight record indicates that resident 3 weighed 120 pounds, showing a weight gain of 5.8 pounds in just 20 days. There is no documentation that her physician was immediately notified of this weight gain. On May 22, 1996, resident 3 weighed 130.8 pounds, a weight gain of 10 pounds. There is no documentation to indicate that her physician was immediately notified of this weight gain. The record indicates only that she would be reweighed. Nine days later, on May 31, 1996, resident 3 was reweighed at 129.6 pounds. It was at this time that her physician was notified. On June 27, 1996, resident 3 weighed 132.4 pounds, exceeding her ideal body weight and appearing obese. In sum, HCFA alleges that resident 3 gained 15 pounds in six weeks, from April 8 to May 22, 1996. HCFA noted also that resident 3 is totally dependent on Petitioner's staff and receives tube feedings and liquid oral intake. HCFA Ex. 15 at 20-21.

Resident 3 is the same resident discussed above at Finding 2. There, with regard to a change in the resident's pressure sore, I determined that there was a significant change in the pressure sore, which change should have prompted Petitioner to immediately inform the resident's physician. Here, it appears that the resident's tube feeding was increased to prevent further weight loss and in order to promote healing of the resident's pressure sores.[19] P. Ex. 112 at 2. Petitioner's nutritionist was

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[18] I note that Title 22 of the California Code of Regulations, Section 7231, states that a physician should be notified where there is a five pound or greater change in weight within a 30 day period. From the record before me, it appears that HCFA has not adopted this provision in its guidance to surveyors in applying the federal regulatory standards. Consequently, I do not find this state requirement persuasive in determining whether the federal provision was violated.

[19] I note here that the record reflects that ideal body weight charts have not been validated for the institutionalized elderly. Thus, weight loss (or gain) is a guide in determining

(continued...)

monitoring the resident's weight monthly. P. Ex. 112. The nutritionist noted that resident 3's weight should not exceed 140 pounds, and it did not do so during the time period covered by this deficiency. P. Ex. 9, 112 at 3. As in Finding 6 at F Tag 274 a above, while there again may be an issue as to whether or not the resident's physician should have been notified about her weight gain, resident 3's weight gain also appears to be a planned and monitored weight gain. There is no showing of a significant change in this resident's condition warranting a new assessment.

7. Petitioner was not in substantial compliance with the participation requirements at 42 C.F.R. § 483.20(b)(4)(iv) during the July survey, with respect to HCFA's finding of a deficiency at paragraph c of F Tag 274, and the deficiency constituted a potential for more than minimal harm.

Based on the July survey, HCFA concluded that Petitioner failed to properly assess resident 5 after a significant change in her condition. Specifically, HCFA alleges that: Resident 5 had an unplanned weight loss from April 19 to May 22, 1996, losing 19 pounds in one month (from 132 pounds to 113.2 pounds). Resident 5's ideal body weight is 121-149 pounds and her usual body weight is 115-125 pounds. On May 22, 1996, documentation on the vital signs and weight record indicates that resident 5 would be reweighed. On May 25, resident 5 was reweighed at 113 pounds. There is no documentation to indicate that her physician was immediately notified of this severe weight loss. Documentation on May 31, 1996, on the vital signs and weight record, indicates that resident 5's physician was notified of the weight loss, nine days after the weight loss was identified. Licensed nursing notes dated May 30, 1996, indicate that the resident is to be weighed weekly. However, there is no documentation of the weekly weight until June 11, 1996. Resident 5 then weighed 114 pounds, which is below her ideal and usual body weights. HCFA Ex. 15 at 22.

Both Petitioner and HCFA appear to agree that a comprehensive reassessment had to be done, given resident 5's 19 pound weight loss, and Petitioner did a full MDS on June 12, 1996. P. Br. at 40, 43; P. Ex. 51.

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[19](...continued)
nutritional status. An analysis of weight loss or gain should be examined in light of a resident's former lifestyle, as well as in light of their current diagnosis. HCFA Ex. 45.

HCFA argues that the assessment should have been completed by June 4, 1996, because the determination that resident 5 had sustained a 19 pound weight loss was made on May 22, 1996.[20] P. Ex. 49 at 2. HCFA asserts that this is because when there is an unplanned weight loss, as here, a facility must complete a comprehensive assessment promptly, i.e., within 14 days after the change is identified. HCFA Br. at 25; Tr. 242, 245, 253, 1163. Petitioner appears to agree that a prompt assessment should have been conducted within 14 days of the weight loss being identified (P. Resp. Br. at 27), but asserts that to meet the regulatory requirement the assessment does not need to be a full MDS. Petitioner argues that resident 5 was assessed on May 30, 1996, after being reweighed on May 25, 1996 (P. Resp. Br. at 27; Tr. 231-232; P. Ex. 49 at 2) and again by the interdisciplinary team by June 3, 1996 (within at least the seven days prior to the assessment reference date of June 10, 1996). Tr. 1169; P. Ex. 51 at 2. I do not find Petitioner's argument to be persuasive. After such a severe weight loss in such a short time,[21] I agree with HCFA that simply reweighing the resident was not a sufficient assessment. Tr. 253-254. I agree with HCFA's witness that, in this case, a full comprehensive MDS assessment needed to be done to ascertain how the resident's severe weight loss impacted or affected resident 5 in other areas, such as cognitive patterns, memory, activities of daily living (ADL) functioning, and continence. Tr. 246-247. Further, I agree with both HCFA and Petitioner's expert witness that the comprehensive assessment should have been completed within 14 days after May 22, 1996. Tr. 1163.

Even if I assume that the re-weighing of resident 5 on May 25, 1996 should have been what tolled the 14 day assessment period, the assessment still should have been completed by June 8, 1996, which is prior to the actual assessment date of June 12, 1996. Thus, Petitioner is out of compliance with this participation requirement.

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[20] Petitioner hypothesizes that it is possible that resident 5 did not, in fact, sustain a 19 pound weight loss, and that the 132 pound weight noted for resident 5 was inaccurate. P. Br. at 43. However, as Petitioner was weighed twice at 132 pounds on March 26, 1996 and once at 132 pounds on April 1, 1996, I do not find Petitioner's hypothesis to be credible. P. Ex. 49 at 2. It is more likely than not that the record reflecting the 19 pound weight loss is correct. P. Ex. 49 at 2.

[21] I note that the vital signs and weight record used by Petitioner considers a weight loss to be severe if a resident loses more than five percent of their body weight in a given month, and to be significant if a resident loses five percent of their body weight over a given month. P. Ex. 49. This comports with HCFA's guidance to surveyors of long term care facilities. HCFA Ex. 45. Here, resident 5 lost more than 5 percent of her body weight, a severe weight loss.

Although I have found Petitioner out of compliance with this participation requirement, there still remains the question of whether the delay in completing the assessment resulted in a potential for more than minimal harm. Petitioner argues that it did not. Petitioner advances two primary arguments. One, there is an absence of proof as to actual harm, as shown by diagnostic studies and, two, no potential for harm existed since Petitioner assessed the weight gain prior to June 12, 1996. P. Resp. Br. at 27-28; Tr. 1163-1165. I reject Petitioner's arguments. The testimony of Petitioner's expert went only to the assessment of the resident's weight, and not to all the domains which the MDS covers. Tr. 231, 233-236, 242, 244-249, 253-254; HCFA Ex. 45.

Furthermore, the record reflects that there is a potential for more than minimal harm here. Every day that this resident was not assessed (and, potentially, treated) could cause this diabetic resident's blood sugar to be lowered, which could affect the rhythm of her heart, cause other damage to her vital organs, and throw her into hypoglycemic shock. Tr. 234-235.

Thus, I believe HCFA here has presented a prima facie case which Petitioner has failed to rebut by a preponderance of the evidence.

8. Petitioner was not in substantial compliance with the participation requirements at 42 C.F.R. § 483.20(d) during the July survey, with respect to HCFA's finding of a deficiency at F Tag 279, and the deficiency constituted a potential for more than minimal harm.

This regulation states, in pertinent part, that a facility must develop a comprehensive care plan for each resident that includes measurable objectives and timetables to meet each resident's medical, nursing, mental, and psychosocial needs, as identified in the comprehensive assessment. The care plan must describe the services to be furnished to attain or maintain the resident's highest practicable physical, mental, and psychosocial well-being as well as any services that would otherwise be required, but are not provided due to a resident's exercise of rights, including the right to refuse treatment under 42 C.F.R. § 483.10(b)(4).

Specifically, based on the State surveyors' observations, interviews and record reviews, HCFA determined that resident 10 (whose care plan indicates had a potential for skin breakdown, and who is totally dependent on staff members for all activities of daily living) was observed with obvious contractures of her fingers, wrists, elbows and lower extremities. Also, on July 10, 1996, she was observed with an anticontracture device in her right hand and bilateral leg anticontracture devices. These devices were not included on her care plan. HCFA Ex. 15 at 23-24.

Moreover, on July 11, 1996, resident 10, who had a stage II pressure sore, was observed in a gerichair positioned on her back for approximately four hours without a position change. Her care plan indicated to turn and reposition her every two hours. HCFA Ex. 15 at 24.

In this case, with regard to the anticontracture devices, Petitioner's DON admitted that this resident's care plan should have contained specifics for the use of the anticontracture devices, i.e., how often they were to be used, in what manner they were to be used, and where they were to be placed. Tr. 854-855. Further, the consultant called by Petitioner testified that resident 10's care plan was not individualized according to her need for the anticontracture devices. Tr. 1185-1186. This information should have been listed under Problem 2 on Petitioner's care plan. P. Ex. 54 at 1.

I find that there is a potential for more than minimal harm here. Petitioner's consultant opined that inconsistent or inappropriate use of the anticontracture devices by Petitioner's staff could lead to a decline in resident 10's contracture condition. Tr. 1189. A State surveyor testified that improper application of the anticontracture devices might render them ineffective, and put resident 10 at risk for problems of circulatory restriction, and at risk also for not receiving the services she required. Tr. 572.

HCFA determined that two other bases existed for its finding of a violation under this F Tag. Specifically, resident 10's care plan indicated to turn and reposition her every two hours. HCFA Ex. 15 at 24. If substantiated, this arguably could have violated the regulation at 42 C.F.R. § 483.20(d)(3)(ii). However, for the reasons set out below at Finding 9, I have found that Petitioner was providing care to resident 10 in accordance with her care plan. Also, initially the statement of deficiencies at F Tag 279 alleged that resident 10 had a Stage II pressure sore on the top of her left foot. However, this allegation was deleted during IDR, and I am not considering HCFA's arguments with regard to it in this decision. Id.

9. Petitioner was in substantial compliance with the participation requirement at 42 C.F.R. § 483.25(c) during the July survey, with respect to HCFA's finding at F Tag 314.

This regulation states that, based on the comprehensive assessment of a resident, a 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) that a resident having pressure sores receives necessary treatment and services to promote healing, prevent infection, and prevent new sores from developing.

Based on the observations of a State surveyor and a review of the records, HCFA determined that Petitioner failed to meet this requirement in the case of resident 10 (the resident discussed above), who is totally dependent. Specifically, resident 10 was observed by a State surveyor on July 11, 1996, positioned on her back in a gerichair from 10:50 a.m. until 2:45 p.m. Resident 10's May 20, 1996 MDS indicated that she had a Stage II pressure sore. Upon observation, and according to the licensed staff member the State surveyor talked to, resident 10 had a Stage II pressure sore on the top of her left foot. Resident 10's June 18, 1996 care plan required avoiding pressure for this. The care plan included changing her position to prevent further skin breakdown. This was not observed to be implemented by the facility. HCFA Ex. 15 at 25-26.

The preponderance of the evidence establishes that, in this case, resident 10's care plan was followed. During cross examination, the State surveyor admitted that she did not observe resident 10 every minute from 10:50 a.m. to 2:45 p.m. Instead, the State surveyor observed resident 10 only at 10:50 a.m., 12:00 p.m., and 2:45 p.m. Tr. 577, 579-580. Moreover, the State surveyor admitted that she did not inquire of Petitioner's staff as to whether resident 10 was repositioned during this time. Tr. 580. Petitioner has submitted the declaration of the CNA who cared for Resident 10 on July 11, 1996, in which the CNA declared that she repositioned resident 10 before resident 10 ate her lunch, which would be in accordance with the time frame for repositioning set out in resident 10's care plan and in her physician's orders. P. Ex. 52, 54 at 1, P. Ex. 60. I reject HCFA's argument that I should give little or no weight to the CNA's declaration. The declaration stands unrefuted. Moreover, HCFA had the opportunity to call this witness for cross examination, but chose not to avail itself of the opportunity.

10. Petitioner was not in substantial compliance with the participation requirements at 42 C.F.R. § 483.25(c) during the July survey, with respect to HCFA's findings of a deficiency at paragraph b of F Tag 314, and the deficiency caused actual harm.

HCFA alleges that the State surveyors' clinical record review revealed that resident 15 had a pressure sore on her right heel, which was resolved on July 1, 1996. Resident 15's care plan for this pressure area was discontinued on that date. On July 11, 1996, the CNA providing resident 15 a shower stated that resident 15's skin was clear of any pressure area. However, the State surveyor observed that resident 15's right heel was red, with a break in the skin. The licensed nursing staff member stated that she was not aware of the pressure area because it had been documented as healed in the care plan and treatment sheet. The pressure area measured 1.5 by 1.5 cm., stage II. On July 11, 1996, at 10:00 a.m., resident 15 was observed in a gerichair with her legs extended and with her heels in direct contact with the gerichair pads. Resident 15 had a physician's order for heel

protectors. However, the heel protectors were not observed to be in use. The CNA was observed by the State surveyor to take them out from the resident's closet. The treatment sheet for the month of June 15, 1996 to July 11, 1996 for application of heel protectors was not signed as provided. HCFA Ex. 15 at 26.

The parties do not dispute that a new pressure sore developed on July 11, 1996, on resident 15's right heel, after previously healing on July 1, 1996. HCFA Ex. 15 at 26 (referencing Petitioner's Plan of Correction). Further, the parties do not dispute that resident 15 was in a compromised position and prone to skin breakdown. Tr. 858-860, 869-870, 872; P. Br. 56-57. The issue is whether Petitioner did all it should have done to ensure that a new pressure sore did not develop on resident 15's heel.

I do not find the fact that the heel protectors were not observed on resident 15's heels right after her shower to be an indication that Petitioner was not doing all it could to prevent a pressure sore from recurring on resident 15's heel. It appears that resident 15 may only have been in the gerichair for minutes following her shower. Tr. 867. Rather, the problem here is that, as the State surveyor's notes and testimony credibly document, the CNA was not clear as to whether or not heel protectors should have been applied at all. HCFA Ex. 33 at 3; Tr. 371. Further, it is not clear from the record that heel protectors were ever applied.

It appears that heel protectors were ordered by resident 15's physician, and that the order for the bilateral heel protectors was placed in resident 15's treatment record. HCFA Ex. 33 at 7; P. Ex. 62. The order for heel protectors was noted as "For Your Information." HCFA Ex. 33 at 7; P. Ex. 62. Unlike the other treatment orders, however, the nurses never documented that the heel protectors were used. Petitioner asserts that it was up to the nurse to decide whether or not to use heel protectors and that it was not required on a "For Your Information" order that the nurses document that the treatment was done on the treatment record. P. Br. at 57; Tr. 861. The State surveyor's conversation with the CNA suggested that there was confusion as to whether heel protectors should have been used at all. The use of "For Your Information" in the treatment record may have contributed to this confusion, because there was no indication as to the frequency and duration of use for the heel protectors.

However, notwithstanding whether or not there was confusion with regard to the use or documentation of whether heel protectors were used, Petitioner has the burden of proof to establish that it took all necessary action to prevent the pressure sore from recurring. Here, that would include using heel protectors to prevent the pressure sore on resident 15's heel from recurring. Tr. 377-378. Petitioner has offered no proof that the heel protectors were applied in accordance with the treatment plan and order. In fact, the documentation in the record, coupled with the observations of the State surveyor, indicate that the heel

protectors were not applied from July 1, 1996, until the new pressure sore was identified on July 11, 1996.[22] Thus, Petitioner has not rebutted HCFA's prima facie case that Petitioner did not do all it could to ensure that this resident's pressure sore did not reoccur.

I find actual harm caused to resident 15 here by Petitioner's failure to ensure that her pressure sores received necessary treatment and services to promote healing, prevent infection, and prevent new sores from developing. This resident had a pressure sore that previously had healed, but which later reopened because Petitioner failed to take the necessary action to prevent the pressure sore: use of resident 15's heel protectors. Tr. 378.

11. Petitioner was in substantial compliance with the participation requirement at 42 C.F.R. § 483.25(d)(2) during the July survey, with respect to HCFA's findings of deficiencies at paragraphs a and b of F Tag 316.

This regulation states that a resident who is incontinent of bladder receive appropriate treatment and services to prevent urinary tract infections and to restore as much normal bladder function as possible.

F Tag 316 a. Based on the State surveyors' record review and observation, HCFA alleges that resident 11 had a physician's order, dated July 1, 1996, to receive bowel and bladder training for 30 days.[23] HCFA alleges that, according to the bowel and bladder retraining program record, the resident had been bladder and bowel trained for 11 days. On July 11, 1996, the licensed nurse indicated that she had discontinued this due to resident 11's incontinence. According to the bowel and bladder record, the resident had been continent in 32 of 132

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[22] I note the declaration of the CNA who apparently treated resident 15 in which the CNA states that she recalls that she was looking for resident 15's heel protectors and was going to check resident 15's heels for sores or red areas when the State surveyor entered resident 15's room. P. Ex. 61. I do not find the CNA's declaration to be credible, at least as to the use of the heel protectors. The contemporaneous documentation from the State surveyor appears to refute the CNA. The CNA did not appear to know whether or not she should apply the heel protectors. Further, since the heel protectors apparently were not readily available, it does not appear that they were in constant, daily use during the time period after July 1, 1996. HCFA Ex. 33 at 3.

[23] A bowel and bladder training program consists of offering a resident, at certain intervals, the use of a commode or some other assistance with toileting, in an effort to allow a resident to identify and establish a pattern of elimination. Tr. 624.

cases from July 1, 1996 through July 11, 1996, when the program was discontinued. HCFA asserts that resident 11 is an alert and interviewable resident. HCFA Ex. 15 at 28.

The record shows that resident 11's physician ordered a 30-day bowel and bladder training program for her on July 1, 1996. The physician ordered further that it be evaluated after seven days. P. Ex. 20 at 7. The physician ordered the bowel and bladder retraining program discontinued on July 12, 1996. It appears from the record that, on July 11, 1996, the resident stated that she did not want to use the bedpan or the bathroom as doing so hurt her tailbone. Instead, Petitioner (acknowledged by HCFA to be an alert and interviewable resident) stated that she wanted to use a diaper provided by her family. P. Ex. 22 at 8, P. Ex. 66 at 2, 4.

Here, HCFA criticizes Petitioner for stopping resident 11's bowel and bladder retraining program after only 11 days. HCFA argues that after resident 11 refused to use the bedpan,[24] Petitioner should have assessed the reason the bedpan hurt, offered the resident other alternatives to get the resident to remain on the program, and informed the resident of the consequences of her refusal (incontinence), in order to give the resident an adequate opportunity to demonstrate her continence. HCFA argues also that, although the resident had a right to refuse treatment, and assuming she did refuse treatment, not just an uncomfortable bedpan, she should have been told of the consequences of her refusal and been given alternate means to use of the bedpan so that she could make an informed decision.

HCFA's arguments do not convince me that, in this instance, the regulations have been violated. Here, resident 11 appears to have decided to wear a diaper, instead of continuing with the bladder and bowel retraining program. P. Ex. 22 at 8, P. Ex. 66 at 2, 4. This is the resident's right. Her physician was informed of her refusal[25] and discontinued the program. Id.; P. Ex. 97. I must assume that if the physician thought the bladder retraining program was absolutely necessary to the patient's health, the physician would not have terminated the program. Thus, I conclude that there is no deficiency.

F Tag 316 b. Based on the State surveyors' July 10, 1996 record review, HCFA alleges that resident 2 had a Foley catheter, as per family request. Approximately two weeks before the review, a family member complained that the leg strap

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[24] I note that the record reflects that resident 11 appears to have refused both a bedpan and the bathroom. P. Ex. 22 at 8, P. Ex. 66 at 2, 4.

[25] Petitioner tried to contact the physician on July 11, 1996, but was not able to contact the physician until July 12, 1996. P. Ex. 22 at 8; P. Ex. 66 at 2.

used to secure the catheter tubing was improperly applied by a CNA. Upon inquiry, facility staff stated that the leg strap was observed applied incorrectly, in that it was applied on top of the catheter which could cause suppression of the flow of urine. On July 10, 1996, with the resident's permission and the assistance of facility staff, the State surveyor observed the leg strap. It was placed three inches above the right knee in a constricting manner, which was obvious to the surveyor as the resident's skin was pinched. A facility staff person stated that the strap was too tight, and proceeded to loosen it. Further investigation revealed that, according to facility staff, there were no instructions given to CNAs on the proper application of the leg strap, and it is not taught in the facility's pre-certification program. Additionally, the application and use of the leg strap were not identified in the plan of care as nursing interventions for the care of the catheter tubing. HCFA Ex. 15, at 28-29.

HCFA did not brief this deficiency. Instead, it rested its case on the evidence of record. HCFA Reply Brief (HCFA Rep. Br.) at 47, n. 11. The State surveyor admitted that if a resident has a Foley catheter the resident is continent. Tr. 263-265. This regulation applies only to a resident who is "incontinent of bladder." Thus, since resident 2 is considered continent, this section of the regulation does not apply. HCFA has not made a prima facie case that a violation of the participation requirement exists.

12. Petitioner was in substantial compliance with the participation requirement at 42 C.F.R. § 483.25(f)(1) during the July survey, with respect to HCFA's finding of a deficiency at F Tag 319.

This regulation states that, based on a comprehensive assessment of a resident, a facility must ensure that a resident who displays mental or psychosocial adjustment difficulty, receives appropriate treatment and services to correct the assessed problem.

Based on the State surveyor's observation, HCFA alleges that on July 10, 1996, Resident 12, who had a diagnosis of schizophrenia, hypertension, facial psoriasis, arthritis, Parkinson's secondary to Haldol and dementia, was in bed the entire day shift. The State surveyor interviewed the CNA, who stated that if resident 12 refuses twice to get up when asked, she leaves him in bed. The State surveyors' review of the clinical record revealed that resident 12 has a primary diagnosis of schizophrenia and has behavior problems such as verbal and physical abuse, socially inappropriate behavior and resistance to care. There is no evidence that the facility had resident 12 evaluated through the Department of Mental Health for required level of services in relationship to his diagnosis. Resident 12 is totally dependent on staff for all activities of daily living. Also on July 10, 1996, HCFA alleges the State surveyor observed resident 12's room

devoid of personal items. The room walls were bare and his surrounding environment contained one water pitcher, one paper cup, and a vaseline jar. Resident 12 was admitted to Petitioner's facility on January 24, 1994.[26] P. Ex. 15 at 30, 33.

HCFA did not brief this issue. Instead, it relied on the evidence of record. HCFA Rep. Br. at 47, n. 11. However, the record reflects that Petitioner appears to have provided appropriate treatment and services to correct the mental and psychosocial problems assessed. Petitioner appears to have been provided continuous psychiatric service and care from Petitioner's social services and activities departments in monitoring his behavior, drug management, and care plan. P. Ex. 114; Tr. 1226-1229. The evidence does not show that resident 12 met the criteria necessitating evaluation through the Department of Mental Health. Rather, there is evidence in the record that he did not meet such criteria. P. Ex. 70-73. With regard to resident 12's refusal to get out of bed, I do not find that this alone contravenes the regulation, nor does it mean that his care was not managed. Finally, with regard to resident 12's environment, I agree with Petitioner (and the guidance to surveyors-long term care facilities) that the absence of a personalized, homelike environment in a resident's room is not meaningful unless it is determined that the absence of personal belongings is a result of facility practices, rather than the result of resident choice or circumstances. Here that was not alleged. P. Ex. 74 at 2.

13. Petitioner was not in substantial compliance with the participation requirement at 42 C.F.R. § 483.75(i) during the July survey, with respect to HCFA's finding of a deficiency at F Tag 501, and the deficiency constituted a potential for more than minimal harm.

This regulation states that a facility must designate a physician to serve as medical director. The medical director is responsible for the implementation of resident care policies and the coordination of medical care in the facility.

Based on the State surveyors' record review and interview, HCFA alleges that resident 3 developed an infection of her pressure sore around June 17, 1996. Although the facility staff left

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[26] Under this deficiency on the HCFA form 2567 is a note to "Refer to F-241 - Resident 12 with a diagnosis of Schizophrenia failed to receive care for residents in a manner and in an environment that maintains or enhances each resident's dignity and respect in full recognition of his or her individuality." HCFA Ex. 15 at 33. This reference was not set forth as a deficiency at F Tag 241, nor was the issue addressed at hearing or in the parties' briefs. If HCFA intended to do so, HCFA has not set forth a prima facie case on this issue.

messages for the physician on June 17, 1996 and June 26, 1996, there was no response from resident 3's physician until June 29, 1996. There was no documentation that the facility attempted to contact another physician to treat resident 3. Upon inquiry, facility staff was unable to explain why the medical director had not been notified regarding this matter. HCFA Ex. 15 at 35, 38.

Based on the State surveyor's conversation with Petitioner's staff, Petitioner's staff told the surveyor that Petitioner's internal policy was to notify the medical director if they could not get in touch with a resident's physician. In this case, this policy was not carried out. Tr. 274-276. I find the testimony of the surveyor, with regard to the staff she interviewed and their admission as to Petitioner's policy, to be credible. Petitioner failed to offer any evidence to rebut this policy. HCFA gave adequate notice in its prima facie case that Petitioner's policy of notifying the medical director when treating physicians do not respond to telephone messages existed. HCFA Ex. 15 at 38. The State surveyor need not interview the medical director to establish a regulatory violation here. Petitioner's staff identified the policy and admitted it was violated. Petitioner did not present any evidence demonstrating that such a policy never existed or that it was followed. If such evidence existed, it was within Petitioner's ability to produce it. I agree with HCFA that it is the medical director's responsibility to assure coordination and implementation of this policy - a policy which, in this case, failed to be implemented.

Here, a potential for more than minimal harm exists. As I found above in another deficiency involving resident 3 (see Finding 2), the delay in treating this resident, with multiple medical problems, put her at risk for sepsis, a condition which can lead to death. Tr. 124-125, 134.

14. Petitioner was in substantial compliance with the participation requirement at 42 C.F.R. § 483.75(l)(1) during the July survey, with respect to HCFA's findings of deficiencies at paragraphs a, b, d, e, and f of F Tag 514.

This regulation states that a facility must maintain clinical records on each resident in accordance with accepted professional standards and practices that are complete, accurately documented, readily accessible, and systematically organized.

Here, HCFA has alleged that Petitioner failed to maintain clinical records on five of 18 sample residents, alleging 7 instances of noncompliance, in accordance with this regulation. However, as discussed below, I find that Petitioner was in substantial compliance with participation requirements with regard to paragraphs a, b, d, e, and f of F Tag 514. HCFA Ex. 15 at 39-41.

F Tag 514 a. Based on the State surveyors' review, HCFA alleges that the bowel and bladder retraining program record for resident 11 contained sporadic documentation. Specifically, there were no entries for the 11-7 shift on July 1, 2, and 5, 1996, or for the 7-3 shift on July 2, 10, or 11, 1996, to indicate whether the resident was continent or incontinent. HCFA Ex. 15 at 39.

The statement of deficiencies indicates that the only deficiency here is Petitioner's failure to provide entries in the bowel and bladder retraining program record for specified dates. HCFA Ex. 15 at 39, HCFA Ex. 29 at 4-5. The State surveyor who reviewed the documentation admitted, however, that CNA documentation for those dates also could be used to determine the state of resident 11's continence (as well as the bowel and bladder retraining program record). Tr. at 721-722. Despite this concession, the State surveyor opined that the documentation in the record failed to provide information about the timeframes (e.g., the particular hour) when the resident eliminated, which was pertinent to determining at what rate the resident eliminated. Tr. at 723. The State surveyor stated that this information is necessary in order to establish a pattern for taking the resident to the bathroom. Tr. 724. However, when the State surveyor first explained the reason for citing this as a deficiency, she stated that the record for the bowel and bladder retraining program was incomplete or not documented, which may have meant that the resident was not offered a bedpan on the shift. Tr. 715.

The CNA documentation, in conjunction with the bowel and bladder retraining program record, presents a vivid picture of a resident who is resistant to use of a bedpan as it causes her pain. Her pain led to the discontinuation, with the approval of her doctor, of the bowel and bladder retraining program. See Finding 11 at F Tag 316 a above. I conclude that Petitioner has established by the preponderance of the evidence that the particular deficiency cited here, lack of documentation regarding resident 11's continence status on specific dates, was met by information in the CNA documentation. HCFA's subsequent attempt at hearing to broaden the deficiency to include the failure to provide hourly documentation of this resident's continence status goes beyond the deficiency as stated.

F Tag 514 b. Based on the State surveyors' review, HCFA alleges that resident 12's MDS (dated February 1, 1996) indicated that he exhibited verbally and physically abusive behavior, socially inappropriate behavior, and was resistant to care. The PAS/PASSARR level screening document (dated February 22, 1996) did not reflect these problematic behaviors. One staff member stated that the information from the MDS was not used when completing this form and that the resident did not require this form since it (the schizophrenia) had been controlled and the resident's behavior did not indicate other placement per the psychiatrist. Resident 12 is a totally dependent resident with a

primary diagnosis of schizophrenia and requires assistance with all activities of daily living. HCFA Ex. 15 at 39.

Here, HCFA has failed to make a prima facie case, in that it has not notified Petitioner as to exactly what Petitioner did to violate the regulations with regard to resident 12. The State surveyor gave confusing and contradictory testimony with regard to the requirements for filling out the PAS/PASSARR level screening documentation. She was unsure of the criteria that would be the basis for such an assessment. Tr. 731. The State surveyor did indicate that the assessment information should be coordinated with other assessment instruments, such as the MDS. Id. The MDS cited in the statement of deficiencies (HCFA Ex. 15 at 39), the document allegedly inconsistent with the PAS/PASSARR document, was never made a part of this record. The State surveyor apparently relied on references in this MDS to resistance to care in formulating the deficiency citation. HCFA Ex. 30 at 3; Tr. 732. However, this reference to resistance to care is not in itself inconsistent with the PAS/PASSARR document (incorrectly dated in the statement of deficiencies as February 22, 1996, when the actual completion date is March 6, 1996 (Tr. 730-731; P. Ex. 71 at 6)) which refers to serious difficulties in interpersonal functioning; concentration, persistence, and pace; and adaptation to change within three to six months of March 6, 1996. HCFA Ex. 71 at 6. Moreover, there is no place on the PAS/PASSARR document to list resistance to care. Also, while the statement of deficiencies refers to problem areas in the MDS beyond the resistance to care, the State surveyors apparently based the deficiency citation on this behavior alone, and, as I noted already, it is not inconsistent with the documented references to the resident's mental status as reflected in the PAS/PASSARR document, which forms the basis of the deficiency. See Tr. 1246. I note also that HCFA's references to documentation showing the resident refused to attend certain activities and remained in bed (such as P. Ex. 75) go beyond the factual basis relied on by HCFA in the statement of deficiencies for this deficiency.

F Tag 514 d. Based on the State surveyors' record review, HCFA alleges that, during a clinical record review, resident 18's Mellaril was increased to five mg. three times a day from two times a day on April 29, 1996. There was no behavior of striking out identified by the licensed nurses. However, the CNAs identified the behavior. This information was not documented in either licensed nurses notes or in the behavior summary sheet. HCFA Ex. 15 at 40.

The record before me does not contain the licensed nursing notes referred to by the surveyor. HCFA Ex. 36 at 3. However, the medication record submitted by Petitioner does refer to the

Mellaril prescription for striking out behavior. P. Ex. 109.[27] The record also contains a copy of the CNA documentation, which does refer to resident 18's combativeness. P. Ex. 86. The physician's progress notes do reflect an increase in the Mellaril, due to resident 18's increased agitation, as reported by his wife. P. Ex. 85. Taken as a whole, while the record may reflect some inconsistency, there is sufficient documentation to support the action taken by the physician. To the extent the documentation in the licensed nursing notes regarding resident 18's behavior may have differed from the other parts of the record, this appears to be a de minimus error which did not impact on the care of this patient. The clinical record includes all the pertinent medical records regarding this resident maintained by Petitioner. While, arguably, the licensed nursing notes may have deficiencies pertaining to the need to increase the resident's psychotropic medication, there is sufficient documentation elsewhere in the record to support the physician's decision. Consequently, I cannot find that Petitioner violated the regulation as alleged by HCFA.

F Tag 514 e. Based on the State surveyors' clinical record review, HCFA alleges that resident 13 had an order for Haldol, two mg., every eight hours. Further review of the clinical record revealed that the behavior monitoring system for striking out was discontinued on July 6, 1996, when the dose was decreased. The licensed staff member initially stated to the surveyor that resident 13 did not need to be monitored because the dose was decreased. However, after he realized that Haldol was a psychotropic medication, he further stated that "it was a mistake from the licensed nurse who took the order." HCFA Ex. 15 at 40-41.

Here, HCFA has failed to set forth a prima facie case notifying Petitioner of a deficiency with regard to this regulatory citation. Rather than addressing a documentation error here, HCFA appears to be contesting the decision, following the decrease in the amount of Haldol prescribed for resident 13, to discontinue the care plan for monitoring for mood swings. P. Ex. 89 at 1; 92. The surveyor asserts that she was told that the behavioral monitoring had stopped. However, my review of the record indicates that the licensed personnel weekly progress

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[27] I note that HCFA has objected to my relying on P. Ex. 109. HCFA Resp. Br. at 81-82. For the reasons set forth at section I.C., above, I have admitted such exhibits into evidence in this case and am relying on them. However, I note that HCFA's reference to Kings View Hospital, DAB CR442 at 7, n. 1 (1996) does not apply here. The administrative law judge in that case rejected an exhibit which HCFA sought to offer after the administrative law judge had closed the case record. Here, the case record had not been closed at the time the exhibit was proffered, and HCFA was offered the opportunity to rebut this exhibit, but chose not to avail itself of the opportunity.

notes, including the charting by the Medicare nurses, reflect consideration of the medication, its side effects, and changes in the resident's behavior, despite the note in the care plan discontinuing the behavioral monitoring. P. Ex. 89.[28] Thus, while the preponderance of the evidence shows a discontinuance of the care plan for monitoring, the documentation in the record is accurate and complete for observing the patient after the Haldol level was decreased. To the extent that the level of monitoring may have decreased, this is not a documentation issue per se, but a question as to whether the decreased level of observation is consistent with the proper standard of care for this patient. However, HCFA has not asserted in its briefing that the alleged deficiency should be cited under any other regulatory section.

F Tag 514 f. Based on the observation of the State surveyor, HCFA alleges that on July 11, 1996, at 8:00 a.m, 10:00 a.m., and 2:00 p.m., resident 13 was observed without bilateral heel protectors in place. Although the resident had no pressure area, a physician's order was written for the heel protectors on July 2, 1996. When questioned, the CNA stated that the resident refused to wear them. Upon further investigation, it was revealed that the heel protectors were inside the closet and had not been applied from 8:00 a.m. to 2:00 p.m. The physician's order had no time interval for use of the heel protectors. HCFA Ex. 15 at 41.

The deficiency as written fails to set out a violation of the regulation cited. This regulation pertains to the adequacy of documentation. The only indication of a documentation error cited in the deficiency is that the physician's order for the heel protectors did not have time intervals for their use. The absence of time intervals suggests that the heel protectors should be in place at all times. This is consistent with a resident who is highly susceptible to pressures sores. The failure to have the heel protectors in place is a quality of care issue, which was addressed elsewhere in the statement of deficiencies; it is not a violation of the regulation regarding documentation, and HCFA's briefing does not indicate that it should be considered a deficiency under any other regulatory section. There is nothing in the record to indicate that Petitioner should have asked the physician to clarify the time period for use of the heel protectors, nor is this alleged in the HCFA Form 2567. Even assuming that the physician intended for

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[28] HCFA argues that I should not consider this exhibit, because pages 3-6 of P. Ex. 89 are in the same hand, of highly questionable value and not credible. HCFA Resp. Br. at 84-85. I disagree with HCFA. I believe the explanation given by Petitioner, that these notes were prepared by a separate Medicare nurse, is credible. I have insufficient information of record to conclude that this charting was done after the State surveyor brought this issue to the attention of the facility. Tr. 894-895.

the heel protectors to be worn at all times, there is nothing in the cited deficiency which gives Petitioner notice that failure to develop clinical records which specifically quantified when the heel protectors were to be worn by the resident, as directed by the physician, was violative of the regulatory requirement.

15. Petitioner was not in substantial compliance with the participation requirements at 42 C.F.R. § 483.75(l)(1) during the July survey, with respect to HCFA's finding of deficiencies at paragraphs c and g of F Tag 514, and the deficiencies constituted a potential for more than minimal harm.

F Tag 514 c. Based on the State surveyors' review, HCFA alleges that resident 8's nursing assessment, dated May 31, 1996, is written over. An interview with the licensed staff members indicated this was entered by another licensed nurse who was off duty that day. The final comprehensive assessment weight record, dated May 30, 1996, indicated the resident weighed 153 pounds, while the dietary record documented the resident's weight on May 31, 1996 as 145 pounds. The MDS dated May 31, 1996, documented the resident's weight at 156 pounds. Upon interviewing staff members, the staff members were unclear about the actual weight. Resident 8 is an alert and interviewable resident who appears average in weight. HCFA Ex. 15 at 39-40.

The record before me reflects, as HCFA alleges, that resident 8's weight on his May 31, 1996 nursing assessment has been written over. P. Ex. 82. Resident 8's May 31, 1996 and June 10, 1996, dietary/nutritional assessments reflect his weight as 145 pounds. P. Ex. 83. However, in an assessment for weight on June 14, 1996, as reflected in resident 8's MDS (erroneously dated May 31, 1996 in the HCFA Form 2567 (HCFA Ex. 15)), resident 8's recorded weight is 156 pounds. P. Ex. 108 at 6. My review of the record establishes also that resident 8's vital signs and weight record has a written over admission weight for May 31, 1996. P. Ex. 81.

The written over weight references are difficult to read and subject to speculation as to the exact weight referenced. Tr. 763-764; P. Ex. 81. The record supports HCFA's allegation that writing over a weight does not comport with standard documentation practice. Supporting this is the testimony of the State surveyor, who testified that writing over an entry is not standard nursing practice for documentation, and is not in accordance with acceptable professional standards and practices for documentation. Tr. 750-751. The State surveyor testified further that what is usually accepted for documentation in this situation is a single line drawn through an entry and re-entry in a different area, with an indication that there was an error. Id. Petitioner does not dispute that this is the acceptable documentation standard.

A potential for more than minimal harm exists here. Inaccurate documentation may lead to inaccurate assessments, which can affect the resident's care planning and the assessment of the resident's actual needs and cause complications in the care of the resident. Tr. 755, 767.

I note Petitioner's argument that: this regulation was cited in the June 1996 survey; all of the dates referring to resident 8 here were prior to the June 21, 1996 completion date in the plan of correction following the June survey; no medical records can be rewritten or altered and any correction dates would have to be from June 21, 1996 forward; thus, there is no violation of the regulation. However, contrary to Petitioner's position, there was no requirement following the June survey **for** a plan of correction relating to this regulation. Instead, it was cited as an "isolated deficiency." P. Ex. 84. Thus, as HCFA determined that the deficiency was isolated, no corrective action was needed. In the July survey, HCFA found further evidence of this practice and cited it as a deficiency requiring correction, and I am upholding the deficiency.

F Tag 514 g. Based on the State surveyors' review of resident 13's care plan, HCFA alleges that resident 13 was identified with "Mood swing secondary to steroid therapy." Below the care plan was a statement "D/C (discontinue) July 9, 1996," which was yellowed out.[29] During inquiry, the licensed staff member was unsure what it meant and stated that the care plan was discontinued and later yellowed out, which meant it was no longer discontinued and that "the problem exit (sic)." However, the steroid medication was discontinued on July 2, 1996. HCFA Ex. 15 at 41.

According to the testimony of a State surveyor, which is not contested by Petitioner, Resident 13 had been on steroid medication, which was discontinued on July 2, 1996. Tr. 466, 471. Resident 13's care plan (P. Ex. 92), identified a problem of mood swings (and infections) secondary to steroid therapy. Id. There is an entry in the care plan, under the column identifying the potential for mood swings, indicating that the problem "D/C'd 7-6-96," (discontinued as of July 6, 1996). P. Ex. 92. In her resident review worksheet for resident 13, the State surveyor noted that the words "D/C'd 7-6-96" were highlighted or yellowed out. HCFA Ex. 31 at 4. When the surveyor asked two licensed nurses providing direct care to this resident to clarify this matter, one nurse said the discontinued order was highlighted because the mood swings were still an existing problem, even after the steroids were stopped. However, the other nurse stated that the first nurse was wrong, and that

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[29] While the July survey statement of deficiencies (HCFA Ex. 15) notes that "D/C" was to take place on July 9, 1996, P. Ex. 92, from which the quote apparently was taken, notes the D/C date as July 6, 1996.

since the steroid medication was discontinued, the problem of mood swings no longer existed. Tr. 464-466, 472-475. Because of this conflicting information, the State surveyor concluded that there was confusion in the documentation as to what was meant by the highlighted phrase "D/C'd 7-6-96." It was this confusion which led the State surveyor to determine that the clinical record was substandard and not accurately documented. Tr. 466-467, 476.

Here, I find that HCFA has made its prima facie case regarding a deficiency in the documentation. The surveyors' assessment is correct. The yellowing out of the phrase in the care plan obviously meant different things to Petitioner's staff. Moreover, there is a potential for more than minimal harm here. If the resident's mood swings had continued to be a problem, but had been discontinued as a problem on the care plan, then the mood swings could have continued or gotten worse, without the facility doing anything about them. On the other hand, if resident 13 no longer had mood swings, then her current needs were not being met, as her care plan had not been properly updated. Tr. 468.

Finally, with regard to F Tag 514 generally, Petitioner argues that HCFA has failed to put forward its prima facie case that any of these alleged violations constituted a "pattern." Specifically, Petitioner argues that the scope of the violations under this F Tag are determined based on the entire census of the facility; that there were 260 residents in the facility during the July survey; and that the five residents involved in this deficiency do not qualify as a pattern. I do not agree with Petitioner. Notwithstanding whether or not a pattern can be shown, for me to sustain HCFA's certification of noncompliance, HCFA need only establish that there was an identified deficiency which posed a greater risk to resident health or safety than the potential for causing minimal harm. 42 C.F.R. § 488.301. Petitioner must prove that it was in substantial compliance with all participation requirements. It has not done so here.

16. Petitioner was not in substantial compliance with Medicare participation requirements regarding SNFs, as reflected in my Findings 1, 2, 4, 5, 7, 8, 10, 13, and 15.

III. Conclusion

I have found Petitioner to be out of substantial compliance with Medicare participation requirements governing SNFs, as reflected in my Findings 1, 2, 4, 5, 7, 8, 10, 13, and 15. Thus, HCFA was authorized to deny Petitioner payment for new admissions, for the period from June 12, 1996 through August 21, 1996.

/s/

Edward D. Steinman
Administrative Law Judge