Department of Health and Human Services

DEPARTMENTAL APPEALS BOARD

Civil Remedies Division

In the Case of:	)	
	)	
Oak Lawn Pavilion, Inc.	)	Date: May 21, 1997
	)	
Petitioner,	)	
	)	
- v. -	)	Docket No. C-95-155
	)	Decision No. CR474
Health Care Financing Administration.	)	
	)	

DECISION

I. Procedural Background and Issue

In this case, Oak Lawn Pavilion (Petitioner) challenges the determination by the Health Care Financing Administration (HCFA) which terminated Petitioner's participation in the Medicare program as a skilled nursing facility (SNF) effective May 31, 1995. HCFA notified Petitioner by letter dated May 3, 1995 that the termination action was based on the findings from two surveys: one which was completed on February 10, 1995 and one which was completed on April 3, 1995. As stated in HCFA's May 3, 1995 notice letter, Petitioner was found out of compliance with five Level A requirements specified by the regulations pursuant to the February 10, 1995 survey conducted by HCFA's agent in Illinois, the Illinois Department of Public Health (IDPH). Based on a resurvey completed by IDPH on April 3, 1995, Petitioner was found to have remained out of compliance with only one of the earlier cited Level A requirements: Quality of Care, as codified at 42 C.F.R. § 483.25.[1] HCFA's May 3, 1995 Notice Letter.

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[1] The regulations governing the surveying and certification of long term care facilities under the Medicare and Medicaid programs were modified, effective July 1, 1995. 59 Fed. Reg. 36117 (Nov. 10, 1994). In this case, the relevant surveys were done prior to July 1, 1995, and HCFA also made its determinations prior to said date. Therefore, I cite in this decision only those regulations which were codified and in effect prior to July 1, 1995.

Petitioner timely requested a hearing to challenge HCFA's determination. Petitioner's hearing request was based on its contention that the survey team did not follow the appropriate protocol and had relied upon errors of fact in determining the scope, severity, and outcome of alleged problems.

The issue in the case was established as follows pursuant to the prehearing conference held on May 2, 1996:

> Issue: The issue in this case is whether Petitioner was out of compliance with the Level A requirement specified at 42 C.F.R. § 483.25 -- Quality of Care, as of the survey date of April 3, 1995, as alleged in HCFA's May 3, 1995 letter.

Order and Notice of Hearing (May 14, 1996). Within the 10 days specified by regulation, neither party objected to the foregoing statement of issue. See, 42 C.F.R. § 498.52(b)(2).

On or about June 10, 1996, HCFA submitted a document titled, "Statement of Facts, Overview of the Law and Issues of Fact and Law" (HCFA Prehearing Brief), while filing its proposed exhibits and lists of witnesses. HCFA noted that, because there were overlaps between regulatory requirements (e.g., dietary deficiencies which impact on quality of care), HCFA anticipated presenting findings from both surveys which relate to the Quality of Care deficiency, regardless of whether the surveyors had specifically recorded the findings under the Quality of Care requirement. HCFA Prehearing Brief, 11. HCFA stated also that it intended to present evidence from the earlier, February 10, 1995, survey as background and as a part of the procedural history of its termination decision, as consistent with an evidentiary ruling I had issued in a similar case. Id. at 12.[2] Since HCFA's Prehearing Brief did not seek relief on any preliminary matter, I did not require Oak Lawn to file a written response. Nor did I issue any ruling or modify my prehearing order dated May 14, 1996 after having read HCFA's brief.

I conducted an in-person hearing in this case during the week of July 15, 1996 in order to resolve the issue as stated in my May 14, 1996 prehearing order: whether Petitioner was out of compliance with the Level A requirement specified at 42 C.F.R. § 483.25 -- Quality of Care, as of the survey date of April 3, 1995, as alleged in HCFA's May 3, 1995 letter. Petitioner, in its opening statement at the hearing, adopted and re-emphasized the foregoing statement of the issue from my prehearing order.

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[2] HCFA cited my ruling in Capitol View Care Center v. HCFA, C-94-332, and attached a copy of said ruling as Attachment D to its prehearing brief.

Transcript (Tr.) 445; see, Tr. 24.[3] During the hearing, I allowed HCFA to introduce certain evidence concerning the earlier survey of February, 1995, to the extent such evidence was relevant to the Quality of Care findings which resulted from the latter April, 1995 resurvey.

After the parties submitted their post-hearing briefs in accordance with 42 C.F.R. § 498.63, the DAB issued its decision in Hillman Rehabilitation Center v. HCFA, DAB No. 1611 (1997), which specified how the burden of moving forward and the burden of persuasion should be allocated in provider sanction cases. Especially because Petitioner had cited one of my rulings in another case and that ruling is not fully consistent with the DAB's legal conclusions in Hillman,[4] I provided the parties with the opportunity to submit written comments on the relevancy of Hillman to the facts in this case and on whether additional proceedings are necessary. Petitioner initially responded by letter dated March 28, 1997 and urged the issuance of a decision in this case without regard for the legal interpretations contained in Hillman.[5] Petitioner later submitted an additional

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[3] During the hearing, Petitioner objected to HCFA's eliciting testimony concerning the February, 1995 survey (HCFA Ex. 2) by stating:

> The exhibit has been admitted and Petitioner is prepared to admit on the record the allegations contained in HCFA Exhibit Number 2.
>
> Having this witness going through observations serves no purpose.

Tr. 24.

[4] For example, at page 3 of Petitioner's post-hearing reply brief, Petitioner stated that it "agrees that this Court's Order in Brighton Pavilion, Docket No. C-96-081, ruling that HCFA has the burden of proof, is controlling in this matter."

In Brighton Pavilion v. HCFA, C-96-081, I issued a ruling on September 11, 1996 which placed the ultimate burden of persuasion on HCFA. Under that ruling, I would set aside HCFA's findings and imposition of enforcement remedies against a provider if the evidence were in equipoise. The DAB's decision in Hillman, by contrast, placed the ultimate burden of persuasion on the provider, so that HCFA's findings and sanctions would be upheld if the evidence were in equipoise.

[5] Petitioner's letter alleged that, because no decision has been issued in this case, Petitioner was losing revenue on a daily basis.

letter dated April 17, 1997, which quoted a portion of my prehearing order governing the standard of proof and the parties' respective burden of production during hearing.[6] Petitioner's position was that, if I conclude that the quoted portion of my prehearing order was wrong under Hillman, then "the hearing must be held again." P. Letter date April 17, 1997 at 2.

I have considered Petitioner's comments and find that no additional proceedings are necessary. In neither of its letters did Petitioner allege that my prehearing order in this case was inconsistent with Hillman. In fact, the portion of my prehearing order quoted by Petitioner is fully in accord with the DAB's conclusion in Hillman that HCFA has the burden of coming forward with evidence sufficient to establish a prima facie case, and the provider has the burden of coming forward with evidence sufficient to establish any affirmative argument or defense. Hillman at 8. My adoption of the preponderance of the evidence standard in the prehearing order was not affected by the Hillman decision. See, Hillman at 10. With respect to Hillman's holding that the ultimate burden of persuasion is on program providers instead of HCFA (i.e., HCFA would prevail if the evidence were in equipoise)(Hillman at 10), Petitioner has not alleged that the evidence in this case is in equipoise. The evidence in this case is not in fact in equipoise. Even though Petitioner's reply brief cited a ruling I had issued in another case on the burden of persuasion issue (and my ruling on said issue is no longer valid under Hillman), Petitioner has not shown that it has been prejudiced by my ruling in the other case. Petitioner's responses to my invitation to comment on Hillman and to suggest

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I note that Petitioner had earlier brought two related cases, which involved Petitioner's request to re-enter the Medicare program after termination and HCFA's refusal to re-admit Petitioner to the Medicare program based on the results of surveys conducted in August and October, 1995. Oaklawn Pavilion v. HCFA, Dec. No. CR426 (1996). I dismissed the requests for hearing in those two cases for lack of jurisdiction because Petitioner had failed to follow the appeals procedures specified by regulation (i.e., Petitioner had failed to request reconsideration prior to requesting a hearing).

[6] The portion of my May 14, 1996 prehearing order quoted by Petitioner is as follows:

> Burden of proof: For purposes of this hearing, HCFA shall have the burden of coming forward, to establish by a preponderance of the evidence, that Petitioner was not in compliance with the cited Level A requirement as of the date specified in HCFA's notice of adverse action. Petitioner has the burden of coming forward with evidence in support of Petitioner's arguments.

appropriate proceedings do not even allege that it would have presented more evidence to support its position if it had known that, under Hillman it would lose if the evidence were in equipoise.[7] Petitioner has not indicated that it would have done anything differently had the DAB settled the burden of proof issue in Hillman prior to the hearing held in this case.

Therefore, for the reasons that follow, I uphold HCFA's determination that Petitioner's participation agreement should be terminated due to its noncompliance with the Level A Quality of Care requirement at the time of the April, 1995 resurvey.

II. Findings of Fact and Conclusions of Law

I discuss each of my findings of fact and conclusions of law in detail in the Analysis section at Part III of this decision.

1. HCFA determined that as of the April 1995 resurvey, Petitioner remained out of compliance with the Level A requirement of Quality of Care.

2. The Level A requirement for Quality of Care contained in 42 C.F.R. § 483.25 requires that each resident must receive, and the facility must provide, the necessary care and services to attain or maintain the highest practicable physical, mental and psychological well-being, in accordance with the comprehensive assessment and the plan of care.

3. HCFA's determination of noncompliance with the Level A Quality of Care requirement is based on the resurvey finding that Petitioner was out of compliance with the Level B Quality of Care requirements pertaining to pressure sores at 42 C.F.R § 483.25(c); urinary incontinence at 42 C.F.R. § 483.25(d); range of motion at 42 C.F.R. § 483.25(e); accidents at 42 C.F.R. § 483.25(h); and activities of daily living at 42 C.F.R. § 483.25(a).

4. The Quality of Care requirement for "pressure sores" at 42 C.F.R. § 483.25(c) requires that based on the resident's comprehensive assessment, the facility must ensure that a resident who enters the facility without pressure sores does not

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[7] Petitioner's March 28, 1997 letter indicates its belief that I need not apply the relevant legal principles set forth by the DAB's Appellate Panel in Hillman. There is, of course, no legal basis for such a belief by Petitioner. Nor is there any legal basis for Petitioner's belief that if a decision in this case had been rendered earlier (by, for example, denying HCFA's right under 42 C.F.R. § 498.63 to submit a post-hearing brief), the Hillman decision would have had no effect on this case." P. Letter dated March 28, 1997 at 2.

develop pressure sores unless the individual's clinical condition demonstrates that they were unavoidable; and a resident having pressure sores receives necessary treatment and services to promote healing, prevent infection and prevent new sores from developing.

5. HCFA established numerous instances, which Petitioner failed to rebut, in which Petitioner failed to meet its obligations under the Level B requirement for pressure sores and failed to follow its written plan of correction to train staff in the importance of quickly assessing skin breakdowns and to take all preventative measures to prevent and heal pressure sores, including repositioning and keeping residents clean and dry.

6. HCFA has proven that Petitioner was out of compliance with the "pressure sore" requirements of 42 C.F.R. § 483.25(c) at the time of the resurvey.

7. The Quality of Care requirement for "urinary incontinence" at 42 C.F.R. § 483.25(d)(2) requires that based on the resident's comprehensive assessment, the facility must ensure that a resident who is incontinent of bladder receives appropriate treatment and services to prevent urinary tract infection and to restore as much normal bladder function as possible.

8. HCFA established several instances, which Petitioner failed to rebut, in which Petitioner failed to meet it obligations under the Level B requirement for "urinary incontinence" as well as failed to follow its plan of correction to assess each resident for their potential to benefit from a restorative bladder and bowel program and to have such a program in place by March 15, 1995.

9. HCFA has proven that Petitioner was out of compliance with the "urinary incontinence" requirements of 42 C.F.R. § 483.25(d)(2) at the time of the resurvey.

10. The Quality of Care requirement for "range of motion" at 42 C.F.R. 483.25(e)(2) requires that based on the resident's comprehensive assessment, the facility must ensure that a resident with limited range of motion receives appropriate treatment and services to increase range of motion and/or prevent further decrease in range of motion.

11. HCFA established several instances, which Petitioner failed to rebut, in which Petitioner failed to meet its obligations under the Level B requirement for "range of motion" as well as failed to follow its plan of correction to train its CNAs on when to and how to use positioning devices; to have its maintenance department evaluate all wheelchairs to make sure that all parts

are in place and are working; and to have its Director of Nursing (DON) and the rehabilitative coordinator monitor compliance in this area.

12. HCFA has proven that Petitioner was out of compliance with the "range of motion" requirements of 42 C.F.R. § 483.25(e)(2) at the time of the resurvey.

13. The Quality of Care requirement for "accidents" at 42 C.F.R. § 483.25(h)(2) requires that the facility must ensure that each resident receives adequate supervision and assistance devices to prevent accidents.

14. HCFA established instances, which Petitioner failed to rebut, in which Petitioner failed to meet its obligations under the Level B requirement for "accidents" by its failure to properly supervise residents and leaving the residents open to significant health and safety risks including the potential for accidents.

15. HCFA has proven that Petitioner was out of compliance with the requirements for preventing accidents under 42 C.F.R. § 483.25(h)(2) at the time of the resurvey.

16. The Quality of Care requirement for "activities for daily living" at 42 C.F.R. § 483.25(a)(3)(A) requires that based on the resident's comprehensive assessment, the facility must ensure that a resident who is unable to carry out activities of daily living receives the necessary services to maintain good nutrition, grooming and personal and oral hygiene.

17. HCFA established numerous instances, which Petitioner failed to rebut, in which Petitioner failed to meet its obligations under the Level B requirement for "activities of daily living" as well as the provisions of its plan of care because residents identified as needing such assistance did not receive needed assistance with grooming and personal hygiene.

18. HCFA has proven that Petitioner was out of compliance with the "activities of daily living" requirements of 42 C.F.R. § 483.25(a)(3)(A) at the time of the resurvey.

19. The regulations at 42 C.F.R. §488.26(a) specify that a decision as to whether there is compliance with Level A requirements will depend upon the manner and degree to which a SNF satisfies the various Level B requirements, and pursuant to 42 C.F.R. § 288.24 (a), noncompliance with Level A requirements will be found for SNF's "where the deficiencies are of such character as to substantially limit the provider's . . . capacity to render adequate care or which adversely affect the health and safety of patients. . . ."

20. The totality of the evidence surrounding the Level B deficiencies preponderate in favor of HCFA's conclusion that there exists systemic problems which arise to noncompliance with Level A requirement for Quality of Care.

III. Analysis

A. The Requirements for Participation in the Medicare Program as a SNF

In order to participate in the Medicare program and thereby receive federal payments for services rendered to Medicare beneficiaries, a provider of services must be a provider within the definition of the statutes and enter into an agreement with the Secretary of Health and Human Services. Sections 1861(u) and 1866 of the Social Security Act (Act); 42 U.S.C. §§ 1395x(u), 1395cc. Sections 1861(j) and 1819(a) of the Act define a facility as a SNF eligible to participate in the Medicare program. 42 U.S.C. §§ 1395x(j), 1395i-3(a). Section 1819 of the Act contains those requirements such as the provision of services, residents' rights, and administration; it states also that a SNF "must meet such other requirements relating to the health, safety, and well-being of residents ... as the Secretary may find necessary." 42 U.S.C. § 1395i-3(d)(4)(B). Those health and safety requirements prescribed by the Secretary are codified in 42 C.F.R. Part 483, subpart B.

During the time relevant to this action, all SNFs wishing to continue participating in the Medicare program must satisfy the major, broad categories of requirements denoted as Level A requirements in 42 C.F.R. Part 483, subpart B. Each Level A requirement is subdivided into related Level B requirements. See, 42 C.F.R. § 483.10 et seq. The decision as to whether there is compliance with Level A requirements will depend upon the manner and degree to which a SNF satisfies the various Level B requirements. 42 C.F.R. § 488.26(a). Noncompliance with level A requirements will be found for SNFs and NFs "where the deficiencies are of such character as to substantially limit the provider's ... capacity to render adequate care or which adversely affect the health and safety of patients...." 42 C.F.R. § 488.24(a). On-site surveys conducted by HCFA or on HCFA's behalf are used to determine whether a SNF continues to meet Medicare participation requirements. 42 U.S.C. § 1395aa(a); 42 C.F.R. §§ 488.10(a)(1), 488.20.

B. The Determinations Made by HCFA

The evidence introduced by HCFA shows, by way of background, that a team from the IDPH, acting as HCFA's agents, completed a survey of Petitioner on February 10, 1995 as part of the annual licensure and certification process it must undergo as a SNF participating in the Medicare program. HCFA Ex. 2. Tr. 18.

Based on the survey completed on February 10, 1995, the IDPH team concluded that Petitioner had five Level A deficiencies. HCFA Ex. 2, 3. In response to the surveyors' findings, Petitioner submitted a Plan of Correction which represented that a it would correct its deficiencies by March 15, 1995. See, HCFA Ex. 2. Thereafter, the IDPH conducted a resurvey which began on March 27, 1995 and ended on April 3, 1995. Tr. 89. The resurvey resulted in the determination made by HCFA that Petitioner remained out of compliance with one of the earlier noted Level A requirements: Quality of Care. HCFA's May 3, 1995 Notice Letter.

The Quality of Care regulation requires as follows:

> Each resident must receive and the facility must provide the necessary care and services to attain or maintain the highest practicable physical, mental, and psychological well-being, in accordance with the comprehensive assessment and the plan of care.

42 C.F.R. § 483.25. In this case, HCFA's determination of noncompliance with the Level A Quality of Care requirement is based, in turn, on the resurvey findings that Petitioner was out of compliance with the Level B Quality of Care requirements pertaining to:

> "Pressure sores" (42 C.F.R. § 483.25(c));
>
> "Urinary Incontinence" (42 C.F.R. § 483.25(d));
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> "Range of motion" (42 C.F.R. § 483.25(e));
>
> "Accidents" (42 C.F.R. § 483.25(h)).
>
> "Activities of daily living" (42 C.F.R. § 483.25(a));

HCFA Ex. 4.

For each Level B determination in dispute, I will discuss below the evidence and arguments I consider significant.

Many of HCFA's level B determinations resulted from and related to the surveyors' having found multiple instances in which Petitioner's staff had failed or refused to render appropriate care to its residents with urinary incontinency problems. When asked what facts stood out in her mind concerning the survey results, the IDPH official responsible for reviewing the findings and submitting IDPH's recommendations to HCFA testified that it was the incontinency problems at the facility, along with the facility's failure to change and reposition its residents -- especially those who had pressure sores or were at high risk for

pressure sores. Tr. 380. Therefore, I will begin with the evidence pertaining to "Pressure sores."

1. The Level B "Pressure sore" Citation

For the "Pressure sores" citation, the regulation relied upon by HCFA states in relevant parts:

> Each resident must receive and the facility must provide the necessary care and services to attain or maintain the highest practicable physical, mental, and psychological well-being in accordance with the comprehensive assessment and the plan of care.
>
> (c) Pressure sores. Based on the comprehensive assessment of a resident, the facility must ensure that --
>
> (1) A resident who enters the facility without pressure sores does not develop pressure sores unless the individual's clinical condition demonstrates that they were unavoidable; and
>
> (2) A resident having pressure sores receives necessary treatment and services to promote healing, prevent infection and prevent new sores from developing.

42 C.F.R. § 483.25(c).

As explained by the witnesses during hearing, pressure sores or decubiti are skin wounds which occur when circulation has been inhibited. Tr. 29. Pressure sores generally occur in areas where bony prominences press against the skin and constrict the flow of blood. Id. Since acids in urine act as irritants to the skin, residents who are incontinent are at high risk for developing decubiti. Tr. 107. Also at high risk for developing decubiti are residents who are unable to reposition themselves without assistance or who are dependent on staff for their nutritional intake. Tr. 43.

There are four stages of decubitus or pressure sores, with Stage IV being the most serious and Stage I being the least serious. Tr. 183. At Stage I, there is redness or discoloration of the skin, evidencing the beginning of cell damage; at Stage II, a break in the skin occurs; at Stage III, all three layers of skin are affected, and there is damage to the underlying tissue or muscle; at Stage IV, there is a breakdown affecting the deep muscles or bones. Tr. 29 - 30, 107, 183 - 184. Necrotic or dead tissues are generally present in Stages III and IV, indicating that the tissues had died from insufficient nutrients and oxygen

caused by pressure on the area. Tr. 184. Decubiti are not only painful, but they can cause infection, blood poisoning, or death. Tr. 37, 109 - 10, 185.

As discussed in greater detail below, the protocol for preventing and treating pressure sores on incontinent residents is to check them as often as possible in order to keep them as clean and dry as possible. Tr. 108, 208. At the very least, all incontinent residents should be checked at least once every two hours. Tr. 108. However, residents may need to be checked and changed more frequently than once every two hours if, for example, they have decubiti or are at high risk for developing them. Tr. 108 - 109. In addition, since decubiti develop due to decreased oxygen and nutrient flow to those areas with bony prominences that have been subjected to prolonged pressures (Tr. 29, 212), an aggressive prevention program must include the frequent repositioning of the residents in order to restore proper circulation in the susceptible areas. Tr. 42 - 43, 213. Even though repositioning must be done at least every two hours, those residents who have decubiti or who are at risk for developing them should be repositioned at even more frequent intervals. Id.

Because Petitioner was cited for numerous deficiencies in its assessment, prevention, and treatment of decubiti during the initial survey of February, 1996, Petitioner had submitted a written plan of correction (POC) in which Petitioner committed to effectuate certain practices by March 15, 1995 notwithstanding its denial of these deficiencies. HCFA Ex. 2 at 96; HCFA Ex. 14 at 10. In its POC, Petitioner promised to provide training to its staff on the importance of quickly assessing skin breakdowns; it promised to take all preventative measures available to prevent and heal decubiti, including repositioning its residents and keeping them dry and clean; and it promised to provide one-on-one hands-on training to its certified nurse aides (CNAs) and professional staff on positioning residents as well as on keeping residents dry and clean. HCFA Ex. 2 at 88; HCFA Ex. 14 at 10. Petitioner made its director of nursing (DON) responsible for monitoring the corrections asserted in the POC. HCFA Ex. 2 at 96; HCFA Ex. 14 at 10.

Notwithstanding Petitioner's commitments to institute corrections such as keeping its residents clean and dry pursuant to its POC by March 15, 1995, the surveyors immediately smelled a strong odor of stale urine on March 27, 1995, when they entered Petitioner's premises to begin the resurvey. Tr. 95, 96, 172. The strong smell of stale urine was present on both floors of the facility even though windows had been opened and the rooms were cold from the outside air. Tr. 171 - 174; HCFA Ex. 4 at 25 - 26. One of the Nurse surveyors on the resurvey team specifically testified that, based on his professional experience, urine odors in nursing homes are usually caused by the staff's failure to

change incontinent residents timely and to dispose of the wet linen in a timely manner. Tr. 172 - 173. In Petitioner's case, the strong smell of urine was not attributable to poor ventilation since the surveyors noted that windows had been opened. Tr. 173.

The surveyors testified that the strong urine odor was subsequently traced to residents who were sitting or lying in their own urine for prolonged periods of time, some of whom had decubiti or were at high risk for developing decubiti. Some of these residents were changed only after the surveyors intervened. In the surveyors' professional opinions, sitting or lying in urine has significant adverse psychological and physiological implications for the residents. E.g., Tr. 182.

In one case, as three surveyors were walking through the hallway of the second floor where Petitioner housed those residents who were to receive heavy or skilled care (Tr. 512 - 513), the three surveyors smelled a "strong urine odor" from a resident who was seated in a wheelchair or geri-chair placed in that hallway. Tr. 174 - 177, 179; HCFA Ex. 4 at 25 - 26. Mr. Gaffud, one of the surveyors, then kept the resident (R 15) under observation for approximately one hour. Tr. 177. During that one hour, Mr. Gaffud saw that nearly all of Petitioner's staff had walked past R 15 sitting in the hallway, but no staff member had stopped to investigate or assist R 15. Tr. 179. After the approximately one hour of observation, Mr. Gaffud requested assistance for R 15 from Petitioner's DON. Staff then put R 15 to bed, and they confirmed that R 15 had been wet. Tr. 179.[8]

The incident is significant for several reasons. First, it can be concluded from the urine smell and from the information that R 15 was wearing an adult diaper (Tr. 177) and that R 15 had been allowed to sit in a considerable amount of urine for an extended period of time. Tr. 181. An adult diaper or pad is likely to suppress urine odor for so long as the quantity of urine does not exceed its capacity to absorb it. Tr. 181. Where the amount of urine can no longer be absorbed by the diaper, the smell would then becomes noticeable to people around the resident. Tr. 181. Therefore, in Mr. Gaffud's opinion, staff members should have suspected the source of the urine odor when they walked past R 15

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[8] Petitioner points out that the DON, Maria Baker, testified that she did not tell any of the surveyors that R 15 had been wet. P. Br., 14 (citing Tr. 513 -14). However, Mr. Gaffud's testimony was that the CNAs who put the resident to bed confirmed the wetness. The record is devoid of any evidence from Petitioner that this resident was not wet or did not have the strong urine odor described by HCFA's witness. Therefore, whether this resident's wetness was in fact confirmed by Petitioner's DON does not appear to be of critical significance.

in the hallway and checked her diaper or pad within 30 minutes at the very latest. Tr. 178, 180. Another surveyor testified also that allowing a resident to sit in urine for one hour does not constitute timely incontinent care. Tr. 110. In addition, Petitioner's DON acknowledged that, barring the existence of an emergency elsewhere, it is not consistent with proper standard of nursing care for a staff member to merely walk by a resident emitting a strong odor of urine without an investigation of whether the resident is wet. Tr. 530, 531, 534 - 535

The incident described above is especially significant because R 15 had a decubitus ulcer at the time of the survey and Petitioner itself had assessed R 15 as being at high risk for developing more decubiti. Tr. 531, 533 - 535. When R 15 was admitted as a resident seven months prior to the resurvey, she had a large Stage IV decubitus or pressure sore on her back; that decubitus had not healed by the time of the resurvey. Tr. 185 - 187, HCFA Ex. 4 at 15. Therefore, in addition to the fact that an episode of incontinence is uncomfortable and has adverse psychosocial effects for any resident (Tr. 182), not timely changing someone with R 15's condition placed her at risk physically for exacerbating her existing decubitus as well as for developing additional decubiti.

The surveyors expressed concerns for the fact that R 15's Stage IV pressure sore had not healed completely in seven months since her admission. They thought that the length of the healing period suggested improper treatment by Petitioner, even if R 15's decubitus had been reduced to a Stage II - III as alleged by Petitioner. Testimony from the surveyors established that, depending on a resident's condition, a Stage IV pressure sore may be cured completely in a week with surgery and in a month without surgery. Tr. 109, 187 - 189. Under proper nursing standards, pressure sores should be treated with aggressive care and proper intervention. Tr. 109, 187 - 189. Aggressive treatment is given under a team approach and extends to surgically covering the affected area with a flap of healthy skin as the highest level of treatment. Tr. 188. However, other aggressive treatments include repositioning the resident more frequently than once every hour and doing treatments more than is minimally required. Tr. 188.

In a written response to the survey findings on R 15, Petitioner had alleged that its staff makes rounds every two hours and that the residents are changed and repositioned every two hours. HCFA Ex. 4 at 15. However, this approach is not consistent with the remediation efforts and principles appearing in the POC Petitioner had submitted to address the same types of problems found during the February survey. HCFA Ex. 2 at 88 and 96; HCFA Ex. 14 at 10. Additionally, every nursing facility has the duty to assess each resident to determine how often he/she should be checked for incontinency and be changed. Tr. 108. The parties

are in agreement that under applicable nursing standards, every incontinent resident should be checked and changed if necessary at least once every two hours. Tr. 108; P. Br., 15. However, a resident may also need to be checked and changed more frequently than once every two hours, if the individual's circumstances warrant it. Tr. 108 - 109. Petitioner's DON acknowledged that R 15 not only had a decubitus but was at high risk for developing other decubiti, and high risk residents such as R 15 should be checked more frequently than every two hours. Tr. 531, 533 - 535.

Petitioner's DON also initially testified that R 15 was a hospice patient and that families of hospice patients do not want Petitioner to provide any aggressive treatment.[9] Tr. 510. However, Petitioner's DON acknowledged during cross-examination that R 15 was not a hospice patient during the time of the resurvey, even though she did die sometime after the resurvey. Tr. 510, 529, 535, 536. Petitioner's DON admitted also that, even if R 15 had been a hospice patient, Petitioner had a duty to at least keep her comfortable. Tr. 510, 535. There does not appear to be any dispute to the fact that pressure sores can be very painful and lead to infections or death. Tr. 110, 183 - 85.

With respect to R 15, HCFA submitted evidence also showing that Petitioner had failed to either accurately assess or fully disclose the seriousness of R 15's decubitus at the time of the resurvey. When the surveyors entered the facility, Petitioner had a duty to submit a list containing the identity of those residents with decubitus and with up-to-date descriptions of their conditions. Tr. 100 - 101, 182, 183, 200, 395. Mr. Gaffud remembered that R 15 was described in such a list prepared by Petitioner as having a Stage II - III decubitus. Tr. 183. This information given by Petitioner is consistent only with its treatment record from March 17, 1995, which predated the beginning of the resurvey by 10 days. Petitioner's records for March 17, 1995 showed that Petitioner considered R 15's decubitus to be a Stage III-II sore, with a measurement of 8 cm by 5 cm and having "meaty red" tissue surrounded by "bright red" tissue exuding bloody drainage. HCFA Ex. 13 at 3; Tr. 388, 391 - 393. However, a week later, on March 24, 1995 (still before the resurvey), Petitioner's treatment records described R 15's decubitus as having increased to Stage IV-II-III. HCFA Ex 13 at 4; Tr. 391. Then during the resurvey, Petitioner's records for

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[9] Petitioner described the DON's testimony as follows:

> She also stated that from March to April 1995, R15's condition worsened. R15 they [sic] became terminal, was a DNR (hospice patient) and has since expired.

P. Br., 14 - 15.

March 30, 1995 also described R 15's decubitus as a Stage IV-II-III, with an increased size of 9 cm x 6 cm, and 1 cm in depth, since the measurements of March 17th. HCFA Ex. 13 at 5; Tr. 392. In addition, Petitioner's records for March 30, 1995 show that there was necrotic tissues scattered throughout the ulcer. HCFA Ex. 13 at 4; Tr. 393. Yet in addition to not having acknowledged the worsening of R 15's decubitus when it prepared the list for HCFA's use at the outset for the resurvey, Petitioner persisted in ignoring the contents of its records in responding to the surveyors' findings on R 15. Petitioner claimed that it had been doing a good job of treating R 15 because her pressure sore had improved from a Stage IV on admission in September of 1994 to an alleged Stage II. Tr. 185; HCFA Ex. 4 at 15.

The above problems with Petitioner's descriptions of R 15's decubitus is significant in light of the fact that during the initial survey of February, 1995, Petitioner had been cited for its failure or inability to identify pressure sores on its residents. HCFA Ex. 2 at 88 - 95. During the February, 1995 survey, surveyors pointed out to Petitioner's staff the existence and locations of numerous pressure sores on at least four residents; those sores were not previously identified by Petitioner's staff. Petitioner denied the existence of such deficiencies and alleged that, in many cases, the decubiti developed on the day that they were noted by the surveyors. Id. Nevertheless, Petitioner had committed to train its staff on the importance of quickly assessing skin breakdown and "to take all preventative measures available to stop them, and heal them." HCFA Ex. 2 at 88. As one witness pointed out, decubiti cannot be treated if they are not identified. Tr. 37. By analogy, I can conclude that, even if Petitioner had not intended to mislead the HCFA surveyors concerning the true state of R 15's decubitus, it would not be possible for Petitioner's staff to provide appropriate treatment of a decubitus when staff fails or refuses to recognize that the decubitus has worsened instead of improved.

I do not find that the merits of HCFA's evidence or conclusions concerning R 15 is significantly rebutted by Petitioner's observations that none of HCFA's witnesses at the hearing testified to having personally reviewed R 15's charts, to having personally observed R 15's decubitus, or to having personally seen R 15 wet. P. Br., 14. Nor do I agree with Petitioner's conclusion that HCFA failed to sustain its burden of proving that R 15 was incontinent and was not receiving the necessary treatment or services required by regulation even if incontinent. P. Br., 16. It is standard survey practice to apportion responsibility for resident record reviews among team members and for these team members to discuss and rely on each other's reviews throughout the survey. Tr. 161 - 162. The totality of the evidence shows that R 15's charts were reviewed by one or more surveyors during the survey process, that the existence of a decubitus on R 15 at the time of survey was not in dispute, and

that the strong urine odor from R 15, in addition to the CNAs' acknowledgement of this residents' wetness when putting her to bed, sufficiently establishes that R 15 was sitting in urine. If R 15 was continent at the time of the survey and what the surveyors observed was an unusual occurrence, these are affirmative defenses that Petitioner must support with a preponderance of the evidence. Yet Petitioner did not endeavor to do so.

During the resurvey which ended in early April, 1995, other residents were also observed to have been left to sit or lie in their own urine without Petitioner's staff having volunteered their assistance. Like R 15, some of these other residents were also at high risk for developing decubiti.

In the case of R 21, Petitioner had identified her as incontinent and at high risk for developing decubiti. Tr. 208. Yet, R 21 was also left lying on a urine soaked pad for approximately one and half hours until a surveyor intervened. According to Mr. Gaffud's testimony, he began observing R 21 in her room at about 2:25 p.m., when she was already lying on a wet bed pad. Tr. 201. Pads of the type used for incontinent residents are generally as large as the bed itself, with a plastic underside to keep the bed dry. Tr. 202 - 203. Mr. Gaffud did not know for how long her pad had been wet or when she was last changed by staff. However, since R 21 had little covering her, Mr. Gaffud was able to see that her pad was already saturated and soaked to its ends at the time he entered the room to begin his observations. Tr. 201.

Mr. Gaffud then followed the usual method adopted by surveyors for ascertaining whether a resident's pad would be changed timely: he wrote on the wet pad his initials and the date and time he began his observations (approximately 2:25 pm), and he checked for the marked pad. Tr. 201 - 202, 278. At 4:00 p.m., Mr. Gaffud found the same wet pad with his markings under R 21. Tr. 208. According to Petitioner's Assistant DON, it is the staff's usual practice to remove and dispose of wet pads when a resident is changed. Tr. 480.

When Mr. Gaffud contacted a charge nurse and asked why R 21 had not been changed, the charge nurse then spoke with a CNA. Tr. 209. Mr. Gaffud was given the response that the CNA had been working from room to room and had not yet reached R 21's room at the time of Mr. Gaffud's observation and inquiry. Tr. 209. Mr. Gaffud noted that Petitioner's staff was following a practice where the higher-level personnel (such as registered nurses (RNs) and licensed practical nurses (LPNs)) would ask the next lower-level employee to look for a CNA in charge of a particular resident to check and change that resident. Tr. 211. Petitioner's staff appeared to have followed this bumping downward process even though a charge nurse had been nearby and was available to change R 21 after she had laid in her urine for

at least one hour and a half, and even though R 21, who was already at high risk for decubitus, needed to be changed more frequently than a CNA's usual work pace allowed. Id.; Tr. 108 - 109.

In the absence of any contrary expert testimony, I accept Mr. Gaffud's opinion that even RNs and LPNs have a duty to change wet pads if they notice or are apprised of a problem relating to residents at high risk for decubiti. Tr. 211. I do not accept Petitioner's contention that, under the circumstances described by the surveyor, Petitioner's allowing R 21 to lie in her own urine for an hour and an half did not constitute a deviation from the standard nursing practice of checking a resident every two hours. See, P. Br., 17. Since Petitioner had already assessed R 21 as being at high risk for decubiti (Tr. 208), depending only on the CNA to check on R 21 and change her when the CNA happened to reach R 21's room (or even depending on the CNA to check on residents such as R 21 only once every two hours) is not appropriate care for R 21. See, Tr. 180, 108 - 109.

In the case of R 32, Mr. Gaffud testified that the wet padding for this incontinent resident was not changed from 8:30 a.m., when Mr. Gaffud began his observations, until 10:30 a.m., when Mr. Gaffud told the charge nurse for a second time that R 32 needed to be changed. Tr. 205. When Mr. Gaffud began his observations at 8:30 a.m., this resident's pad was only a little wet; as time went by, the pad became saturated. Id. Mr. Gaffud continued his observations after having marked R 32's pads with his signature in the presence of another surveyor. Tr. 206. At approximately 9:30 a.m., a CNA was seen in the room repositioning R 32. Tr. 205 - 207. However, Mr. Gaffud said the CNA did not change the pads even though in repositioning R 32, the CNA should have noticed the wetness--especially when the CNA removed the resident's covers, held the resident while repositioning him, rolling the resident from side to side during the repositioning process. Tr. 205 - 207.

Having seen no effort by the CNA to change R 32, Mr. Gaffud then notified the charge nurse on the floor at approximately 9:30 a.m. that R 32 should be changed. Tr. 205. At approximately 10:30 a.m., Mr. Gaffud saw that R 32 was still lying on the same wet pads which he had earlier marked for identification. Tr. 206. Then Mr. Gaffud sought out the charge nurse for a second time and asked why R 32 had not been changed. Tr. 206.

As with R 21, a nurse employed by Petitioner did not undertake to change R 32 even though a surveyor had twice told the nurse that R 32 needed to be changed. After R 32 had been left in his own urine for the two hours between 8:30 to 10:30 a.m., the charge nurse on R 32's floor said that she had told someone else to change the resident. Tr. 206. The charge nurse expressed surprise to the surveyor that R 32 had not been changed by

someone else. Tr. 206. When she disputed the surveyor's representation that R 32 had been wet for those two hours, the surveyor showed her the marked pads under the resident. Tr. 206. As I noted earlier in discussing R 21's situation, any member of Petitioner's nursing staff has an obligation to assist an incontinent resident if the resident's need is known and the resident's usual caregiver is not available. Tr. 211 - 12.

Petitioner contends that Mr. Gaffud could not have actually seen the care given to R 32 by the CNA at about 9:30 a.m., since Mr. Gaffud was outside the resident's door and there was a privacy curtain in the resident's room. P. Br., 17 - 18. Petitioner notes also that the CNA involved in the incident testified that he had changed R 32 on the morning in question. P. Br., 18. Moreover, Petitioner suggested that Mr. Gaffud's recollection may have been flawed since the surveyors' written report gave the time of the incident as 8:35 a.m. and three of Petitioner's employees, the CNA (Michael Sroka), the charge nurse (Maria Baker), and the DON (Maria Baker), all recalled that the incident occurred at 8:30 a.m. P. Br., 18. Petitioner suggests also that since Mr. Sroka testified that sometimes two pads (one overlapping the other) are placed under a resident, Mr. Gaffud may have marked the dry pad; therefore, the marked pad remained even though the wet pad had been removed by Mr. Sroka. P. Br., 18.

I find HCFA's evidence to be more credible, and HCFA's conclusions to be more reasonable, than the testimony and theories offered by Petitioner. Mr. Gaffud and his colleagues have no motive to lie about their observations concerning R 32, especially when they had repeatedly requested assistance for R 32 and Mr. Gaffud had especially marked the wet pad in order to verify his observations. By contrast, Mr. Sroka had an obvious motive to lie concerning the events of that day. As the DON testified, a CNA like Mr. Sroka would be disciplined or fired if he failed to change a resident after having been told to do so. Tr. 542. No one saw Mr. Sroka change R 32, even though Petitioner chose to believe that Mr. Sroka had done so. Tr. 459, 541. The testimony that Mr. Sroka was in R 32's room at 8:30 s.m. instead of 9:30 a.m. does not materially affect Mr. Gaffud's testimony that he told the charge nurse, Ms. Chisholm, at 9:30 a.m. and again at 10:30 a.m. that R 32 was wet. Moreover, even before Petitioner's witnesses gave their sequence of events, Mr. Gaffud had said the reference to 8:30 a.m. in the written report was a typographical error. Tr. 280 - 281.

With respect to Petitioner's theory that Mr. Sroka had changed R 32's wet pad but not the dry one containing Mr. Gaffud's markings, HCFA correctly pointed out in its reply brief that Mr. Gaffud testified to having marked "pads" -- not just one pad. Therefore, Mr. Gaffud could have ascertained if only one pad had been changed. More significantly, Mr. Sroka did not testify

during direct examination that two pads had been placed under R 32 on the day in question. He said only that two pads are usually placed under "heavy wetters" and R 32 "can be" such a person. Tr. 500. However, Mr. Sroka grew more certain on the use of two pads for R 32 during cross-examination, and he testified in response to HCFA's questions that he had placed both pads from R 32's bed into the laundry hamper. Tr. 505. Thus, if Mr. Sroka had been telling the truth, there should have been no marked pad or pads left.

In the case of R 23, Mr. Gaffud and a fellow surveyor saw her being brought into the dining room and seated with others for luncheon service. After about 10 minutes of observations, the surveyors saw liquid trickling down R 23's chair and forming a puddle under her chair.[10] Tr. 231 - 239. Mr. Gaffud testified that he was certain the liquid they saw was urine, as he had placed his finger in the liquid and smelled it. Tr. 233 - 234. There were staff members all about R 23 in the dining room, and one staff member was even sitting next to R 23 while feeding someone else. Tr. 233. No staff member attempted to give assistance to R 23 even though some staff members were seen trying to avoid stepping into the puddle. Id. After seeing that no assistance was being given to R 23 during the ten minutes following her episode of incontinency, one of the surveyors told the problem to Petitioner's owner, who was present also in the dining room. Tr. 234. Petitioner's owner then instructed some nurses to take R 23 out of the dining room and check her. Tr. 236.

Even though Petitioner's owner did not attempt to give an excuse for the incident on that day (Id.), Petitioner later alleged that what the surveyor observed was spilt lemonade. HCFA Ex. 4 at 8. However, the surveyors saw no lemonade being served to R 23 or anyone else at her table since R 23 was brought into the dining room. Tr. 235. Nor did they see any lemonade pitchers or cups on the table. Id. Mr. Gaffud's testimony established the liquid in question as urine by smell. Tr. 234.

On the Statement of Deficiencies, the surveyors had placed the incident involving R 23 as a violation of resident's dignity under the Quality of Life requirement. HCFA Ex. 4 at 7. However, HCFA maintains in its brief that the incident exemplifies Petitioner's failure to keep its residents as dry as possible under the Quality of Care requirement. HCFA Brief, 27.

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[10] Mr. Gaffud explained why his testimony concerned R 23 when the Statement of Deficiencies (HCFA Ex. 4 at 7) attributed this incident to R 24. Mr Gaffud testified that the Statement of Deficiencies contained a typographical error. It misidentified the resident as R 24 when, in fact, it should have identified the resident as R 23. Tr. at 237 and 239.

I do not find HCFA's approach to be improper since a reasonable reading of the Statement of Deficiencies shows that discussions of those incidents described under each broad category were provided as examples of the thought processes by which certain conclusions were reached. The incidents described in the document do not form a definitive or exhaustive list of all violations under each program requirement. HCFA Ex. 4. In addition, Mr. Gaffud explained during the hearing that his colleagues and he had discussed where to place the example involving R 23 because the incident pertained not only to a resident's dignity but also to the development of decubiti. Tr. 240. The example of R 23 could have been cited also for the Quality of Care deficiency since changing an incontinent resident timely, keeping the resident dry, and placing her on an appropriate toileting schedule are all factors relevant to the prevention of decubiti. Tr. 241. It was due to the lack of time that the surveyors had failed to cross-reference the example to various program requirements as they had intended. Tr. 241.

After the surveyor testified that the observations concerning R 23 could have been placed under either the Quality of Care requirement as well as the Quality of Life requirement, Petitioner had the opportunity to introduce evidence concerning its treatment of R 23 under one or both of those requirements. Petitioner presented no evidence at the hearing to refute HCFA's observations and conclusions concerning R 23. Moreover, HCFA's evidence on R 23 is consistent with other evidence concerning Petitioner's treatment of other incontinent residents. HCFA's observations of R 23's situation corroborates its contention that various system-wide problems have resulted in Petitioner's violation of the Quality of Care requirements.

Under 42 C.F.R. § 493.25(c), HCFA not only introduced evidence concerning Petitioner's failure to keep residents clean and dry in accordance with established protocol for preventing and treating decubiti, HCFA showed also that Petitioner had also failed to reposition residents who had decubiti or were at high risk for decubiti. As noted above, repositioning must be done at least once every two hours, but should be done even more frequently if the resident's condition so warrants. In response to earlier findings of deficiencies under the same requirement, Petitioner had submitted a POC which committed to providing training to staff on the use of repositioning to prevent and treat pressure sores.

One day during the resurvey, surveyors observed three residents (R 31, R 35, R 36) sitting continuously in geri chairs from 10 am to 2 pm. HCFA Ex. 4 at 15 - 16. All three residents had been identified by Petitioner as being at high risk for development of decubiti. Tr. 285. Petitioner's records for R 35 even showed that she had a Stage II decubitus on her buttock. HCFA Ex. 4 at 16.

These three residents were not repositioned by staff during the four hours that Mr. Gaffud and another surveyor had kept them under observation. Tr. 215 - 216. The care plan for all three residents showed that they needed assistance for transfers and mobility. Tr. 215. None of them were observed to have shifted their weight independently during the four hours described by the surveyor. Tr. 215 - 216. During the time he was observing these residents, Mr. Gaffud heard an announcement over the public address system to reposition residents, but these residents were not repositioned. Tr. 220.

All three residents had been left in geri chairs with lap trays in place, which restricted the movements of the residents. Tr. 216. These residents also could not be repositioned by Petitioner's staff unless the trays on their geri chairs were first removed. Id. Therefore, to corroborate the accuracy of his and other surveyors' visual observations of these three residents, Mr. Gaffud placed tape across the tray tables' latches so that, if the trays were removed, the tapes would be broken. Id. Mr. Gaffud then checked the tape every hour during the four hour period. Id. At no time was the tape broken to suggest that any of the three residents had been repositioned. Id. Other surveyors continued the observations of the three residents when they were taken into the dining room for meal service. Tr. 217 - 218. Not only were these three residents not repositioned during the four hours between 10 am to 2 pm, these residents were not even toileted during that period. Tr. 218.

In response to the survey findings, Petitioner alleged generally that residents are repositioned every two hours when its staff makes rounds. HCFA Ex. 4 at 15. However, Petitioner did not deny that the three residents observed by surveyors were never repositioned for four hours. Instead, Petitioner merely implied that there was no need to reposition them since they allegedly could shift their own weight without assistance and therefore did not place pressure on any given area of their body. HCFA Ex. 4 at 15. Petitioner's explanation for its failure to reposition these residents ignores the fact that Petitioner itself had assessed them as being at high risk for development of decubiti, as well as the impossibility of removing weight from the buttocks area for any period of time even when a healthy and otherwise mobile person is sitting in a geri chair for four hours with a tray table in place.

Petitioner alleged also that the surveyors had neglected to observe that, after lunch, all three residents were taken out of the dining room and toileted. HCFA Ex. 4 at 16. However, Petitioner did not explain why the tapes on the tray latches remained intact until 2:00 pm. Therefore, I do not find Petitioner's contention credible.

Petitioner pointed out in its posthearing brief that neither Mr. Gaffud nor anyone else on behalf of HCFA had alleged that R 31, R 35 or R 36 was incontinent. P. Br., 19. However, even if there was no evidence of these residents' incontinency,[11] there is already sufficient support for HCFA's conclusion that these residents needed repositioning pursuant to 42 C.F.R. § 483.25(c): i.e., the expert testimony of record concerning the development and exacerbation of decubiti, coupled with the fact that Petitioner's own assessments placed all three residents at high risk for development of decubiti and as needing assistance in transfers and mobility. In addition, there is no evidence on which to conclude that even continent residents who are at risk for decubiti and who need assistance in transfers and mobility, and who were seated behind tray tables attached to their geri-chairs, need not be taken to the toilet by staff (and therefore receive de facto repositioning) during the four hours observed by the surveyors. If Petitioner's theory is that these residents did not need to be toileted or repositioned from 10:00 a.m. to 2:00 p.m. because they were continent, then Petitioner has failed to introduce any evidence to support this affirmative defense.

Petitioner has asked that the examples of R 21, R 31, R 32, and R 36 be stricken because these residents did not have any decubitus even though the deficiency identifier ("F 320") used by HCFA relates only to residents with decubiti. P. Br., 16 - 17, 19. However, as HCFA correctly pointed out in opposing Petitioner's request, the regulation codified at 42 C.F.R. § 483.25(c)(1) (which should be denoted by "F 319") required Petitioner to prevent the development of pressure sores in persons who do not have pressure sores. HCFA Reply, 19 - 20. HCFA contends that it was reasonable for the surveyors to cite these related deficiencies under one F tag, especially since there is no support for striking "a validly cited failure to meet the regulation as a whole" and doing so would defeat the intent of the regulation. HCFA Reply, 20.

I agree with HCFA's views. As discussed above, all four residents had been assessed by Petitioner as being at high risk for the development of decubiti; yet Petitioner's staff had left them lying on urine soaked bed pads (R 21 and R 31) or sitting in geri-chairs with attached trays for several hours without being repositioned or taken to the toilet (R 32 and R 36). The evidence discussed above concerning these four residents supports

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[11] However, there is evidence of record that these three residents were incontinent, as they were among those residents whose care plans were reviewed by HCFA surveyors during March and April to verify Petitioner's toileting of incontinent residents and to ascertain whether Petitioner had a restorative bladder and bowel program for incontinent residents. HCFA Ex. 4 at 16 - 17; Tr. 227 - 28.

the conclusion that Petitioner was out of compliance with the requirements of 42 C.F.R. § 483.25(c)(1), even though HCFA had not earlier cited these violations under 42 C.F.R. § 483.25(c)(1) in its Statement of Deficiencies. Since HCFA's factual findings with respect to these four residents (albeit under F Tag 320 instead of under F Tag 319) have been known to Petitioner since the issuance of the Statement of Deficiencies, allowing HCFA to conform its legal conclusions to the evidence cannot result in undue prejudice to Petitioner.

Additionally, the expert testimony of record establishes the relatedness between these regulatory requirements in that aggressive interventions and care are necessary for the prevention of decubiti in persons at risk for their development as well as the treatment of existing decubiti. Therefore, even if the evidence concerning R 21, R 31, R 32, and R 36 do not show deficiencies under 42 C.F.R. § 483.25(c)(1) or F Tag 319, such evidence at the very least corroborates HCFA's findings and conclusions which were made explicitly under 42 C.F.R. § 483.25(c)(2) or F Tag 320.

2. The Level B "Urinary Incontinence" Citation

With respect to the "Urinary Incontinence" citation, HCFA relied upon the following regulatory requirements:

> Each resident must receive and the facility must provide the necessary care and services to attain or maintain the highest practicable physical, mental, and psychological well-being in accordance with the comprehensive assessment and the plan of care.
>
> (d) Urinary Incontinence. Based on the resident's comprehensive assessment, the facility must ensure that --
>
> (2) A resident who is incontinent of bladder receives appropriate treatment and services to prevent urinary tract infection and to restore as much normal bladder function as possible.

42 C.F.R. § 483.25(d)(2).

There exists a relationship between the strong urine odor noted by surveyors at Petitioner's facility and Petitioner's failure to use a program to restore as much normal bladder function as possible. See, Tr. 113 - 14. Generally, the number of incontinent residents and the amount of odor would be reduced if

a facility has a restorative bladder and bowel (B & B)[12] program in place. Tr. 114. B & B is a restorative type of program which entails assessing the voiding patterns of the residents and the use such restorative techniques as pushing fluids. Tr. 112, 222. Regular toileting of residents is not a substitute for a B & B program. Tr. 111, 113, 229. Whereas regular toileting is merely timed or scheduled toileting, a B & B is a restorative program based on the resident's individualized needs and potential for returning to continency. Tr. 111, 221 - 222. Upon admitting each resident and at periodic intervals thereafter, facilities are required to assess each resident's potentials and needs; the assessments and the programs suitable to their needs and potentials should appear on the resident's care plan. Tr. 114 - 115. 221 -223.

During the February survey, Petitioner was found out of compliance with the foregoing Level B requirements. HCFA Ex. 2 at 104 - 105. The survey team on the February survey found that Petitioner did not have a B & B program even though it had identified 30 residents with bladder incontinence and two residents with bowel incontinence. HCFA Ex. 2, 104 - 105. The POC submitted by Petitioner represented that it had, since the February survey, assessed its residents for their potential to benefit from a B & B programs and was setting forth this information on the residents' care plans. The POC stated also that the B & B program was "in progress" and would be completed by March 15, 1995. Tr. 229; HCFA Ex. 14 at 10. Such a program was to be monitored by Petitioner's DON. Id. Because the administrator of a facility and its DON usually prepare the POC, HCFA expected Petitioner's professional staff to know the differences between scheduled toileting and a B & B program. Tr. 230.

When the surveyors returned for the resurvey in late March, one of the surveyors asked an LPN whether a B & B program was in place. Tr. 113. The surveyor asked the question due to the urine odor in the facility and its likely relationship with the absence of intervention given to incontinent residents. Tr. 114. The LPN responded that there was no B & B program in place. Tr. 114. According to the surveyor, an LPN should have known what is a B & B program, as opposed to regular toileting of residents. Id.

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[12] Even though the deficiencies relate only to residents with urinary incontinency problems, I will use the abbreviation of B & B to denote the type of program Petitioner was required to have under the regulations to restore as much bladder function as possible for residents with urinary incontinency.

It was Petitioner's responsibility to assess each resident to determine whether the resident could benefit from a restorative program such as a B & B program. Tr. 112, 222 - 223. Therefore, during the resurvey, the surveyors also reviewed the care plans for six incontinent residents. However, the surveyors found no such assessments. Tr. 114 - 116, 227 - 228. One of the surveyors, Ms. Langford, reviewed the care plans for three incontinent residents; she found on these care plans that Petitioner had acknowledged three residents' urinary incontinency, but there was no indication that Petitioner had assessed these three residents for any B & B program. Tr. 116, 163 - 164. Mr. Gaffud reached the same findings after reviewing the care plans of another three residents who were assessed by Petitioner as incontinent. Tr. 227 - 228; HCFA Ex. 4 at 16 - 17.

The care plans reviewed by Mr. Gaffud were for R 31, 35, and 36. Tr. 228. As discussed above, these same residents were observed by the surveyors left sitting in a geri chair without repositioning or toileting for four hours. These residents' care plans only contained their toilet schedules. Tr. 228, 230. However, Mr. Gaffud's testimony established that these residents were not even toileted according to the schedules written on their care plans by Petitioner. Tr. 230, 321.

Petitioner disputes HCFA's conclusions under 42 C.F.R. § 483.25(d)(2) on several specific grounds which I do not find persuasive. First, I do not read the regulation as meaning that a deficiency exists only if a facility fails to restore as much normal bladder function as possible, as well to prevent urinary tract infections. Thus, it is immaterial whether, as argued by Petitioner, HCFA has not alleged a failure by Petitioner to prevent urinary tract infections in its residents. See, P. Br., 20. Second, Petitioner has failed to prove its affirmative defense that it had a restorative program which it did not call a B & B program. See, P. Br., 21. Even though there is no requirement that a program for restoring as much bladder functioning as possible be called any particular name, Petitioner cannot simply rely on an assertion that it has such a program by an unspecified name. The evidence of record shows only that Petitioner's residents were supposed to be on specified toileting schedules which Petitioner did not always maintain (see discussions of R 31, R 35, and R 36); there is no evidence showing that these residents are likely to regain their bladder functioning capabilities if Petitioner were to toilet them on the specified schedules.

Nor do I find persuasive Petitioner argument that, with respect to two residents (R 31 and R 35) who were left in their geri-chairs for four consecutive hours without toileting, HCFA has failed to demonstrate that Petitioner was not providing them with services to restore as much normal bowel and bladder function as possible. P. Br., 22. The evidence shows that members of the

resurvey team had looked at these residents' daily toileting schedules as contained in their care plans and determined that Petitioner's failure to toilet them for four consecutive hours was not consistent with their toileting schedules. HCFA Ex. 4 at 17. There is no evidence to suggest that not toileting residents in accordance with the schedules specified in their care plans might help restore their bladder or bowel functions. There is also no evidence that Petitioner had even made the necessary assessments of these two or any other cited residents to ascertain whether they would benefit from a restorative program such as a B & B program; nor has Petitioner introduced evidence that it had any bowel or bladder restorative program called by whatever name, even though the POC submitted in response to the February survey findings had committed to institute such a program. In essence, HCFA's evidence pointing to Petitioner's failure to meet its obligations under the regulations is unrebutted by contrary evidence from Petitioner.

Nor was I persuaded by Petitioner's argument that no deficiency has been proven because the surveyors observed only one day of technical violation during which regular toileting schedules were not followed for some residents. P. Br., 22. Such is the nature of a survey, which spot-checks Petitioner's compliance and relies upon reasonable inferences from observations, interviews, and record reviews. The evidence from HCFA is sufficient for having shifted the burden of moving forward to Petitioner, who chose not to submit any evidence to show how it was restoring as much function as possible for its residents in accordance with the regulatory requirements.

Finally, I agree with HCFA that the absence of restorative program such as a B & B program is a systemic problem at Petitioner's facility. HCFA Br., 23. All of the evidence introduced by HCFA (including the examples of six residents) shows that such a program did not exist at the time of the resurvey, and Petitioner has not introduced any evidence to establish that it does exist. Therefore, I do not find valid Petitioner's contention that HCFA has not established sufficient frequency of the incidents to justify a Level B deficiency. See, P. Br., 21. There is simply no indication from the record that HCFA might have found a restorative program if, for example, HCFA had studied more care plans, observed more residents, or extended the days of the resurvey as suggested by Petitioner's arguments on frequency. Moreover, there is no bright line test for Level A or Level B findings. See, Tr. 78 - 292.

3. The Level B "Range of motion" Citation

For the "Range of motion" citation, HCFA relied upon the following regulatory requirements:

> Each resident must receive and the facility must provide the necessary care and services to attain or maintain the highest practicable physical, mental, and psychological well-being in accordance with the comprehensive assessment and the plan of care.
>
> (e) Range of motion. Based on the comprehensive assessment of a resident, the facility must ensure that --
>
> (2) A resident with a limited range of motion receives appropriate treatment and services to increase range of motion and/or to prevent further decrease in range of motion.

42 C.F.R. § 483.25(e)(2)

During the initial survey conducted in February of 1995, surveyors found that Petitioner had failed to provide proper range of motion treatment or services to five residents from the selected samples and five residents from outside the selected samples. HCFA Ex. 2 at 106 - 11. The citations of deficiencies from the February survey included findings such as Petitioner's failure to have hand rolls or like positioning devices in place for those residents who were assessed by Petitioner as having hand contractures or as being at high risk for hand contractures. Tr. 45 - 46. (Hand rolls should be used for any resident whose inability or unwillingness to extend or contract his hand is likely to cause the hands to form a tight fist; bones will become fixed if the tight fist remains in place, thereby causing a painful condition, with a possibility for infection and the growth of nails into the palms of the hand. Tr. 45 - 46.) Other citations of deficiencies from the February survey involved the absence of proper foot support for residents, which can cause a condition called "foot drop" where the muscles contract and the foot hangs out of position without normal flexibility. Tr. 118, 305.

The POC submitted by Petitioner to address the February survey findings included its commitment to train CNAs on when to and how to use positioning devices; having its maintenance department evaluate all wheelchairs to make sure that all parts are in place and are working; and to have the DON and the rehabilitations coordinator monitor compliance in this area. HCFA Ex. 2 at 111. Petitioner's POC committed to having the deficiencies corrected by March 1, 1995. Id.

During the resurvey conducted from March 27 to April 4, 1995, surveyors observed R 14, R 37, and R 38 sitting with their feet dangling above the floor in their wheelchairs or geri-chairs, without any foot support. Tr. 116 - 118. The footrests of wheelchairs and geri-chairs are supposed to be in place. Tr. 117. Without these footrests in place, and without having any other kind of foot support, these residents were at risk for having their range of motion reduced through the development of "foot drop." See, Tr. 118, 305. Despite Petitioner's commitment in its earlier submitted POC to repair all wheelchairs by March 1, 1995, Mr. Gaffud still saw missing footrests during the resurvey, and to having seen feet dangling above these missing footrests. Tr. 305.

Even though R 37 had been identified by Petitioner as ambulatory, development of "foot drop" due to proper foot support could reduce the range of motion in his feet and therefore his ability to ambulate. Tr. 118. The other two residents, R 14 and 38, were identified by Petitioner as having weakness in their lower extremities and in need of range of motion exercises. Tr. 118 - 119; HCFA Ex. 4 at 18. None of these three residents had full ranges of motions. Therefore, having these three residents sit in wheelchairs or geri-chair without foot support and placing them at risk for "foot drop" were not consistent with Petitioner's affirmative obligations under 42 C.F.R. § 483.25(e)(2) to not only provide residents with a limited range of motion with appropriate treatments or services to increase their range of motion, but to also prevent further decrease in their range of motion.

Petitioner argued that R 37 was never in danger of developing "foot drop" because one of its nurses, Mary Chisholm, testified that R 37 was ambulatory and that the only time R 37 was in a wheelchair was during mealtime. P. Br., 25. However, the fact that R 37 has some range of motion limitations is implied by the fact that he needs to sit in a wheelchair despite Petitioner's assessment that he is ambulatory. Therefore, Petitioner had a duty under the regulations to provide appropriate treatment or services which would increase this resident's range of motion and to prevent further decreases in his range of motion.

HCFA pointed out in response, moreover, that Ms. Chisholm acknowledged on cross-examination that it was not mealtime when the surveyors observed R 37 sitting in a wheelchair without footrests. HCFA Reply, 25 - 26 at n. 27 (citing Tr. 490 - 491). One of HCFA's surveyors, Ms. Langford, also testified that when she observed R 37 in the wheelchair without footrests, it was "well between either mealtime." Tr. 123. Since Petitioner was keeping an allegedly ambulatory resident in a wheelchair when he should not be in a wheelchair, I am unable to accept Petitioner's hypothesis that this resident was in no danger of developing

"foot drop" from the lack of footrests on his wheel chair because he was ambulatory and should only be in a wheelchair during mealtime.

Petitioner argued also that, according to Ms. Chisholm's testimony, R 38 was a stroke victim who was paralyzed on one side; the footrest of her wheelchair was intentionally not in place to enable her to use her good foot to ambulate in the wheelchair. P. Br., 25. There are several problems with Ms. Chisholm's testimony and Petitioner's reliance on it. Most fundamentally, there is no evidence explaining how a stroke victim paralyzed on one side of her body could maneuver the wheelchair with sufficient control to ambulate with her one good foot. But even assuming that one footrest should be removed in order to allow her to use her good foot as alleged by Petitioner, there is no evidence from Petitioner to explain why the other footrest was not left in place to support her paralyzed foot. (In other words, Petitioner has not shown that it should not provide the requisite support for this resident's paralyzed foot while allegedly allowing freedom of movement for her other foot.) Moreover, there is no evidence from Petitioner that any professional staff had made an assessment that R 38's footrests should be removed, or that the benefits of having her propel herself with her good foot outweighed the risk of having her develop "foot drop" in her paralyzed foot. Absent such evidence, Ms. Chisholm's testimony and Petitioner's affirmative arguments based on her testimony appear contrived.

To the extent that Petitioner argues HCFA has not proven that the cited incidents occurred with sufficient frequency to justify a Level B deficiency finding (P. Br., 25, 26), I note that Petitioner's explanations for even the foregoing residents show a failure or refusal to acknowledge the need for proper foot support. Whereas the testimony introduced by Petitioner on this issue was largely unpersuasive, HCFA presented persuasive testimony concerning the surveyors' observations[13] and

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[13] Petitioner points out that only Ms. Langford testified with regard to the deficiency under 42 C.F.R. § 483.25(e), and she only made personal observations with respect to R. 37. P. Br., 25. However, there is no requirement for each surveyor to testify about his or her own personal observations which are set forth in a report generated in the ordinary course of business. The other surveyors' observations concerning R 38 and R 14 were set forth in the Statement of Deficiencies. These observations are not unreliable or incredible on their face. If Petitioner disputed these observations concerning R 38 and R 14, it had the opportunity to subpoena the responsible surveyors to testify concerning their observations. Petitioner could have also presented evidence to refute these surveyors' observations, if Petitioner thought such observations untrue. Petitioner has not

conclusions from the resurvey which were consistent with the findings from the initial survey. Even though Petitioner had submitted a POC containing detailed commitments to be completed by March 1, 1995, it does not appear that Petitioner had done what it said it would do. In addition, if Petitioner truly believed that HCFA's examples failed to reflect Petitioner's usual practices on improving or maintaining ranges of motion limitations, Petitioner was in a position to show how it was meeting the regulatory requirements with respect to other residents; but Petitioner introduced no such evidence. Therefore, the totality of the record leads me to conclude that there existed a systemic problem under 42 C.F.R. § 483.25(e)(2) at the time of the resurvey.

4. The Level B "Accidents" Citation

For the "Accidents" citation, I will consider HCFA's reliance upon the following regulatory requirements[14]:

> Each resident must receive and the facility must provide the necessary care and services to attain or maintain the highest practicable physical, mental, and psychological well-being in accordance with the comprehensive assessment and the plan of care.
>
> (h) Accidents. The facility must ensure that --

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taken these foregoing courses of action. Consequently, the facially credible observations recorded in the Statement of Deficiencies concerning R 38 and R 14 stand unrefuted.

[14] For several reasons, I will not include an analysis of the evidence relevant to 42 C.F.R. § 483.25(h)(1). HCFA has alleged that Petitioner violated this regulation by failing to have a call light in what Petitioner calls its hydrotherapy room at the time of the resurvey. HCFA Ex. 4 at 27. However, as pointed by Petitioner in its written response, the absence of a call light had been cited as a deficiency under a different regulation during the February survey. HCFA Ex. 4 at 27; HCFA Br., 56. More importantly, Petitioner believed that this deficiency from the February survey had been deleted. Id. I find Petitioner's belief to be credible because even HCFA admits that the surveyor responsible for citing said deficiency during the February survey thought that the deficiency had been deleted by her superiors. HCFA Reply, 28. Under these circumstances, Petitioner cannot be considered to have had notice that HCFA would expect the installation of a call light in the hydrotherapy room by the time of the resurvey in order for Petitioner to be considered in compliance with 42 C.F.R. § 483.25(h)(1). Therefore, I do not find it appropriate to reach the merits of HCFA's citation under 42 C.F.R. § 483.25(h)(1).

> (2) Each resident receives adequate supervision and assistance devices to prevent accidents.

42 C.F.R. § 483.25(h)(2).

The resurvey at issue was commenced in late March of 1995 partly because Petitioner was found to have been out of compliance with the foregoing requirements during the February survey. Findings from the February survey in this area included those incidents relating to R 15 and R 16. Four days prior to the February survey, R 15 had fallen while being showered at Petitioner's facility and was hospitalized as a result. Tr. 54. The CNA who was showering R 15 knew that this resident was ambulatory, was being treated with anti-psychotic medication for a mental disorder, was easily agitated, and had a history of falls which resulted in two fractured hips and two prior fractured arms. Tr. 54 - 55. However, the CNA who was showering R 15 when she again fell four days prior to the survey neither used a gait belt (a canvas safety belt placed around the waist of unstable or unpredictable residents), nor sought assistance to help her support R 15. HCFA Ex. 2 at 118 - 119; Tr. 54 - 55. The results of the February survey included citations of Petitioner's failure to provide proper supervision for R 16. R 16 had a diagnosis of severe dementia and manic psychosis; he was identified in his care plan as being able to ambulate independently, but in need of constant supervision. Tr. 56; HCFA Ex. 2 at 120. However, he was observed during the survey wandering about in the dining room unsupervised, removing sweaters from the backs of other residents' wheelchairs, removing other residents' lap blankets, taking others' newspapers, and drinking out of other residents' cups without their apparent permission. Id. While R 16 was engaged in these activities, two CNAs were in the room engaged in a private conversation; they did not stop R 16's behavior or appeared to have noticed it. Tr. 56. The surveyors believed that R 16's unsupervised conduct posed health and safety risks for himself as well as other residents. Tr. 56.

When the surveyors returned to the facility in late March of 1995 to conduct the resurvey, they again evaluated the supervision being given to the resident previously designated as R 16 in the February survey and now re-designated as R 37 in the resurvey. The surveyors found that, instead of being allowed to wander about as during the February survey, this resident was now left alone in a hallway sitting in a geri-chair with a tray table attached. Tr. 122. To the surveyors, he appeared anxious and agitated, and seemed to have been rocking his geri-chair in an effort to get out. Tr. 122. It was 10:25 AM when this resident was so observed, even though this resident was not supposed to have been in restraints at any time other than meal time. Tr. 123. There is no dispute that 10:25 AM was not mealtime at Petitioner's facility. Tr. 123, 491.

As was noted during the February survey, this resident was assessed by Petitioner as having severe dementia and manic psychosis, and as being in need of constant supervision. Tr. 56. The surveyor who made the observations concerning this resident during the resurvey testified that confining him to a geri-chair with a tray table in place did not constitute adequate supervision, especially when this resident is known to be agitated. Tr. 125. She testified also that the resident was rocking the geri-chair in an apparent effort to get out, that the geri-chair was not very stable, and that the geri-chair could have tipped over. Tr. 123 - 124.

The team that conducted the resurvey also found deficiencies with respect to R 8. During three days of the resurvey, R 8 was seen in a wheelchair with her back against the dining room, and surrounded by a C-shaped table pushed up against her wheelchair. Tr. 242 - 243. These so-called "C tables" are supposed to be used by staff during mealtime to help feed multiple residents simultaneously. Tr. 243 - 246, 492. When a C table is properly used, a staff member sits within the smaller curvature and multiple residents sit around the larger, outer curvature, so that the staff member can assist and supervise these multiple residents during meal time. Tr. 243 . However, in the case of R 8, the C table was not being used by a staff member to feed one or more residents; rather, the C table was being used as a restraint for R 8, who was in a wheelchair situated within the smaller or inner semi-circle of the table where a staff member should have sat had the table been used for feeding multiple residents. Tr. 243 - 246, 492. The resident did not respond when one of the surveyors attempted to communicate with her to ascertain if she wished to be in that position. Id. However, R 8 appeared not to have wanted to be in that position as she was observed attempting to push the C table away and trying to reach over the table to get nearby objects. Tr. 244.

On one occasion, Mr. Gaffud and other surveyors saw R 8 against the wall in a wheelchair and behind a C table in the dining room for the entire morning. Tr. 245 - 246. There was no staff members present in the dining room to provide supervision except during lunch and during activity time. Tr. 249. No one removed the C table from in front of R 8 until she was taken for her afternoon nap. Tr. 249. Mr. Gaffud's review of R 8's records maintained by Petitioner showed that she had "senile dementia," which is a subset of Alzheimer's disease. Tr. 261. Mr. Gaffud's review of R 8's records showed also that she had been in an accident within 30 days of the resurvey. Tr. 263. In his opinion, leaving R 8 in the position observed during the resurvey was likely to result in another accident. Tr. 263.

Petitioner alleged that it had a reasonable explanation for having placed R 8 behind the C table: R 8 was a diabetic, and the table is used to keep R 8 from taking other residents' food

while allowing him to eat independently. P. Br., 32. I find, however, that whatever need there might be to keep R 8 from taking others' food does not excuse Petitioner's having kept R 8 behind a C table when there was no meals being served and when there was no staff to supervise him sitting in a wheel chair behind a C table. Petitioner's treatment of R 8 was cited as a deficiency because there was a failure of supervision and the likelihood of another accident to R 8.

I am also not persuaded by Petitioner's argument that HCFA has not shown sufficient frequency to justify a citation of deficiency under 42 C.F.R. § 483.25(h)(2). See, P. Br., 31. Here, even in the two examples relied upon by HCFA, the evidence pointed to very significant health and safety risks created by the staff's very obvious lack of concern for residents. Even one example may suffice, if, as here, the dangers are very significant. See, Tr. 434 - 437. In addition, as I noted above, even after having been cited for its failure to properly supervise R 16 during the February survey, Petitioner's staff was still failing to properly supervise the same resident (now identified as R 37) during the resurvey. In addition, the evidence shows that confining R 8 behind a C table without proper supervision continued for three days, despite the fact that Mr. Gaffud had brought this problem situation to the attention of key staff members on the very first day of the resurvey. Tr. 264. Even though Petitioner had specific notice that proper supervision was not being provided to at least these two residents, Petitioner failed to remedy the situations, choosing instead to rely on contrived excuses such as the alleged need to use a C table to prevent R 8 from taking others' food. Thus, I do not view the examples cited by HCFA as isolated incidents of Petitioner's inadvertence. Rather, the examples cited by HCFA under 42 C.F.R. § 483.25(h)(2) are consistent with other incidents discussed in this decision which also point to the conclusion that there existed system-wide practices which violated program participation requirements because Petitioner and its staff simply did not care about the residents' health, safety, or general well-being even when surveyors are scrutinizing the staff's conduct.

I conclude that HCFA has established Petitioner's failure to comply with the requirements of 42 C.F.R. § 483.25(h)(2).

5. The Level B "Activities of daily living" Citation

For the "Activities of daily living" citation, HCFA relied upon the following regulatory requirements:

> Each resident must receive and the facility must provide the necessary care and services to attain or maintain the highest practicable physical, mental, and

> psychological well-being in accordance with the comprehensive assessment and the plan of care.
>
> (a) Activities of daily living. Based on the comprehensive assessment of a resident, the facility must ensure that --
>
> (3)(A) A resident who is unable to carry out activities of daily living receives the necessary services to maintain good nutrition, grooming, and personal and oral hygiene.

42 C.F.R. § 483.25(a)(3)(A).

During the February survey, the surveyors found that various residents (six of 24 in the designated sample group, and 5 from outside the designated sample group) were not receiving the assistance they needed to maintain good grooming and personal hygiene. HCFA Ex. 2 at 83 - 86. The examples cited by HCFA were compelling, including not only dependent residents who were unshaven, had uncombed hair, and exhibited long fingernails or toe nails (some of which had buildups, were discolored, or were irregular), but also dependent residents in wheelchairs who had on soiled clothing or emitted a strong odor of urine. Other residents were seen wearing unmatched clothing, a shirt with a hole, or a soiled sling. In one case, a resident's family told the surveyors that they (the family) had to wipe dried feces from the resident, even though this resident was blind and needed extensive to total assistance in activities of daily living from Petitioner's staff. Another resident who was dependent on staff for care not only had body odor and urine smell, but she was also observed to have had a dried substance on her fingers which looked like dried feces.

Petitioner's responses to these February findings included allegations of resident preferences (e.g., some residents wanted to wear the same clothes each day or refused baths) and that the surveyors saw some residents before they were bathed according to their daily schedule. HCFA Ex. 2 at 81 - 86. Nevertheless, Petitioner submitted POC in which it committed to provide inservice training to staff on dressing, grooming, and cleaning residents in order to maintain their hygiene. HCFA Ex. 2 at 87.

During the resurvey, surveyors proceeded on the basis of a list prepared by Petitioner, which identified those residents who needed assistance with their activities of daily living (ADLs). Tr. 129, 132 - 34. The surveyors then concluded that 11 residents were not receiving the needed assistance with grooming and personal hygiene. HCFA Ex. 4 at 12 - 13; Tr. 125 - 26, 128 - 129. For example, of those residents who, according to Petitioner's Assistant DON, needed prompting to do their ADLs, R 16 was seen sitting in a wheel chair with a strong odor of urine

about her, and R 7, R 12, R. 24, and R 27 were observed in need of oral hygiene at 11:20 AM (approximately an hour to an hour and a half after their morning snack). HCFA Ex. 4 at 13; Tr. 452. The surveyors made additional observations that R 27 was wearing shoes without socks, that R 11 and R 25 were in need of personal hygiene, and that R 25, R 27, and R 29 had messy hair. HCFA Ex. 4 at 13.

One of the residents who was identified during the February survey as having long fingernails was again found as having long, jagged fingernails in need of trimming during the resurvey.[15] HCFA Ex. 16, p. 2. The Assistant DON testified that this resident is "generally very unkempt." Tr. 126, 128. Two other residents, R 29 and R 30, were also observed during the resurvey as having long, jagged fingernails in need of trimming. HCFA Ex. 4 at 23; Tr. 126, 128. The DON confirmed that R 30 relies on staff to cut her nails. Tr. 453, 486, 487. One of HCFA's surveyors testified that long, jagged nails can cause scratches and infection, as well as have an adverse psychological affect on the resident. Tr. 126, 128.

The surveyors found also that R 11 wore the same clothing all three days of the survey, along with shoes and socks which were not only mismatched, but stained (i.e., her right leg prosthesis was in stained hosiery and a heavily stained tennis shoe, while her left leg was in a short white sock and a brown leather shoe). HCFA Ex. 4 at 13, 14; Tr. 131 - 132. R 11 told one of the surveyors that, even though she was able to apply the prosthesis by herself, she was unable to care for the shoe, the stocking, or her prosthesis. Tr. 132 - 133. This resident complained also that her prosthesis was loose fitting. Tr. 134. The surveyor's review of those assessments done by Petitioner showed that R 11 needed assistance with grooming and hygiene. Id. The surveyor found nothing indicated in R 11's care plan for maintenance of R 11's prosthesis, as required by law. Tr. 134 - 135. However, since R 11 was receiving rehabilitation services and gait training, Petitioner's staff should have been aware that this resident's prosthesis was loose. Tr. 136.

Petitioner's Assistant DON, Mary Chisholm, testified that R 11 was a diabetic with an artificial limb below the knee. Tr. 455 - 456. Even though the surveyors observed a white sock and a brown leather shoe on R 11's left leg and foot, Ms. Chisholm testified that this resident was wearing a white sock and a gym shoe on her

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[15] This resident was identified as R 46 in the February survey and as R 28 during the resurvey. In addition to long nails, this resident also had uncombed hair and appeared in need of a shave during the February survey. HCFA **Ex. 2 at 81.** HCFA cited the appearance of this resident under a related tag number in its survey report. Id.

left leg and foot during the resurvey due to circulatory problems which caused her skin to break down. Tr. 455 - 456. Petitioner alleged also that R 11 was independent and liked to do things her own way. P. Br., 11; HCFA Ex. 4 at 13.

I do not find Petitioner's explanations for R 11 credible given that the record as a whole establishes a general lack of concern on the part of Petitioner's staff for the residents' health and psychological well being. I do not believe Petitioner's explanation that R 11 was wearing stained items of clothing, mismatched items of clothing, and the same clothes for three days because R 11 had insisted on doing so even though Petitioner's staff was available to help her dress in unstained, matched, and different clothes each day. Instead, HCFA's theory that R 11 and others were not being provided with the necessary assistance in daily grooming and hygiene is consistent with other evidence of record, such as the pervasive smell of stale urine on the premise, the absence of footrests on wheelchairs, the poor grooming and hygiene of other dependent residents also observed by the surveyors, and the residents who were left to sit or lie in their own urine even after the surveyors intervened.

Moreover, even if I were to assume as true that R 11 preferred to wear the same clothes for several consecutive days along with different socks on each leg and different shoes on each foot, this does not account for the stains noted by the surveyors. Nor would such an assumption account for Petitioner's failure to properly maintain this resident's prosthesis. There is no evidence from Petitioner that R 11's preferred items of clothing was being worn around the clock or that the stained items could not have been cleaned when R 11 took them off in order for Petitioner to help her maintain appropriate grooming or personal hygiene. Nor has Petitioner given an explanation for the looseness of R 11's prosthesis, which was also cited by HCFA as a basis for the deficiency.

Even though each of the examples cited by HCFA under 42 C.F.R. § 483.25(a)(3)(A) might be arguably insignificant when viewed individually, together they show Petitioner's lack of concern for the dependent residents' grooming and hygiene that is very consistent with other evidence of record discussed herein. Accordingly, I conclude that Petitioner has violated the requirements of 42 C.F.R. § 483.25(a)(3)(A).

6. The Level A "Quality of Care" Citation

As noted above, the regulations specify that a decision as to whether there is compliance with Level A requirements will depend upon the manner and degree to which a SNF satisfies the various Level B requirements (42 C.F.R. § 488.26(a)), and noncompliance with Level A requirements will be found for SNFs "where the deficiencies are of such character as to substantially limit the

provider's ... capacity to render adequate care or which adversely affect the health and safety of patients...." (42 C.F.R. § 488.24(a)). Based on my evaluation of the evidence discussed above, I find that a preponderance of the evidence supports HCFA's determination that the manner and degree of Petitioner's noncompliance with the specified Level B requirements also placed Petitioner out of compliance with the Level A requirement for Quality of Care.

In reaching this conclusion, I have considered the various resident-specific defenses presented by Petitioner (see discussions above), as well as the three main lines of arguments articulated in Petitioner's posthearing briefs: (1) that HCFA's findings are invalid because the surveyors had allegedly failed to follow certain guidelines contained in the State Operations Manual (SOM); (2) that HCFA's evidence is not sufficient for proving the severity and frequency of the deficiencies noted by the surveyors; and (3) that Petitioner's expert consultant, Kathleen Baker, was of the opinion that the Statement of Deficiencies written by the surveyors does not contain adequate information to supporting HCFA's findings of deficiencies.

I address these three lines of arguments as a group here because they all appear to suggest that the surveying process is an exact science, under which results are computed based on the application of precise formulas. My review of the evidence persuades me that the surveying process is not an exact science. The SOM and like publications contain guidelines -- not precise or inflexible formulas -- for trained surveyors to apply in accordance with their professional judgment and the exigencies of circumstances, for the protection of Medicare beneficiaries and Medicaid recipients. The evidence in this case has established to my satisfaction that the surveyors conducted the resurvey at issue reasonably and appropriately, and in a manner consistent with the regulations.

Without doubt, the severity or frequency of alleged problems are relevant to the ultimate issue of whether "the deficiencies are of such character as to substantially limit the provider's ... capacity to render adequate care or which adversely affect the health and safety of patients...." 42 C.F.R. § 488.24(a). However, there exists no bright-line test for determining when problems are of the severity or frequency to substantially limit a facility's capacity to render adequate care or to affect adversely the health and safety of patients. Nor can such bright-line tests be created. In some instances, for example, surveyors are not likely to have the opportunity to personally observe the full or actual extent of harm to residents because surveys are conducted during limited periods of time. In other situations, more severe or more widespread harm to residents may not have been observed on the days of survey due to the interventions exercised by the surveyors for the residents'

protection. The expert witnesses for both parties in this case agree that actual harm to residents is not necessary to justify a finding of noncompliance. Tr. 434 - 435, 662. As even Petitioner's expert witness, Kathleen Baker, testified, "There really aren't any clear definitions of what constitutes a Level A" (Tr. 599 - 600), and whether deficiencies amount to a Level A noncompliance rests "ultimately ... [on] a judgment call" (Tr. 635).

For these reasons, I have relied on the totality of evidence in this case, including all reasonable inferences arising therefrom, in concluding that Petitioner's deficiencies substantially limited its capacity to render adequate care or adversely affected the health and safety of its residents. My reliance upon the totality of the evidence means that I have looked beyond what is within the four corners of the survey report criticized by Kathleen Baker, Petitioner's expert consultant. There is more evidence in this case than the written report of the surveyors. Additionally, Ms. Baker testified that she did not participate in the surveying of Petitioner (Tr. 641) and that she based her opinions solely on her review of the Statement of Deficiencies from the resurvey (Tr. 604 - 605). In contrast to Ms. Baker, who was not present during the testimony of other witnesses (Tr. 3 - 4), I have had the benefit of listening to surveyors and other witnesses explain their observations and conclusions under oath over a period of several days during the hearing.

I am aware that several of the examples of deficiencies cited by HCFA may appear to be insubstantial if each of them is viewed in isolation as urged by Petitioner. However, when all of these examples are viewed together, the facts and inferences underlying them preponderate in favor of HCFA's conclusion that there exists systemic problems which arise to a Level A Quality of Care noncompliance. See, e.g., HCFA Reply, 23.

As indicated in my discussions of various Level B citations, I attached weight also to the fact that Petitioner was not only on notice to correct certain deficiencies prior to the resurvey but had, in many instances, committed to correct them prior to the resurvey; yet, the same types of deficiencies continued to be present during the time of the resurvey. As also indicated in my earlier discussions, I attached weight to the fact that Petitioner's staff was unmindful of the residents' needs and well-being even when staff was aware that surveyors were on premise making observations and intervening to request the delivery of appropriate care to residents. The lack of concern for residents' needs and well-being shown on the days of the resurvey led me to believe that Petitioner's noncompliance with the Quality of Care requirements would not have been better on those days when it knew no surveyors were present.

IV. Conclusion

Thus, for the foregoing reasons, I uphold HCFA's termination of Petitioner's participation agreement due to its noncompliance with the Level A Quality of Care requirement at the time of the April, 1995 resurvey.

/s/

Mimi Hwang Leahy

Administrative Law Judge