Department of Health and Human Services

DEPARTMENTAL APPEALS BOARD

Civil Remedies Division

In the Case of:	)	
	)	
Golden State Manor Nursing and Rehabilitation Center,	)	DATE: February 28, 1996
	)	
Petitioner,	)	
	)	
- v. -	)	Docket No. C-94-364
	)	Decision No. CR412
Health Care Financing Administration.	)	
	)	

DECISION

This case is before me on Petitioner's request for an administrative law judge hearing on the determination by the Health Care Financing Administration (HCFA) that January 31, 1994 should be the effective date of Petitioner's participation as a Medicare provider. I sustain HCFA's determination.

An initial Medicare survey of Petitioner was conducted on December 14-23, 1993, for purposes of determining whether Petitioner could be certified as a Medicare provider of skilled nursing services. As a result of this survey, HCFA informed Petitioner that deficiencies were identified which evidenced a lack of full compliance with the requirements of 42 C.F.R. Part 483.

On January 31, 1994, Petitioner submitted its plan of correction. By letter dated February 23, 1994, HCFA notified Petitioner that it was certifying Petitioner as a provider in the Medicare program, effective January 31, 1994, the date of Petitioner's acceptable plan of correction. HCFA Exhibit (Ex). 5.[1]

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[1] HCFA subsequently issued an amended letter dated February 28, 1994, to Petitioner. The only change from the earlier letter dated February 23, 1994, is that a different fiscal intermediary is named. HCFA Ex. 6.

(continued...)

Petitioner requested, and was granted, reconsideration of HCFA's determination of its effective date of Medicare participation. HCFA Ex. 7. By letter dated March 25, 1994, HCFA reaffirmed its earlier decision to certify Petitioner as of January 31, 1994. HCFA Ex. 8. Petitioner again requested that HCFA reconsider its determination.

By letter dated May 6, 1994, HCFA reaffirmed its decision to accept Petitioner's agreement to participate in the

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[1] (...continued)

HCFA submitted HCFA Exs. 1-15. Petitioner submitted Petitioner's Exhibits (P. Exs.) 1-4, 9-10, 19-32, 34-36, 41, 43-53. At the hearing, I admitted HCFA Exs. 1-15 and P. Exs. 1-4, 9-10, 19-32, 34-36, 41, 43-48, and 50-53 into evidence. I rejected P. Ex. 49. Petitioner provided a list with its opening posthearing brief stating the exhibits which were admitted in this case. Upon examining Petitioner's list and carefully checking the record, I have determined that Petitioner's list is inaccurate.

The parties' posthearing briefs, the transcript of the hearing, and my findings of fact and conclusions of law will be cited as follows:

Transcript of Hearing	Tr. (page)
HCFA's Opening Posthearing Memorandum	HCFA Br. at (page)
Petitioner's Posthearing Brief	P. Br. at (page)
HCFA's Posthearing Response	HCFA Resp. Br. at (page)
Petitioner's Opposing Brief (to HCFA's Opening Post-Hearing Memorandum)	P. Resp. Br. at (page)
HCFA's Posthearing Reply	HCFA Rep. Br. at (page)
Petitioner's Reply Brief to HCFA Post-Hearing Response	P. Rep. Br. at (page)
My Findings of Fact and Conclusions of Law	FFCL (number)

Medicare program effective January 31, 1994. HCFA Ex. 9. By letter dated May 13, 1994, Petitioner requested a hearing to contest HCFA's determination. The case was assigned to me for a hearing and a decision.

On December 15, 1994, I issued a Ruling on Subpoena Requests, the purpose of which was to decide Petitioner's written requests, filed on September 13, 1994, for the issuance of subpoenas for the production of the surveyors' notes. In this ruling, I found Petitioner's justification for the subpoena requests to be inadequate and insufficient to satisfy its burden under the regulations and applicable case precedent. Furthermore, I ruled that the surveyors' notes are part of the deliberative process and were protected from disclosure by the deliberative process privilege.

On January 17-20, 1995, I conducted an in-person hearing in San Diego, California. Because the hearing did not conclude on January 20, I continued it to March 6, 1995. On March 6-10, 1995, I conducted the remainder of the in-person hearing in San Diego, California. The parties filed posthearing briefs, followed by posthearing response briefs and reply briefs.

I. Findings of Fact and Conclusions of Law[2]

1. Petitioner is a skilled nursing facility, with approximately 300 beds, located in San Diego, California. Tr. 1644.

2. The San Diego District Office of Licensing and Certification, California Department of Health Services (DHS) is authorized to perform surveys of skilled nursing facilities in order to make recommendations to HCFA on whether such facilities meet the federal requirements for participation in the Medicare program. 42 U.S.C. § 1395aa(a).[3]

3. The Medicare survey of Petitioner began on December 14, 1993 (Tr. 1590-1592) and was completed on December 23, 1993 (Tr. 109).

4. Although the State surveyors found Petitioner to be in compliance with all Level A requirements imposed by HCFA for skilled nursing facilities, there were numerous Level B deficiencies identifie at the time of the survey. HCFA Ex. 2.

5. Title XVIII of the Social Security Act, 42 U.S.C. §§ 1395 et seq., commonly known as the Medicare Act, establishes a federally subsidized health insurance

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[2] FFCL 1-10 are HCFA's Proposed Findings of Fact and Conclusions of Law 1, 2, 7-8, 28-30, and 32-34, which I have adopted, in pertinent part. Petitioner did not object to these specific findings of fact and conclusions of law and, thus, I am adopting them. Where necessary for purposes of clarity and consistency of style, I have made editorial changes, which do not alter the substance of the findings.

Although there were other proposed findings of fact and conclusions of law submitted by HCFA to which Petitioner did not object, I have chosen not to adopt them.

I have made my own findings of fact and conclusions of law based on my independent review of the record, and these are set forth beginning at FFCL 11.

[3] Hereinafter, I refer to the San Diego District Office of Licensing and Certification as "DHS-San Diego."

program for the elderly and disabled which is administered by the Secretary of Health and Human Services (the Secretary).

6. The Secretary has delegated to HCFA the responsibility for carrying out many of the duties under this program.

7. Skilled nursing facilities or other entities may participate in the Medicare program by entering into a "provider agreement" with the Secretary. 42 U.S.C. §§ 1395x(u) and 1395cc.

8. The results of Medicare related surveys are used by HCFA as the basis for its decisions regarding a facility's initial or continued participation in the Medicare program.

9. The findings of State agencies are recommendations to HCFA, which makes the actual determination as to whether a facility is eligible to participate or to remain in the program. 42 C.F.R. § 489.10.

10. Onsite inspections (surveys) of facilities must be conducted without any prior notice to the facility. See 42 U.S.C. § 1395i-3(g)(2)(A).

11. A skilled nursing facility is defined as an institution which is primarily engaged in providing skilled nursing care and related services for residents who require medical or nursing care, or rehabilitation services for the rehabilitation of injured, disabled, or sick persons, and is not primarily for the care and treatment of mental diseases. 42 U.S.C. 1395i-3(a).

12. A skilled nursing facility must meet also the requirements of 42 U.S.C. 1395i-3(b), (c), and (d).

13. On December 14-23, 1993, Petitioner was surveyed on behalf of HCFA by surveyors from DHS-San Diego. The purpose of the survey was to determine whether Petitioner was conducting its operations in compliance with the requirements of the Medicare program.

14. DHS-San Diego then issued to Petitioner a document captioned "Statement of Deficiencies and Plan of Correction" (HCFA 2567), which sets out the deficiencies identified during the survey.

15. Petitioner was found to have failed to comply with various regulations governing a skilled nursing facility's participation in Medicare, and these were: 42

C.F.R. §§ 483.13(a); 483.15(h)(3); 483.20(b)(1); 483.20(b)(5); 483.20(b)(6); 483.20(c)(1); 483.20(d)(1); 483.230(d)(2)(ii); 483.20(d)(2)(iii); 483.20(d)(3); 483.25; 483.25(c)(2); 483.25(e)(2); 483.35(f)(3); 483.65(a)(1); 483.65(a)(3); 483.70(d)(1); and 483.75(l)(1).

16. On January 31, 1994, Petitioner submitted its plan of correction to DHS. HCFA Ex. 2.

17. By letter dated February 23, 1994, HCFA notified Petitioner that it was certifying Petitioner as a provider in the Medicare program, effective January 31, 1994, the date of Petitioner's acceptable plan of correction. HCFA Ex. 5.

18. On February 28, 1994, HCFA sent an amended notification letter (changing only the designation of fiscal intermediary). HCFA Ex. 6.

19. HCFA reconsidered its determination at Petitioner's request, but, by letter dated May 6, 1994, notified Petitioner that it found no basis to alter its initial determination. HCFA Exs. 7, 9.

20. Petitioner requested further review of the HCFA 2567 findings, and HCFA again reaffirmed its decision to accept Petitioner's agreement to participate in the Medicare program effective January 31, 1994. HCFA Ex. 10.

21. The survey team that conducted the December 14-23, 1993 survey of Petitioner consisted of Glenda Shekell, Carol Pettengill, Cindy Cox, and Judith Chute. Tr. 85-86, 1590.

22. At the time of the December 1993 survey, Petitioner had 230 residents. Tr. 1644.

23. On December 23, 1993, the last day of the survey of Petitioner, the survey team held an exit conference with Petitioner's representatives. Tr. 103-104, 109.

24. Petitioner's representatives were briefed thoroughly by the survey team on December 23, 1993. Tr. 2191.

25. Glenda Shekell is a health facility evaluator nurse with DHS-San Diego. Tr. 79-80, 83-84.

26. Ms. Shekell has worked at DHS-San Diego since April 1988 and estimates that she has performed 200 surveys of long-term care facilities. Tr. 80, 81-82.

27. Ms. Shekell's primary duty until April 1994 was to conduct licensing and certification surveys of long-term care facilities. Tr. 81.

28. Ms. Shekell was the team leader of the survey team that performed the survey of Petitioner on December 14-23, 1993. Tr. 84, 90.

29. At the time of the December 1993 survey, Ms. Jacqy Downing was Ms. Shekell's supervisor. Tr. 87.

30. Cynthia Cox is a health facility evaluator nurse with DHS-San Diego and has been at her current position since January 1990. Tr. 990.

31. Ms. Cox estimated that she has participated in approximately 150 certification surveys of skilled nursing facilities. Tr. 991.

32. Ms. Cox stated that she received training in how to conduct surveys and write deficiencies pursuant to HCFA's regulations regarding Medicare certification for skilled nursing facilities. Tr. 991.

33. During Ms. Cox's third year working at DHS-San Diego, Ms. Downing became her supervisor and was her supervisor until early 1994. Tr. 992, 993-994.

34. Martha Carrillo is a certification specialist with the Provider Certification Unit of DHS-San Diego. Tr. 921.

35. At the request of her supervisor, Ms. Carrillo reviewed the HCFA 2567 to check the validity and accuracy of the deficiencies, and whether the plan of correction submitted by Petitioner was valid. Tr. 923-924.

36. Nelson Ford is a health facility evaluator supervisor with DHS-San Diego and has been a supervisor for three years. Tr. 1582-1583.

37. In his position as supervisor, Mr. Ford schedules surveys and acts as a resource and consultant to survey teams when they are conducting surveys. Tr. 1583-1584.

38. Since December 1992, one of the facilities assigned to Mr. Ford has been Petitioner. Tr. 1585, 1592.

39. Dan Murray was employed as the hospital administrator of Petitioner from December 1993 to September 21, 1994. Tr. 2188, 2193.

40. Mr. Murray was in the facility during the time of the December 1993 survey and spoke with the surveyors. Tr. 2191.

41. Mr. Murray prepared most of Petitioner's Plan of Correction and submitted it to HCFA on January 31, 1994. Tr. 2190-2191.

42. Joan Allison is employed by the DHS as chief of field operations for the southern region in the licensing and certification program. Tr. 2735-2736.

43. DHS-San Diego is one of the offices in Ms. Allison's region. Tr. 2736.

44. Ms. Allison participated in an internal investigation in October and November 1993 involving the San Diego DHS office. Tr. 2738-2739, 2781.

45. Ruth Patience, who has a nursing background, has worked for HCFA for four years as a survey and certification review specialist. She is "responsible for assisting and overseeing and managing the state agencies who survey and certify health care facilities." Tr. 2436, 2437, 2439-2440.

46. Ms. Patience conducts surveys by which HCFA evaluates the effectiveness of the state surveys and also participates in training surveyors. Tr. 2437.

47. Ms. Patience estimated that, during her employment with HCFA, she has participated in approximately 120 surveys of long-term care facilities. Tr. 2437-2438.

48. Prior to working for HCFA, Ms. Patience worked as a state surveyor for a year and a half. Tr. 2438. As a surveyor, she surveyed about 60 long-term care facilities. Id.

• Evaluation of the credibility of Jacqy Downing (pp. 35-40)[4]

49. Ms. Downing is the "assistant administrator" of Petitioner and a "registered nurse consultant for the nursing department within the facility." Tr. 1687.

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[4] The pages cited in the parentheses refer to the pages in the decision where these findings are discussed.

50. Ms. Downing was recruited to work for Petitioner by Dan Murray and began working for Petitioner on January 17, 1994. Tr. 1687-1688, 2101.

51. Prior to her employment at Petitioner, Ms. Downing worked for approximately six years at DHS-San Diego, beginning in March 1988. Tr. 1688, 2066.

52. At DHS-San Diego, Ms. Downing was a surveyor for two and a half years, and was promoted to health facility evaluator supervisor on October 1, 1990. Tr. 1688, 1691, 2067.

53. Ms. Downing participated in approximately two to three surveys a month when she was at DHS-San Diego. Tr. 1690.

54. When she was with DHS-San Diego, Ms. Downing followed the State Operations Manual Transmittal No. 250 (SOM 250) guidelines after they were implemented in April 1991 and instructed her survey team to follow these guidelines. Tr. 2130.

55. As a supervisor, Ms. Downing never referred to or used the "Resident Assessment Instrument Training Manual and Resource Guide" (P. Ex. 52), nor did her survey team members use this manual. Tr. 2138.

56. P. Ex. 52 had not been disseminated as of January 1994, according to Ms. Downing. Tr. 2138.

57. Ms. Downing did not have supervisory responsibilities over the survey team that conducted the December 1993 survey of Petitioner. Tr. 1690, 2072, 2138.

58. Ms. Downing was not onsite at Petitioner during the survey.

59. Following the survey of Petitioner, Ms. Downing did not participate in writing any findings for the HCFA 2567. Tr. 1698.

60. In October and November 1993, Ms. Allison and Paul Keller participated in an internal investigation involving DHS-San Diego, the purpose of which was to determine whether someone in that office had altered complaint documents. Tr. 2738-2739, 2781.

61. Ms. Allison and Mr. Keller went to the San Diego district office and interviewed the district manager, the district administrator, all of the supervisors (including

Ms. Downing), and one of her surveyors, who allegedly falsified the documents. Tr. 2740; see also Tr. 2755-2756.

62. The investigation revealed that approximately 80 survey documents had been altered and that the falsified documents had Ms. Downing's name "signed as the supervisor." Tr. 2743.

63. The investigation revealed that Ms. Downing's name was the only name signed as supervisor on all of the falsified documents. Tr. 2743.

64. The investigation revealed that "Ms. Downing had given specific directions to the surveyor in terms of how to prepare these complaint documents including whiting out the information and preparing the complaint documents in that way. And then, subsequently, in approving and sending forward all of these complaints as if they had, in fact, been legitimately investigated." Tr. 2745.

65. Ms. Allison stated that no other supervisors were the focus of the investigation. Tr. 2743.

66. DHS's audits and investigations division conducted a second investigation, which confirmed the results of the initial investigation. Tr. 2778-2779.

67. As a result of the investigation, DHS served both Ms. Downing and the evaluator in December 1993 with an action to dismiss from State service. Tr. 2746, 2756, 2759-2760.

68. Prior to a State hearing, DHS and Ms. Downing reached a stipulated agreement, which required Ms. Downing to resign effective January 14, 1994. HCFA Ex. 14; Tr. 2746, 2758, 2779. A hearing did not take place. Tr. 2758. Ms. Downing resigned in accordance with the stipulated agreement. Tr. 2779.

69. Ms. Downing left the DHS on January 7, 1994. Tr. 2071.

70. Contrary to what actually occurred, Ms. Downing testified under oath that:

> a. She had no knowledge of problems regarding the falsification of complaints in the office. Tr. 2074.

b. She "didn't have any clear understanding of what the investigation was" (Tr. 2084), had no knowledge that the focus of the investigation was that complaint results were being reported which had not been investigated, and was never informed of this by any of the investigators. Tr. 2096.

c. She was not "personally confronted" with charges concerning the investigation nor were any allegations concerning any impropriety brought to her attention during her interview with the investigators. Tr. 2084, 2086-2087.

d. No one told her that the complaints at issue originated out of her survey team. Tr. 2084.

e. The investigation did not specifically concern herself and Ms. Chute. Tr. 2075-2076.

f. She left DHS because she "chose to retire" and denied that she was asked to leave DHS. Tr. 2074-2075.

g. She filed for retirement in mid-December 1993 and, in the retirement papers, had given her intention to retire in January 1994. Tr. 2079-2081.

71. I find Ms. Downing's testimony regarding the circumstances surrounding the DHS-San Diego investigation and the reasons why she left DHS less than forthright and, at times, not consistent with the actual events surrounding her departure from DHS.

72. Ms. Downing's attempt to hide the true nature of the DHS investigation that began in October 1993 greatly undermines my confidence in her credibility.

73. I find Ms. Allison's testimony to be credible and accept it as being a truthful and accurate account of the events in question.

74. Based on Ms. Allison's testimony and the contents of the stipulation and settlement, I find not credible Ms. Downing's assertions that she had already planned to retire and that she had filed for retirement in mid-December 1993, since Ms. Downing did not produce any documents to support her assertion.

75. Whether Ms. Downing intended to retire or not, the circumstances of the investigation and proposed adverse action overtook any such plans and were the actual reasons for her departure from DHS in January 1994.

76. Ms. Downing's testimony regarding the internal investigation and the circumstances of her resignation was less than truthful. Her questionable credibility requires me to take a cautious approach in ascribing weight to her other testimony on the substantive matters of this case.

• Non-Applicability of 42 C.F.R. Part 488, Subpart C -- Survey Forms and Procedures (pp. 40-63)

77. The nursing home reform provisions of the Omnibus Budget Reconciliation Act of 1987 (OBRA '87) set minimum statutory standards that skilled nursing facilities (SNFs) must meet to participate in Medicare and nursing facilities (NFs) must meet to participate in Medicaid, provided nursing home residents with certain rights, and established a structure for State and federal surveys and certifications of nursing homes. 42 U.S.C. §§ 1395i-3 and 1396r. These requirements were in effect as of October 1, 1990. Sections 4202(a) and 4214(a) of OBRA '87.

78. OBRA '87 specifies the content, procedures, and frequency of surveys as well as survey team composition. 42 U.S.C. § 1395i-3(g)(2) and 42 U.S.C. § 1396r(g)(2).

79. Under OBRA '87, each state is responsible for certifying that SNFs are in compliance with the requirements of the Act through the use of surveys conducted pursuant to certain specified protocols.

80. Congress specified in OBRA '87 that by no later than January 1, 1990, the Secretary develop, test, and validate survey protocols for the standard and extended surveys required by law.

81. Congress stated further that the failure of the Secretary to carry out these mandates by January 1, 1990 shall not relieve any state or the Secretary of the responsibility to conduct surveys required by OBRA '87. 42 U.S.C. §§ 1395i-3 and 1396r.

82. OBRA '87 fundamentally changed the survey and certification process by establishing a patient-oriented system to assess the quality of care actually furnished. See 42 U.S.C. § 1395i-3(f) and (g); 42 U.S.C. § 1396r(f) and (g).

83. The legislative history regarding OBRA '87 confirms the intent of Congress to implement major reforms in nursing home care and to create a resident-centered, outcome-oriented survey process. See H.R. Rep. No. 391,

100th Cong., 1st Sess., pts. 1 & 2 (1987), reprinted in 1987 U.S. Code Cong. & Admin. News 2313-1; and H.R. Conf. Rep. No. 495, 100th Cong., 1st Sess. (1987), reprinted in 1987 U.S. Code Cong. & Admin. News 2313-1245.

84. In July, October, and November 1987, HCFA published proposed rules which dealt with the survey and certification process, conditions of participation, and enforcement regulations. 52 Fed. Reg. 24,752 (1987); 52 Fed. Reg. 38,582 (1987); 52 Fed. Reg. 44,300 (1987).

85. On June 17, 1988, HCFA, acting in accordance with a February 18, 1988 court order in Estate of Smith v. Bowen, 656 F. Supp. 1093 (D. Colo. 1987), promulgated final regulations amending the Medicare and Medicaid survey regulations then in effect. These final regulations were based on the proposed regulations published in July 1987. 53 Fed. Reg. 22,850 (1988).

86. Among the new regulations promulgated were 42 C.F.R. Part 488, Subpart C. In the preamble, HCFA acknowledged Congress' enactment of OBRA '87 and stated, among other things, that "[a] new survey process is required by OBRA '87, effective in 1990." 53 Fed. Reg. at 22,853.

87. The survey procedures and guidelines in 42 C.F.R. Part 488, Subpart C were revised by HCFA to comply with congressional directives in OBRA '87 to develop new protocols. These protocols were published in April 1992 as SOM 250.

88. In August 1992, HCFA published proposed regulations which would further implement provisions of OBRA '87, as further amended by 1988, 1989, and 1990 legislation. 57 Fed. Reg. 39,278 (1992).

89. The Federal Register preamble to the final publication of 42 C.F.R. Part 488, Subpart C, notified interested parties that (1) this Subpart pertained to conditions of participation for long-term care facilities that were in effect at the time of publication and (2) HCFA was, at the time of publication, in the process of making significant and wide-ranging changes to the existing conditions of participation based on various amendments to the law, principally OBRA '87. 53 Fed. Reg. 22,850-22,853 (1988).

90. At least as of August 1992, HCFA put SNFs on notice that the interpretive guidelines and survey procedures used in federal and state surveys were revised in April 1992. 57 Fed. Reg. at 39,283 (1992).

91. At the time of its December 1993 survey, Petitioner was bound by the survey protocols and by the applicable regulations pertaining to the conditions of participation found at 42 C.F.R. § 483, Subpart B.

92. The survey procedures set out in 42 C.F.R. Part 488, Subpart C do not reflect the new and expanded requirements created by OBRA '87, including those in the areas of residents' rights, quality of patient life, quality of care, and dietary, dental, pharmacy, nursing, and physician services. See 42 U.S.C. §§ 1395i-3(b)-(d); 1396r-3(b)-(d); 42 C.F.R. § 483.10-483.75; 54 Fed. Reg. 5354-5355 (1989).

93. Subpart C is inconsistent with and does not implement the OBRA '87 revisions to the health and safety requirements that a long-term care facility must meet to participate in the Medicare and Medicaid programs.

94. Subpart C pertains to survey methodology and conditions of participation which became obsolete with the implementation of the new conditions of participation and survey processes mandated by OBRA '87, which did not go into effect until October 1990.

95. HCFA's failure to withdraw Subpart C and to formally publish the revised protocols in formal regulations does not elevate outdated, obviously obsolete, survey procedures and guidelines to a legal status which is inconsistent with congressional intent.

96. The contents of 42 C.F.R. Part 488, Subpart C were never modified and HCFA never formally repealed or withdrew Subpart C.

97. Where an administrative regulation conflicts with a statute, the statute controls. U.S. v. Doe, 702 F.2d 819, 823 (9th Cir. 1983).

98. A federal court ordered HCFA not to repeal Subpart C. Estate of Smith v. Sullivan, (D. Colo. 1990). (HCFA Attachment 2 at 1, 3).

99. A federal court permitted HCFA, on an interim basis, to use the new survey protocols. Id.

100. Any alleged non-conformity with the requirements of the Administrative Procedure Act (APA) on HCFA's part is moot in light of the district court's interim order.

101. HCFA has followed its regulations, procedures, and precedents. Because Subpart C became null and void and, thus, without any operative effect, HCFA's departure from this subsection was justified.

102. HCFA did not violate any administrative norm by its non-adherence to the survey procedures and guidelines contained in Subpart C.

103. HCFA was not legally required to formally withdraw or repeal Subpart C in order for this subsection to be rendered inoperative by the passage of OBRA '87, the provisions of which became effective on October 1, 1990.

• SOM 250 and its operational significance (pp. 64-67)

104. The provisions of SOM 250 are not "substantive," but "interpretive". Alcarez v. Block, 746 F.2d 593, 613 (9th Cir. 1984); American Hospital Association v. Bowen, 834 F.2d 1037, 1045 (D.C. Cir. 1987); Guadamuz v. Bowen, 859 F.2d 762, 771 (9th Cir. 1988).

105. HCFA published SOM 250 to provide guidance to state surveyors, who are responsible for determining compliance by long-term care facilities with federal requirements imposed by statute and regulations.

106. SOM 250 was not intended to impose any requirements that are not otherwise set forth in the statute or regulations (HCFA Ex. 13 at 2-137); therefore, HCFA was not required to formally publish these instructive guidelines to state surveyors in the form of a regulation.

107. SOM 250 must be read in connection with the statutory and regulatory provisions regarding SNFs to determine the operative protocols, definitions, and standards that were applicable at the time of the survey in issue.

• 42 C.F.R. § 489.13 (pp. 67-74)

108. The parties do not disagree that 42 C.F.R. § 489.13 requires Petitioner to be in compliance with Level A requirements on the date of the survey.

109. The final regulations published by HCFA on February 2, 1989 (effective August 1, 1989, except where specified otherwise) made clear that all regulatory requirements were to be enforced to the fullest extent possible, not just the more serious Level A type of deficiencies. 54 Fed. Reg. 5317-5318 (1989).

110. In the Federal Register preamble to the publication of the September 1991 regulations, HCFA reiterated that long term care facilities, including SNFs, were subject to enforcement for all violations of requirements and that it was never intended that the Level A and Level B designations imply a hierarchy of importance. 56 Fed. Reg. 48,827.

111. There no longer exists any distinction between Level A and Level B requirements because every violation is considered to be potentially sufficient to deny certification.

112. The phrase "all other requirements" contained at 42 C.F.R. § 489.13 means that SNFs not only must meet all requirements established by regulation, but that any violation of the regulatory requirements can provide a basis to deny certification. Transitional Hospitals Corporation -- Las Vegas, DAB CR350 (1995); SRA, Inc. D/B/A St. Mary's Parish Dialysis Center, DAB CR341 (1992).

- 42 C.F.R. § 488.110(j) (pp. 74-76)

113. Petitioner did not prove that it met all federal requirements by the completion date of the survey; therefore, its certification can only be the earlier of the date on which it met all requirements or the date when it submitted an acceptable plan of correction or approvable waiver request to HCFA. 42 C.F.R. § 489.13.

114. Petitioner did not prove, or even allege, that it had made a waiver request or that one was granted.

115. The only issues that are relevant to the determination of the effective date in this proceeding relate either to the date the deficiencies were corrected or the date HCFA accepted Petitioner's plan of correction.

116. Section 488.110(j) provides that the state agency is to forward HCFA 2567 to facilities within 10 days after a survey is completed. Ten calendar days from December 23, 1993 is January 2, 1994.

117. Neither 42 C.F.R. § 488.110(j), nor any other provision in this section, contains any penalty provision for the agency's failure to comply with this 10-day requirement.

118. There is no provision in 42 C.F.R. § 489.13 to respond to situations where HCFA delays transmittal of the form 2567 to a SNF.

119. An administrative law judge does not have the authority to equitably split the difference or fashion a remedy based on HCFA's noncompliance with the 10-day requirement.

120. As an administrative law judge, I do not have the authority to find the regulations ultra vires the Act, which is what I would have to do in order to grant Petitioner the relief it seeks.

121. I interpret the alleged 10-day "requirement" as a goal which HCFA should strive to meet in all cases, but not as something which should either invalidate the survey nor mandate that HCFA grant the SNF with an earlier certification date than it was given, in cases where this goal is not met.

• Case-mix stratified sample (pp. 76-79)

122. SOM 250 contains detailed instructions and guidance to enable surveyors to carry out "case-mix stratified sampling." HCFA Ex. 13 at P-9 - P-12.

123. The regulation set out at 42 C.F.R. § 488.110(d) ("Task 2 -- Resident Sample -- Selection Methodology") refers to a random sample.

124. Subpart C of 42 C.F.R. Part 488, which describes random sampling, does not conform to the case-mix stratified sampling requirement of OBRA '87 (and codified at 42 U.S.C. §§ 1395i-3(g)(2)(A)(ii) and 1396r(g)(2)(A)(ii)).

125. The correct and appropriate sampling methodology to be used, since the enactment of OBRA '87, is the case-mix sampling approach, which is elaborated upon in the SOM 250.

126. The survey team members referred to the SOM 250 in selecting resident samples. Tr. 2136.

127. The surveyors' use of a case-mix stratified sample was in accordance with the law. Tr. 1648-1650, 1670, 2450, 2456.

• Deficiencies set out in the HCFA 2567 (HCFA Ex.2) (pp. 79-183)

128. The provisions of SOM 250 are the applicable criteria to follow in determining whether a deficiency has been established.

129. SOM 250 directs the surveyor to analyze the frequency and severity of noncompliance with regulatory requirements and to determine whether the facility is in compliance with an individual requirement by assessing the frequency or severity of the alleged violation.

130. Specifically, SOM 250 directs the surveyor to take into account negative resident outcomes.

131. A deficiency can occur when there is evidence of noncompliance with a regulatory requirement in 42 C.F.R. § 483, and the noncompliance has a serious negative impact on the resident or residents, such as harm or a strong potential for harm.

• F221 (Resident's right to be free from restraints) (pp. 84-90)

132. Ensuring that residents are restrained only to the extent absolutely necessary for their medical well-being or safety was of paramount concern to the authors of the law and the regulations. H.R. Rep. No. 391, 100th Cong., 1st Sess., part 1, at 932 (1987); 42 C.F.R. § 483.13(a).

133. The SOM 250 guidelines direct that an SNF document that the facility has considered less restrictive alternatives to restraints. HCFA Ex. 13 at P-76 - P-77.

134. The record contains nothing which would indicate that the interdisciplinary team ever considered less restrictive alternatives for resident 16.

135. The statutory and regulatory framework, the language of the regulation, and the guidance contained in SOM 250 all support that it is incumbent upon Petitioner to document that the restraint was necessary for the resident's medical or safety needs.

136. Petitioner did not prove that it ever considered less restrictive alternatives for resident 16 because the evidence HCFA has offered is persuasive, credible and unrebutted.

137. HCFA has proven that Petitioner was in violation of the regulatory requirement set forth at 42 C.F.R. § 483.13(a) with respect to resident 16.

138. Without adequate documentation that other less restrictive alternatives were not available, placement of resident 16 in a vest restraint could result in a potential negative outcome. P. Exs. 1, 27; HCFA Ex. 13 at P-76 - P-77.

• F 262 (Facility must maintain a sanitary, orderly and comfortable interior) (pp. 90-93)

139. An inadvertent typographical error occurred in the HCFA 2567 when Ms. Shekell apparently mistyped "F 262" on her lap-top computer instead of "F 261." The computer is programmed by HCFA to automatically display the applicable regulatory citation that corresponds to the "F" number entered. Tr. 112-113, 115-116, 121.

140. The regulatory citation corresponding to F 261 is 42 C.F.R. § 483.15(h)(2). Tr. 121; HCFA Ex. 13 at P-96 - P-97.

141. Subsection (h)(2) of 42 C.F.R. § 483.15 is the most appropriate subsection for this deficiency since the findings set forth in the HCFA 2567 pertain to the facility's sanitary condition. HCFA Ex. 2 at 2-3.

142. Petitioner received adequate notice of the deficiency even considering the incorrect reference to the regulations.

143. Petitioner offered no witness who was present during the survey who specifically contradicted the observations of Ms. Shekell.

144. Petitioner's non-compliance with the regulatory requirements could potentially compromise the residents' health and safety or at least compromise their mental or psychosocial well-being.

• F 272 (Facility must make a comprehensive assessment of a resident's needs. . .) (pp. 93-107)

145. The record of resident 12 is the only resident record against which Petitioner could adequately prepare a defense with respect to F 272. P. Ex. 3.

146. With respect to the other residents referred to in the HCFA 2567, HCFA was unable to specifically identify them or the records alleged to be deficient.

147. HCFA did not prove that Petitioner's treatment of other residents, in addition to resident 12, violated 42 C.F.R. § 483.20(b)(1).

148. A new minimum data set (MDS) must be completed promptly after a resident experiences a significant change in physical or mental condition. In no case can the MDS be done less than once every twelve months. 42 C.F.R. § 483.20(b)(4)(iv)-(v); see Tr. 138.

149. Depending on a particular response on the MDS, an "automatic trigger" or "potential trigger" may be indicated, and such triggers direct the staff to fill out the corresponding category on another document called the Resident Assessment Protocol Summary (RAPS).

150. Resident 12's MDS was completed on July 30, 1993. P. Ex. 3 at 2. The relevant section of the MDS for purposes of this deficiency is Section H, which has the heading "Mood and Behavior Patterns". P. Ex. 3 at 3-4.

151. Resident 12 showed an indication of a potentially serious psychological problem. P. Ex. 3 at 15 (9/15/93 psychological report).

152. Petitioner did not conduct a new MDS in September 1993 and left the July 1993 MDS in place, unchanged. In doing so, Petitioner thus inaccurately represented that the July 1993 MDS continued to reflect the current condition of resident 12 although it did not.

153. Petitioner should have completed a new MDS after resident 12's psychological interview to reflect the change in her psychosocial status.

154. The resident was provided weekly individual and/or group psychotherapy by a psychologist starting September 15, 1993 through December 22, 1993. P. Ex. 3 at 16 - 19.

155. Resident 12's desire to isolate herself was care-planned (addressed in the plan of care) on September 1, 1993. P. Ex. 3 at 24.

156. Resident 12's suicidal ideation, as illustrated by her expressing a desire to die on September 15, 1993, was not care-planned until November 17, 1993. Id.

157. Petitioner delayed over two months before implementing a care plan to address resident 12's suicidal ideation.

158. Resident 12 manifested serious problems in terms of her psychosocial well-being, and her July 30, 1993 MDS was inaccurate with respect to her psychosocial status as of at least September 15, 1993, or earlier, possibly September 1, 1993, which is the first indication in the record that she wanted to isolate herself.

159. There is no evidence that Petitioner ever completed a new MDS for resident 12.

160. Petitioner violated the requirement found at 42 C.F.R. § 483.20(b)(1), with respect to resident 12.

161. Petitioner's failure to maintain an accurate assessment of resident 12's condition as the level of her depression worsened prevented the formulation of a timely comprehensive care plan prepared using the protocols specified by HCFA and which corresponded to her change in psychosocial well-being.

162. By failing to accurately document resident 12's depression in the assessment instrument, Petitioner ignored the directives of OBRA '87 and contravened its obligation to provide appropriate "individualized care" of high quality to its residents.

• F 289 (Review of assessments) (pp. 107-122)

163. At the time of resident 16's admission, on May 1, 1993, a bowel and bladder assessment was done, which reflected that resident 16 was "inc[ontinent] of b[owel] and b[ladder] and "not a candidate for bladder and bowel retraining [secondary to] unawareness of bodily function." P. Ex. 4 at 11.

164. On resident 16's MDS, which was completed on May 14, 1993, Petitioner's staff assessed her as being incontinent of bowel and bladder. P. Ex. 4 at 3.

165. In the November 5, 1993 quarterly assessment, Petitioner failed to reflect accurately resident 16's bladder continence status, in violation of 42 C.F.R. § 483.20(b)(5).

166. From November 30, 1993 through December 2, 1993, resident 16 underwent a "3-day evaluation for baseline data -- bladder training". P. Ex. 4 at 12.

167. The result of the 3-day evaluation was that resident 16 was assessed to be continent. P. Ex. 4 at 34 (duplicated at P. Ex. 4 at 13).

168. Petitioner failed to complete a new MDS and simply left in place the MDS completed on May 14, 1993, which assessed resident 16 as being incontinent of bladder (and bowel).

169. By not updating the MDS, Petitioner plainly violated 42 C.F.R. § 483.20(b)(5), which required Petitioner, as appropriate, to revise resident 16's assessment to assure its continued accuracy.

170. Resident 16 was not incontinent during December 1993.

171. By ignoring its obligation to comply with 42 C.F.R. § 483.20(b)(5), Petitioner was essentially representing that between May 1993 and the time of the survey (December 1993), resident 16 had not undergone any changes at all with respect to her continence status and remained totally incontinent.

172. Failure to have an accurate assessment of resident 16's continence prevented this resident from attaining her highest practicable level of physical, mental, and psychosocial well-being and potentially could have compromised her health and safety, since she could have been exposed to infection if continence had not been maintained.

173. HCFA's allegation in the HCFA 2567 that resident 16's care plan was not updated to reflect her actual status is extraneous to 42 C.F.R. § 483.20(b)(5), and I did not consider it.

174. The part of the deficiency, as set forth in the HCFA 2567, which alleges that there was no routine individualized toileting schedule developed to meet resident 16's needs (HCFA Ex. 2 at 5) is extraneous to 42 C.F.R. § 483.20(b)(5), and I did not consider it.

175. HCFA did not prove that resident 12's October 27, 1993 quarterly review is inaccurate.

176. Resident 12's July 30, 1993 MDS is inaccurate and there is no evidence in the record that Petitioner ever completed a new MDS for resident 12. FFCL 152, 159.

177. Petitioner violated 42 C.F.R. § 483.20(b)(5) with respect to resident 12.

178. The August 23, 1993 quarterly review, which indicated that resident G.B. had no mood problems in the last seven days, is accurate. P. Ex. 9.

179. Petitioner inaccurately assessed resident G.B.'s mood problems in the quarterly reviews dated May 28, 1993 and December 1, 1993.

180. Petitioner failed to complete a new MDS for resident G.B. in December 1993, when G.B. began to refuse treatment, a significant change in behavior.

181. Petitioner violated 42 C.F.R. § 483.20(b)(5) with respect to resident G.B.

• F 290 (resident's comprehensive care plan) (pp. 123-125)

182. Resident 16's care plans, dated May 1, 1993 and November 7, 1993, were inaccurate because they failed to mention resident 16's improvement in bladder condition from incontinency to continence.

183. Petitioner violated 42 C.F.R. § 483.20(b)(6) by failing to revise resident 16's care plan once she was assessed by Petitioner's staff to be continent.

184. Petitioner's failure to revise resident 16's care plan had the potential to cause a negative outcome for this resident.

• F 292 (Each assessment must be conducted or coordinated with the appropriate participation of health professionals) (pp. 125-128)

185. The rehabilitation screen is part of the assessment process, but is not part of the assessment instrument.

186. After completing resident 13's rehabilitation screen, the physical therapist should have participated also in formulating the body control problems section of resident 13's MDS.

187. Although a licensed vocational nurse (LVN) completed the body control problems section on resident 13's MDS, she was not the appropriate health professional to complete this section.

188. Petitioner's failure to involve a physical therapist in the completion of the MDS did not negatively impact resident 13.

189. The omission of contractures on the MDS did not adversely impact the completion of the other sections. P. Ex. 20 at 4.

190. There is no evidence that resident 13 suffered any harm or that a potential for harm existed.

191. Petitioner did not violate 42 C.F.R. § 483.20(c)(1).

- F 295 (Comprehensive care plans) (pp. 128-141)

192. Petitioner failed in February 1993 to contemporaneously care-plan the physician's February 11, 1993 order that resident 1 could have her own medications at bedside, in violation of 42 C.F.R. § 483.20(d)(1).

193. The record contains only a December 2, 1993 care plan relating to self-medication. P. Ex. 21 at 30.

194. Resident 1's medical chart contains two assessment forms titled "Self-Administration of Medication Assessment," dated April 1, 1993 and December 2, 1993. P. Ex. 21 at 26-27.

195. According to the April 1, 1993 assessment, which was signed by a licensed nurse and a physician, resident 1 was evaluated as not being mentally or physically able to self-administer medication. P. Ex. 21 at 27.

196. According to the December 2, 1993 assessment, which was signed also by a licensed nurse and a physician, resident 1 was found to be a candidate for safe self-administration of medications. P. Ex. 21 at 26.

197. Whether it was the February 11, 1993 physician order or the December 2, 1993 assessment that triggered the 12/2/93 care plan, once Petitioner was aware of the February 11, 1993 order, it should have initiated a care plan consistent with such order. This was not done.

198. There were instances in December 1993 when resident 1 refused to allow Petitioner's staff to monitor her self-administration of her medications. P. Ex. 21 at 31-34.

199. Such refusals on the part of resident 1 were not minor or inconsequential.

200. Resident 1's actions of non-compliance directly conflicted with the December 2, 1993 care plan approaches.

201. Once it was ascertained that the December 2, 1993 care plan approaches could not be carried out successfully due to resident 1's refusals and her own

physical condition, Petitioner should have developed a new care plan which addressed fully resident 1's current needs.

202. There is no evidence of a care plan that mentions the problems of resident 1's refusals and her physical inability to self-administer medicines or addresses how to adequately monitor her taking of medications in light of these problems and difficulties.

203. Petitioner's failure to develop a new care plan on these grounds establishes further that it violated 42 C.F.R. § 483.20(d)(1). FFCL 202.

204. The Social Services notes (see P. Ex. 21 at 17-19) state that the resident exhibited yelling and screaming on October 4, 1993, October 8, 1993, and November 15, 1993, and manifested confusion on October 8, 1993 (P. Ex. 21 at 18).

205. Resident 1's November 30, 1993 quarterly review was inaccurate in its assessment that resident 1 had no mood or behavior problems. P. Ex. 21 at 7-8, 17-19.

206. Resident 1's mood and behavior problems should have been reflected in the December 2, 1993 care plan, and Petitioner's failure to do so constitutes a further violation of 42 C.F.R. § 483.20(d)(1).

207. By leaving a misleading and inaccurate care plan in place, thereby representing it to be accurate and up-to-date, Petitioner potentially could have jeopardized resident 1's health, safety, and well-being.

• F 297 (A resident's care plan must be prepared by an interdisciplinary team) (pp. 141-143)

208. There is nothing in the findings with respect to F 297 that identifies Petitioner's conduct in contravention of the requirements of 42 C.F.R. § 483.20(d)(2)(ii), which are limited to a resident's care plan.

209. The evidence offered by HCFA in the HCFA 2567 relating to Resident 1's assessments is extraneous and goes beyond the regulation at issue.

210. The deficiency, as set forth in the HCFA 2567, fails to state with sufficient particularity the care plan in issue, the make-up of the interdisciplinary team who prepared such care plan, and how that grouping was in violation of the cited regulation.

211. Petitioner did not violate 42 C.F.R. § 483.20(d)(2)(ii).

• F 298 (comprehensive care plan must be periodically reviewed and revised after each assessment) (pp. 143-150)

212. At the time of the surveyor's observation, resident 20 was using a postural seating system which had been instituted pursuant to a physician's order dated September 28, 1993, which is noted in the care plan also. P. Ex. 23 at 4, 12.

213. Although the care plan does not specify the type of seating system used on resident 20, the seating system which was in place for resident 20 at the time of Ms. Cox's observation was a Linard seating system. Tr. 1308.

214. The scenario involving resident 20 occurred as Ms. Cox described it.

215. Petitioner presented no testimony from anyone on its staff who was present at the time of Ms. Cox's observation of resident 20 to contradict her testimony.

216. Petitioner's staff changed resident 20's seating system. The staff placed resident 20 in a "saddle type of thing" and replaced his chair to alleviate his discomfort and help him sit upright. Tr. 1062, 1308, 1310.

217. The changes made by Petitioner's staff were significant and constituted more than a simple re-adjustment of resident 20's existing seating system. As such, Petitioner's staff was required to update resident 20's care plan contemporaneously to reflect this change. FFCL 216.

218. By its failure to revise resident 20's care plan, Petitioner did not comply with 42 C.F.R. § 483.20(d)(2)(iii).

219. The existence of the 4/12/94 entry in resident 1's care plan indicating the addition of a "western saddle" (P. Ex. 23 at 12) does not disprove Ms. Cox's testimony that a saddle was provided to resident 20 at the time of the survey in December 1993.

220. Petitioner's representation in its plan of correction that resident 20's care plan had been updated to reflect the change is uncorroborated by the record before me.

221. While there is no evidence of actual harm to resident 20's health or safety, I find that there existed the potential of harm to resident 20.

• F 300 (Services provided by the facility must be provided by qualified persons in accordance with each resident's care plan) (pp. 150-158)

222. Petitioner does not dispute the facts relating to resident 24's E-Z boot as cited in the deficiency, which were based on Ms. Cox's observations. P. Resp. Br. at 24.

223. HCFA did not offer in evidence a plan of care which implements the physician's order requiring use of the E-Z boot.

224. While Ms. Cox could not recall at the hearing what the plan of care said about application of the E-Z boot, she did testify that she reviewed the care plan in connection with preparation of this deficiency. Tr. 1069-1070.

225. Besides Ms. Cox's testimony, my review of this resident's records, including the minimum data set, quarterly review, rehabilitation screen and physician's order, leads me to conclude that a care plan was developed for this resident which carried out the physician's order for application of the E-Z boot. P. Ex. 24.

226. Even without having the care plan in evidence, there is sufficient evidence to create a strong inference that such plan existed and was relied on by Ms. Cox in preparing this deficiency.

227. Petitioner had the burden to come forward with evidence proving that the care plan did not cover the E-Z boot. This Petitioner failed to do.

228. Based on the record as a whole, I find that Petitioner failed to carry out the physician's order in accordance with the resident's care plan.

229. Petitioner failed to prove that the deficiency was corrected prior to completion of the survey.

230. From December 10 through December 21, 1993, the E-Z boot was either missing or unavailable. P. Ex. 24 at 12. Petitioner's staff did nothing to locate the missing boot or take steps to get a new boot. Tr. 1069-1070; P. Ex. 24 at 11, 12.

231. Petitioner's failure to have a monitoring system in place contributed to its failure to locate the E-Z boot until the surveyor directed the attention of the staff to its absence.

232. Petitioner did not prove, or even allege, that a monitoring system was in place or put in place at the time of the completion of the survey.

233. This deficiency was not corrected at the completion of the survey.

234. The lack of a monitoring system placed resident 24 and other residents at risk that their treatment would not be provided as ordered by their physicians and implemented in their care plans.

235. Resident 8's care plan specifically provided that his fluid intake would be at least 1700 cc's of fluid over a 24-hour period. P. Ex. 25 at 5.

236. The care plan mandates that 1700 cc's was the minimum amount of fluid that this resident was to be provided within a 24-hour period.

237. During the period December 2 - 19, 1993, resident 8 met the objective only on December 2 and 17, 1993. P. Ex. 25 at 2-4.

238. Petitioner failed to have this resident meet the 1700 cc daily objective called for in the care plan. P. Ex. 25 at 2-4.

239. Petitioner's staff monitored the resident's fluid intake and output. P. Br. at 92.

240. Monitoring resident 8's fluid intake and output and encouraging increased intake was not a substitute for following the specific intake objective contained in the plan of care.

241. Petitioner failed to treat resident 8 in accordance with his written plan of care and thereby violated 42 C.F.R. § 483.20(d)(3)(ii).

242. Reduction of this resident's fluid intake below the care plan objective might have placed him at risk for pneumonia and skin breakdown. Tr. 1078; 2588-2589.

• F 309 (Necessary care and services to attain or maintain the highest practicable physical, mental, and psychosocial well-being, in accordance with the comprehensive assessment and care plan) (pp. 158-164)

243. Resident 20's weight upon his admission to the facility on March 30, 1993 was 108.4 pounds. P. Ex. 26 at 10.

244. Resident 20 had, among other conditions, Parkinson's disease and difficulty in swallowing (dysphagia). P. Ex. 26 at 1, 10.

245. Resident 20 continued to lose weight during his stay at Petitioner. P. Ex. 26.

246. The record as a whole reflects that resident 20 was attempting to eat his meals independently but was unable to do so and was unable to consume sufficient nourishment with the assistance that was being provided by Petitioner. P. Ex. 26; Tr. 233-236.

247. The only methods attempted by Petitioner to assist resident 20 were providing him with a special spoon and offering him additional nourishment.

248. The record reflects that both of these methods were ineffective, as resident 20 was observed as not being able to eat independently and was not amenable to accepting the additional nourishment offered by Petitioner.

249. Petitioner could have tried other methods, short of tube feeding or force feeding, to attempt to enable resident 20 to eat more, but Petitioner failed to do so.

250. There is no evidence in the record that resident 20 was ever reassessed or that his care plan was adjusted in light of the difficulties he was having in consuming sufficient nourishment. P. Ex. 26.

251. Petitioner failed to provide resident 20 with the care necessary to maintain or attain his highest practicable well-being, in violation of 42 C.F.R. § 483.25.

252. Resident 16 began the RNA ambulation program on June 15, 1993, and the initial program was for her to ambulate with a front wheel walker 20 feet to 60 feet with the assistance of two persons, as tolerated, seven times a week. P. Ex. 27 at 13-14; Tr. 1091-1092.

253. Resident 16 was ambulating from 60 to 100 feet during the period June 15 - June 30, 1993, and from 80 to 100 feet during the period July 1 - July 31, 1993. P. Ex. 27 at 13, 15.

254. On August 9, 1993, resident 16 was discontinued from the RNA program. P. Ex. 27 at 17-18.

255. Nurse assistant records in resident 16's chart indicated that resident 16 was ambulated daily throughout November and December 1993. Tr. 1517-1523, P. Ex. 1 at 14-17.

256. Resident 16 was ambulated routinely following the conclusion of the RNA program. Id.

257. HCFA did not prove that resident 16's ambulation declined.

258. The testimony of HCFA's witnesses on this issue is conflicting and unpersuasive.

259. HCFA did not prove that resident 16 was not maintained at her highest practicable level with respect to her ambulation.

260. Petitioner was not deficient with regard to maintaining the ambulation of resident 16 at its highest practicable level.

• F 320 (Pressure sores) (pp. 164-167)

261. The purpose of using a Tegaderm dressing in treating resident 31 was to act as a barrier to protect her pressure sores from bacteria, to keep in place the gel that was used to treat the sores, and to prevent further skin breakdown caused by the open sores coming into contact with the resident's bed or bedding. Tr. 2620-2621.

262. At the time of the survey, the surveyor observed that the dressings were not in place. Tr. 241.

263. Resident 31 had more than one Tegaderm dressing missing. Id. This put her at a greater risk for bacterial infection. Tr. 2621.

264. Resident 31's treatment record indicated that the dressings were in place and had been checked for proper placement on the previous shift. Tr. 241.

265. Petitioner failed to follow the physician's order concerning treatment of resident 31's pressure sores.

266. Petitioner violated 42 C.F.R. § 483.25(c)(2) with respect to the treatment of resident 31.

• F 324 (Range of motion) (pp. 167-168)

267. HCFA has conceded that resident 2 is not the correct subject of this deficiency. HCFA Br. at 72.

268. Examples of residents who were discussed in other deficiencies would not corroborate the allegations in this deficiency, because the HCFA 2567 mentioned no cross-references with regard to this deficiency.

269. HCFA did not prove that Petitioner was in violation of 42 C.F.R. § 483.25(e)(2).

• F 373 (facility must offer snacks at bedtime daily) (pp. 168-174)

270. Petitioner's monthly flow sheets, particularly those with dashes, "NA", "N", and "no", support a finding that a number of residents were not offered bedtime snacks and were not on special diets which would have precluded the consumption of such food.

271. Ms. Downing's explanation of the meaning of a dash, and arguably similar meanings for "N", and "no", is lacking in credibility.

272. Bedtime snacks were neither offered nor provided.

273. While Petitioner provided special snacks to residents who requested something different than the routine snacks (Tr. 2039-2040; Id. at 73-93), this does not demonstrate compliance with the regulation, which requires Petitioner to offer bedtime snacks to all residents unless it is medically contraindicated.

274. There is no credible evidence that Petitioner's policy was revised before the survey was completed.

275. Petitioner implemented the "Procedure for Bed Time (H.S.) Snack" policy reflected in P. Ex. 30 at 94-95 after the survey was completed and the plan of correction was submitted.

276. Petitioner demonstrated a pattern of violating the regulation requiring residents to be offered bedtime snacks.

277. Petitioner's failure to provide snacks as required by regulation would likely result in a diminishment of the mental and psychosocial well-being of its residents.

278. Petitioner failed to provide bedtime snacks daily to all of its residents, in violation of 42 C.F.R. § 483.35(f)(3).

• F441 (Infection control program) (pp. 174-181)

279. The nurse's actions at issue were inconsistent with standard protocol.

280. The gravity of this breach in acceptable protocol was a substantial action supporting the deficiency.

281. The medication nurse's acts of placing a juice container from the medication cart onto the over-bed table of a resident on contact isolation with MRSA [methicillin resistant staphylococcal aureaus], and then returning the container to the medication cart, represented a failure by Petitioner to control and prevent infections as required by 42 C.F.R. § 483.65(a)(1).

282. The statement that Petitioner failed to use sterile and/or aseptic technique in the care of residents with decubitus open areas, as written in the HCFA 2567, is vague and confusing. The document did not make clear whether this part of the alleged deficiency related to the observation of the treatment of one resident or more than one resident, and whether the deficiency related to the failure to follow sterile technique, aseptic technique, or both.

283. Ms. Shekell's testimony as a whole emerged confused and contradictory.

284. HCFA failed to prove what specific policies and procedures Petitioner was required to follow, and did or did not follow, with respect to sterile and/or aseptic treatment of resident wounds.

285. HCFA did not prove that Petitioner failed to use sterile and/or aseptic technique when required.

286. HCFA did not prove that sterile and/or aseptic technique was not followed by Petitioner when required to control and prevent infection as required by 42 C.F.R. § 483.65(a)(1).

• F 443 (Infection control program) (p. 181)

287. The HCFA 2567 does not set forth a finding or basis for F 443.

288. Ms. Shekell admitted that F 443 had been inadvertently keyed into the computer. Tr. 257.

289. There is no deficiency here.

• F 462 (Resident rooms) (p. 182)

290. HCFA did not prove this deficiency.

• F 527 (Clinical records) (p. 182-183)

291. HCFA did not prove this deficiency.

• Findings summarized and concluded (p. 183)

292. Under 42 C.F.R. § 489.13, even one deficiency could be the basis for a delay in the effective date of certification.

293. Deficiencies showing a lack of compliance with 42 C.F.R. § 483 et. seq. were present during the survey of Petitioner, were not corrected at completion of the survey, and were the subject of an acceptable plan of correction submitted on January 31, 1994.

294. Accordingly, I affirm HCFA's determination that Petitioner's certification as a Medicare provider was effective on January 31, 1994.

II. Background

Title XVIII of the Social Security Act, 42 U.S.C. §§ 1395 et seq., commonly known as the Medicare Act, establishes a federally subsidized health insurance program for the elderly and disabled which is administered by the Secretary of the Department of Health and Human Services (the Secretary). The Secretary has delegated to HCFA the responsibility for carrying out many of the duties under this program.

Skilled nursing facilities or other entities may participate in the Medicare program by entering into a "provider agreement" with the Secretary. 42 U.S.C. §§ 1395x(u) and 1395cc. A skilled nursing facility is defined under section 1819(a) of the Social Security Act (Act) as an institution which is primarily engaged in providing skilled nursing care and related services for

residents who require medical or nursing care, or rehabilitation services for the rehabilitation of injured, disabled, or sick persons, and is not primarily for the care and treatment of mental diseases. Additionally, such an institution must meet also the requirements of 42 U.S.C. 1395i-3(b), (c) and (d).

DHS-San Diego is authorized to perform surveys of skilled nursing facilities to make recommendations to HCFA on whether such facilities meet the Federal requirements for participation in the Medicare program. 42 U.S.C. § 1395aa(a). Onsite inspections (surveys) of facilities must be conducted without any prior notice to the facility. See 42 U.S.C. § 1395i-3(g)(2)(A). The results of Medicare related surveys are used by HCFA as the basis for its decisions regarding a facility's initial or continued participation in the Medicare program. The findings of state agencies are recommendations to HCFA, which makes the actual determination as to whether a facility is eligible to participate or to remain in the program. 42 C.F.R. § 489.10.

Petitioner is a skilled nursing facility, with approximately 300 beds, operating in San Diego, California. Tr. 1644.

On December 14-23, 1993, Petitioner was surveyed on behalf of HCFA by surveyors from DHS-San Diego. The purpose of the survey was to determine whether Petitioner was conducting its operations in compliance with the requirements of the Medicare program.

Following the survey, DHS-San Diego issued to Petitioner a document captioned "Statement of Deficiencies and Plan of Correction" (HCFA 2567), which sets out the deficiencies identified during the survey. Although the State surveyors found Petitioner to be in compliance with all Level A requirements imposed by HCFA for skilled nursing facilities, there were numerous Level B deficiencies identified at the time of the survey. HCFA Ex. 2. Petitioner was found to have failed to comply with various regulations governing a skilled nursing facility's participation in Medicare. These were: 42 C.F.R. §§ 483.13(a); 483.15(h)(3); 483.20(b)(1); 483.20(b)(5); 483.20(b)(6); 483.20(c)(1); 483.20(d)(1); 483.20(d)(2)(ii); 483.20(d)(2)(iii); 483.20(d)(3); 483.25; 483.25(c)(2); 483.25(e)(2); 483.35(f)(3); 483.65(a)(1); 483.65(a)(3); 483.70(d)(1); and 483.75(l)(1). Id.

On January 31, 1994, Petitioner submitted its plan of correction to the DHS. HCFA Ex. 2.[5] By letter dated February 23, 1994, HCFA notified Petitioner that it was certifying Petitioner as a provider in the Medicare program, effective January 31, 1994, the date of Petitioner's acceptable plan of correction. HCFA Ex. 5. On February 28, 1994, HCFA sent an amended notification letter (changing only the designation of fiscal intermediary). HCFA Ex. 6.

HCFA twice reconsidered its determination at Petitioner's request. By letters dated March 25, 1994 and May 6, 1994, HCFA notified Petitioner that it found no basis to alter its original determination. HCFA Exs. 8, 9. Petitioner requested further review of the HCFA 2567 findings by DHS headquarters in Sacramento. DHS informed Petitioner that the earliest possible certification date was January 31, 1994. HCFA Ex. 10.

III. Evaluation of the credibility of Jacqy Downing

At the hearing, I heard testimony regarding the circumstances surrounding an internal investigation of DHS-San Diego where Ms. Downing worked and the reasons why Ms. Downing left her position at DHS-San Diego in January 1994. This testimony is relevant to the extent that it enables me to assess the credibility of Ms. Downing, one of Petitioner's primary witnesses in this case.

Ms. Downing denied any knowledge of problems regarding the falsification of complaint documents in her office. Tr. 2074. She stated merely that "[t]here were many allegations going on in that department." Id. The allegations "involved everybody in the office including myself and the supervisor." Id.

Ms. Downing testified that a complaint is filed by a third party (private citizen or an employee or anonymously) to DHS-San Diego regarding a particular facility. Tr. 2087-2088. The surveyors in the office then investigate the complaints that are filed against the facilities. Tr. 2089. The surveyors are supposed to investigate every complaint. Id. One example of a

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[5] Petitioner was instructed to prepare a written plan of correction to resolve the deficiencies and to describe the proposed corrections in the right-hand columns of the HCFA 2567. The HCFA 2567 which is in evidence contains also Petitioner's plan of correction. HCFA Ex. 2.

complaint that might be filed by the public would be that the facility is not providing a relative or loved one with the appropriate care. Id.

Ms. Downing admitted that an investigation "was going on" in the office "at the time [she] retired." Tr. 2078. She stated that she "didn't have any clear understanding of what the investigation was." Tr. 2084. She denied any knowledge that the focus of the investigation was that complaint results were being reported which had not been investigated. Tr. 2096. She claimed that she was never informed of this by any of the investigators. Id.

Ms. Downing stated that she was not "personally confronted" with charges concerning the investigation nor were any allegations concerning any impropriety brought to her attention during her interview with the investigators. Tr. 2084, 2086-2087. She stated further that no one told her that the complaints at issue originated out of her survey team. Tr. 2084. She also denied that the investigation specifically concerned herself and Judith Chute. Tr. 2075-2076.

To counter the testimony of Ms. Downing, HCFA presented the testimony of Joan Allison, who works for DHS in the licensing and certification program as the chief of field operations for the southern region. Tr. 2735-2736.

After reviewing the testimony of Ms. Downing and that of Ms. Allison, as well as the other evidence, I conclude that Ms. Downing's testimony regarding the circumstances surrounding the DHS-San Diego investigation and the reasons why she left DHS-San Diego was less than forthright and, at times, not consistent with the actual events surrounding her departure from DHS. I find Ms. Allison's testimony, which I discuss below, to be credible and accept it as being a truthful and accurate account of the events in question. Ms. Downing's attempt to hide the true nature of the DHS-San Diego investigation that began in October 1993 greatly undermines my confidence in her credibility.

Ms. Allison testified that she participated in an internal investigation in October and November 1993 involving DHS-San Diego. Tr. 2738-2739, 2781. She stated that

> the focus of the investigation was to determine whether or not complaint documents had been altered in the San Diego district office.

Tr. 2738.

Ms. Allison explained why the investigation was initiated:

> A surveyor in the San Diego district office pulled a facility file and discovered a 2567 that she had completed and found that the date had been whited out, the signatures for the evaluator and the supervisor had been whited out, the complaint numbers had been whited out. She was disturbed at that and looked further in the folders and found that her 2567 has been duplicated and then other information had been written in to represent a 2567 on another complaint investigation.

Tr. 2738; see also Tr. 2743.

Ms. Allison indicated that she and Paul Keller, who was then chief of field operations for the southern region, went to DHS-San Diego and interviewed the district manager, the district administrator, all of the supervisors, including Ms. Downing, and one of her surveyors who allegedly falsified the documents. Tr. 2740; Tr. 2755-2756.

Ms. Allison testified that approximately 80 survey documents had been altered. Tr. 2743. She stated that the falsified documents had Ms. Downing's name "signed as the supervisor." Id. Ms. Downing's name was the only name signed as supervisor on all of the falsified documents. Id.

Ms. Allison stated:

> The investigation determined that Ms. Downing had given specific directions to the surveyor in terms of how to prepare these complaint documents including whiting out the information and preparing the complaint documents in that way. And then, subsequently, in approving and sending forward all of these complaints as if they had, in fact, been legitimately investigated.

Tr. 2745.

It was determined that Ms. Downing had given her approval and sent forward all of these complaints as falsified. Tr. 2745. Ms. Allison stated that no other supervisors were the focus of the investigation. Tr. 2743.

Ms. Allison testified also that the department's audits and investigations division conducted a second investigation. Tr. 2778, see Tr. 1758. The results of this investigation confirmed the findings of her and Mr. Keller's investigation. Tr. 2778-2779.

Thus, contrary to Ms. Downing's claims of lack of knowledge regarding the details of the internal investigation, there can be little doubt that Ms. Downing was being investigated regarding the allegations and was aware of it. Although Ms. Downing had claimed in her testimony that she was never confronted with charges involving herself, Ms. Allison testified that

> Ms. Downing was notified that both -- that both she and the -- a particular evaluator were specifically being investigated relative to the charges. Tr. 2782.

Ms. Allison testified that when Ms. Downing was asked if she participated in the falsification of the documents, Ms. Downing did "[n]ot categorically" deny it. Tr. 2755. Ms. Allison stated that, by way of explanation, Ms. Downing had said that her surveyor may have misunderstood her directions, and also that she (Ms. Downing) may not have paid close attention to work since her parents were not well. Tr. 2755. Ms. Allison went on to say that Ms. Downing had said "that when she advised her evaluator to do some cut and paste, it had not been her intention that they would reflect investigations that had not been completed." Id.

Based on Ms. Allison's testimony, I find Ms. Downing's earlier testimony that she "didn't have any clear understanding of what the investigation was" (Tr. 2084) is simply not factual and demonstrates her attempt to recast the events as favorably as possible with respect to her involvement in the investigation.

At the hearing, when asked by HCFA's counsel why she left DHS, Ms. Downing responded that she "chose to retire." Tr. 2074. She denied that she was asked to leave DHS. Tr. 2075. Ms. Downing stated that she had made the decision to retire on her birthday the year before. Tr. 2077. She testified that she was eligible for retirement in the state system and claimed to have filed for retirement in mid-December 1993. Tr. 2079-2081. In the retirement papers, Ms. Downing stated that she had given her intention to retire in January 1994. Tr. 2081.

Ms. Allison's testimony also called into question the veracity of Ms. Downing's testimony regarding her retirement from DHS. Ms. Downing testified that she was not asked to leave DHS (Tr. 2075). However, according to Ms. Allison, as a result of the investigation, in December 1993, DHS served both Ms. Downing and the evaluator with an action to dismiss from State service. Tr. 2746, 2756, 2759-2760.[6]

Prior to a State hearing, DHS and Ms. Downing reached a stipulated agreement, which required Ms. Downing to resign effective January 14, 1994. Tr. 2746, 2758, 2779. A hearing did not take place. Tr. 2758. Ms. Downing resigned in accordance with the stipulated agreement. Tr. 2779.

When asked by Petitioner's counsel whether Ms. Downing had applied to retire before any adverse action was taken against her by DHS, i.e., before December 30, 1993, Ms. Allison responded that she was unaware that Ms. Downing had submitted anything prior to being served with the adverse action. Tr. 2757, 2766-2767. She stated that she also had no knowledge as to whether Ms. Downing expressed a desire to resign earlier than January 14, 1994. Tr. 2780. Ms. Allison expressed her belief that DHS would not have issued the dismissal notice to Ms. Downing if it had known that Ms. Downing was planning to retire. Tr. 2780.

The record before me contains the stipulation and settlement entered into between Ms. Downing and DHS in February 1994. HCFA Ex. 14. Among its provisions, this document states that DHS "agrees to withdraw its Notice of Adverse Action against Appellant [Ms. Downing] dated December 30, 1993." Another provision states that the "Appellant agrees to resign from state service effective January 14, 1994." HCFA Ex. 14. Based on Ms. Allison's testimony and the contents of this document, Ms. Downing's assertions that she had already planned to retire and that she had filed for retirement in mid-December 1993, seem suspect. Although she claimed to have filed retirement papers, which state January 1994 as her intended retirement date, no such documents were ever produced. While it may have been Ms. Downing's choice to

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[6] Ms. Allison testified that the investigation concluded in November 1993 or early December 1993. Tr. 2757, 2781. Ms. Allison stated also that DHS "took constructive action to review the complaints to determine" if they needed to be reopened or investigated. Tr. 2746.

retire, the evidence strongly indicates that, had she not resigned, DHS would have proceeded with its adverse action against her. I need not determine whether Ms. Downing had intended to retire. Whether she had that intention or not, the circumstances of the investigation and proposed adverse action overtook any such plans and were the actual reasons for her departure from DHS in January 1994.

Ms. Downing's testimony regarding the internal investigation and the circumstances of her resignation was less than truthful. Her questionable credibility requires me to take a cautious approach in ascribing weight to her other testimony on the substantive matters of this case. She clearly was an advocate for the positions put forth by Petitioner, her employer. She has credible credentials in the field of nursing and knowledge of the survey methodology followed by the DHS while she was employed there. However, I found that testimony, which, at times, supported positions taken by HCFA in this proceeding, was given by Ms. Downing with reluctance and hesitation. Moreover, at times, her testimony supporting Petitioner's positions did not comport with other, credible, evidence. Ms. Downing's testimony will be discussed with greater particularity in relation to the specific deficiencies to which her testimony applies.

Petitioner has raised a number of legal issues regarding the applicability and effect of the regulations pertaining to the DHS survey in December 1993 and HCFA's selection of January 31, 1994 as the effective date of Petitioner's Medicare participation. I will address each of these issues seriatim.

IV. Issue:

Whether 42 C.F.R. Part 488, Subpart C -- Survey Forms and Procedures, was controlling on the survey conducted in this case.

HCFA argues that the guidelines applicable to the survey in this case are contained in State Operations Manual 250 (SOM 250) and that the survey materials set forth at 42 C.F.R. Part 488, Subpart C, "became obsolete and devoid of legal force or effect when the OBRA '87 [Omnibus Budget Reconciliation Act of 1987] provisions went into effect on October 1, 1990." HCFA Resp. Br. at 58. HCFA contends that the "survey forms, procedures and guidelines contained in Subpart C not only are inconsistent with and do not implement these new health care requirements, they conflict" with the OBRA '87

requirements. Id. HCFA alleges that the Subpart C survey materials have been replaced by those contained in SOM 250. HCFA claims that "Petitioner has never maintained that it was unable to respond to the survey findings due to the use of the SOM 250 protocols." HCFA Resp. Br. at 68. Finally, HCFA asserts that a federal district court order suspended Subpart C and gave HCFA the authority to use SOM 250 "on indefinite interim basis." HCFA Resp. Br. at 56 9.

In response, Petitioner disputes that OBRA '87 impliedly repealed 42 C.F.R. Part 488 Subpart C. (P. Br. at 8) and argues that HCFA's position "has no legal basis." P. Br. at 13. Petitioner contends that "42 C.F.R. § 488.110 [is] still valid and binding on HCFA." P. Br. at 20. Petitioner argues that the SOM 250 survey procedures "effectively change those set forth in 42 C.F.R. § 488.110." Id. Petitioner claims that the SOM 250 procedures should have been promulgated in accordance with the rulemaking requirements of the Administrative Procedure Act because they are "substantive" in nature, and the failure to have done so renders them invalid. P. Br. at 17-20.

In discussing this issue, it is necessary to review the historical background of OBRA '87 and the efforts undertaken by HCFA to implement it.

A. OBRA '87

The nursing home reform provisions of OBRA '87 set minimum statutory standards that skilled nursing facilities (SNFs) must meet to participate in Medicare and nursing facilities must meet to participate in Medicaid, provided nursing home residents with certain rights, and established a structure for state and federal surveys and certifications of nursing homes. 42 U.S.C. §§ 1395i-3 and 1396r. These requirements were in effect as of October 1, 1990. Sections 4202(a) and 4214(a) of OBRA '87.

OBRA '87 fundamentally changed the survey and certification process by establishing a patient-oriented system to assess the quality of care actually furnished. See 42 U.S.C. § 1395i-3(f) and (g); 42 U.S.C. § 1396r(f) and (g). These revisions established new standards governing the provision of care in nursing facilities, including requirements relating to the quality of patient life, licensed nursing services, nurse aide training, residents' rights, and many other aspects of nursing home operation and administration. 42 U.S.C. § 1395i-3(b), (c) and (d); 42 U.S.C. § 1396r(b), (c) and (d). The

statute specifies the content, procedures and frequency of surveys, as well as survey team composition. 42 U.S.C. § 1395i-3(g)(2) and 42 U.S.C. § 1396r(g)(2).

Under OBRA '87, each state is responsible for certifying that SNFs are in compliance with the requirements of the Act through the use of surveys conducted pursuant to certain specified protocols. Congress specified in OBRA '87 that the Secretary develop, test and validate by no later than January 1, 1990 survey protocols for the standard and extended surveys required by law. Also, by such date, the Secretary was to develop minimum qualifications for members of the team who are to conduct such surveys. Congress further stated that the failure of the Secretary to carry out these mandates by January 1, 1990 shall not relieve any state or the Secretary of the responsibility to conduct surveys required by OBRA '87. 42 U.S.C. §§ 1395i-3 and 1396r.

In the legislative history of OBRA '87[7], the House committee explained that the bill would repeal the current Medicare participation requirements for SNFs, as well as the current survey and certification requirements, and replace them with new requirements. H.R. Rep. No. 391, 100th Cong., 1st Sess., part 2, at 926, 938 (1987).

The report states that "[a] skilled nursing facility must care for its residents in such a manner and in such an environment as would promote maintenance or enhancement of the quality of life of each resident." Id. at 927. Further, the report indicates that, for this goal to be attained, certain shortcomings in the current law must be addressed. For example, the report notes, among other things, that the current law does not require the use of resident assessments nor does it require that a resident assessment be linked or coordinated with a resident's care plan. Id. at 926. To remedy the aforementioned shortcomings, the committee set forth requirements in the

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[7] There are two House reports which comprise the legislative history for H.R. 3545 (OBRA '87): H.R. Rep. No. 391, 100th Cong., 1st Sess., pts. 1 & 2 (1987), reprinted in 1987 U.S. Code Cong. & Admin. News 2313-1; and H.R. Conf. Rep. No. 495, 100th Cong., 1st Sess. (1987), reprinted in 1987 U.S. Code Cong. & Admin. News 2313-1245.

bill concerning written care plans and resident assessments.[8] The report states:

> The Committee intends that the resident assessment instrument or instruments developed by the Secretary have the following characteristics. First, when used by a trained observer, the instrument should describe the capacity of the resident, at the time of observation, to function independently. Second, when used by another trained observer on the same resident at the same time, the result should be the same as that obtained by the first observer. Finally, the descriptive portions of the resident assessment instrument should be helpful to nursing facility staff in planning care, but the assessment of the resident's functional capacity should not be either prognostic or prescriptive. . . .
>
> Because the resident assessment is one of the critical underpinning at high quality care, accuracy in describing the functional capacity and health status of each resident is essential. To clarify accountability, section 4111 of the Committee amendment would require that a registered professional nurse sign and certify the accuracy of each assessment. . . .

H.R. Rep. No. 391, 100th Cong., 1st Sess., part 1, at 465 (1987).[9]

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[8] These requirements are codified at 42 U.S.C. § 1395i-3(b)(2) and (3).

[9] The quoted text appears in the section of the report in which the congressional committee discusses Medicaid-certified nursing facilities. The statutory provisions regarding the resident assessment for Medicaid-certified nursing facilities are found at 42 U.S.C. § 1396r(b)(3). The statutory provisions regarding the resident assessment for Medicare-certified skilled nursing facilities are identical and are found at 42 U.S.C. § 1395i-3(b)(3) of the Act. Accordingly, although the quoted text is referring to nursing facilities participating in the Medicaid program, I find that it is applicable to skilled nursing facilities participating in the Medicare program.

The report states, among other things, the committee's view on physical restraints:

> The committee is very concerned about reports of deaths due to physical restraints, and so to better protect residents, restraints may only be imposed to ensure the physical safety of the resident or other residents and only upon the written order of a physician that clearly specifies the duration and circumstances under which the restraints may be used. However, in emergency situations, as specified by the Secretary, to protect the safety of the resident or other residents in the facility, the resident could be restrained for a short period of time until a physician order could reasonably be obtained. The committee intends that restraints used in emergency conditions would be used only in unanticipated situations and that every effort would be made to obtain a physician's written order as quickly as possible.

Id. at 932.

With respect to the survey and certification process, the report states:

> The current survey and certification system has been in effect since 1974. It focuses on structural requirements (e.g., written policies and procedures, staff qualifications and functions, and physical plant characteristics), not on resident outcomes (e.g., presence or absence of bedsores or infections, extent of cognitive impairment). The IOM Committee identified a number of major problems with the current survey process, including predictability, inefficiency, an emphasis of paper compliance, insensitivity to resident needs, inconsistency, and lack of coordination with ombudsman programs and other monitoring processes. The IOM Committee urged the adoption of a resident-centered, outcome-oriented survey process . . .

Id. at 466.[10]

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[10] The committee reference to the IOM Committee is a reference to the Institute of Medicine (IOM) of the

(continued...)

The conference report states:

> The conferees also suggest that the Secretary consider, in establishing criteria by which the standard survey will measure quality of care furnished by a facility, such factors as vision and hearing; activities of daily living; use of physical restraints; accidents; nutrition and fluid intake; cognitive, behavioral, and social functioning; use of urinary catheters; prevention and care of pressure ulcers; and use of drugs.

H.R. Conf. Rep. No. 495, 100th Cong., 1st Sess., 715 (1987).

This legislative history demonstrates congressional intent to implement major reforms in nursing home care and to create a resident-centered, outcome-oriented survey process. Congress, moreover, intended to significantly alter the conditions of participation for SNFs and to direct the focus and format of surveys conducted by states to those new conditions of participation. In fact, the Secretary was directed to

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[10] (...continued)
National Academy of Sciences, which, at the request of HCFA, undertook "a study of the policies and regulations governing the certification of nursing homes participating in Medicare and Medicaid." The IOM Committee on Nursing Home Regulation issued a comprehensive 415-page report in March 1986 titled "Improving the Quality of Care of Nursing Homes." Id. at 452.

Although the quoted text appears in the section of the report concerning nursing facilities under Medicaid, I find that the concerns expressed by the committee regarding the survey process apply equally to SNFs under Medicare.

The statutory provisions concerning the survey and certification process for Medicaid-certified nursing facilities are found at 42 U.S.C. § 1396r(g). The statutory provisions concerning the survey and certification process for Medicare-certified skilled nursing facilities are identical and are found at 42 U.S.C § 1395i-3(g).

develop new survey protocols which were consistent with the mandates of OBRA '87.

B. HCFA's rule-making activities from July 1987-November 1994

In July, October, and November 1987, HCFA published proposed rules which dealt with the survey and certification process, conditions of participation, and enforcement regulations. 52 Fed. Reg. 24,752, 38,582, and 44,300.[11] While HCFA was considering public comments on the latter two proposed sets of regulations, Congress enacted OBRA '87 in December 1987.

In the preamble to the July 1, 1987 proposed regulations, HCFA stated that it was proposing these regulations in response to the U.S. District Court decision in Estate of Smith v. Bowen, 656 F. Supp. 1093 (D. Colo. 1987), in which the court found that an earlier rule published on June 13, 1986, titled "Medicare and Medicaid Programs -- Long-Term Care Survey" was procedurally invalid. The court had ordered HCFA to publish a new proposed rule by July 1, 1987 addressing the problems which had been identified. 52 Fed. Reg. 24,752-24,753.

On June 17, 1988, HCFA, acting in accordance with a February 18, 1988 court order in Smith v. Bowen, promulgated final regulations amending the Medicare and Medicaid survey regulations then in effect. These final regulations were based on the proposed regulations published in July 1987. 53 Fed. Reg. 22,850 (1988). Among the new regulations promulgated were 42 C.F.R. Part

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[11] The July 1, 1987 proposed rule was titled "Medicare and Medicaid Programs; Long Term Care Survey"." The October 16, 1987 proposed rule was titled "Conditions of Participation for Long Term Care Facilities." The November 18, 1987 proposed rule was titled "Survey and Certification of Health Care Facilities." HCFA intended that the latter two sets of proposed regulations "would revamp the long term care requirements under Medicare and Medicaid to be a resident-oriented system capable of consistent implementation by States." 53 Fed. Reg. 22,850.

HCFA later withdrew the November 1987 proposed rule. See 57 Fed. Reg. 39,279 (1992) (recited as part of supplementary background information).

488 Subpart C. The preamble acknowledges Congress' enactment of OBRA '87:

> [a] new survey process is required by OBRA '87, effective in 1990. In addition, due to the new statutory provisions, we are withdrawing our proposed rule on Survey and Certification of Health Care Facilities (52 FR 44300), and will publish a new proposed rule incorporating the OBRA '87 provisions.
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> *****
>
> We are developing final rules on conditions of participation for long term care facilities . . . In the meantime, we are complying with the court order by publishing these regulations, and we are planning additional revisions to the survey process rules at a later date after we issue a final rule that revises the conditions of participation.

Id. at 22,850, 22,851.

With regard to survey forms and guidelines, the preamble emphasizes that

> [w]e are deferring major forms design and content changes to coincide with the planned refinements in the overall survey process that will be necessitated in conjunction with the revised long term care conditions of participation and the new OBRA '87 requirements. [Id. at 22,856.]
>
> When the new conditions of participation are published as final regulations, we will make necessary refinements to the survey process, forms and guidelines. [Id. at 22,853.]

The preamble notes the breadth of the changes under consideration:

> Although we are publishing this final rule now, in compliance with the court's order, we are also in the process of instituting more far-reaching changes in the nursing home conditions of participation and enforcement regulations that underlie the long term care survey process. [Id. at 22,850.]

> . . . OBRA '87 and the revised conditions of participation for long term care facilities will implement substantive changes to the nursing home requirements and corresponding changes to the long term care survey process. [Id. at 22,851.]

Also, the preamble states unequivocally that the survey procedures and guidelines being published at that time were "rooted in the current nursing home requirements which are the conditions of participation for SNFs. . ." Id. at 22,853.

HCFA's rule-making activities continued in February 1989, when it published as final regulations (with a comment period) a revised version of its October 1987 proposed rule. 54 Fed. Reg. 5316 (1989). These regulations, effective August 1, 1989 (except when specified otherwise in the Federal Register), concerned requirements that long-term care facilities were required to meet to participate in the Medicare and Medicaid programs.[12] In the preamble, HCFA stated that, "[i]n addition to numerous technical revisions made by OBRA '87, in this final rule, we are incorporating the following major OBRA '87 requirements . . ." 54 Fed. Reg. 5317. HCFA stated also that it "plan[ned] to publish other, related regulations in addition to this final rule" to implement OBRA '87. Id. HCFA stated further that "[t]his legislation [i.e., OBRA '87] covered many of the provisions that appeared in the proposed rule. Therefore, many of the provisions that we are adopting in this final rule are now legislative provisions." 54 Fed. Reg. 5355. Due to the extensive revisions to the regulations mandated by numerous OBRA '87 provisions, HCFA published a derivation table setting forth the source of each of the newly promulgated conditions of participation contained in the final regulations. 54 Fed. Reg. 5354-5355.

In September 1991, HCFA published final regulations which revised the February 2, 1989 final regulations. 56 Fed. Reg. 48,826 (1991). These 1991 regulations reflected

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[12] The effective date was later changed to January 1, 1990. See 56 Fed. Reg. 48,826 (1991).

HCFA's response to public comments and included some changes required by OBRA '90. In the preamble, HCFA explained:

> The February 2, 1989 revision of the nursing home regulations was the most extensive set of Federal regulatory changes in this area of the health care industry in 15 years. We revised the requirements that long term care facilities must meet in order to receive Federal funds for the care of residents who are Medicare beneficiaries or Medicaid recipients. We issued the regulations . . . to refocus the requirements for participation in both programs to actual facility performance in meeting residents' needs in a safe and healthful environment. The previous set of requirements had focused on the capacity of the facility to provide appropriate care. In addition, we needed to simplify Federal enforcement procedures by using a single set of requirements that apply to all activities common to [skilled nursing facilities], [intermediate care facilities], and [nursing facilities]. . . .
>
> OBRA '87 departs from previous Congressional practice by specifying many details which prior law leaves to the authority of the Secretary. It also contains entirely new requirements which are also specified in detail.

56 Fed. Reg. 48,826.

Based on this preamble language, there can be little doubt that HCFA was continuing to respond to the enactment of OBRA '87 by making numerous changes in the regulatory requirements concerning conditions of participation and the survey process for long-term care facilities.

In August 1992, HCFA published proposed regulations which would further implement provisions of OBRA '87, as further amended by 1988, 1989, and 1990 legislation. 57 Fed. Reg. 39,278 (1992). With regard to survey procedures and guidelines, HCFA provided in the preamble the following background information to the survey process that existed as of August 1992:

> Sections 1819(g)(2) and (3) and 1919(g)(2) and (3) of the Act, as added by sections 4202 and 4212 of OBRA '87 specify the requirements for

> types and periodicity of surveys that are to be conducted for each facility; including standard, special, partial extended, extended, and validation surveys. These provisions include specific contents and procedures, frequency, consistency, and team composition. These regulatory provisions are an integral part of the long term care survey and enforcement system and along with the requirements for long term care facilities published in a final rule on September 26, 1991 (56 FR 48826), and the interpretive guidelines and survey procedures issued in September 1989, and revised in April 1992 [emphasis added[13]], complete the execution of the long term care survey and certification process mandated under OBRA '87. This fully integrated system provides the comprehensive framework to ensure uniform surveyor interpretation of substandard care, and to guide recommendations with respect to the determination of appropriate remedies.

57 Fed. Reg. 39,283 (1992).

HCFA further described in the preamble the purpose and framework for the recently published interpretive guidelines and survey procedures as follows:

> The interpretive guidelines and survey procedures direct the State agency surveyors to gather information on facility performance relating to the delivery of care and services to the residents in the facility. These surveyor instructions structure the information gathering process and assist the surveyors in identifying situations that are indicative of a facility's compliance with the regulations.

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[13] Although the passage quoted above does not contain a specific reference to the State Operations Manual, Transmittal No. 250, commonly known as SOM 250, one can infer that HCFA, by mentioning that the guidelines and survey procedures were revised in April 1992, is referring to this manual. SOM 250 was published in April 1992. Testimony from the state surveyors makes evident that they received extensive training from HCFA and were expected to implement the survey process set forth in SOM 250 in all surveys conducted after April 1992. See section VI. of this decision, infra.

> Moreover, the surveyor guidelines provide the surveyors with a consistent structure to evaluate the situation and the framework to analyze the information prior to making a compliance decision.
>
> . . . The survey guidelines provide the surveyors with structured information gathering procedures and interpretations related to the requirements that permit the surveyors to make consistent deficiency determinations. However, we do recognize that in many instances the decision with respect to whether a deficiency exists is ultimately a decision of professional judgment related to the particular situation observed and the context of the regulations. Therefore, to assure consistency, we promote team decision making and provide comprehensive training on the regulations and documentation techniques.

Id.

The language cited above spells out the evolving process undertaken by HCFA in carrying out the OBRA '87 mandates. The survey procedures and guidelines in 42 C.F.R. Part 488, Subpart C, were revised by HCFA to comply with congressional directives in OBRA '87 to develop new protocols. These protocols were published in April 1992 as SOM 250. While HCFA made no specific reference to SOM 250 in the preamble to the August 1992 proposed regulations, the scope and purpose of this publication is also evident. When the proposed regulations were published in final form in November 1994, with an effective date of July 1, 1995, HCFA, in response to comments concerning the variation in surveys conducted by state and federal surveyors, stated:

> [T]he long term care survey protocol has only been in effect since October 1990, with appropriate instruction enhancements for the final long term care regulations which were effective April 1, 1992. It is not unusual that some variation in emphasis will occur in a new survey process [emphasis added].

59 Fed. Reg. 56,116, 56,145 (1994).

Of particular interest to this proceeding is HCFA's response to a comment that a facility would not know what was required of it prior to being cited for a deficiency:

> There is no reason why any Medicare or Medicaid provider should be unaware of program participation requirements. The requirements are public knowledge, and it is incumbent upon facilities that enter into Medicare and Medicaid agreements to familiarize themselves with the requirements with which they have voluntarily agreed to comply. Moreover, copies of the State Operations Manual Transmittal No. 250, which contains the interpretive guidelines, procedures and forms used by surveyors to assess facility compliance are available to the public . . . [emphasis added].

Id. at 56,227-56,228.

Even though this quoted language from the Federal Register post-dates the survey of Petitioner in December 1993, HCFA correctly stated that any facility, such as Petitioner, is expected to know of the regulations governing its facility and of the interpretive guidelines governing the conduct of surveyors who measure the facility's compliance with such regulations. As of December 1993, Petitioner had been the subject of prior state surveys and was or should have been on notice as to the requirements imposed by OBRA '87 on SNFs.

HCFA referred to SOM 250 in several instances when responding to public comments. For example, on the topic of a facility's attempt to accommodate a resident in terms of care alternatives, HCFA responded, in part, "[w]e believe such specific instructions are more appropriately located in the State Operations Manual than in the regulation itself, so we are not incorporating them into the regulation." 59 Fed. Reg. 56,134. In responding to another comment on the topic of nursing services staff, HCFA said: "[w]e do specifically address a review of staffing in Appendix P of the State Operations Manual Transmittal No. 250." Id. HCFA again directs attention to Appendix P of the SOM 250 when it discusses audits, reiterating its belief that "such detailed instruction is more appropriate in the manual than in the regulation itself, and so we are not including it in the regulation." 59 Fed. Reg. 56,135.

The preamble addresses also survey protocol and instances where there may have been a failure to completely comply with such protocol. HCFA stated:

> Sections 1819(g)(2)(C) and 1919(g)(2)(C) of the Act reveal the intent of the Act very clearly. These sections state that standard surveys must be conducted based upon a protocol, but add that the failure of the Secretary to develop, test or validate such a protocol will not relieve any State or the Secretary of the responsibility to conduct surveys. Because the Congress intended for survey results to be binding even when surveys were conducted in the absence of a formal protocol, it is clear that the Congress views the substance of survey findings to be of greater importance than the process used to identify them.

59 Fed. Reg. 56,133-56,134 (emphasis added).

HCFA further stated:

> Moreover, since the source of binding requirements on facilities is not in the survey protocol, but in the Act and regulations, the ultimate, and proper, test of facility noncompliance will not rest on whether the survey protocol was rigorously followed, but on whether a requirement of the Act or the regulations has been violated.

Id. at 56,134.

While these explanations of HCFA's intentions regarding the interplay between 42 C.F.R. Part 488, Subpart C, and SOM 250 post-date the survey in issue in this case, they are instructive in understanding HCFA's position and providing guidance in construing the application of Subpart C and the survey protocols in SOM 250.

As illustrated by the foregoing section, HCFA's efforts to carry out the statutory mandates of OBRA '87 thus spanned several years following its enactment. It is evident that to successfully implement the provisions of OBRA '87, HCFA was required to revise, rewrite, and add numerous regulations. It is also apparent that the June 1988 final regulations, which included 42 C.F.R. Part 488, Subpart C, were promulgated by HCFA with great reluctance and only after being mandated by the court. An obvious concern of HCFA was the evolving process by which it was implementing the provisions of OBRA '87 and

the need to develop a mechanism which provided flexibility and allowed for revisions in instructions to state agencies without the need to institute formal rulemaking every time changes were necessary.

C. Analysis

In determining the present force and effect of the survey procedures in 42 C.F.R. Part 488, Subpart C, I am guided by the fact that those survey procedures and guidelines were the subject of lengthy deliberations by HCFA, involving several separate Federal Register pronouncements, with all of these activities predating the effective date of OBRA '87. Equally persuasive is the fact that the Federal Register statement accompanying the final publication of Subpart C leaves no doubt that 1) this Subpart pertained to conditions of participation for long-term care facilities that were in effect at the time of publication and 2) HCFA was, at the time of publication, in the process of making significant and wide-ranging changes to the existing conditions of participation based on various amendments to the law, principally OBRA '87.

A review of Subpart C survey procedures demonstrates that they do not reflect the new and expanded requirements created by OBRA '87, including those in the areas of residents' rights, quality of patient life, quality of care, and dietary, dental, pharmacy, nursing and physician services. See 42 U.S.C. §§ 1395i-3(b)-(d), 1396r-3(b)-(d); 42 C.F.R. § 483.10 - 483.75; 54 Fed. Reg. 5354-5355 (1989). Moreover, the above cited references to the Federal Register demonstrate that HCFA put SNFs on notice as early as August 1992 that the interpretive guidelines and survey procedures used in federal and state surveys were revised in April 1992. At the time of the December 1993 survey, Petitioner was bound by these survey protocols and by the applicable regulations pertaining to the conditions of participation set out in 42 C.F.R. Part 483, Subpart B.

I concur with HCFA's position that Subpart C is inconsistent with and does not implement the OBRA '87 revisions to the health and safety requirements that a long-term care facility must meet to participate in the Medicare and Medicaid programs. HCFA Resp. Br. at 56-58. Subpart C, while technically still in effect, does not have any current operational significance since it pertains to survey methodology and conditions of participation which became obsolete with the implementation of the new conditions of participation and

survey processes mandated by OBRA '87, which did not go into effect until October 1990.[14]

The legal underpinning for Subpart C no longer exists. Congress directed the Secretary to develop new survey protocols to implement OBRA '87. Subpart C has been replaced by these protocols. HCFA's failure to withdraw Subpart C and to formally publish the revised protocols in regulations does not elevate outdated, obviously obsolete survey procedures and guidelines (Subpart C) to a legal status which is inconsistent with congressional intent.[15] Moreover, Congress was cognizant of the

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[14] HCFA points to Estate of Smith v. Sullivan, (D. Colo. 1990) for support of the position that Subpart C was rendered obsolete by the passage of OBRA '87. HCFA Resp. Br. at 56. In this case, the court ordered, effective October 1, 1990, that the "Secretary shall be permitted on an interim basis to require the use of the new survey forms, procedures and interpretive guidelines" and Subpart C "shall be suspended but not repealed pending further orders of this Court. . ." HCFA Attachment 2. (I discuss this order further in section V. of this decision). HCFA contends that the new survey forms, procedures and interpretive guidelines are those outlined by SOM 250. HCFA Resp. Br. at 56. I am convinced that this district court case demonstrates that HCFA was implementing OBRA '87 by means other than Subpart C but based on this interim court order, HCFA could not repeal that Subpart. Certainly, HCFA could have dispelled any confusion about the operational validity of Subpart C by publishing in the Federal Register a specific statement relating to Subpart C. Unfortunately, this was never done. That failure, however, cannot be used to validate the survey process in Subpart C, which process HCFA was required to replace with the implementation of OBRA '87.

[15] It is noteworthy that a simple reading of the chart found at 42 C.F.R § 488.115 demonstrates an internal inconsistency, for the regulations referenced in the chart pre-date OBRA '87, and, thus, have been made inert by Congress and by HCFA's rule-making activities. The referenced regulations are outdated and no longer in existence today. Accordingly, it would be impossible to "apply" this chart to any surveys which were conducted post-OBRA '87. A review of the derivation table published in the Federal Register leaves no doubt that the regulations referenced in the chart at 42 C.F.R. § 488.115 were superseded by the new regulations published

(continued...)

possibility that the Secretary would not develop the survey protocols by January 1, 1990 and directed the states and Secretary to carry out the mandates of OBRA in the absence of such protocols. See section IV.A. of this decision, supra.

Apparently ignoring the cited statutory language, legislative history, and statements by HCFA in publications of the Federal Register post-OBRA '87, Petitioner argues that the "[e]nactment of OBRA 1987 has not changed a single regulatory requirement for the conduct of surveys." P. Resp. Br. at 3. This position is so totally inconsistent with the record in this case that I do not give it any serious consideration. One argument Petitioner appears to make is that the OBRA '87 requirement that each survey include a "case-mix stratified sample of residents" does not change any requirement of Subpart C. Id.[16] This is incorrect. 42 C.F.R. § 488.110(d) (which is found in Subpart C) refers to a random sample and not the case-mix stratified sample which is required by OBRA '87.[17] Thus, Petitioner's own reference demonstrates that Subpart C, as I have found, does not track or adhere to the requirements of OBRA '87. HCFA's counsel gives other examples of the inconsistency between OBRA '87 requirements and 42 C.F.R. § 488.110 in her reply brief at pages 34-35.

As previously stated in this decision, there is ample support for the conclusion that OBRA '87 made substantial changes in the conditions of participation and survey process for long term care facilities. The statute itself reflects this and HCFA's extensive analyses of OBRA '87 in the Federal Register leave no doubt as to its interpretation of the impact of OBRA '87 on then-existing statutory and regulatory requirements.

Petitioner further argues that 42 C.F.R. § 488.110 is binding on HCFA and the survey protocols and definitions contained therein were operative at the time Petitioner was surveyed in December 1993. In support of this

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[15] (...continued)
in February 1989, which became effective on August 1, 1989. See 54 Fed. Reg. 5316, 5356-5358.

[16] Unfortunately, Petitioner's brief is garbled on this point and I am therefore forced to interpret the confused language. P. Resp. Br. at 3-4.

[17] I discuss resident selection methodology further in Section IX of this decision.

position, Petitioner points out that 1) HCFA never formally withdrew 42 C.F.R. § 488.110 after OBRA '87 was enacted, and 2) all volumes of the Code of Federal Regulations (C.F.R.) for the years 1992 to the present continue to contain this Subpart without revision. Petitioner concludes that, since Subpart C is the operative standard for the conduct of surveys under OBRA '87 and HCFA did not follow this standard in conducting the survey of Petitioner in December 1993, the survey results are a nullity and cannot be used to delay its certification for Medicare. P. Resp. Br. at 4-6.

There is no dispute of the obvious fact that, despite OBRA '87, HCFA has never formally withdrawn 42 C.F.R. Part 488, Subpart C and has continued to publish it in the C.F.R. This circumstance presents several legal issues which I will now address.

V. Issue:

> Whether HCFA was legally required to formally withdraw or repeal 42 C.F.R. Part 488, Subpart C.

Petitioner contends that HCFA never formally repealed 42 C.F.R. § 488.110 (which is included in Subpart C) in accordance with the requirements of the Administrative Procedure Act (APA), and that its failure to do so makes the agency bound by the contents therein. P. Br. at 15. Petitioner argues also that the fact that Subpart C was recently re-published, without any changes, in the C.F.R. is indicative of its present-day validity. P. Resp. Br. at 5.

HCFA claims that Subpart C was inconsistent with and did not carry out the directives of OBRA '87 and, thus, lost operational significance "as a matter of law." HCFA Resp. Br. at 58. HCFA contends that, with the enactment of OBRA '87, "the survey forms, procedures, and guidelines of Subpart C were nullified: administrative repeal was not required." Id. at 60.

I find that HCFA was not legally required to formally withdraw or repeal Subpart C in order for this subsection to be rendered inoperative by the passage of OBRA '87, the provisions of which became effective on October 1, 1990.

In examining the interrelationship between administrative regulations, statutory language, and congressional intent, the Supreme Court has expressed the well-settled principle that congressional desire discerned from a

statute is to be effectuated through promulgated regulations:

> [t]he power of an administrative officer or board to administer a federal statute and to prescribe rules and regulations to that end is not the power to make law . . . but the power to adopt regulations to carry into effect the will of Congress as expressed by the statute. A regulation which does not do this, but operates to create a rule out of harmony with the statute, is a mere nullity.

Manhattan General Equipment Co. v. Commissioner of Internal Revenue, 297 U.S. 129, 134 (1935). In a later case, the Court again recognized that "regulations, in order to be valid, must be consistent with the statute under which they are promulgated." U.S. v. Larionoff, 431 U.S. 864, 873 (1977). Also, a regulation is invalid if it is "fundamentally at odds with the manifest congressional design," even if it is not "technically inconsistent" with the statutory text. U.S. v. Vogel Fertilizer Co., 455 U.S. 16, 26 (1982).

There is no dispute that the contents of Subpart C were never modified and that HCFA never formally repealed or withdrew Subpart C. It follows logically that, because Subpart C was never formally repealed, HCFA was required to re-publish this section in the C.F.R. However, the mere fact of publication has little bearing on the issue of whether this subpart has any operational significance today. In light of the principles enunciated above by the Supreme Court, the appropriate analysis begins by focusing on the congressional purpose in enacting OBRA '87.

As discussed previously, the legislative history of OBRA '87 demonstrates that Congress intended to make far-reaching changes in the survey and certification process to remedy shortcomings in the law as it then existed. Moreover, the legislative history underscores congressional intent to create a patient-centered, outcome-oriented survey process. It is fair to conclude that the intent of Congress, as expressed in the legislative history of OBRA '87, is unambiguous.

As discussed earlier in section IV. of this decision , I find that OBRA '87 imposes many new requirements on long-term care facilities. These provisions explicitly carry out the congressional objective of comprehensive nursing home reform. I conclude that the contents of Subpart C became obsolete with the implementation of the OBRA '87

provisions (section IV., supra). Subpart C did not address the new conditions of participation and survey processes statutorily mandated by OBRA '87. Based on this, it cannot be disputed that Subpart C is "out of harmony" with OBRA '87 and, thus, at odds with the will of Congress. To give any effect to Subpart C would clearly frustrate the congressional purpose in passing OBRA '87. Moreover, "[w]here an administrative regulation conflicts with a statute, the statute controls." U.S. v. Doe, 701 F.2d 819, 823 (9th Cir. 1983). Subpart C must thus be considered to have lost any operational significance by virtue of the fact that it conflicts with, and does not carry out, the directives of OBRA '87.

I agree with HCFA that formal repeal of Subpart C was not required. Petitioner cites to the case of Am. Fed'n. of Gov't. Employees v. Fed. Lab. Rel. Auth., 777 F.2d 751, (D.C. Cir. 1985), among others, in support of its argument that Subpart C should have been repealed in accordance with the APA rule-making process:

> "[A]n agency seeking to repeal or modify a legislative rule promulgated by means of notice and comment rulemaking is obligated to undertake similar procedures to accomplish such modification or repeal . . . .

Id. at 759.

However, the Supreme Court decisions cited above make no mention of formal repeals in the instances where a regulation does not effectuate the congressional design. For example, the Court has held that certain Defense Department regulations conflicted "with the congressional intention in enacting the VRB program, and hence [are] invalid." U.S. v. Larionoff, 431 U.S. at 877. The absence of any explicit reference by the Court regarding repeal gives rise to the inference that such regulations are to be found null, and thus, invalid. Furthermore, because the Court in Larionoff did not refer at all to APA requirements in declaring the regulations to be invalid, I infer that such requirements do not have to be met. Even without this interpretation, it can be argued that the import of repealing the regulation is to provide notice to the public that the agency is no longer relying on such regulation in carrying out the congressional mandate upon which the regulation is based. Here, the Federal Register references previously cited in section IV., reflect the fact that HCFA specifically and clearly notified the public that the survey protocols and procedures in Subpart C were replaced by SOM 250.

In any event, in the matter before me, it appears that HCFA was prohibited from repealing Subpart C based on the interim order issued by the federal court in Colorado in the case of Estate of Smith v. Sullivan, on September 27, 1990. The order stated, in part: "Effective October 1, 1990, the Secretary shall be permitted on an interim basis to require the use of the new survey forms, procedures and interpretive guidelines described above. The current regulations providing certification survey forms and guidelines, 42 C.F.R. Part 488, Subpart C, shall be suspended but not repealed pending further orders of this Court . . . " HCFA Attachment 2 at 1, 3. Thus, HCFA could not repeal Subpart C; nevertheless, it was allowed by the court to use the new survey protocols. Any alleged non-conformity with the requirements of the APA on HCFA's part is therefore moot in light of the court's interim order.

Accordingly, because Subpart C conflicts with the congressional design underlying OBRA '87, it became void of any effect and validity; it was rendered "a mere nullity" as a matter of law, without necessitating a repeal or withdrawal by any formal means.

I find unpersuasive Petitioner's argument that HCFA has acted in disregard of its own rules. Petitioner cites Morton v. Ruiz, 415 U.S. 199, 235 (1974), as well as other cases, for the proposition that "[a]dministrative agencies are under an obligation to observe their own regulations." P. Br. at 12. This general statement of law cannot be disputed. But what Petitioner ignores is that such general statement cannot be applied to circumstances where the regulation in issue no longer carries out the will of Congress and has been replaced by other administrative directives, such as SOM 250.

Here, HCFA has followed its regulations, procedures, and precedents. Because Subpart C became null and void and, thus, without any operative effect, HCFA's departure from this subsection was justified. The order of remand issued by the Appeals Council of the Social Security Administration in Health Care Financing Administration v. Devon Gables Health Care Center (Dec. 7, 1994), further supports HCFA on this point. In stating the background of the case, the Appeals Council first explained that the administrative law judge in the case had held that

> the survey process and subsequent findings resulting therefrom are invalid as a matter of law, given that [HCFA] did not follow its own binding regulations

> relating to the survey process, as contained in 42 C.F.R. Part 488, Subpart C.

HCFA Attachment 3 at 3.[18]

The Appeals Council concluded that the administrative law judge had erred in finding the survey process and subsequent findings to be invalid:

> Under the Administrative Procedure Act, an Administrative Law Judge is subordinate in matters of policy to the Secretary of Health and Human Services. The Secretary, acting through the Administrator of HCFA, determined that OBRA '87 and 42 C.F.R. Part 488, Subpart C are not consistent, and made the policy decision to give effect to the pertinent provisions of OBRA '87 by means of interpretive manuals, procedures and statements of policy which have not been published as regulations. The Secretary further determined to apply nationwide the September 27, 1990 Smith court order which suspended 42 C.F.R. Part 488, Subpart C, and required use of the unpublished forms, procedures and interpretive guidelines in order to implement the changes mandated by OBRA '87.

HCFA Attachment 3 at 4.

The legal and factual basis of the remand order issued by the Appeals Council is consistent with my analysis of this case.[19] Further support for the position can be

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[18] In his decision dated August 21, 1992, the administrative law judge had stated the issue "as being whether the Health Care Financing Administration's (HCFA) failure to follow and apply the survey process set forth in 42 C.F.R., Part 488, Subpart C, and the use of unpublished survey procedures and materials as contained in Appendix P of the State Operations Manual and the HCFA Self-Instructional Manual, rendered the survey findings and HCFA's January 11, 1991 certification of non-compliance invalid as a matter of law." HCFA Attachment 3 at 2.

[19] The Appeals Council in Devon Gables stated further:

(continued...)

inferred from the fact that the regulations found in this Subpart refer to other regulations that are outdated and no longer exist. For example, as a result of the numerous and substantial revisions to the regulations concerning conditions of participation and other requirements mandated by OBRA '87, the regulations referenced in the chart at 42 C.F.R. § 488.115 were made inert by Congress and by HCFA's own rule-making activities. These referenced regulations, which pre-date OBRA '87, no longer have any viability, for they are no longer in existence. (See fn 15 for a discussion of this chart.)

Having recognized that Subpart C was contrary to OBRA '87, the Secretary thus chose to effectuate the OBRA '87 provisions by means of "unpublished forms, procedures and interpretive guidelines." It is noteworthy that the Appeals Council's reference to the unpublished materials is a reference to the contents of Appendix P of the State Operations Manual (250) and, also, the HCFA Self-Instructional Manual. HCFA Attachment 3 at 2; see fn 18. Thus, HCFA's use of the SOM 250 in place of the now-obsolete Subpart C complied fully with the Secretary's policy decision and was consistent with its obligation to

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[19] (...continued)
The manner in which the Secretary selects to implement the Congressional mandate in order to both effectuate the will of Congress and comply with the Court's directives in the Smith litigation is not subject to review by an Administrative Law Judge. The Council can discern no authority for the Administrative Law Judge to rule on the validity or invalidity of a regulation or interpretive rule.

HCFA Attachment 3 at 4.

I do recognize that I do not have authority to declare a regulation invalid. David S. Muransky, DAB CR95 (1990), aff'd DAB 1227 (1991); Hanlester Network, et al., DAB CR181 (1992); Charles J. Barranco, DAB CR187 (1992). However, despite this admonition, in fairness to Petitioner, I have carefully examined its position and responded to the issues raised by Petitioner regarding the operational effect of 42 C.F.R. Part 488, Subpart C. My analysis as to the operational effect of Subpart C is based on the actions taken by the Secretary in carrying out her responsibilities under OBRA '87 and not on my own interpretation of the legality of these regulations.

abide by its own rules and regulations. Accordingly, HCFA did not violate any administrative norm by its non-adherence to the survey procedures and guidelines contained in Subpart C.[20]

Furthermore, this case is distinguishable from Morton v. Mancari, 417 U.S. 535, 549 (1974), in which the Court, quoting Posadas v. National City Bank, 296 U.S. 497, 503, (1936), stated that "repeals by implication are not favored." In Morton v. Mancari, the Court considered the issue of whether the Indian employment preference in the Bureau of Indian Affairs contained in the Indian Reorganization Act was impliedly repealed by the Equal Employment Opportunity Act of 1972. As part of its analysis, the Court stated that "[i]n the absence of some affirmative showing of an intention to repeal, the only permissible justification for a repeal by implication is when the earlier and later statutes are irreconcilable." Id. at 550. The Court found that the employment preference was not impliedly repealed by the 1972 Act.

Here, unlike Morton v. Mancari, the issue is not whether one statute conflicts with another statute, but whether promulgated regulations conflict with the intent of Congress as expressed in a specific statute, namely, OBRA '87. As I discussed above, Subpart C did not address or implement the new requirements contained in OBRA '87 affecting nursing homes and the survey process. This being the case, Subpart C was rendered void and without operative effect. Using the analysis of Morton v. Mancari, the record demonstrates that Subpart C is "irreconcilable" with the requirements of OBRA '87 and is arguably repealed by implication.

Furthermore, HCFA, through the previously enumerated cited sections in the Federal Register, made its position quite clear concerning the applicability of Subpart C. Notice was given to SNFs that, in implementing the federal requirements covering the conduct of long-term care facilities, the Secretary no longer was relying on the survey protocols and procedures set forth in Subpart C. I have no authority to question that decision or second guess the Secretary.

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[20] I discuss the operational significance of the SOM 250 in section VI. of this Decision.

VI. Issue:

Whether SOM 250 is applicable to the survey of Petitioner.

Petitioner contends that, to the extent that SOM 250 alters the substance of Subpart C, HCFA was required to promulgate the provisions of SOM 250 in accordance with the rulemaking requirements of the APA; otherwise, such requirements would be invalid. P. Br. at 17-20.

I do not agree that, because HCFA did not issue SOM 250 in the form of a formal regulation, it is null and void . The provisions of SOM 250 are not "substantive," but "interpretive". Alcarez v. Block, 746 F.2d 593, 613 (9th Cir. 1984); American Hospital Association v. Bowen, 834 F.2d 1037, 1045 (D.C. Cir. 1987); Guadamuz v. Bowen, 859 F.2d 762, 771 (9th Cir. 1988). HCFA published SOM 250 to provide guidance to state surveyors who are responsible for determining compliance by long-term care facilities with federal requirements imposed by statute and regulations. The following references in SOM 250 set forth HCFA's purpose in disseminating this document to state agencies:

> 2712. USE OF THE SURVEY PROTOCOL IN THE SURVEY PROCESS
>
> [Survey protocols] are the authorized interpretations of mandatory requirements set forth in provisions of the Social Security Act . . ., and in the regulations.
>
> Survey protocols identify relevant areas and issues to be surveyed as specified in each regulation, and, in some cases, the methods to be used to survey those areas and issues. These protocols promote consistency in the survey process. They also assure that a facility's compliance with the regulations is reviewed in a thorough, efficient and consistent manner. . .
>
> Included in the survey protocols are Interpretive Guidelines which serve to interpret and clarify the conditions of participation, conditions for coverage, and requirements of participation for specific types of entities. The Interpretive Guidelines contain authoritative interpretations and clarifications of statutory and regulatory requirements and are to be used to make

> determinations about a provider's compliance with requirements. These Interpretive Guidelines merely define or explain the relevant statutes and regulations and do not impose any requirements that are not otherwise set forth in the statute or regulations. . . .
>
> *****
>
> 2803. SURVEY PROTOCOL
>
> A. Introduction.-- This protocol is established pursuant to §§ 1819(g)(2)(C) and 1919(g)(2)(C) of the Act to provide guidance to surveyors conducting surveys of long-term care facilities participating in the Medicare and Medicaid programs. The protocol consists of survey procedures, work sheets and Interpretive Guidelines. It serves to explain and clarify the requirements for long-term care facilities and is required to be used by all surveyors measuring facility compliance with Federal requirements. The purpose of this protocol is to provide suggestions, interpretations, check lists, and other tools for . . . use both in the preparation for the survey and . . . onsite performing the survey[.] These Interpretive Guidelines merely define or explain the relevant statutes and regulations and do not impose any additional costs or place other burdens on any health care facility. (See § 2712.)

HCFA Ex. 13 at 2-137, 2-183.

Since SOM 250 was not intended to "impose any requirements that are not otherwise set forth in the statute or regulations," HCFA would not need to formally publish these instructive guidelines to state surveyors in the form of a regulation. Consequently, SOM 250 must be read in connection with the statutory and regulatory provisions regarding SNFs to determine the operative protocols, definitions, and standards that were applicable at the time of the survey in issue. I conclude that the appropriate approach is to review the relevant statutory provisions, regulations, and interpretative guidelines of HCFA as a whole in determining whether HCFA can support the deficiencies cited in the Statement of Deficiencies, i.e., HCFA 2567.

Petitioner would have me, as the adjudicator, alter the focus of the hearing from whether deficiencies exist to whether the state surveyors complied with the applicable survey protocols. The focus of this hearing is on Petitioner's practices in operating its SNF and whether those practices resulted in deficiencies arising from the requirements of 42 C.F.R. Part 483, Subpart B, Requirements for Long Term Care Facilities.

HCFA recognized that Congress, in enacting OBRA '87, did not intend for survey procedures, in and of themselves, to be elevated above surveyors' legitimate findings of deficiencies. HCFA states, "[t]o invalidate legitimate determinations of noncompliance and leave them unaddressed would be in opposition to the mandate of OBRA '87 that all requirements be met and enforced, and would lead to inconsistent application of the law." 59 Fed. Reg. 56,133. To allow deficiencies that are "otherwise well documented" to be challenged and possibly invalidated merely because a surveyor did not comply with "every last detail of the survey protocol" would, in HCFA's view, "be surrendering all substance to form and would clearly thwart Congressional will." Id.

Moreover, it is noteworthy that, although Petitioner vigorously argues in its briefs that the surveyors acted in disregard of proper survey procedures in adhering to the directives contained in SOM 250, counsel for Petitioner had expressed the following opinion at the in-person hearing:

> Whatever HCFA instructed them to use, assume it was SOM 250, whatever her boss, "her" being Ms. Downing's boss at the time, instructed her to use, assume it was SOS [sic] 250, assume it was a piece of toilet paper, it's irrelevant. The only standard by which this case is going to be judge [sic] is whether or not the 2567 and whatever is being written up does or does not state violations that amount to deficiencies within the meaning of 42 C.F.R. 540(N) [sic]. The fact that they internally either did or didn't give correct instruction, they did or didn't perform an adequate survey, it's immaterial. Either there's a violation within the meaning of the regulation and proof that supports it or there isn't. It doesn't make any difference if they were instructed properly or improperly. We're not concerned with that. We're only concerned here with whether or not the regulations have been violation [sic], because that's what's set forth in the 2567,

> and, if so, whether there's been any proof, among the other issues, but that's all. There isn't any other standard. There's nothing here in this 2567 about SOM 250.

Tr. 2134-2135.

In the quoted colloquy above, Petitioner contends, at length, that whether or not the survey was performed adequately is "immaterial" and that the only "standard" is whether or not the 2567 states "violations that amount to deficiencies." Petitioner, by later arguing in its briefs about the non-applicability of the SOM 250 to the survey, attempts to have it both ways. While I disagree with Petitioner as to the non-applicability of SOM 250 to this case for the reasons I previously cited, I do agree that the ultimate determination as to whether a deficiency exists will depend on the contentions in HCFA 2567 and proof offered by the parties. As I have discussed earlier in section IV.B of this decision, this interpretation is consistent with HCFA's own interpretation of its responsibilities in carrying out the congressional intent behind the enactment of OBRA '87 and of the corresponding responsibilities of SNFs who are or seek to be Medicare providers.

VII. Issue:

> Whether 42 C.F.R. § 489.13 permits HCFA to deny certification on the date the survey is completed if all Level A requirements are met and only Level B deficiencies exist.

The regulation at 42 C.F.R. § 489.13[21] states:

> Effective date of agreement.
>
> (a) All Federal requirements are met on the date of the survey. The agreement will be effective on the date the onsite survey is completed (or on the day following the expiration date of the current agreement) if, on the date of the survey, the

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[21] I am quoting this regulation as it was published in the 1992 version of the C.F.R. This regulation was subsequently amended in the 1994 publication of the C.F.R. However, Petitioner was surveyed in December 1993, prior to the time the 1994 changes were in effect. Therefore, the controlling regulation on this issue is the one that was in effect at the time of the survey, i.e., the 1992 version.

> provider meets all Federal health and safety conditions of participation or Level A requirements (for SNFs), and any other requirements imposed by HCFA.
>
> (b) All Federal requirements are not met on the date of the survey. If the provider fails to meet any of the requirements specified in paragraph (a) of this section, the agreement will be effective on the earlier of the following dates:
>
> (1) The date on which the provider meets all requirements.
>
> (2) The date on which the provider submits a correction plan acceptable to HCFA or an approvable waiver request, or both.

At issue in this case is the interpretation of this regulation. The parties do not disagree that 42 C.F.R. § 489.13 requires Petitioner to be in compliance with Level A requirements on the date of the survey. However, Petitioner contends that it is virtually "impossible to be in 100 percent compliance with the myriad regulations governing skilled nursing facilities." P. Br. at 4. According to Petitioner, a single violation, such as a "dirty plate, failed light bulb, unmade bed, late meal, or documentation error, can all violate some regulation governing skilled nursing facilities." Id. at 5. Therefore, Petitioner argues that it is "inconceivable that [42 C.F.R.] § 489.13 was intended to require 100 percent compliance with "every single regulation as a condition of certification." Id. As such, Petitioner interprets 42 C.F.R. § 489.13 as requiring that Petitioner can be denied certification only when it fails to meet a Level A requirement or, alternatively, when "the Level B deficiencies are of a sufficient number or type so as to render the facility in non-compliance with a Level A requirement." Id.

HCFA contends that the "any other requirements" language contained in the regulation refers to Level B deficiencies, or for that matter any other requirement imposed upon SNFs by regulation. Accordingly, HCFA's position is that, under the regulation, it may impose any additional requirement on SNFs as necessary to insure the health and safety of the program beneficiaries. HCFA Br. at 13.

HCFA's position is supported by the plain meaning of the regulation, as well as by regulations which were promulgated to implement the OBRA '87 changes to requirements for SNFs. The plain meaning of 42 C.F.R. § 489.13 is that the phrase "any other requirements" means

just that. While the regulation does not define what is meant by "any other requirements", Administrative Law Judge Steven Kessel has interpreted the "any other requirements" language to mean "all conditions, standards, and elements established as prerequisites for certification." Transitional Hospitals Corporation -- Las Vegas, DAB CR350, at 8 (1995). In other words, a provider must meet all requirements imposed upon it by HCFA before it can be certified. Id.; SRA, Inc. D/B/A St. Mary's Parish Dialysis Center, DAB CR341, at 5 (1992). This interpretation is in accord with the plain meaning of the regulation and is supported by the regulations that have been promulgated to implement OBRA '87.

Petitioner argues that "[i]f HCFA intended that a provider was required to meet every last regulation, irrespective of the severity of the violation or the number, then it would have so stated." P. Br. at 6. However, the explanatory material contained in the preamble to the regulations that enacted 42 C.F.R. § 489.13 contains comments on this very point.

> Comment: Two commentors asked for further clarification of the phrase "all Federal requirements are fully met" in § 405.606(d).[22] In particular, they asked whether "requirements" include factors and elements which, though not met, do not put the provider out of compliance with the pertinent standard.
>
> Response: The final regulations have been revised to specify that "all Federal requirements" includes the health and safety requirements [conditions, standards, factors, and elements], financial interest disclosure, and the civil rights provisions of 45 C.F.R. Parts 80, 84 and 90.

45 Fed. Reg. 22,933, 22,934 (1980).

Additionally, many regulations have been published subsequent to OBRA '87 that unequivocally state that SNFs are required to comply with each and every regulatory requirement. On February 2, 1989, HCFA published final regulations (effective August 1, 1989, except where specified otherwise) and solicited comments. 54 Fed. Reg. 5316 (1989). The regulations revised and consolidated the requirements for long term care

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[22] This section is the former codification of 42 C.F.R. § 489.13.

facilities (including SNFs). Id. These regulations declared, in effect, that all regulatory requirements were to be enforced to the fullest extent possible, not just the more serious Level A type of deficiencies.

> [W]e wish to be certain that the public realize that all requirements for certification must be met by nursing facilities if they are to avoid some measure of adverse action. We believe that, to the extent that Federal requirements were set forth in what appeared to be a qualitative hierarchy, that there might be some misunderstanding that violations of the "lesser" requirements would not be subject to Federal enforcement.
>
> Additionally, the OBRA '87 requirements have recast substantive requirements so as not to use the traditional "conditions" and "standards" terminology.
>
> Accordingly, in this final rule, we have attempted where appropriate to retain the organization of the various proposed requirements, but have revised the terminology. Thus, those requirements that previously were identified as conditions of participation (appearing as individual sections within a subpart) are now designated as level A requirements. Those requirements that previously were identified as standards (appearing as individual paragraphs within a section) are now designated as level B requirements. These designations are intended to communicate that all of the nursing facility requirements are binding and are not part of a qualitative hierarchy, while at the same time recognizing that violations of these requirements (depending on their type or severity) may be remedied through the different enforcement mechanisms available to the Department.

54 Fed. Reg. 5317-5318.

In the preamble addressing the resident rights requirement, the authors of the preamble stated that "Since we do not use the "condition of participation" or "standard" terminology any longer, and we are committed to enforcement of all requirements equally, we do not think the title used to describe resident rights will bring about less or greater enforcement." 54 Fed. Reg. 5318-5319.

Emerging from these regulations, which were drafted as requirements for long-term care facilities under OBRA '87, is a clear picture of a mechanism of enforcement in which there is no hierarchy of violations; that is, every violation that is committed by a long-term care facility is to be taken seriously and is to provide a potential basis for enforcement. This picture clearly accords with HCFA's view of how the regulations are to be applied in this case and does not accord with Petitioner's interpretation of the regulatory requirements in 42 C.F.R. § 489.13. Petitioner's contentions that 42 C.F.R. § 489.13 does not require 100 percent compliance with every single regulation as a condition for certification and permits HCFA to deny certification only when Petitioner fails to meet a Level A requirement, or, alternatively, when the "Level B deficiencies are of a sufficient number or type so as to render the facility in non-compliance with a Level A requirement" (P. Br. at 5), are without merit.

Further support for this position can be found in subsequent preambles of the regulations implementing the OBRA '87 requirements and published in the Federal Register. For example, as I discussed earlier in section IV., in 1991, HCFA published final regulations which revised and consolidated the 1989 regulations. 56 Fed. Reg. 48,826. These regulations were effective as of April 1, 1992.

In the preamble accompanying these regulations, HCFA reiterated that long term care facilities, including SNFs, were subject to enforcement for all violations of requirements and that "[i]t was never intended that the Level A and Level B designations imply a hierarchy of importance." 56 Fed. Reg. 48,827. The preamble text went on to state that a long-term care facility (including an SNF)

> must be in compliance with all the requirements of sections 1819(b) through (d) and 1919(b) through (d) in order to participate in the Medicare and Medicaid programs.
>
> Every requirement in these regulations must be enforced and penalties must be assessed in accordance with regulations issued pursuant to sections 1819(h) and 1919(h) of the Social Security Act (The Act).

56 Fed. Reg. 48,827.

These regulations went one step further than their predecessor, however, and actually eliminated the designations of Level A and Level B. The preamble notes this change:

> Comment: A number of commentors, especially those dealing with resident activities and social services, objected to the Level A and Level B designations used in the organization of these requirements. Their principal objection centered around a belief that Level B requirements were less important than Level A requirements.
>
> Response: In order to prevent any further confusion over this issue, we have decided to delete from part 483 all references to Level A and Level B requirements.

Id.[23]

Finally, as I discussed earlier, in 1992, HCFA published another set of proposed regulations, which specified the process for surveying SNFs under Medicare and NFs under Medicaid and for certifying that these facilities meet federal requirements for participation in Medicare and Medicaid. 57 Fed. Reg. 39278 (1992). With regard to the conditions of participation that must be met by prospective providers, the preamble for the 1992 proposed regulations stated:

> Specifically, we note that the Act, at sections 1819(a) and 1919(a), defines a skilled nursing facility and nursing facility, respectively, as one which "* * * meets the requirements * * * described in subsections (b), (c), and (d) of this section." Similarly, the enforcement sections of the Act, at sections 1819(h) and 1919(h), speak clearly to the need for remedial action if a facility fails to meet "a" requirement or "any" requirement set forth in the Act.

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[23] The preamble went on to say that "[i]t is therefore necessary from an administrative standpoint to continue to use the Level A and Level B designations for all surveys until a new enforcement system and accompanying forms and procedures are in place." 56 Fed. Reg. 48,827-48,828. The preamble further stated that remaining references to Level A and Level B would be removed in the OBRA '87 enforcement regulation to be issued later. 56 Fed. Reg. 48,828.

> We realize that this approach would be a marked contrast from the current system in which facilities may be approved for program participation with level B deficiencies as long as all level A requirements are met. Congress, however, has removed this flexibility from the survey and certification system by admonishing the Secretary for having used a hierarchy of Federal requirements (as are represented by condition, standard, and element levels) and by removing the concept of "substantiality" from determinations of compliance. What will be in place under sections 1819 and 1919 is a "horizontal" system of requirements which obliges nursing home providers to comply with all such requirements, not just a portion of them.
>
> We are fully cognizant that this approach to provider certification is a stringent one, but one that we believe reflects the plain language of the Act that Congress expects us to execute.

57 Fed. Reg. 39,282.

Again, HCFA reiterated its commitment to enforcing all requirements for program participation, not just ones that rise to a certain threshold level. Throughout the process of promulgating regulations, HCFA has consistently interpreted OBRA '87 as requiring compliance with all regulatory requirements. Furthermore, as the quoted preamble language makes clear, any deficiency with regard to any regulatory requirement can be sufficient basis to deny certification to a facility.

The preamble language emphasizes that enforcement will not proceed on a hierarchical or two-tiered basis. Instead, SNFs must be in compliance with every regulatory requirement, and a deficiency with regard to any regulatory requirement can provide sufficient basis to deny certification. There simply no longer exists any distinction between Level A and Level B requirements because every violation is considered to be potentially sufficient to deny certification.

Accordingly, the plain meaning, applicable case law and the Federal Register preamble text cited above provide overwhelming support for HCFA's position that the phrase "all other requirements" contained at 42 C.F.R. § 489.13 means that SNFs not only must meet all requirements established by regulation, but that any violation of the regulatory requirements can provide a basis to deny certification. Petitioner's contention that it can only be denied certification if found deficient with respect

to Level A requirements or, alternatively, if found to have Level B deficiencies which are of sufficient number or type to constitute non-compliance with a Level A requirement, is without merit. Any deficiency can form the basis to deny certification.

VIII. Issue:

> Whether failure to meet the 10-day requirement contained in 42 C.F.R. § 488.110(j) can be used to alter the requirements of 42 C.F.R. § 489.13.

Petitioner takes several stances regarding the date on which it claims HCFA should have certified its facility. Initially, Petitioner contends that it should be certified effective December 23, 1993, because that was the date that HCFA completed the survey of Petitioner and conducted the exit conference. P. Br. at 1-2. In sum, there is no evidence that Petitioner met all federal requirements by the completion date of the survey; therefore, its certification can only be the earlier of the date on which it met all requirements or the date when it submitted an acceptable plan of correction or approvable waiver request to HCFA.[24] 42 C.F.R. § 489.13.

Secondly, Petitioner contends that it should be certified effective January 12, 1994. P. Br. at 9, 21. As support for its position, Petitioner cites the regulation found at 42 C.F.R. § 488.110(j) which directs surveyors to "In accordance with your Agency's policy, present the Statement of Deficiencies, form HCFA-2567, on site or after supervisory review, no later than 10 calendar days following the survey." Ten calendar days from December 23, 1993 is January 2, 1994. Petitioner contends, however, that HCFA did not have the HCFA 2567 ready until January 22, 1994. P. Br. at 21.[25] Allowing for an extra day for the fact that January 2, 1994 was a Sunday,

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[24] Petitioner never alleged that it had made a waiver request nor does the record reflect that any waiver was granted. Thus, this basis for altering the effective date is not an issue in this proceeding. The only issues that are relevant to the determination of the effective date in this proceeding relate either to the date the deficiencies were corrected or the date HCFA accepted Petitioner's plan of correction.

[25] This conflicts with testimony from Mr. Murray, who says that he picked up the HCFA 2567 from the DHS office on January 19, 1994. Tr. 2189.

Petitioner contends that HCFA violated the regulation by failing to provide Petitioner with the survey results within 10 calendar days following the survey. Petitioner avers that had HCFA provided it with the HCFA 2567 within 10 calendar days as directed by regulation, Petitioner would have submitted a plan of correction on January 12, 1994.

Petitioner therefore contends that it was HCFA's delay in providing it with the HCFA 2567 that prevented it from submitting its plan of correction before January 31, 1994. Accordingly, Petitioner requests that I find that it met the requirements of participation as of January 12, 1994, the date upon which it claims it would have submitted its plan of correction had HCFA provided it with HCFA 2567 within 10 days of the exit conference.

Admittedly, Petitioner did not get the HCFA 2567 until January 19, or 22, 1994. I cannot speculate as to when Petitioner would have submitted the plan of correction had HCFA been able to provide Petitioner with the HCFA 2567 within the ten days after completion of the survey.

The regulation at 42 C.F.R. § 489.13 is clear on its face. Once HCFA, via a survey, finds a facility has deficiencies, that facility cannot be certified until it meets all requirements or submits an acceptable plan of correction (or an approvable waiver request), whichever date is earlier. Where there has been no evidence presented of correction of the deficiencies, Petitioner can be certified only upon submission of an acceptable plan of correction. 42 C.F.R. § 489.13; SRA, Inc., DAB CR341, at 5; Transitional Hospitals Corp., DAB CR350, at 8.

Moreover, although Petitioner's arguments may be based on fundamental fairness, I do not have the authority to equitably split the difference or fashion a remedy based on HCFA's non-compliance with the 10-day requirement. More importantly, I do not have the authority to find the regulations ultra vires the Act, which is what I would have to do in order to grant Petitioner the relief it seeks.

As an essential and necessary step toward granting Petitioner the relief it is seeking, I would first have to ignore the explicit directive of the regulations, which states that, absent evidence of correction of the deficiencies, Petitioner can be certified only upon HCFA's receipt of an acceptable plan of correction. 42 C.F.R. § 489.13(b)(2). My authority to hear and decide

this case simply does not give me the leeway to ignore regulatory provisions.

Moreover, the provision that, according to Petitioner, mandates to HCFA to provide the facility with HCFA 2567 within 10 calendar days is phrased in terms of the agency's policy. 42 C.F.R. § 488.110(j). The provision contains the words "in accordance with your agency's policy." Neither 42 C.F.R. § 488.110(j) nor any other provision in this section contains any penalty provision for the agency's failure to comply with this 10-day requirement. Additionally, as I stated in section IV. of this decision, Subpart C of 42 C.F.R. Part 488, of which 42 C.F.R. § 488.110(j) is a subsection, has been rendered inoperative by the nursing home reform provisions of OBRA '87. As I have already noted, not only does the legal underpinning for Subpart C no longer exist, but Subpart C is inconsistent with the OBRA '87 provisions and, indeed, has been replaced by new survey protocols implemented by HCFA to carry out the congressional mandate of OBRA '87.

These factors, coupled with the mandates contained at 42 C.F.R. § 489.13, favor an interpretation of the alleged 10-day "requirement" as a goal which HCFA should strive to meet in all cases, but not as something which should either invalidate the survey or mandate that HCFA grant the SNF an earlier certification date than it was given, in cases where this goal is not met. In short, there is no provision in 42 C.F.R. § 489.13 to respond to situations where HCFA delays transmittal of the form 2567 to a SNF.

Petitioner would have me act in such a way as to void a regulation that is still in effect in favor of a provision that is contained in a subpart which has been rendered inoperative by law and which, by its very language, is merely a guideline. I am unable to do so, and accordingly, find that the 10-day "requirement" contained in 42 C.F.R. § 488.110(j) is not controlling here. To find otherwise would be contrary to the regulations and would also be outside of my delegated authority.

IX. Issue:

> Whether the surveyors' use of a case-mix stratified sample was in accordance with the law.

Petitioner argues that the surveyors were required to use the selection methodology described in 42 C.F.R. § 488.110(d) in selecting the resident sample to be

reviewed. P. Br. at 10. Petitioner contends that the surveyors did not select the residents in a random manner nor did they comply with the other requirements of this regulation. Id. at 8, 10-11.[26]

HCFA argues that the Act, as amended by OBRA '87, requires surveyors to use a "case-mix stratified sample" of residents. 42 U.S.C. §§ 1395i-3(g)(2)(A)(ii) and 1396r(g)(2)(A)(ii). HCFA Rep. Br. at 34. HCFA contends that, as a result of implementation of the OBRA '87 requirements, this sampling methodology superseded the random sampling approach described in Subpart C and is thus the correct one to be used. Id.

The OBRA '87 requirement concerning resident sampling, which is codified at 42 U.S.C. §§ 1395i-3(g)(2)(A)(ii) and 1396r(g)(2)(A)(ii), states, "Each standard survey shall include, for a case-mix stratified sample of residents . . . ." (emphasis added). The term "case-mix stratified sample" is not defined. However, I have examined SOM 250 and found that it contains detailed instructions and guidance to enable surveyors to carry out "case-mix stratified sampling". HCFA Ex. 13 at P-9 - P-12. The SOM 250, in a section titled "Task 4 - Resident Sampling", states: "The general objective is to select a case mix stratified sample of residents for the Standard Survey to conduct Individual Resident Rights, Quality of Care, Environmental Quality and Dining Assessments." HCFA Ex. 13 at P-9. The SOM 250, under a subheading titled "Case-mix Categories", lists four case-mix categories, and gives a description of the type of resident who would fall in each category. Id. The four categories are the following: case-mix group A -- "Light Care" residents; case-mix group B -- "Heavy Care" residents; case-mix group C -- "Non-interviewable light care"; and case-mix group D -- "Non-interviewable heavy care". The SOM 250 gives surveyors guidance in how to select the resident sample and lists various factors to be considered in the selection process, such as residents with physical restraints, special resident care needs, residents with complex or multifaceted problems requiring

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[26] Petitioner appeared also to make a contradictory argument that the OBRA '87 requirement that each survey include a "case-mix stratified sample of residents" does not change any requirement of Subpart C. P. Resp. Br. at 3. It is noteworthy that, with this particular contention, Petitioner appears to concede that the proper sampling methodology is case-mix stratified sampling, which was what was employed by the surveyors in this case.

interdisciplinary interventions, and residents with psychosocial, interactive, and/or behavioral dysfunction. Id. at P-10. To determine the minimum sample size, SOM 250 refers the surveyors to a table. HCFA Ex. 13 at P-9, P-11.

As I stated earlier, 42 C.F.R. § 488.110(d) ("Task 2 -- Resident Sample -- Selection Methodology") refers to a random sample. Specifically, this subsection states:

> This methodology is aimed at formulating a sample that reflects the actual distribution of care needs/treatments in the facility population. Primarily performed on a random basis, it also ensures representation in the sample of certain care needs and treatments that are assessed during the survey. . . . After determining the appropriate sample size, select residents for the sample in a random manner. (emphasis added).

This section on resident sampling ends with the following statement: "Always keep in mind that neither the random selection approach nor the review of residents within the specified care categories precludes investigation of other resident care situations that you believe might pose a serious threat to a resident's health or safety. Add to the sample, as appropriate." 42 C.F.R. § 488.110(d).

As I previously stated, Subpart C, which describes random sampling, does not conform to the case-mix stratified sampling requirement of OBRA '87 (and codified at 42 U.S.C. §§ 1395i-3(g)(2)(A)(ii) and 1396r(g)(2)(A)(ii)). I find that the implementation of OBRA '87 ushered in a new selection methodology and resulted in the demise of the approach provided for in 42 C.F.R. § 488.110(d). The appropriate and correct methodology to be used, since the enactment of OBRA '87, is the case-mix sampling approach, which is elaborated upon in SOM 250.

Congress, by expressly referring to case-mix stratified sampling in OBRA '87, intended that this methodology be used by surveyors once OBRA '87 became effective. In the legislative history of OBRA, the congressional committee states, "The surveyors should be allowed to spend as much time as they deem necessary to properly survey a statistically significant case-mix stratified sample of residents to determine compliance with the requirements contained in this bill." H.R. Rep. No. 391, 100th Cong., 1st Sess., pt. 2, at 939 (1987).

Based on the testimony of HCFA's witnesses, there appears to be no dispute that the surveyors in this case followed the instructions contained in SOM 250 in determining the resident sample and, thus, used a case-mix stratified resident sample. Nelson Ford, a health facilities evaluator supervisor employed by the DHS, testified that the surveyors followed the resident sample selection table in SOM 250. Tr. 1648-1650. When asked how to proceed when a provision in SOM 250 conflicts with the applicable regulation, he testified that "[they] follow the SOM 250." Tr. 1662. Mr. Ford stated that there did exist "a rule that tells you how to sample or the number in which -- of those patients falling within those categories", and that this instruction is set forth in SOM 250. Tr. 1670.

Another witness, Ruth Patience, who is a HCFA survey and certification review specialist, testified that SOM 250 gives instructions on the subject of sampling and that the sampling methodology described beginning on page P-9 of SOM 250 "is the methodology that we expect the state agency surveyors to use when choosing their resident sample". Tr. 2450, 2456. Ms. Patience stated that this methodology was in effect in December 1993. Tr. 2456.

I find that the surveyors' use of a case-mix stratified sample was in accordance with the law. The surveyors' adherence to the sampling instructions and guidance contained in SOM 250, which amplified the case-mix sampling methodology required by the Act, was neither improper nor irregular. Their course of conduct did not violate any rights of Petitioner.

X. Issue:

> Whether any of the following alleged deficiencies as set forth in the HCFA 2567 were proven.

The SOM 250 defines deficiency for the purposes of determining whether Petitioner was in compliance with the standards for participation as a Medicare provider. Petitioner contends that the definition of what constitutes a deficiency, i.e., what is the threshold for determining whether a deficiency exists, differs depending upon whether 42 C.F.R. § 488.110 or SOM 250 is controlling. I have determined that the provisions of SOM 250 are the applicable criteria to follow in determining whether a deficiency has been established. In accordance with that finding, it will be useful to review such guidelines before I analyze each of the

deficiencies cited by the surveyors in the HCFA 2567 pertaining to Petitioner.

The SOM 250 contains the following definition:

> . . . D. Criteria.--To determine if a level B deficiency exists, use the following definitions:
>
> > o A "deficiency" is noncompliance with a regulatory requirement. A deficiency may be cited if there are situations identified during the course of a survey of sufficient severity and/or frequency that indicate an individual requirement is not met.
> >
> > o "Frequency" means the incidence or extent of the occurrence of an identified situation in the facility. The situation can affect a single resident or several residents.
> >
> > o "Severity" means the seriousness of the identified situation (e.g., the degree to which the problem compromises the resident's health and safety, or fails to achieve the highest practicable level of physical, mental, and psychosocial well-being).
> >
> > For all requirements, the threshold at which the frequency or severity of occurrences amounts to a deficiency varies from situation to situation. One occurrence directly related to a life-threatening or fatal outcome or high potential for such an outcome may be cited as a deficiency including a determination of immediate and serious threat.

HCFA Ex. 13 at P-29.

The SOM 250 provides additional guidance as follows:

> The following three sections contain guidance on using the information gained concerning Environmental Quality, Dining, Quality of Care Assessment, and Residents Rights Assessment.

E. Decisions Concerning Environmental Quality and Dining.-- When making decisions regarding compliance with those requirements reviewed during the EQA and dining observation, use the following guidelines:

o Review all worksheets and documentation or "B" and "C" ratings. Consider the actual circumstances, i.e., your observations and interview information, that caused each "B" and "C" rating.

o Make your compliance decisions based on the frequency or severity of the combination of ratings for each tag number. For example, for a specific tag, there may be 15 observations, with 11 "A" ratings, 3 "B" ratings and 1 "C" rating. Do not determine that a deficiency exists solely because there was 1 "C" rating or four negative ratings. Rather, make your determination based on the documented circumstances that represent the frequency or severity necessary to substantiate non-compliance.

F. Decisions Concerning Quality of Care Assessment.--Again consider your observations in the context of frequency and severity. In determining the severity of a situation, consider negative resident outcomes, i.e., the impact of the facility's deficient practice on the resident.

For all sampled residents, a negative resident outcome which you determine was avoidable, i.e., due to the facility's actions or lack of action, and not due to the resident's clinical condition, or exercise of his or her rights, provides strong evidence of noncompliance. Negative outcomes related to quality of care generally fall into three categories:

o Physical, mental or psychosocial deterioration (e.g., development of, or worsening of, a pressure sore, insertion of an indwelling catheter when the resident was admitted to the facility without one, loss of dignity lying in a urine saturated bed for a prolonged period, social isolation caused when staff fail to assist the resident to participate in scheduled activities).

o Lack of reaching the highest practicable level of physical, mental or psychosocial well-being. No deterioration occurred, but the facility failed to provide necessary care for resident improvement. For example:

- The facility identified the resident's desire to reach a higher level of ability, e.g., improvement in ambulation, and care was planned accordingly. However, the facility failed to implement, or failed to consistently implement, the plan of care, and the resident failed to improve, i.e., did not reach his/her highest practicable well-being;

- The facility identified a problem/need in the comprehensive assessment, e.g., the resident was withdrawn/depressed, but did not care plan for it or prioritize it to address it at a later time. The resident received no care or treatment to address the problem/need and did not improve, i.e., remained withdrawn/depressed. Therefore, the resident was not given the opportunity to reach his/her highest practicable well-being; or

- The facility failed to identify the resident's need/problem/ability to improve, e.g., the ability to eat independently if given assistive devices, and therefore, did not care plan. As a result, the resident failed to reach his/her highest practicable well-being, i.e., eat independently.

o A strong potential for harm. This may be identified when an observed facility practice is so divergent from accepted principles of practice that a future negative outcome or harm is probable. For example, nurse aides in a facility often do not wash their hands between caring for residents, including those times that they change a bed soiled with feces. Although there has been no evidence of a high

> facility infection rate, or of spread of infection from one resident to another, if a resident contracts an infection or becomes colonized with a highly contagious bacteria, there is a high potential for a major outbreak of nosocomial infection.

HCFA Ex. 13 at P-29 - P-30.

As shown above, SOM 250 directs the surveyor to analyze the frequency and severity of noncompliance with regulatory requirements and to make determinations as to whether the facility is in compliance with an individual requirement by assessing the frequency or severity of the alleged violation.

Specifically, SOM 250 directs the surveyor to take into account negative resident outcomes. It provides flexibility in guiding surveyors in what constitutes a deficiency and acknowledges that a deficiency is a very situation specific occurrence. In short, a deficiency can occur when there is evidence of noncompliance with a regulatory requirement in 42 C.F.R. § 483, and the noncompliance has a serious negative impact on the resident or residents, such as harm or a strong potential for harm. Examples of negative outcomes include situations where the resident's health and safety has been compromised, or where the facility failed to enable the resident to achieve his or her highest practicable level of physical, mental or psychosocial well-being.

A. Issue: Whether HCFA provided adequate notice to Petitioner of the underlying facts of the deficiencies cited in the HCFA 2567.

At various times throughout the hearing and in its briefs, Petitioner contended that HCFA had taken a "moving target/shell game" approach in presenting its case. P. Br. at 44-45, 79; see P. Resp. Br. at 21. For example, with respect to F 272, Petitioner complained of the "vague, uncertain and inappropriate nature [sic] manner in which this deficiency was set forth." P. Br. at 44-45. Petitioner stated further:

> It is not possible to defend against claims of which petitioner had no notice and when such claims are disclosed, then become subject to repeated changes. Petitioner repeatly [sic] referred to this approach as a "shell game." The Administrative Law Judge repeatedly rejected the accusation. Whatever the label, it is not fair to require petitioner to have to

> guess at what it is supposed to be defending against. This, by itself, disqualifies this deficiency as part of any basis for failure to certify.

P. Br. at 45.

I do not agree with Petitioner's characterization that HCFA took a "moving target/shell game" approach. The HCFA 2567 sets forth the alleged deficiencies which were identified by the surveyors during the survey. The surveyors testified concerning the underlying facts supporting the deficiencies cited in the HCFA 2567. In instances where a surveyor's testimony with respect to a particular deficiency was unclear or confusing, I ascribed as much weight to that testimony as was appropriate. I did not consider allegations in the HCFA 2567 against which Petitioner could not adequately defend due to a lack of specificity or notice. Further, in instances where HCFA did not prove a certain allegation, I have so indicated.

B. Set out below, in relevant part, is the statement in the HCFA 2567 concerning the alleged deficiency identified as F 221 (HCFA Ex. 2 at 1-2):

> 42 C.F.R. 483.13 (a) (a) Restraints. The resident has the right to be free from any physical or chemical restraints imposed for purposes of discipline or convenience, and not required to treat the resident's medical symptoms [.]
>
> *****
>
> Based on record review and observation[,] the facility failed to provide each resident the right to be free from physical restraint.
>
> Findings include:
>
> Resident 16 was assessed by licensed staff as wandering and attempting to climb out of bed. A vest restraint was ordered 5/13/93, and continues to be used, restricting her to a wheelchair during the day. Her ability to ambulate has declined and the facility has failed to adequately assess use of less restrictive restraints, or the possibility of discontinuation of the restraint, if staff was more focused toward maintaining or improving her independence in ambulation.

Resident 16 was admitted to Petitioner's facility on May 1, 1993. P. Ex. 1 at 1. A physician's order dated May 12, 1993, mandates the use of a vest restraint on Resident 16 at all times for safety and proper body alignment. P. Ex. 1 at 3. The 90-day and 180-day assessments show that the order for Resident 16 to be restrained in a vest restraint was in place through the time HCFA completed its survey of Petitioner on December 23, 1993, over seven months after the physician's initial order. P. Ex. 1 at 1-4; P. Ex. 27 at 1-7.[27]

At the hearing, Ms. Cox testified that she saw Resident 16 on more than one occasion during the survey and that, each time, the resident was confined in a vest. Tr. 1003-1004, 1023. Ms. Cox testified that she found no evidence that Resident 16 had ever been considered for a less restrictive restraint other than a vest because there was nothing in the resident's record to indicate that Resident 16 was ever assessed at any time to determine if some lesser restraint could be used, or if any restraint were necessary. Tr. 2463-2464.

The rehabilitation screen supports HCFA's position because the screen has a specific line for stating the reasons for using any physical restraint. P. Ex. 1 at 4. The line on Resident 16's rehabilitation screen is blank. P. Ex. 1 at 4. According to HCFA, reevaluation of the use of a restraint is critical to the health and well-being of patients because "[a]nytime a person is immobilized it's going to decrease their strength and their ability to walk and use their muscles . . . they're going to get weaker." Tr. 1020.

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[27] Although factual allegations regarding whether Resident 16 was properly ambulated and whether her ability to ambulate declined as a result of Petitioner placing her in a vest restraint appear also on the HCFA 2567 with respect to F 221, they are not relevant to the issue of whether Petitioner adequately assessed Resident 16 for a less restrictive restraint as required by 42 C.F.R. § 483.13(a) and F 221. They are relevant in assessing whether a negative or potentially negative outcome resulted from this deficiency. I address the factual allegations concerning resident 16's ambulation in the context of my discussion of F 309 (section X.L. of this decision).

In support of HCFA's contention that the resident should be reassessed periodically to determine whether a less restrictive alternative would be feasible, Ms. Patience testified that it is important that

> the restraint not be used for discipline or convenience. We survey for that by looking for whether or not less restrictive measures were used before the restraint was applied and whether or not there was an assessment . . . Less restrictive means that the facility has tried other methods . . . .

Tr. 2464.

At issue in this deficiency is whether Petitioner violated the requirement at 42 C.F.R. §483.13(a) (F 221) by failing to adequately assess Resident 16 for the use of less restrictive restraints. SOM 250 provides specific guidance for SNFs regarding the need for documenting that the facility has considered less restrictive alternatives to restraints:

> When coupled with appropriate exercise, therapeutic interventions such as pillows, pads, or removable lap trays, are often effective in achieving proper body position, balance and alignment, and preventing contractures without use of restraints. Attention to individual, mental, physical and psychosocial needs, meaningful activity, environmental changes, and aggressive nursing rehabilitation or restorative programs are other examples of less restrictive methods of meeting resident needs. If the restraint is used to enable the resident to attain or maintain his or her highest practicable level of functioning, a facility must have evidence of consultation with appropriate health professionals, such as occupational or physical therapists. This consultation should consider the use of less restrictive therapeutic intervention prior to using restraints. . .
>
> The use of therapeutic interventions must be justified through the care planning process and demonstrate that these interventions promote the care and services necessary for the resident to attain or maintain the highest practicable well-being. . . .
>
> The decision to apply physical restraints should be based on the assessment of each resident's capabilities, an evaluation of less restrictive alternatives and the ruling out of their use. The

> plan of care should also contain a schedule or plan of rehabilitative training to enable the progressive removal of restraints or the progressive use of less restrictive means, as appropriate. This systematic approach assures that restraints would not be applied for purposes of discipline or convenience and only to enable treatment of medical symptoms.

HCFA Ex. 13 at P-76 - P-77.

Ms. Patience stated that any resident who was being subjected to a vest restraint should have, in his or her medical record, evidence showing that less restrictive restraints had been considered. Tr. 2485-2486. Ms. Patience testified further that such evidence might be documented in the therapy notes, nurses' notes, physicians' notes, or social services notes. Tr. 2486. According to Ms. Patience, in light of SOM 250, such evidence would need to demonstrate

> an assessment of the resident's mobility, cognition, vision, and any other less restrictive measures that were used; how long they were used for; and what the results of the use of those less restrictive measures were.

Tr. 2487.

I find credible the testimony of Ms. Patience which indicates that there should be documentation in the record to reflect that less restrictive alternatives to a vest restraint were attempted or at the very least, considered for this resident. Tr. 2486-2487. Her testimony is supported by the plain meaning of the regulation and the guidance contained in SOM 250, as noted above.

However, Petitioner attempts to attack HCFA's finding of deficiency by contending that there is no evidence that resident 16 spent all of her time in a vest restraint in a wheelchair, since the surveyor was not present at all times. Additionally, Petitioner contends that medical records establish that Resident 16 was not constantly restrained in a vest restraint. P. Br. at 24-25. These contentions are not germane to the issue at hand, because the issue with regard to this deficiency is whether Petitioner ever considered resident 16 for less restrictive alternatives to the vest restraint, not whether resident 16 was under restraint at all times.

Petitioner contends also that the evidence does not lend support to HCFA's finding that Petitioner was deficient with regard to F 221 because resident 16's chart reflects that: 1) a physician ordered the use of the vest restraint for Resident 16 and repeated the order every 30 days; 2) the staff recommended to the physician that resident 16 wear a safety belt at all times; 3) the interdisciplinary team agreed with the use of the vest restraint at all times; and 4) the continued use of the vest restraint was considered on a quarterly basis. P. Br. at 25.

This dispute, simply stated, is whether Petitioner is required to document that a less restrictive restraint was considered for resident 16. Petitioner argues that there exists no regulation or other requirement to compel Petitioner to document why a lesser or different restraint should not be used when a physician has explicitly ordered a specific type of restraint for a resident. P. Br. at 25.

Petitioner contends that, to the extent it is required to examine why resident 16 continued to need a vest restraint, such examination was undertaken by the interdisciplinary team. P. Br. at 29. Moreover, Petitioner contends that neither SOM 250 nor the regulation can be read to require the substance of the subjects discussed by the interdisciplinary team to be set out in writing. According to Petitioner, the fact that the interdisciplinary team approved the use of the restraint is sufficient to satisfy the regulatory requirements. P. Br. at 31. Distilled to its essence, Petitioner's argument on this issue is that the repetition of a physician's order and the repeated approval of the interdisciplinary team suffice.

Petitioner's arguments on this issue are not supported by the record because the record contains nothing which would indicate that the interdisciplinary team ever considered less restrictive alternatives. While there is a repeated note from the interdisciplinary team to use a vest restraint on resident 16, there is nothing in the record to establish that this was anything more than an approval of what had been done before. P. Ex. 1; P. Ex. 27 at 6, 22. Even assuming arguendo that it was medically appropriate to treat resident 16 by placing her in a vest restraint at all times, the issue remains whether Petitioner satisfies the statutory and regulatory mandate that the resident has a right to be free from restraint. The statutory and regulatory framework, the language of the regulation, and the guidance contained in SOM 250 all support that it is incumbent upon Petitioner

to document that the restraint was necessary for the patient's medical or safety needs. These same factors further mandate that it is also incumbent upon Petitioner to show that less restrictive alternatives were attempted or at least considered.

Without such information, Petitioner did not prove that it ever considered less restrictive alternatives for resident 16 because the evidence HCFA has offered is persuasive, credible, and unrebutted. I find that Petitioner's reliance on the mere repetition of an order that resident 16 be restrained is insufficient, given the requirements of OBRA '87 and SOM 250.

I find that HCFA has proven that Petitioner was in violation of the regulatory requirement set forth at 42 C.F.R. § 483.13(a) with respect to resident 16. The regulations require more from Petitioner than merely a repeated order that the resident be restrained. While there are notations that indicate that resident 16 was initially placed in a restraint for reasons of safety and proper body alignment, there is nothing in the record from which I can conclude that Petitioner ever considered the resident for a less restrictive restraint. P. Ex. 1 at 2, 22; P. Ex. 27.

Ensuring that residents are restrained only to the extent absolutely necessary for their medical well-being or safety was of paramount concern to the authors of the law and the regulations. H.R. Rep. No. 391, 100th Cong., 1st Sess., part 1, at 932 (1987). They expressed a legitimate concern that restraints were being used merely for the convenience of the facility and in ways that were detrimental to the residents. The regulations mirror this concern.

It is this interest and concern of Congress that places a duty on Petitioner to justify the use of a particular type of restraint on resident 16 and to demonstrate that a less restrictive alternative was considered and found inappropriate in light of this resident's condition. It was incumbent upon Petitioner to document that its decision to continually restrain resident 16 in a vest restraint was not a mere rubber stamp, but a decision that actually considered less restrictive alternatives. The record in this case fails to establish not only that less restrictive restraints were used on resident 16, but that less restrictive restraints were even considered for resident 16.

Moreover, based on the evidence of record and applying the SOM 250 guidelines, I conclude that, without adequate documentation that other less restrictive alternatives were not available, placement of resident 16 in a vest restraint could result in a potential negative outcome. Accordingly, I find that the record more than adequately supports that Petitioner was in violation of the regulatory requirement set forth at 42 C.F.R. § 483.13 with respect to resident 16.

C. Set out below is the statement in the HCFA 2567 concerning the alleged deficiency identified as F 262 (HCFA Ex. 2 at 2-3):

> 42 C.F.R. 483.15(h)(3) (3) Clean bed and bath linens that are in good condition;
>
> *****
>
> Based upon observation of residents rooms it was determined that furniture was in need of cleaning.
>
> Findings include:
>
> During tour of the facility, interviews, and room visits, it was noted that overbed tables and bedside cabinet tops had food and liquids [sic] rings indicating a lack of daily cleaning of the room furniture.

At the hearing, Ms. Shekell testified that an inadvertent typographical error occurred in the HCFA 2567 when the she apparently mistyped "F 262" on her lap-top computer instead of "F 261." The computer is programmed by HCFA to automatically display the applicable regulatory citation that corresponds to the "F" number entered.

Ms. Shekell testified that "262 addresses primarily linens, whereas 261 is sanitary cleanliness." Tr. 116. The corresponding regulatory citation for "F 261", according to Ms. Shekell and the SOM 250, is 42 C.F.R. § 483.15(h)(2). Tr. 121; HCFA Ex. 13 at P-96 - P-97.

A reading of the pertinent regulations suggests that the correct citation could have been either 42 C.F.R. § 483.15(h)(1), which states: "A safe, clean, comfortable, and homelike environment, allowing the resident to use his or her personal belongings to the extent possible" or subsection (h)(2), which states: "Housekeeping and maintenance services necessary to maintain a sanitary, orderly, and comfortable interior." In my opinion,

subsection (h)(2) is the most appropriate subsection for the deficiency cited.

Petitioner argues that, based on HCFA's failure to cite the correct regulatory citation, it was not given adequate and proper notice of the deficiency to enable it to prepare a defense. It further argues that, due to such failure, HCFA should be estopped from proving the existence of this deficiency. Moreover, Petitioner contends that the facts cited do not constitute a violation of the regulation, and there is a failure of proof of violation. Tr. 116-120; P. Br. at 33-35.

In response, HCFA states that the deficiency was correctly cited in the HCFA 2567 and Petitioner has had access to that document for over a year prior to the hearing. In addition, HCFA asserts that Petitioner addressed the cited deficiency when it submitted its plan of correction. Tr. 118; HCFA Br. at 22.

When this issue was first raised at the hearing, I expressed my concern that Petitioner's due process rights be protected. I allowed testimony on the cited deficiency with the admonition that I would rule on Petitioner's arguments after reading the parties' posthearing briefs. After fully considering the notice issue, I conclude after examining HCFA 2567 that Petitioner received adequate notice of the deficiency even considering the incorrect reference to the regulations. The applicable regulations are a matter of public record and were available to Petitioner at the time of the survey. To allow Petitioner to adequately defend against this deficiency, HCFA 2567 needed to set out the facts the surveyor found that supported her determination that a deficiency was present. Petitioner was presented with those facts. The cited regulation clearly did not apply to the deficiency cited, and Petitioner could easily have ascertained knowledge of the correct regulation or regulations by making reference to them. There is no evidence that Petitioner was incapable of responding to this deficiency in its plan of correction or at the hearing. Therefore, I conclude that Petitioner's due process rights were not impaired by HCFA's inadvertent reference to the wrong regulation when citing this deficiency in the HCFA 2567.

Ms. Shekell testified that her observation of the cited deficiency was based on her daily tour of Petitioner while conducting the survey:

> I noted that particularly over-bed tables were not well cleaned; they had rings. And I would never cite if there was just one or two that a patient had just been fed or if fluid had just been s[e]t down and rings from something like that just on a few tables. This was pervasive throughout room after room.

Tr. 122.

Petitioner objected to this testimony because it allegedly went beyond the parameters of the cited deficiency when Ms. Shekell testified that the deficiency was "pervasive" throughout the facility. Petitioner's counsel argued that HCFA should be limited to the allegations specifically written in the HCFA 2567. Tr. 123-126. As to the observations of Ms. Shekell, Petitioner responds that "[t]here was no testimony as to how many days she was in the facility, how often she observed the tables, any investigation as to how long the liquid rings on the over[-]bed tables had been there, any facts to indicate that they had been there an inordinate length of time to indicate a lack of cleaning or any facts other than . . . self-serving speculation . . . ." P. Br. at 34. In contrast, Petitioner pointed out that Ms. Downing testified that the facility was cleaned daily and over-bed tables were cleaned after each meal if the resident ate in bed and spilled his or her meal. Petitioner argued further support for Ms. Downing's testimony could be found in Petitioner's Housekeeping Department policies. P. Br. at 34; Tr. 1750-1751; P. Ex. 2 at 1.

I find unpersuasive Petitioner's argument that Ms. Shekell's testimony went beyond the deficiency cited. With respect to this deficiency, the HCFA 2567 indicates that "[b]ased upon observation of residents rooms it was determined that furniture was in need of cleaning." HCFA Ex. 2 at 2. Moreover, the surveyor noted the unclean surroundings "[d]uring tour of the facility, interviews, and room visits." Id. Thus, the HCFA 2567 on its face indicates that the observation was not based on an isolated observation but on a pattern of sightings that occurred during Ms. Shekell's inspection of the facility. This is consistent with her testimony. Petitioner's counsel was advised at the hearing that he had the opportunity through cross examination to test the

validity of Ms. Shekell's observations. This he chose not to do.

Despite the testimony of Ms. Downing and reference to housekeeping policies requiring daily cleaning of resident rooms, including over-bed tables, Petitioner offered no witness who was present during the survey who specifically contradicted the observations of Ms. Shekell. The only evidence offered was Ms. Downing's testimony and the housekeeping policy. Such evidence is not reliable or probative as to whether Ms. Shekell's observations were accurate. Ms. Downing was not employed by Petitioner at the time of the survey, nor was she present during the survey. Nor is there any testimony from anyone who was employed at the facility at the time of the survey that the housekeeping polices were in fact followed during the period of the survey. If it exists, such evidence would have been available to Petitioner. Its absence suggests that Petitioner cannot directly contradict the findings of the State surveyor.

Therefore, when I review the record as a whole, the testimony of Ms. Shekell concerning her findings supporting this deficiency are amply supported and establish the existence of the cited deficiency. Having concluded that Petitioner has failed to maintain a sanitary, orderly, and comfortable interior for its residents, it follows that such non-compliance with the regulatory requirements could potentially compromise such residents' health and safety or at least compromise their mental or psychosocial well-being. Residents have a right to reside in a clean, safe and healthy environment. Petitioner's conduct is in variance to this right imposed by OBRA '87.

D. Set out below is the statement in the HCFA 2567 concerning the alleged deficiency identified as F 272 (HCFA Ex. 2 at 3-4):

> 42 C.F.R. 483.20(b)(1) (1) The facility must make a comprehensive assessment of a resident's needs, which --
> (i) Is based on a uniform data set specified by the Secretary and uses an instrument that is specified by the State and approved by the Secretary; and (ii) Describes the resident's capability to perform daily life functions and significant impairments in functional capacity.

> (2) The comprehensive assessment must include at least the following information:
>
> *****
>
> Based upon observation, interview and medical record review[,] it was determined that comprehensive assessments contained inaccuracies of residents functional ability.
>
> Findings include;
>
> Inaccuracies were noted on 3 [o]f 5 medical records reviewed of residents capacity to perform daily life functions, i.e.; toileting, incontinence, activities of daily living, transfer, locomotion, personal hygiene, and psycho-social functioning. Many of the activities of daily living were contradictive and did not reflect the residents admission or current status.
>
> For example, resident 12 was assessed to require supervision with transfers, ambulate and toilet independently but required assistance with personal hygiene. Furthermore, the psycho-social assessment indicated there were no problems, however the resident is [sic] in fact been seeing the psychologist weekly for several months and receives Elavil 50 mg. on a daily basis for depression.[28]

Petitioner argues that the only resident who was identified as being the subject of the surveyor's allegations was resident 12. P. Br. at 36, 38. Petitioner contends that "[t]here was a complete failure of proof concerning the allegations of inaccuracies (with respect to resident 12) regarding transfers, ambulation, and psychosocial assessment." Id. at 40. Petitioner contends that Ms. Shekell's testimony was inconsistent and that resident 12's MDS [minimum data set] "complied with the regulations." Id. at 44. Petitioner states also, among other things, that the testimony of Ms. Patience suggests that F 272 was incorrectly cited, and

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[28] At the hearing, Ms. Shekell testified that she was the surveyor who had written the specific allegations under this regulation. Tr. 127.

that the proper citation should have been F 287. P. Br. at 47, 118.[29]

As a preliminary matter, I must first address the issue of which residents were identified to Petitioner as being the basis of the allegations. Although the HCFA 2567 mentions that "3 of 5 medical records" were reviewed, I find that this did not adequately identify the other residents in addition to resident 12 who were the subject of Ms. Shekell's findings such that Petitioner could have a meaningful opportunity to respond to the allegations. At the hearing, when asked if she recalled identifying any specific patient records to Petitioner during the survey or exit conference, Ms. Shekell testified, ". . . we don't really discuss the specific patients during the exit conference. However, during the survey process we talk to the facility staff regarding individual patients in which we find inconsistencies or problems." Tr. 154. Ms. Shekell stated that she spoke to Petitioner's staff about resident 12, but she could not recall whether she spoke to them about the other patient records she alluded to in her findings on the HCFA 2567. Tr. 155.

Thus, despite the fact that Ms. Shekell referred to other patient records in HCFA 2567, the record of resident 12 is the only resident record against which Petitioner could adequately prepare a defense with respect to F 272. With respect to the other residents referred to in HCFA 2567, HCFA was unable to specifically identify them or the records alleged to be deficient. HCFA did not prove that Petitioner's treatment of other residents, in addition to resident 12, violated 42 C.F.R. § 483.20(b)(1). Accordingly, I am deciding whether HCFA has proven its claim that Petitioner was in violation of section 483.20 (b)(1) (F 272) based only on my consideration of the medical record of resident 12.[30]

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[29] In its discussion of F 272, Petitioner quotes statements made by myself and by HCFA's counsel (Tr. 168, 164) at the hearing. P. Br. at 37-39. Petitioner apparently means to illustrate that my statements and those of HCFA's counsel were made in conjunction with the testimony taken concerning F 272. However, an examination of the transcript indicates that these statements were made in conjunction with the testimony concerning F 289, not F 272.

[30] I do not hold that HCFA must identify in its 2567 each resident whose records were reviewed in connection with a cited deficiency. However, the

(continued...)

Furthermore, Ms. Shekell testified on cross-examination that the sentence "For example, resident 12 was assessed to require supervision with transfers . . . personal hygiene" which she wrote in the HCFA 2567 is not a deficiency, but merely "a statement of fact." Tr. 323. Ms. Shekell stated that the actual deficiency she is alleging is described in the following sentence: "Furthermore, the psycho-social assessment indicated there were no problems, . . . on a daily basis for depression." Tr. 324.[31] Ms. Shekell agreed with Petitioner's characterization that her basis for finding fault with resident 12's record "is that one part of it seems to say that the patient didn't have any psychosocial problems when in fact [she] believe[d] other parts of the record indicate to the contrary." Tr. 324.

HCFA argues that "[w]ith respect to resident 12, her mood and behavior patterns (i.e. her mental and psychosocial status) and her recurrent thoughts of death are not accurately described on the underlying resident assessment instrument approved by the Secretary (the MDS and its quarterly reviews)." HCFA Resp. Br. at 14. HCFA claims that resident 12's MDS is "inconsistent, both internally and with the documentation contained in other parts of the resident's chart." HCFA Resp. Br. at 12. Simply stated, according to Ms. Patience, ". . . the minimum data set didn't match what was going on with the resident." Tr. 2681.

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[30] (...continued)
deficiency must provide sufficient information such that Petitioner, exercising reasonable diligence, could determine to whom the deficiency relates. Here the deficiency failed to supply such information. Such failure could be overcome where the evidence shows that Petitioner received identifying information either in the course of the survey process or through documentary evidence submitted in preparation for the hearing. Neither of these circumstances occurred in this case with respect to this deficiency. Moreover, HCFA's principal witness on this deficiency could not offer any testimony or exhibits to support the allegations relating to the other residents cited in the deficiency.

[31] Ms. Patience testified that she did not see "a psychosocial assessment per se" in P. Ex. 3. She stated that she believed that the term "psycho-social assessment" used in the HCFA 2567 is a reference to section H of the MDS. Tr. 2685.

The MDS document is required to be completed for every resident within the first 14 days after admission (42 C.F.R. § 483.20 (b)(4)(i); Tr. 136), and addresses 18 areas, including delirium, cognitive loss/dementia, ADL [activities of daily living] functional/Rehabilitation potential, urinary incontinence and indwelling catheter, psychosocial well-being, mood state, behavior problems, falls, nutritional status, dehydration/fluid maintenance, pressure ulcers, and physical restraints.[32] The SOM 250 states: "The information required in § 483.20(b)(2)(i - xiii) is incorporated into the MDS, which forms the core of each State's approved RAI [Resident Assessment Instrument]." HCFA Ex. 13 at P-100. A facility assesses a resident in each area by filling in boxes on the MDS with either checks or numbers.[33] A new MDS must be initiated promptly after a resident experiences a significant change in his physical or mental condition. In no case can the MDS be done less than once every twelve months. 42 C.F.R. § 483.20(b)(4)(iv)-(v); Tr. 138.[34]

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[32] On the MDS document, below the title "Minimum Data Set," is the phrase "For Nursing Facility Resident Assessment and Care Screening (MDS)." P. Ex. 3 at 2.

[33] There is evidence that the terms "comprehensive assessment" and "MDS" are interchangeable. Ms. Shekell testified:

> The minimum data set is -- that's where they get the word comprehensive assessment because it goes through cognitive, communicative, vision, hearing, skin care, ability of the patient to take care of themself [sic], psychosocial well being, health conditions, their ability for activity levels, for functioning levels, nutritional levels, their potential for accidents, their skin problems, et cetera. In other words, it's kind of looking at the patient from head to toe.

Tr. 136.

Ms. Cox testified also that the MDS is the comprehensive assessment. Tr. 1275.

[34] Ms. Shekell testified that if a resident goes to the hospital or is out of the facility for a short period of time, the facility may still be able to refer

(continued...)

Depending on a particular response on the MDS, an "automatic trigger" or "potential trigger" may be indicated, and such triggers direct the staff to fill out the corresponding category on another document called the Resident Assessment Protocol Summary (RAPS).[35] The RAPS lists the identical 18 areas found on the MDS (i.e., delirium, cognitive loss/dementia, visual function, communication, ADL function/rehabilitation potential, etc.). The facility is instructed to show, for each RAP area triggered, whether it is proceeding with a care plan intervention by checking either "proceed" or "not proceed" next to the problem area that was triggered. The facility is also to show where the appropriate documentation (i.e., problems, complications, risk factors, reasons for deciding to proceed or not to proceed to care planning) can be found.

Resident 12's MDS was completed on July 30, 1993. P. Ex. 3 at 2. The relevant section of the MDS for purposes of this deficiency is Section H, which has the heading "Mood and Behavior Patterns". P. Ex. 3 at 3-4.[36] In

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[34] (...continued)
back to the last MDS instead of doing another MDS. Tr. at 671. However, if the resident's hospital admission altered the patient's status, or the reason that the resident was sent out of the facility was due to a change of condition, then the facility would have to complete a new MDS upon the resident's return to the facility. Tr. at 672.

[35] The SOM 250 states, "Additional assessment information is also gathered using triggered RAPS." HCFA Ex. 13 at P-100. Ms. Shekell testified that the "identified problems must be transferred to th[e] RAPS, and then this is the basis for forming a patient care plan." Tr. 140. Ms. Shekell testified further that the MDS and the RAPS have to correspond with each other and contain the same information. Id.

[36] The signatures section on the MDS indicates which staff members participated in its completion, the particular section(s) of the MDS each staff member completed, and the date of completion. P. Ex. 3 at 2.

Although there is a signature of the staff person who completed sections G & H of the MDS, the date of

(continued...)

subsection H.1 ("Sad or Anxious Mood"), Petitioner's staff has checked off Boxes "a" and "e" to indicate that the resident had exhibited "verbal expressions of distress" and "pervasive concern with health" during the last thirty days, i.e., June 30 - July 30, 1993.[37] P. Ex. 3 at 3. There were no checks in Boxes "b"- "tearfulness, emotional groaning, sighing, breathlessness"; "c"- "motor agitation such as pacing, handwringing or picking"; "d"- "failure to eat or take medications, withdrawal from self-care or leisure activities"; "f"- "recurrent thoughts of death and "g"- suicidal thoughts/actions". The absence of checks reflected these behaviors were not exhibited in the covered period. In subsection H.2 ("Mood Persistence"), Petitioner's staff filled in a "0" (i.e., zero) next to the phrase "Sad or anxious mood intrudes on daily life over last 7 days -- not easily altered, doesn't "cheer up". P. Ex. 3 at 3. The zero represents that resident 12 had not experienced any sad or anxious mood during the time frame of July 24-30, 1993. Also, in subsection H.6, Petitioner's staff indicated that the resident had not had a change in mood in the 90 days preceding. Id.

As discussed earlier, certain responses on the MDS will set off "triggers" which direct the staff to fill out the corresponding section on the RAPS. Then, based on the information contained in the MDS and the RAPS, Petitioner formulates an individualized care plan which will be responsive to the resident's problems and needs. see Tr. 2504.

Here, with respect to resident 12, the presence of "verbal expressions of distress" and "pervasive concern with health", as indicated on the MDS, constitute

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[36] (...continued)
completion of these sections is missing. P. Ex. 3 at 2.

Thus, I am using July 30, 1993 as the completion date because it is the latest completion date given and is also the date when the RN Assessment Coordinator signed the MDS.

[37] I construe this section as requiring the facility to check any of the eight specified indices of a sad or anxious mood that occurred on any day during the last 30 days where such behavior would significantly impact on the resident's care in the facility. Therefore, a single expression of a suicidal thought or action would require the facility to note such expression in the MDS.

"automatic triggers". I find that Petitioner filled out the RAPS for these two problem areas which were triggered (P. Ex. 3 at 6) and that the RAPS, with accompanying notes, are consistent with the July 1993 MDS. P. Ex. 3 at 6, 9.

Resident 12's record contains also a care plan entry dated September 1, 1993. Petitioner's staff wrote, under "psychosocial needs", the following: "Resident chooses not to leave her room except for dialysis 3x/wk & group psychotherapy 1x/wk." P. Ex. 3 at 24. The "measurable and time oriented objectives" stated that the "resident will receive socialization from staff, family or other residents QD x 3 months by 12/1/93." Id. The "approaches/actions" to be taken included encouraging family visits and participation, and group and individual psychotherapy. Id. These care plan entries appear to have been written in response to a Social Assessment completed on September 1, 1993, on which a social worker indicated that the resident was depressed due to illness and separation from family, and was motivated to progress. P. Ex. 3 at 21.

On September 13, 1993, a physician's order in resident 12's chart states that the resident "may attend psychological meeting Q Wednesday". Also, a physician's order dated September 14, 1993 states "psychology eval & tx as indicated by psychologist." P. Ex. 3 at 10-11.

On September 15, 1993, the resident underwent a diagnostic interview with a psychologist, and the psychological diagnostic interview report states that the resident had been referred due to "depressive Sx, difficult adjustment to losses, and isolation". P. Ex. 3 at 15. In giving the mental status exam results and the interview findings, the examining psychologist wrote that she "appears to be experiencing major depression today, speaking of being ready for death (suicide risk minimal)[.] No signs of delusions/hallucinations. Cooperative and desirous of pleasing examiner." Id. Although the form contains a depression scale, this was left blank. Id.

Based on this 9/15/93 psychological report, I find that the resident showed an indication of a potentially serious psychological problem. However, Petitioner did not conduct a new MDS at this time and left the July 1993 MDS in place, unchanged. In doing so, Petitioner thus inaccurately represented that the July 1993 MDS continued to reflect the current condition of resident 12 although it did not. As of September 15, 1993, based on the psychological report, the assessment of the resident's

mood and behavior patterns as stated in the July 1993 MDS was no longer accurate due to the resident's change in her psychosocial status. The fact that the resident was experiencing a level of depression which had not been noted previously, as described by the psychologist, constituted a significant change in her condition within the meaning of SOM 250.[38]

Ms. Patience testified:

> If the resident is exhibiting a change then there may be a new minimum data set indicated, and that needs to be done if the resident's got a significant change.

Tr. 2495.

When asked what type of mood change would necessitate a change in the assessment, Ms. Patience responded:

> If the resident's a little bit blue that might not indicate that there needs to be a whole new MDS. If the resident is depressed, definitely there needs to be a new MDS done. Because the depression can impact things like eating, mobility, whether or not the resident wants to interact with other residents; all of those can be affected by depression.

Tr. 2496.

Ms. Patience stated also that resident 12's treatment by a psychologist and the order for Elavil would constitute a significant change in her condition. Tr. 2501; see Tr. 2497. She expressed her opinion that, with respect to resident 12, she "would have expected a new minimum data set sometime in September." Tr. 2501; see Tr. 2674.

Petitioner should have completed a new MDS after resident 12's psychological interview to reflect the change in her psychosocial status. The completion of a new MDS would have resulted in boxes "g" and "d" under section H.1. being checked, indicating that the resident had "suicidal

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[38] According to SOM 250, an example of a "significant change" would be "deterioration in behavior or mood, to the point where daily problems arise or relationships have become problematic and staff conclude that these changes in the resident's psychosocial status are not likely to improve without staff intervention." HCFA Ex. 13 at P-104.

thoughts/actions," and exhibited "withdrawal from self-care or leisure activities," respectively. P. Ex. 3 at 3. These boxes had not been checked off on the July 1993 MDS. In addition, the presence of these symptoms are "automatic triggers", which would then have directed Petitioner to fill out the RAPS for these specific areas. This process did not occur.

The resident was provided weekly individual and/or group psychotherapy by a psychologist starting September 15, 1993 through December 22, 1993.[39] P. Ex. 3 at 16 - 19. The weekly entries suggest some improvement in her mental state over this period of time. Id. A physician order dated 10/12/93 in the resident's chart states "D/C Restoril; Elavil 50 mg. HS [hour of sleep] (insomnia)."[40] In her medication records, there is an entry dated October 12, 1993 that states "Monitor episodes of depression as evidenced by expressing wanting to die. Hs. (Elavil). P. Ex. 3 at 12. Despite her serious depression with suicidal ideation on September 15, 1993, her medication was not changed or monitoring initiated until October 12, 1993.[41] Almost 30 days elapsed from the time of the resident's 9/15/93 psychological

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[39] In the progress notes, the psychologist indicated that one of the resident's treatment goals was "stabilization of depressed mood." P. Ex. 3 at 16-19. For September 1993, the psychologist indicated that the resident had moderately progressed toward achieving this goal. In October 1993, the progress notes show that the resident's progress toward stabilizing her depressed mood was at about the same level as in September. Id. at 17. In November 1993, the progress notes indicate that resident 12 was continuing to make progress and was benefitting from group dynamics. Id. at 18. In December 1993, the notes state that she was concerned with family issues but her underlying mood was of "strength and optimism." Id. at 19.

[40] Elavil is an antidepressant. Tr. 142.

[41] There is a care plan dated September 1, 1993 for the resident's unwillingness to leave her room except for dialysis and group therapy. P. Ex. 3 at 24. The approaches/actions stated relate to encouraging increased socialization and initiating group and individual psychotherapy. Id. It was during the diagnostic interview by the psychologist on September 15, 1993 that her suicidal ideation and major depression was noted. P. Ex. 3 at 15.

interview before Petitioner began to more aggressively treat her depression with medication and increased monitoring. This delay in providing additional treatment was potentially detrimental to resident 12 when one considers that her initial depression had deteriorated from observable signs of isolation to suicidal thoughts, a clear indication of a worsening in her depressive state.

With respect to care-planning, the record indicates that her isolation was care-planned on September 1, 1993. P. Ex. 3 at 24. Her suicidal ideation, as illustrated by her expressing a desire to die on September 15, 1993, was not care-planned until November 17, 1993. Id. The approaches/actions which Petitioner's staff listed in connection with the November 1993 entry included encouraging the resident to socialize, encouraging activities of choice of interest, and having cheerful dialogue with the resident while giving care. Id. Thus, Petitioner delayed over two months before implementing a care plan to address resident 12's suicidal ideation. More importantly, Petitioner delayed approximately one month before responding to her worsening depression with Elavil and monitoring her for suicidal ideation. Such a delay could have had serious detrimental consequences on her health and safety. The protections afforded residents through the MDS assessment protocols were obviated by Petitioner when it failed in September 1993 to record her deteriorating mental condition which would have triggered a formal assessment of her mental state and consideration of whether a new plan of care was necessary to respond to the change in her condition. Additionally, one of the mechanisms built in to the assessment process to ensure a resident's proper care and treatment is that a resident's care plan must be prepared by an interdisciplinary team made up of the appropriate persons. With respect to the care plan entries of September 1, 1993 and November 17, 1993, there is nothing in the record to indicate that these entries were formulated in accordance with these protocols.

Ms. Shekell testified:

> You would expect to see that somebody that has a mood disturbance over a period of time that it would be reflected in the assessments. According to their assessments that has not been identified as a problem, and the regulation does state that the record must show

> an accurate and concise assessment of the patient at any time.
>
> *****
>
> The goal is that the staff must make a complete assessment of the patient to actually reflect what the patient's needs are, and from that they develop a patient care plan for which they care for the patient based on that assessment of identified needs, and then they can set goals to help the patient with the identified problems.

Tr. 148, 150-151.

Resident 12 manifested serious problems in terms of her psychosocial well-being and her July 30, 1993 MDS was inaccurate with respect to her psychosocial status as of at least September 15, 1993, or possibly as early as September 1, 1993, which is the first indication in the record that she wanted to isolate herself[42]. Moreover, there is no evidence in the record that Petitioner ever completed a new MDS for resident 12. While the resident did appear to benefit from weekly group and individual psychotherapy sessions and become less depressed, as indicated by the progress notes for September 1993 through December 1993 (P. Ex. 3 at 16-19), her depressive symptoms were never totally eliminated.

Based on the above, Petitioner violated the requirement found at 42 C.F.R. § 483.20(b)(1), with respect to this resident. Section 483.20 mandates that the resident assessment conducted by the facility be an accurate comprehensive assessment of the resident's functional capacity. Sections 483.20(b)(1)(i) and (ii) mandate that 1) such assessment be "based on a uniform data set specified by the Secretary and uses an instrument that is specified by the State and approved by the Secretary" and 2) such assessment "describe the resident's capability to perform daily life functions and significant impairments in functional capacity." In short, the MDS should accurately reflect the resident's functional capabilities. This instrument is used to prepare a comprehensive care plan for any medical condition assessed by the facility as impacting on the resident's ability to function -- the goal being to assist the resident in attaining and maintaining his or her highest practicable physical, mental, and psychosocial well-

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[42] See, P. Ex. 3 at 22.

being. 42 C.F.R. § 483.20(d). Here, Petitioner's failure to maintain an accurate assessment of this resident's condition as the level of her depression worsened prevented the formulation of a timely comprehensive care plan prepared using the protocols specified by HCFA and which corresponded to her change in psychosocial well-being.

While the July 1993 MDS may have been accurate at the time it was completed, it no longer reflected the true condition of resident 12's psychosocial status as of September 1993. Petitioner failed to conduct a new MDS in September 1993, and by leaving an inaccurate MDS in place, it did not comply with 42 C.F.R. § 483.20(b). By failing to accurately document resident 12's depression in the assessment instrument, Petitioner acted contrary to the directives of OBRA '87 and contravened its obligation to provide appropriate "individualized care" of high quality to its residents. Congress intended that the resident assessment instrument accurately describe a resident's functional capacity and health status. See section IV. of this decision. In imposing this obligation on a facility, Congress recognized that a comprehensive resident assessment was crucial to providing high quality care to a resident. Id.

As part of its response to this deficiency, Petitioner argued that F 272 was cited in error:

> Ms. Patience finally testified that the indicated deficiencies concerning the failure to update assessments to conform to the condition of the patient (asserted inaccuracies) are not in fact the subject of F272 but are actually addressed in F287, which is the only F tag that covers her criticisms.

P. Br. at 47, citing Tr. 2658-2659.

At the hearing, Ms. Patience did acknowledge that, if a deficiency was based on failure to complete an MDS after a significant change in a resident's condition, the appropriate citation would be F 287. Tr. 2658-2659, 2683. In addition, Ms. Patience stated that a failure to change the MDS "could trigger other Ftags." Tr. 2683.

Ms. Patience did express her opinion that the alleged findings concerning resident 12 would lead to a deficiency under F 287. Id. However, contrary to what Petitioner contends, Ms. Patience did not testify that F 287 was the only applicable citation for the alleged

deficiency. In response to my questioning, Ms. Patience stated that the alleged findings relating to resident 12

> could also trigger 272. We sometimes use 272 to illustrate a pattern of deficient practice in relation to the minimum data set in the assessment process. And, so it wouldn't be entirely improper that it was under 272.

Tr. 2683-2684.

According to SOM 250, the regulation which is the basis of F 287 is 42 C.F.R. § 483.20(b)(4)(iv), which states that a facility must conduct assessments "promptly after a significant change in the resident's physical or mental condition". HCFA Ex. 13 at P-103. As I have discussed, when resident 12 exhibited symptoms of major depression and spoke of being ready to die in September 1993, these circumstances constituted a significant change in her psychosocial condition which warranted the completion of a new MDS.[43]

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[43] In its opening brief, Petitioner argued that "[t]his is clearly an area where nursing judgment dictates when assessments should be modified" and stated that Ms. Patience had "conceded that this was an area of judgment." P. Br. at 119. While the judgment of Petitioner's staff does play a role in determining whether a resident's change in condition is a "significant" change warranting completion of a new MDS, HCFA has provided guidance, in the form of the SOM 250, to facilities in exercising that judgment. As Petitioner pointed out in its brief, Ms. Patience did testify:

> Some of it is the nursing judgement [sic]; some of it is -- are the examples that are contained here in the 250s; some of it is contained in the direction for the resident assessment protocols.

Tr. 2677-2678.

Ms. Patience went on to testify that it was her belief that resident 12's change in condition "does fall in with some of these parameters." Tr. 2678. Ms. Patience thus was of the opinion that the proper exercise of nursing judgment with respect to resident 12 would take into consideration the SOM 250 and the facility's own RAPS instructions. I agree; nursing judgment cannot exist in a vacuum, and with respect to resident 12, the comments

(continued...)

Additionally, with respect to Petitioner's contention that "there was no "pattern" of inaccurate MDS record-keeping in the facility" (P. Resp. Br. at 14), I find this argument to be inapposite. To meet its burden of proof with respect to this alleged deficiency, HCFA did not have to prove that a pattern of inaccurate MDS documentation existed with other residents. As stated in SOM 250, a situation that affects a single resident may be cited as a deficiency. There is no specific standard that must be met. The threshold of what constitutes a deficiency varies from situation to situation. HCFA Ex. 13 at P-29. The SOM 250 guideline does state that a single occurrence directly related to a "life-threatening or fatal outcome or high potential for such outcome may be cited as a deficiency." Id. However, I do not construe this guideline as precluding a finding of a deficiency where such an outcome cannot be demonstrated. This guideline is written in the permissive sense and does not mandate that such an extreme negative outcome must be shown to conclude a deficiency exists where there is only one occurrence. Here, I conclude that Petitioner's failure to comply with the cited regulatory requirement negatively impacted on the resident's treatment. Such a finding is sufficient to support the existence of a deficiency.

E. Set out below is the statement in the HCFA 2567 concerning the alleged deficiency identified as F 289 (HCFA Ex. 2 at 4-5):

> 42 C.F.R. 483.20(b)(5) (5) Review of assessments. The nursing facility must examine each resident no less than once every 3 months, (quarterly) and as appropriate, revise the resident's assessment to assure the continued accuracy of the assessment.
>
> *****
>
> Based on record review and interview the facility failed to review each resident's assessment for continued accuracy.

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[43] (...continued)
by the psychologist, care plan entries, and her medication indicate that her mood and behavior deteriorated sufficiently to constitute a significant change in condition. See HCFA Ex. 13 at P-104.

Thus, arguably, the survey team should have cited F 287, in addition to F 272, for this deficiency.

Findings include:

> Resident 16 was incontinent of bladder on admission 5/1/93. She was but [sic] on a bladder training program. A licensed nurse's note at that time indicated that the resident would tell when she had to go. The licensed nurse's assessment 11/11/93, indicates she is incontinent of bladder, as does the current plan of care. Licensed nurse's notes 12/3/93 state that she is continent, however the next weekly summary states she is incontinent. The nurse aide flow sheets from 12/1-12/15/93 reflect that she is continent. Licensed staff interviewed were not sure which of these documents were accurate. The resident has not been accurately assessed and the care plan updated to reflect the actual status of the resident. On 11/7/93 an entry in the plan of care indicates that she tries to climb out of bed. A nursing approach to toilet the resident when her restraints are released, is included. There was no routine individual schedule developed to meet the resident's needs. Cross reference F290.
>
> Residents medical records reviewed indicated inaccuracies of the resident mental, physical, and psychosocial status on an ongoing basis. Records indicated no mood, behavioral and psychological problems when they were in fact receiving psychotropics, antianxiolytic, sedative and/or hypnotic drugs. The assessments were not congruent with the physicians progress notes or nurses notes. The assessments were not consistent with current treatment needs or the current patient care plans.
>
> The quarterly assessments did not reflect the residents status on the 18 elements of the resident assessment protocol summary (RAPS).

The first part of this alleged deficiency concerns resident 16 and the issue of whether Petitioner accurately assessed resident 16's state of bladder continence. HCFA argues that "neither the MDS nor the quarterly evaluations reflected [the] significant change in resident 16's state of bladder continence" and contends that there was "apparent confusion and lack of documentation in the medical record as to her actual

state of continence at any given time". HCFA Br. at 30, 33.

Petitioner argues, among other things, that the resident's assessment "was accurate and did not require change more than once every three months"; confusion on the part of Petitioner's staff did not "violate the regulation or require a change in the resident's assessment because her condition was in a continual state of change"; and "[t]here are no standards other than nursing judgment which determine when a change in a patient's state of continence requires a change in the assessment other than a drastic change." P. Br. at 48.

Resident 16 was admitted to the facility on May 1, 1993. P. Ex. 4 at 1. At the time of admission, a bowel and bladder assessment was done, which reflected that the resident was "inc[ontinent] of b[owel] and b[ladder] and "not a candidate for bladder and bowel retraining [secondary to] unawareness of bodily function." P. Ex. 4 at 11. On resident 16's MDS, which was completed on May 14, 1993, Petitioner's staff assessed her as being incontinent of bowel and bladder. P. Ex. 4 at 3.[44]

The medical documentation for resident 16 includes also quarterly reviews for the quarters ending August 12, 1993 (90-day assessment) and November 5, 1993 (180-day assessment).[45] P. Ex. 4 at 7-8.

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[44] Ms. Cox testified that her findings concerning the alleged deficiency with respect to resident 16 have to do with only bladder incontinency. Tr. 1436.

On the MDS, continence is rated on a scale of 0 to 4, with 0 representing continence and 4 representing incontinence. P. Ex. 4 at 3.

[45] The November quarterly review was dated 11/5/93 and, also, 11/11/93. P. Ex. 4 at 8. Ms. Cox stated at the hearing "The assessment sheet is filled out for 8-12-93 and 11-11-93 which is quarterly." Tr. 1190. However, Ms. Patience explained that, because an LVN signed the assessment on 11/5/93, that 11/5/93 would be considered the proper date of this assessment. Tr. 2510-2511. Based on her reasoning, I am using 11/5/93 as the date of the November quarterly. Based on this date, the 14-day time frame for purposes of bladder continence status is 10/22/93 - 11/5/93. Had I used 11/11/93 as the date of the November quarterly, the 14-day time frame would be 10/29/93 - 11/11/93.

(continued...)

On these assessments, Petitioner's staff has indicated in the relevant section (Section F) that resident 16 was incontinent of both bowel and bladder for the last 14 days of these two quarterly periods. P. Ex. 4 at 7-8. The specific time frames, then, for which Petitioner was assessed as incontinent of bladder for purposes of these quarterly reviews were 7/29/93 - 8/11/93, and 10/22/93 - 11/5/93.

With respect to the August 1993 quarterly assessment, I find that it does not appear to be one of the assessments underlying HCFA's allegations in the HCFA 2567. With the exception of the reference to resident 16's 5/1/93 admission, the findings alleged in the HCFA 2567 in support of this deficiency relate to the months of November and December 1993. Accordingly, I will not address the August 1993 quarterly assessment, as it falls outside of the relevant time frame focused upon by HCFA in this alleged deficiency.

With respect to the November 1993 quarterly assessment, which is relevant, the issue of whether or not Petitioner's staff accurately assessed resident 16 as being incontinent during the time frame of 10/22/93 - 11/5/93 (i.e., the last 14 days prior to the quarterly assessment) necessitates a review of the documentation pertinent to this time period. The October 1993 flow sheets show that for the "Day Shift" during the period October 22-31, Petitioner's staff had written the notation "x3" or "3" in the boxes on the "incontinent"

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[45] (...continued)

I examined the flow sheet notations for the time frame of 10/22/93 - 11/5/93 and concluded that, based on these notations, resident 16 evidenced continency status a significant amount of the time. However, I also examined the flow sheet notations through 11/15/93, which indicate also that resident 16 was mostly continent for the first half of November.

There is also a quarterly review for the quarter ending 2/10/94 (270-day assessment). P. Ex. 4 at 7. However, because the assessment of continence in this review would relate to the time period of 1/27/94 - 2/10/94 (i.e., the last 14 days prior to the quarterly review), I do not address this quarterly assessment, since it is outside of the relevant time frame for purposes of this decision.

(bladder) line. P. Ex. 4 at 15.[46] During the "P.M. Shift" for this same time frame, Petitioner's staff had written in "0" in the boxes on the "incontinent" (bladder) line. Id. at 16.[47] For the "night shift", a "1" was written in for 10/22, and 10/24 - 10/26, a "0" was written in for 10/23, and for 10/28 - 10/31, and a "4" was written in for 10/27. Id. at 17.[48] Based on the October flow sheet notations, it appears that, during October 22 - 31, 1993, resident 16 was incontinent three times daily during the "day shift," was not incontinent at all during the "P.M. Shift", and was not incontinent for five of the ten days during the "night shift."

The 11/1 - 11/15/93 flow sheets indicate that, during the "night shift", resident 16 was found to be incontinent of bladder on November 1 and 2, but was continent the rest of the time. P. Ex. 4 at 18.[49] See Tr. 1435. For the "Day Shift" during this same time period, several types of notations were written in by Petitioner's staff: "C", "C/I", "I/3", "x3", "C/2", "C/3", "3".[50] During the

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[46] In the bladder section of the flow sheet, there is also a "Continent/Catheter" line. For the "day shift" during the 10/22 - 10/31/93 period, Petitioner's staff wrote in "0" for these dates on the "Continent/Catheter" line. P. Ex. 4 at 15.

[47] On the "Continent/Catheter" line on the flow sheet, Petitioner's staff wrote in a "2" for the dates 10/22 - 10/23, 10/25 - 10/31, and a "3" for the date 10/24/93. P. Ex. 4 at 16.

[48] On the "Continent/Catheter" line of the flow sheet, Petitioner's staff wrote in, for the night shift of 10/22 - 10/31/93, a "2" for 10/22 and 10/24, a "3" for 10/23, 10/25, 10/28, and 10/30, a "1" for 10/26, a "0" for 10/27, and a "4" for 10/29 and 10/31. P. Ex. 4 at 17.

[49] According to the legend given on the chart, "I" represents incontinent and "C" represents continent. In the night shift section, Petitioner's staff had written in "I's" for November 1 and 2, 1993 and "C's" for November 3, 1993 through November 15, 1993.

[50] The notation forms of "C/I", "C/(number)", and "I/(number)" do not correspond to the legend and are nowhere explained. Although Ms. Cox did not testify specifically on these "day shift" notations, she later

(continued...)

"P.M. shift", there is a "C" written in for each date, indicating that resident 16 was found to be continent during this entire time period. P. Ex. 4 at 18.

In light of the flow sheet evidence that resident 16 was exhibiting continent behavior a significant amount of time during the end of October and beginning of November 1993, I find that the 11/5/93 quarterly assessment indicating that she was incontinent is inaccurate. While Petitioner did conduct a quarterly review, it failed to reflect accurately resident 16's bladder continence status, in violation of 42 C.F.R. § 483.20(b)(5).[51]

According to the flow sheets for 11/16/93 - 11/30/93, resident 16 was continent during the "night shift" throughout this entire time period. P. Ex. 4 at 19. However, with respect to the "day shift" and "P.M. shift" for this time period, there are notations written in the form of "C/(number)" and ""C x (number)", which are unclear, do not correspond to the legend, and are nowhere explained. The fact that there are "I's" and "C's" written over each other in some of the boxes make the entries even more cryptic.[52] Thus, the only conclusion I

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[50] (...continued)
attempted to interpret similar notations elsewhere in the chart.

[51] Had the quarterly review been accurately completed by Petitioner with respect to her bladder continence status, this would then have triggered the completion of new RAPS, which, in turn, would have led to appropriate care-planning for the resident.

There is also an interdisciplinary team note dated 11/11/93 which states, in part, "Discussion on whether the resident has made any actual improvements/declines in her ADL functioning. Incontinent of B & B." P. Ex. 4 at 10. Based on the flow sheet data, I find that these notes do not give an accurate assessment of resident 16's bladder continence status.

[52] With respect to the bladder "day shift" notations, Ms. Cox attempted to interpret them:

> "Day shift it says incontinent times three, I guess, incontinent times three, incontinent times four, incontinent times four, and then

(continued...)

can make is that resident 16 was continent at least during the night shift of the second half of November. P. Ex. 4 at 18-19.

From November 30, 1993 - December 2, 1993, resident 16 underwent a "3-day evaluation for baseline data -- bladder training". P. Ex. 4 at 12.[53] The chart indicates that, on each of these days, she was found to be "dry" whenever checked by Petitioner's staff. According to this chart, resident 16 was never found to

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[52] (...continued)
the rest of the time it says continent, across the rest of the page. So that's four days incontinent and the rest continent.

Tr. 1436-1437.

In attempting to get further clarification, I asked Ms. Cox:

> And then the -- so the number after the letter would be the number of times that they were either incontinent or continent?
>
> THE WITNESS: Well, to me this is the number of times they're incontinent . . .
>
> . . . to me this is not very clear documentation, but if you have a continent and then have a slash, and they have a two, to me that means something a little different than -- see, if you go back three days it says: "Continent times" whatever that is, it looks like a nine actually. That's under the 25th day. . . . Some of this is a little more clear than others. If you just have a "C/2" that does not mean continent times two, to me. It could mean continent and the slash two, or it could mean continent and perhaps in there indicating that resident's incontinent. This is very -- just a very poor way -- method of charting. Tr. 1439.

With respect to the "P.M. Shift", Ms. Cox was unable to interpret the notations. Tr. 1437-1438.

[53] At the hearing, in response to my questioning, Ms. Cox confirmed that this particular document "refers to an evaluation to determine whether or not someone will be a candidate for bladder training." Tr. 1431.

be "wet" on each of the three days. Id. An entry in the progress notes dated November 30, 1993 reads "On B & B training. continent X 1 -- able to ask CNA that she wants to go to bathroom. will continue to monitor." P. Ex. 4 at 33-34.

In her testimony regarding the "3-day evaluation for baseline data -- bladder training" chart, Ms. Cox stated that she did not see any indication on the chart that the resident was incontinent, and "that would indicate that the times that you checked her she was either dry or she was capable of voiding. Whether they took her to the toilet or bedpan, I don't know, it doesn't always indicate. But it indicates that she would have some control." Tr. 1432-1433. In the licensed nurses' progress notes, an entry dated December 3, 1993 at the bottom of the page reads "3 day eval. for baseline data-bladder training completed & pt. is continent; she'll tell when to go to the bathroom." P. Ex. 4 at 13. (duplicated at P. Ex. 4 at 34).[54] Thus, the result of the three-day evaluation is that resident 16 was assessed to be continent.

Such a change in resident 16's condition constituted a "significant change" that should have resulted in Petitioner completing a new MDS some time following the three-day evaluation. 42 C.F.R. § 483.20(b)(4)(iv). Petitioner failed to do this and simply left in place the MDS completed on May 14, 1993, which assessed resident 16 as being incontinent of bladder (and bowel). By not updating the MDS, Petitioner plainly violated 42 C.F.R. § 483.20(b)(5), which required Petitioner, as appropriate, to revise resident 16's assessment to assure its continued accuracy.

Petitioner's witness, Ms. Downing, testified herself that a resident's quarterly assessment is changed more often than quarterly "[i]f there is a drastic or significant change in the condition." Tr. 1796; see Tr. 1798. She stated also that "You do a new MDS, complete new MDS if there's a change in condition." Tr. 1796.[55] Although Ms. Downing was of the opinion that "[T]here was nothing here [sic] a drastic or significant change that warranted

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[54] Although the page is a poor copy, the date of the entry appears to be December 3, 1993.

[55] On the MDS form itself, under section A, there is a place to indicate the "reason for assessment". One of the six choices is choice number 5 -- "Significant change in status."

a new MDS" (Tr. 1796), I disagree. Resident 16 did experience a significant change in her bladder condition. Although she was assessed as being incontinent of bladder on the MDS in May 1993, other medical documentation in her record established that her condition improved significantly such that she was no longer totally incontinent.

I note that the record contains also a weekly summary progress note dated 12/10/93 and flow sheets for the period 12/1/93 - 12/31/93. P. Ex. 4 at 14, 20-21. The 12/10/93 progress note states, in part, "Incont. of B & B". P. Ex. 4 at 14 (duplicated at p. 35).[56]

With respect to the December 1993 flow sheets, they contain also notations other than a simple "C" or "I", and which resemble notations previously discussed. P. Ex. 4 at 20-21. For the first half of December 1993 (12/1-12/15), in the "Night shift" section, there are some "C's" written in the chart to describe the resident's bladder condition, as well as "C/2", "C/3", "I/3", "I/4", and "I/0" in some of the boxes. P. Ex. 4 at 20. In the "Day Shift" section, Petitioner's staff has written in the notations "Cx3", "C/3", "C/2", and "C/4". Id. The notations "C/1", "C/2", and "C/3" appear in the bladder section under the "P.M. Shift". Id. When asked about these notations (for the period 12/1-12/15/93), Ms. Cox stated, "Well, I see the same type charting, some of which I don't understand, I have to admit. And I can only say that it is not clear to me what this means." Tr. 1441.[57] Notations of similar form

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[56] A progress note dated 12/3/93 (7:30 p) contains a reference to resident 16's continence status. P. Ex. 4 at 34. It states on the third line what appears to be the following phrase: "Incontinent of B/B". However, the first two letters of "Incontinent" are lined through, which could indicate that "In" is being crossed out. If this is the case, then it may be that Petitioner's staff had mistakenly written "Incontinent" when he/she had meant to write "continent." The manner in which to interpret this was disputed at the hearing. I find that it is unclear and ambiguous; accordingly, I do not consider this entry in discussing resident 16's bladder condition.

[57] Ms. Cox had expressed the same confusion earlier on direct examination when asked to give her interpretation of "a C with a slash" :

(continued...)

appear in the nurse assistant record for the period of 12/16-12/31/93. P. Ex. 4 at 21.[58]

When asked about the "night shift" bladder notations for the first half of December 1993 (12/1-12/15/93), Ms. Downing interpreted them in the following manner[59]:

> It has incontinent on the 10th times three.
> Incontinent on the 11th times four.
> Incontinent on the 13th times, it says zero.
> So, I would assume that means she was dry that day.

Q [Petitioner's counsel]: "That's just the -- that's just the night shift?" A [Ms. Downing]: "Right. That's the number of times she was checked." Tr. 1777.

With respect to the "day shift" bladder notations for this same time frame (12/1-12/15/93) (P. Ex. 4 at 20), Ms. Downing stated "I would say it looks like she was incontinent [sic] -- continent or dry on the day shift." Tr. 1777. When asked about the resident's bladder condition during the "p.m. shift", Ms. Downing testified, "It looks like, yes she was continent on those days." Id. Based on her review and interpretation of these notations for all three shifts, Ms. Downing expressed her opinion that the statement in the HCFA 2567 that the 12/1-12/15 flow sheets reflect the resident to be

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[57] (...continued)
. . . It could be that the person was continent twice, but that doesn't answer when she was incontinent or how many times she went totally, or it could say that she was continent but the two were -- the three or whatever numbers there perhaps indicates that that's the number of times she was incontinent so it could be either way. I'm not sure what that means.

Tr. 1039; see also Tr. 1040-1042.

[58] On direct examination regarding P. Ex. 4, pg. 21, Ms. Cox did state "it's not totally clear to me, but obviously the C means continent times three, if that speaks for itself it means she was continent three times." Tr. 1042.

[59] In the transcript, Ms. Downing stated that the period 12/1-12/15 is referenced on P. Ex. 4 at 16. However, this page is a flow sheet for October 1993. The correct page cite is P. Ex. 4 at 20.

continent was "inaccurate". Ms. Downing stated, "No, she was not totally continent". Tr. 1778.

HCFA's witness, Ms. Patience, also was questioned about the December 1993 flow sheets. With regard to the 12/1-12/15 flow sheet (P. Ex. 4 at 20), Ms. Patience stated the information in the chart indicated "[t]hat the resident was continent from December 1st through December 15th -- continent of bladder." Tr. 2508. Ms. Patience testified further that the information on the 12/16-12/31 flow sheet indicated "[t]hat the resident from December 16th through December 31st was also continent of bladder." Tr. 2508.

The testimony of Ms. Downing and Ms. Patience concerning the 12/93 flow sheet notations calls into question the validity of the 12/10/93 weekly summary progress note. Also, given that resident 16 was assessed as "continent" following the three-day evaluation, which was completed on 12/2/93, the weekly progress note appears to be inaccurate. In light of the testimony of both Ms. Downing and Ms. Patience, it appears that, while resident 16 may not have been "totally continent" during the first half of December, she could possibly be described as being mostly continent for the month of December. In any event, I conclude that resident 16 was not incontinent during December 1993.

By ignoring its obligation to comply with 42 C.F.R. § 483.20(b)(5), Petitioner was essentially representing that between May 1993 and the time of the survey (December 1993), resident 16 had not undergone any changes at all with respect to her continence status and remained totally incontinent. Such misleading and inaccurate information about resident 16's health status was precisely what OBRA '87 was intended to prevent with its patient-oriented reforms. 42 C.F.R. § 483.20(b)(5) mandates that a facility must conduct quarterly assessments and "as appropriate, revise the resident's assessment to assure the continued accuracy of the assessment." Petitioner should have had updated and accurate assessments in resident 16's medical record which documented that her condition changed significantly from being incontinent of bladder to either continent or mostly continent. In sum, Petitioner's November 1993 quarterly assessment of resident 16 was inaccurate and, based on the evidence of continence following the 3-day bladder evaluation, there was evidence based on that data alone to conclude a significant change in resident 16's status had occurred to warrant a modification of her assessment instruments. Failure to have an accurate assessment of her continence prevented this resident from

attaining her highest practicable level of physical, mental, and psychosocial well-being and potentially could have compromised her health and safety, since she could have been exposed to infection if continence had not been maintained.

Ms. Cox alleged further in the HCFA 2567 that resident 16's care plan was not updated to reflect her actual status. HCFA Ex. 2 at 5. This allegation pertaining to resident 16's care plan is extraneous to the regulation and, therefore, I do not consider it.[60]

Petitioner argues that Ms. Patience acknowledged that there are no specific documentation standards governing what length of time of continence or incontinence is needed to be demonstrated in order to necessitate changing a resident's assessment. P. Br. at 55. Petitioner avers that, outside of a drastic change in a resident's condition, nursing judgment should control as to when a resident's assessment should be revised due to a change in continence status. Id. Petitioner's argument is without merit. I find that Ms. Cox did, in effect, defer to nursing judgment in reviewing resident 16's medical chart. Ms. Cox based her findings on notations and entries written by Petitioner's staff and found that Petitioner's staff made a determination at one point in time that the resident had become continent. Based on this assessment of the resident by Petitioner's staff, Ms. Cox then concluded that Petitioner should have completed a new assessment of the resident which accurately stated her improved bladder condition. Contrary to what Petitioner argues, it appears that Ms. Cox gave great weight to the nursing judgments contained in the various medical documents.

Ms. Cox testified also that "[t]he nurse aide flow sheets and the weekly nurses' summaries were in conflict with each other compared to their bladder assessment that was finished 12-3. . . . None ever [sic] that information agreed." Tr. 1240-1241. Ms. Cox testified further that Petitioner's staff "were not sure which documents were accurate." Tr. 1241. In response to these claims, Petitioner argued that the "confusion of the licensed staff is not a violation of the cited regulation." P. Br. at 55. While section 483.20(b)(5) does not address internal consistency of documentation per se, it is evident that the objective of this regulation is to

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[60] Ms. Cox testified that the regulation concerns "quarterly [assessments] and revising as appropriate to insure accuracy." Tr. 1190.

describe a resident's condition and health status as accurately as possible. The fact that the documents in resident 16's medical chart appear to demonstrate some internal inconsistency underscores further the inaccuracy of the recordkeeping with respect to her bladder condition.

The next part of the deficiency, as set forth in the HCFA 2567, alleged:

On 11/7/93 an entry in the plan of care indicates that she tries to climb out of bed. A nursing approach to toilet the resident when her restraints are released, is included. There was no routine individual schedule developed to meet the resident's needs.

HCFA Ex. 2 at 5.

This allegation is extraneous to the regulation and, therefore, I do not consider it.

With respect to the group of allegations in the HCFA 2567 concerning "Residents medical records reviewed indicated inaccuracies of the resident mental, physical, and psychosocial status on an ongoing basis . . . ", Ms. Shekell stated that she "contribute[d] to writing [this] deficiency." Tr. at 162. Apparently, another surveyor, Ms. Chute, who has since passed away, also had reviewed some of the records which are the basis for these findings. Tr. at 181, 193.

Ms. Shekell testified that resident 12, who had been the subject of another alleged deficiency (F 272), was one of the subjects of this group of allegations. Ms. Shekell stated that resident 12's quarterly reviews failed to indicate that she had mood problems and were thus inaccurate. Tr. 176-178; P. Ex. 10 at 16. Resident 12's chart contains quarterly reviews dated October 27, 1993, January 28, 1994, and April 22, 1994. P. Ex. 3 at 7. I do not discuss the latter two quarterly reviews since they are outside of the relevant time frame for purposes of this decision.

With respect to resident 12's 10/27/93 quarterly review, I find that HCFA did not prove that it is inaccurate. On the 10/27/93 quarterly review, Petitioner's staff had written in a zero in section H.2 next to the phrase "Sad or anxious mood intrudes on daily life over last 7 days - not easily altered, doesn't 'cheer up.'" The zero represents that resident 12 had not displayed this mood pattern during the relevant time frame, i.e., October 20 - 27 1993. The progress notes for October 1993 show that

the resident's progress toward stabilizing her depressed mood was at about the same level as in September. P. Ex. 3 at 17. An entry dated October 6 states: "spirits up -- probably due to word (incl. pictures) from family in Philippines. Another entry dated October 27 states that the resident "has established ties c grp members & is speaking more to them in & outside of grp. She also is able to converse more openly, a big step." Id. Based on these entries, the 10/27/93 quarterly review is not inaccurate.

However, in examining the documentation outside of the October 1993 quarterly review time frame, I previously concluded in section X.D. of this decision that resident 12's July 30, 1993 MDS was inaccurate with respect to her psychosocial status as of at least September 15, 1993, or earlier, possibly September 1, 1993, which is the first indication in the record that she wanted to isolate herself (P. Ex. 3 at 22). There is no evidence in the record that Petitioner ever completed a new MDS for resident 12. Because Petitioner failed to "assure the continued accuracy" of resident 12's assessment instrument", I conclude that it violated 42 C.F.R. § 483.20(b)(5) with respect to resident 12.

Additionally, Ms. Shekell testified that P. Ex. 9 (resident G.B.) was one of the resident records that was "part of the survey team's basis" for this alleged deficiency. Tr. at 195. Ms. Shekell stated that she did not herself view the resident whose record is P. Ex. 9; she believed that this resident's record had been identified and reviewed by Ms. Chute. Tr. at 191-193.

In discussing resident G.B., Ms. Shekell stated that there was an inconsistency between his MDS, which indicated that the resident did not have any mood problems, and his care plan, which indicated that he was taking antidepressant medication and had an episode of crying on February 24, 1993. Tr. 195-198. See P. Ex. 9 at 2, 5. Ms. Shekell testified also that a Social Services note dated November 30, 1993 stated that the resident was "taking an antidepressant to reduce episodes of crying related to neurogenic pain. Social Services will provide emotional support to resident during one on one visits." Tr. at 199-200; P. Ex. 9 at 19. Ms. Shekell stated further that another entry dated December 13, 1993, written by a licensed social worker mentioned, among other things, that "referral to psychologist is appropriate [to] address his refusal of treatment." Tr. at 201. See P. Ex. 9 at 20. Ms. Shekell noted that, according to the Physician Orders, the resident had been on Prozac, which was discontinued sometime around May 24,

1993, at which time the resident was started on 25 mg. of Desipramine, which was increased to 50 mg. after four days. Ms. Shekell stated that a Physician Order dated November 16, 1993 indicated that the resident was receiving 150 mg of Desipramine daily (at bedtime) for depression. Tr. at 201-202; P. Ex. 9 at 21, 23. Ms. Shekell expressed her opinion that this "would indicate to [her] that the patient had an escalating problem for the doctor to increase his orders to that extent." Tr. at 202.

In addition, HCFA argued that resident G.B.'s quarterly reviews dated May 28, 1993, August 23, 1993, and December 1, 1993, did not indicate that he had any mood or behavior problems. P. Ex. 9 at 6-7; HCFA Br. at 36.[61]

Based on Ms. Shekell's testimony and the record before me, the August 23, 1993 quarterly review, which indicated that resident G.B. had no mood problems in the last seven days, is accurate. A social services note dated 8/23/93 stated, among other things, that "Episodes of crying are being monitored by nursing staff [with] a total of 6 from May - July." P. Ex. 9 at 16. Based on this information, G.B. apparently had not experienced any mood problems in the month of August.

However, I find that Petitioner inaccurately assessed resident G.B.'s mood problems in the quarterly reviews dated May 28, 1993 and December 1, 1993. According to these assessments, G.B. did not display any "sad or anxious mood" over the last seven days of these two quarterly periods (section H.2.). P. Ex. 9 at 6. However, it cannot be disputed that G.B. was experiencing depression, for which he took Prozac, and that, in late May, he was discontinued from Prozac and put on Desipramine. Moreover, the 11/30/93 Social Services note which mentions that G.B. is "taking an antidepressant to reduce episodes of crying related to neurogenic pain. SS will provide emotional support to resident during 1:1 visits" (P. Ex. 9 at 19) is further evidence that G.B. was experiencing mood problems. These quarterly assessments are thus inaccurate, and Petitioner's failure to maintain an accurate assessment of G.B.'s psychosocial status represented a breakdown in the assessment process which could have a potentially negative impact on G.B.'s psychosocial well-being and the treatment of his depression. I thus find that, with respect to resident G.B., Petitioner violated 42 C.F.R. § 483.20(b)(5).

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[61] Resident G.B. was admitted on February 17, 1993. P. Ex. 9 at 1.

Resident G.B.'s chart does contain a 2/24/93 care plan entry noting "Episode of crying", and a corresponding objective for G.B. to "have less than 3 episodes x 1 month; x 3 months", which is further dated May 24, 1993, August 24, 1993, and November 24, 1993. P. Ex. 9 at 2. While it appears based on this information that Petitioner was taking into account resident G.B.'s mood problem through his care-planning, I do not conclude that these care plan entries were formulated in conjunction with the proper assessment protocols. Because Petitioner did not have in place accurate assessments, upon which a care plan is based, it is questionable whether the protocols mandated by the regulations were in place and used with respect to resident 12.

Petitioner also should have completed a new MDS for resident G.B. some time following the 12/13/93 multi-disciplinary report entry which noted that he was refusing treatment. P. Ex. 9 at 20. Because there is no date for resident G.B.'s MDS which is in the record before me, I assume that it was completed upon G.B.'s admission on February 17, 1993 (P. Ex. 9 at 13), or within 14 days of his admission.[62] According to this MDS, G.B. was not resisting care. P. Ex. 9 at 5.

However, when resident G.B. began to refuse treatment in December 1993, this represented a significant change in behavior. Petitioner should have completed a new MDS for G.B., but failed to do so. As I have discussed earlier, the MDS must accurately reflect the resident's functional capabilities. By failing to "assure the continued accuracy" of resident G.B.'s assessment instrument, Petitioner further violated 42 C.F.R. § 483.20(b)(5) with respect to this resident.

As for the last part of the allegations in the HCFA 2567 with respect to F 289 ("The quarterly assessments did not reflect the residents status on the 18 elements of the resident assessment protocol summary (RAPS)."), HCFA stipulated at the hearing that it was no longer asserting this part as a basis for a violation under F 289. Tr. 1832-1834.

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[62] The first page of the MDS, which would have signatures and dates, was not included in the exhibit.

F. Set out below is the statement in the HCFA 2567 concerning the alleged deficiency identified as F 290 (HCFA Ex. 2 at 6):

> 42 C.F.R. 483.20(b)(6) (6) Use. The results of the assessment are used to develop, review, and revise the resident's comprehensive plan of care, under paragraph (d) of this section.
>
> *****
>
> Based on record review and interview the facility failed to review and revise each resident's plan of care.
>
> Findings include:
>
> Resident 16 was assessed as being incontinent of bladder at the time of admission. When the resident's condition improved and she was continent the plan of care was not changed.
>
> Cross reference F 289.

With respect to this alleged violation, HCFA notes that it involves one of the residents who had been the subject of F 289. HFCA asserts that, while the deficiency under F 289 was premised on Petitioner's failure to "review and revise the assessment for resident 16", this deficiency under F 290 "concerned the facility's failure to use the results of the most current assessment of the resident's condition with respect to bladder continence to revise her Comprehensive Care Plan." HCFA Br. at 37.

Petitioner contends that "[a] finding of a deficiency under F290 is dependent upon the existence of an [sic] deficiency under F289 . . .". P. Br. at 58. Petitioner contends further that "[t]here is a significant evidentiary problem because the patient's plan of care was apparently not put in evidence by HCFA at the hearing. . .". Id. at 59. Petitioner alleges that the relevant plan of care was not made part of the record before me and, thus, HCFA has failed to prove this deficiency. Id.

I note that, in testifying that resident 16's care plan was not updated to account for her change in bladder condition (Tr. 1442), Ms. Cox stated that she didn't have the care plan before her. Tr. 1238, 1239, 1247, 1442. While the possibility exists that there may be other care plans for resident 16 which were not included among the medical documentation comprising P. Ex. 4, my analysis of

whether or not Petitioner was deficient in resident 16's care-planning rests solely on what I admitted into evidence, my previous analysis of F 289 and Petitioner's failure to rebut Ms. Cox's observations cited in the deficiency by offering into evidence a care plan in variance with her observations.

The two relevant care plan entries dated May 1, 1993 and November 7, 1993 which are included in P. Ex. 4, at pp. 22-23, note resident 16's incontinency, but make scant reference to her condition. In the November 7, 1993 care plan, in the "Patient Problems/Needs" column, there is an entry that says "At risk for impaired skin integrity related to: incontinence, immobility." P. Ex. 4 at 22. In the "Approaches/Actions" column of this care plan, there is an entry that says "Cleanse & dry skin PRN after incontinence." Id. The care plan dated May 1, 1993 contains an approach/action to "Toilet and/or check for incontinency when restraints are released." P. Ex. 4 at 23.

As I concluded in my analysis of F 289, resident 16 was mostly continent for the first half of November 1993 and also was continent at least during the night shift of the second half of November. P. Ex. 4 at 18-19. Furthermore, upon completion of her three-day evaluation for bladder training on 12/3/93, Petitioner's staff assessed resident 16 to be continent and that "she'll tell when to go to the bathroom." Id. at 13 (duplicated at P. Ex. 4 at 34). However, nowhere in the above-mentioned care plans does Petitioner's staff mention resident 16's improvement in bladder condition from incontinency to continence.[63] Thus, they were inaccurate. The obvious purpose of the care plan is to implement procedures which are correlated to the findings from the comprehensive assessment of the resident. Here, the resident was demonstrating an ability to control her bladder. This is a very favorable event, since it would likely enhance her well-being and reduce the opportunity for infection. Under OBRA, Petitioner is responsible for providing this resident with services necessary to attain

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[63] The record does not contain a care plan for this resident that is consistent with my finding that her incontinent status changed to continent. It is not necessary for me to have the particular care plan that Ms. Cox may have reviewed during the survey. The record is sufficiently clear that whatever care plan she may have seen failed to reflect the resident's change in continency. Her testimony is credible because it is supported by the record as a whole.

or maintain her highest practicable physical, mental, and psychosocial well-being as required under 42 C.F.R. § 483.25. Thus, Petitioner was required to follow up on these indications of an ability to be continent and institute procedures which would reinforce such beneficial behavior by the resident in order to ensure that her continence is maintained. The care plan is the vehicle in which those procedures are documented for Petitioner's staff who treat this resident. This was not done and is violative of the regulations.

Petitioner thus violated 42 C.F.R. § 483.20(b)(6) by failing to revise resident 16's care plan once she was assessed by Petitioner's staff to be continent. Such failure had the potential to cause a negative outcome for this resident.

G. Set out below is the statement in the HCFA 2567 concerning the alleged deficiency identified as F 292 (HCFA Ex. 2 at 6-7):

> 42 C.F.R. 483.20(c)(1) (i) Each assessment must be conducted or coordinated with the appropriate participation of health professionals.
>
> *****
>
> Based on observation and medical record review it was determined that the comprehensive assessment was inaccurate and did not include the participation of all health professionals.
>
> Findings include:
>
> Resident 13's comprehensiv [sic] assessment was dated 12/10/93. Section E-4 for body control problems indicates only a balance problem. Observation of the resident and review of the medical record revealed that the resident has multiple join [sic] contractures, progressive weakness, loss of mobility and a decrease in independent transfers. The comprehensive assessment is inaccurate and does not correspond to the plan of care.

During the survey, the surveyor noted that, with regard to resident 13, his comprehensive assessment was inaccurate and did not correspond to the plan of care. HCFA Br. at 38. Resident 13's comprehensive assessment, dated December 10, 1993, indicates only a balance problem under Section E4 (Body Control Problems), although

observation of the resident and review of his record revealed other physical problems. P. Ex. 20 at 4; HCFA Ex. 2 at 7. This section was completed by a licensed vocational nurse (LVN). Id. at 3.

When asked what contractures are, Ms. Patience stated:

> [t]hey're portions of the body that are bent permanent -- bent at an angle and require, if they're -- if the joint is going to straighten, then it requires some sort of therapy, either with a -- restorative aid or with a physical therapist.

Tr. at 2537.

Ms. Patience noted also that the resident's care plan states that resident 13 had multiple joint contractures as of December 10, 1993. P. Ex. 20 at 8. However, the minimum data set, also dated December 10, 1993, in the section designating contracture to arms, legs, shoulders, or hands, is blank. Id. at 4; Tr. at 2538.

Ms. Patience expressed her belief that it is important to a resident's health and safety that contractures be noted on the MDS. Tr. 2539. It was her opinion that, on admission, if a resident has contractures, the failure to note them is not the type of omission on the MDS that can be corrected within the 14 days allowed for correction of "errors" on the MDS. Id. Ms. Patience testified that

> [c]ontractures aren't things that are easily missed. And, if they didn't for whatever reason pick it up when the resident first came in, then I would think that you would need to do a whole new minimum data set because it does have impact on whether or not the resident's going to be able to ambulate, feed themselves . . . that's a pretty important component and if that was missed, then they may have missed other things as well.

Tr. 2539-2540.

Ms. Patience stated further that "[w]e would expect, as far as the contracture go, for it to designate exactly where, what the degrees were of the contracture, in other words, how severe the contracture was." Tr. 2540-2541.

Ms. Patience testified that although the rehabilitation screen notes the resident's contractures, it does not "correct" the inaccurate information on the MDS, nor can it be used in place of the MDS. Tr. 2541. HCFA argues that, more importantly, the MDS does not contain the

signature of the physical therapist, Donna Hambright, who authorized the rehabilitation screen (see P. Ex. 20 at 3), and was "the one individual who apparently did at least recognize the existence of [the resident's] contractures." HCFA Br. at 40-41.

Petitioner argues that the surveyor's findings do not make a reference to a failure of participation of any health professional and thus do not constitute a violation of the regulation. P. Br. at 59. Moreover, Petitioner contends that the surveyor's findings "refer to an alleged inaccuracy in the assessment concerning a patient's physical condition, i.e., the allegation is that the assessment refers only to a balance problem whereas the resident has joint contractures, progressive weakness, loss of mobility and a decrease in the ability to transfer independently." P. Br. at 60-61. Petitioner argues that even if the comprehensive assessment was inaccurate and did not correspond to the care plan, "the alleged findings have nothing to do with the regulation in question and there has therefore been no adequate notice of the deficiency to which [P]etitioner is required to respond." P. Br. at 61. Petitioner believes that the information regarding resident 13's contractures and other physical problems was accurately assessed because "this information was contained in a rehabilitation screen performed by an appropriate health care professional. The rehabilitation screen is part of the assessment." P. Br. at 60; P. Resp. Br. at 17-19. Petitioner argues further that "there is nothing in the record to indicate that the location of the screen vis a vis in the MDS form or its contents adversely affected the patient's health, i.e., no evidence of any negative outcome." P. Resp. Br. at 19.

The purpose behind 42 C.F.R. § 483.20(c) is to assure that the appropriate health professionals complete a resident's assessment accurately. As discussed earlier in this decision, the assessment instrument is the MDS. The accuracy of the MDS is thus dependent upon the appropriate health professionals completing the appropriate sections. By signing their names to the MDS, Petitioner's staff certifies that they have completed their respective sections accurately and have acted in coordination with each other in the formulation of the MDS.

I conclude that the rehabilitation screen is part of the assessment process, but is not part of the assessment instrument. The physical therapist, after completing resident 13's rehabilitation screen, should have participated also in formulating the body control

problems section of resident 13's MDS. Although a LVN completed the body control problems section on the MDS, she was not the appropriate health professional to complete this section.

I find, however, that Petitioner's failure to involve a physical therapist in the completion of the MDS did not negatively impact the resident. The omission of contractures on the MDS did not adversely impact the completion of the other sections because the other sections appear to be accurately completed. P. Ex. 20 at 4. It is therefore likely that Petitioner's staff did take into account the fact that this resident has contractures. Moreover, on the MDS, it appears that the appropriate actions were triggered, i.e., it appears that Petitioner completed the appropriate RAPS for this resident. Furthermore, the resident's care plan reflects his contractures and is thus accurate. A care plan entry dated December 10, 1993, noted that the resident had multiple joint contractures and set forth objectives which included decreasing the resident's knee contractures and increasing his ankle range of motion. P. Ex. 20 at 8. I conclude that there is no evidence that the resident suffered any harm or that a potential for harm existed. While the failure to use a physical therapist to complete the Body Control section of the MDS should have been brought to the attention of Petitioner, it should not have been cited as a deficiency. It clearly was a minor omission that did not compromise the care of this patient. Accordingly, I find that Petitioner did not violate 42 C.F.R. § 483.20(c)(1).

H. Set out below is the statement in the HCFA 2567 concerning the alleged deficiency identified as F 295 (HCFA Ex. 2 at 7-9):

> 42 C.F.R. 483.20(d)(1) (1) The facility must develop a comprehensive care plan for each resident that includes measurable objectives and timetables to meet a resident's medical, nursing, and mental and psychosocial needs that are identified in the comprehensive assessment. The plan of care must deal with the relationship of items or services ordered to be provided (or withheld) to the facility's

responsibility for fulfilling other requirements in these regulations.[64]

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Based on observation, interviews, and medical record review it was determined that staff failed to develop a comprehensive care plan for each resident based upon the comprehensive assessment.

Findings include:

Resident #1 was admitted to the facility on 2/1/93. The physician wrote an order on 2/11/93 that she may self administer medications and to store them at her bedside. Neither of these special needs were addressed on resident #1's plan of care until 12/2/93. Approaches for the self administration of medication and bedside storage included the following:

1. Ordered 2/11/93 may have own medications at bedside.

2. Check with resident about the time in administering medication.

3. Check the medication container by the date the medication was taken.

4. Count the medication in the bottle and log it as she took it.

5. Monitor as scheduled in administering her meds. Educate resident re: self administration of meds: Remind to be careful with self administration of meds; to list the meds she have [sic] taken each day.

6. Observe resident for an [sic] unusual occurrences and remind resident to report to charge nurse if complaints of persistent

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[64] The latter sentence does not appear in the regulatory language of 42 C.F.R. § 483.20(d)(1). For this reason, I am ignoring this sentence. The sentence in question apparently is a quotation from the SOM 250.

> headache, projectile vomiting, increased temp, etc.
>
> Interviews with licensed nurses and resident #1 revealed that this resident refused to allow nurses to observe her administer her medications. She also refused to let the nurses check her medication bottles. The facility failed to develop the approaches to address her needs for 10 months and failed to follow the plan of care after it was developed.
>
> Medical record review revealed inconsistencies between the assessments, RAPS, and patient care plan indicating a lack of coordination of information collected during the assessment process as well as the evaluation of the care needs from the entire interdisciplinary care team. The patient care plan must reflect the residents care needs as reflected by the ongoing assessment and changing needs.
>
> Cross Reference - F297

Petitioner argues that it did develop a care plan for resident 1. P. Br. at 67. Petitioner contends that HCFA's criticism is based on "an alleged failure to follow the developed care plan, which is not a violation of the regulation." Id. Moreover, Petitioner asserts that it did follow the care plan. It further argues that "[n]one of [the witnesses'] testimony has anything to do with the development of a comprehensive care plan but rather with its implementation or modification." P. Br. at 80.

At the hearing, Ms. Shekell testified that she did not write this deficiency. Tr. 432, 836. She stated that the deceased surveyor, Ms. Chute, had prepared this deficiency. Tr. 369.

Ms. Shekell testified that the actual description of the deficiency in the HCFA 2567 is set forth at page 9 of HCFA Ex. 2 and begins with the sentence "Interviews with licensed nurses and resident #1 revealed that this resident refused to allow nurses to observe her administer her medication. . ." Tr. 386-387, 391-392. Ms. Shekell stated that she was not present when the interviews with the licensed nurses and resident 1 occurred. Tr. 397. She did not know what particular time period had been discussed in Ms. Chute's interviews with the nurses. Tr. 408. Ms. Shekell testified that she did not discuss with Ms. Chute what was said at those

interviews. Tr. 397-398. Ms. Shekell testified further that she "remember[ed] Miss Chute during our team meetings discussing with the team that she had identified a patient that was taking her medications without being properly monitored." Tr. 399.

In describing the deficiency, Ms. Shekell testified as follows: "Well, they have stated in their approach that they are going to monitor and check the patient and count the medications and then they couldn't do that. So then they needed to develop another Plan of Care that, so that they could adequately monitor the medications." Tr. 402. In addition, this testimony was elicited from her:

> A [Ms. Shekell]: As I stated yesterday, I am reviewing this record in the absence of the evaluator that wrote the deficiency. It is not totally clear to me what she meant by the 10th month. I can only make the assumption that the original physician's order was written that the patient may have her meds at the bedside, was written on February the 11th and was -- this care plan was initiated on 12-2, approximately 10 months lager [sic].
>
> Q [Counsel for Petitioner]: And so you're making the assumption that the care plan was initiated as a result of an entry made 10 months before. Am I understanding you rightly?
>
> A [Ms. Shekell]: That's what it appears to me.

Tr. 825.

In response to my inquiry whether a care plan should have been prepared in response to the physician's 2/11 order, Ms. Shekell responded "[t]hat's -- yes there should have been." Tr. 414-415; see Tr. 2556-2557 (testimony of Ms. Patience). Ms. Shekell testified that the only care plan she had before her was the one dated December 2, 1993. She stated "[i]f I had the entire medical record, I would be able to tell you whether they had developed one and then discarded it and then developed another one." Tr. 415. In questioning Ms. Shekell, counsel for Petitioner indicated that the only care plan that was prepared for this resident reflecting self medication was the plan of care completed on December 2, 1993. Tr. 417.

It appears that the surveyor determined that Petitioner had violated the regulation cited here because (1) Petitioner failed to care-plan the physician's order of February 11, 1993 that she "may have own meds at bedside"

until approximately ten months later, on December 2, 1993; (2) once it became apparent that the December care plan approaches could not be successfully carried out due to resident 1's refusals and her own physical condition, Petitioner should have, but failed, to develop a care plan for resident 1 that enabled Petitioner's staff to effectively monitor her taking of her medications; and (3) despite the statement in the 12/2/93 care plan that Petitioner's staff would monitor resident 1's administration of her medication, no monitoring of resident 1's bedside medications occurred until December 6, four days later.

The medical chart for resident 1 which has been admitted into evidence contains a physician's order dated 2/11/93 which states that she "may have own meds at bedside." P. Ex. 21 at 29.[65] Based on the record, however, there is no indication that Petitioner's staff contemporaneously care-planned the 2/11/93 physician's order. Although resident 1's medical chart does contain an earlier care plan containing February 1993 entries, nowhere on this care plan does Petitioner mention the 2/11/93 order. See P. Ex. 21 at 12. The February 1993 care plan would have been an appropriate document in which Petitioner could have contemporaneously noted the 2/11/93 physician's order. However, the record contains only a 12/2/93 care plan relating to self-medication. P. Ex. 21 at 30.

On this 12/2/93 care plan (P. Ex. 21 at 30), in the left-hand column ("patient problems/needs"), Petitioner's staff has written "Info.: Administer some of her medications. Info.: may have own meds @ bedside (as ordered)." Petitioner's staff wrote also that there was a "potential for taking too many meds too often." P. Ex. 21 at 30. In the far right column ("Approaches/Actions") of the care plan, Petitioner's staff listed the "approaches/actions" to be followed with respect to resident 1's self-administration of medication. Id. The first "approach/action" states: "Ordered 2/11/93 may have own meds @ bedside." (emphasis added). The other "approaches/actions" focused on such things as checking resident 1 with respect to the time for administering her medicines, counting the medication in the bottles and logging it as she took it, and monitoring her as scheduled. Id. (I will not repeat verbatim the approaches here because they were included among the findings in the HCFA 2567, which I have already listed above.)

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[65] Resident 1 was admitted to the facility on February 1, 1993. P. Ex. 21 at 1.

The regulation requires that Petitioner have a care plan in place that "includes measurable objectives and timetables to meet a resident's medical, nursing, and mental and psychosocial needs" and describes the "services that are to be furnished to attain or maintain the resident's highest practicable physical, mental, and psychosocial well-being." This Petitioner did not do, for it failed in February 1993 to contemporaneously care-plan the physician's 2/11/93 order that resident 1 could have her own medications at bedside, in violation of 42 C.F.R. § 483.20(d)(1).

Resident 1's medical chart contains also two assessment forms titled "Self-Administration of Medication Assessment", dated April 1, 1993 and December 2, 1993. P. Ex. 21 at 26-27.[66] According to the April 1, 1993 assessment, which was signed by a licensed nurse and a physician, resident 1 was evaluated as not being mentally or physically able to administer medication. P. Ex. 21 at 27. Petitioner's staff wrote that she "gets confused about medication being given. [O]ften forgets" and concluded that she was not a candidate for safe self-administration of medications. Id. Following this assessment, HCFA argued, in effect, that Petitioner was obliged to develop a care plan which set forth measurable objectives and timetables correlating to resident 1's status that she should not be permitted to self-administer medications.[67] See Tr. 2557. Counsel for HCFA seeks such a finding. HCFA Resp. Br. at 28. I am unwilling to make this finding because there is no reference in the HCFA 2567 relating to any intervening circumstances warranting additional care plans. Petitioner has not been put on notice of this particular alleged deficiency. I indicated to the parties that I would construe these deficiencies in a manner consistent

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[66] Ms. Shekell explained that self-administration of medication "means that the patient has the ability to have medications in their room and take them as they feel that they need them or per -- for example, if they wanted to take some cough medicine they could take a cough medicine and have it at their bedside and give it to them whenever they felt that they needed it." Tr. 217.

[67] There is no indication that, based on the documents comprising resident 1's medical chart which is in evidence, the earlier 2/11/93 doctor's order permitting resident 1 to have her medicines at bedside was withdrawn or changed.

with the due process principles of notice and opportunity to defend.[68]

According to the assessment dated December 2, 1993, which also was signed by a licensed nurse and a physician, resident 1 wished to self-administer medications. P. Ex. 21 at 26. She was found mentally and physically able to do so. Petitioner's staff concluded that resident 1 was a candidate for safe self-administration of medications. Id.

Petitioner argues that the 12/2/93 care plan entries (discussed above) were written in conjunction with this 12/2/93 self-administration assessment. P. Br. at 73. I have nothing in this record which allows me to identify with any certainty what was the precise trigger for the 12/2/93 care plan. Whether it was the 2/11/93 physician order or the 12/2/93 assessment, once Petitioner was aware of the 2/11/93 order, it should have initiated a care plan consistent with such order. This was not done. Moreover, Petitioner's contention is plainly inconsistent with the fact that the 12/2/93 care plan specifically mentions the 2/11/93 physician's order.[69]

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[68] In light of HCFA's position that there should have been a care plan in April 1993 in response to the 4/1/93 assessment that resident 1 could no longer self-medicate, I find that the statement in the HCFA 2567, "The facility failed to develop the approaches to address her needs for 10 months. . ." is not accurate. HCFA Ex. 2 at 9. According to the record, the actual time frame during which resident 1 was capable of self-medicating appears to have been from February 11 to April 1, 1993. For the time period of April 1993 to December 1993, Petitioner cannot be said to have failed to have a care plan in place for resident 1 that allowed self-medication, since, as of April 1, 1993, she was no longer a candidate for safe self-administration of medications. The April 1993 assessment, moreover, has no bearing on the 12/2/93 care plan.

[69] Interestingly, Petitioner's own written procedures regarding self-administration of medications state, among other things, that "Licensed nurses will assess the safety and compliance of self administration of medication by the resident, and document on weekly nurses progress notes. The patient care plan will reflect information regarding self-administration by the resident." P. Ex. 21 at 35. Petitioner thus violated its own written procedures, as well as 42 C.F.R. § 483.20(d)(1).

It is not entirely clear from reading the HCFA 2567 as to when resident 1 refused to allow nurses to observe her taking her medicines and to check her bottles. However, I note that, as part of resident 1's medical chart, Petitioner included her medication record for December 1993 (P. Ex. 21 at 31-34).[70] Additionally, there is an interdisciplinary team note dated 11/30/93 which states, in part, "Resident chose not to attend PCP. All disciplines present & participated. . . Refusal of antibiotic discussed." (At the end of this entry, there are four signatures.) P. Ex. 21 at 28. My discussion will thus focus on these particular documents.

Resident 1's December 1993 medication record (P. Ex. 21 at 31-34) establishes that there were instances in December when resident 1 refused to allow Petitioner's staff to monitor her self-administration of her medications. In explaining the medication record, Ms. Shekell stated that the initials in the boxes belonged to whichever nurse had been providing the care during that particular shift. Ms. Shekell testified that the initials, when present, were "supposed to mean" that the nurse "either saw the patient take the medication or administered the medication." Tr. 421. She testified further that a circle around an initial "would normally indicate that the patient refused the medication" and could also represent that the patient "refused to allow monitoring of the medication." Tr. 422. Elsewhere, Ms. Shekell elaborated that, if a medication "is not given, it's circled" and "the reason for is documented other -- some place else in the medical record." Tr. 426-427.[71]

On one page of resident 1's December 1993 medication record is listed the medicines Riopan Plus, Robitussin, and Sucrets. Under each of these medicines, Petitioner's staff has written "may keep at bedside and monitor q

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[70] Petitioner questioned Ms. Shekell on this medication record.

[71] Ms. Shekell testified that the medication record found at P. Ex. 21 at 31 consisted only of the front side and was missing the back side. She stated that, if a resident refused to take medicine, staff "would put date and time and state that the patient refused to take their medication for whatever reason." Tr. 426.

shift." P. Ex. 21 at 31.[72] Among the charting notations for these medicines, however, one finds instances where circled initials were recorded.[73] Thus, based on this evidence, resident 1 apparently refused several times to allow Petitioner's staff to monitor her self-administration of medications.

Petitioner's counsel argues that "[t]he number of instances where there was refusal to permit monitoring of self-medications compared with the number of instances where the care plan was followed and monitoring occurred, did not justify a change in the comprehensive care plan." P. Br. at 68. I find unpersuasive Petitioner's argument. Although Ms. Shekell appeared to agree with Petitioner's counsel that resident 1 "refused a very small number of times out of the total" (Tr. 423), the fact remains that refusals did occur. Such refusals on the part of resident 1 were not minor or inconsequential. Resident 1's actions of non-compliance directly conflicted with the 12/2/93 care plan approaches. Ms. Shekell testified:

> And then this care plan was not further developed when they saw that they couldn't -- that it was ineffective. In other words, staff could not monitor, the patient wouldn't let them count her medications.

Tr. 417.

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[72] For December 1993, resident 1 was permitted also to keep Antivert, vitamin C tablets, multi-vitamin tablets, and Premarin vaginal cream at her bedside. P. Ex. 21 at 33. Petitioner's staff indicated for each of these medications that the resident was to be monitored.

[73] In the Riopan Plus and Robitussin sections, there are two instances of a circled initial recorded at the 3-11 shift for both December 17 and December 21. P. Ex. 21 at 31. In the Sucrets section, there is a circled initial recorded at the 3-11 shift for December 17 and what could be a circled initial at the 3-11 shift for December 21. Id.

Additionally, there are also two blank boxes in each of these three medication sections, where nothing was recorded, for the 3-11 shift on December 19 and the 11-7 shift on December 20. Ms. Shekell referred to these blanks as representing that the nurse "didn't do any monitoring or didn't initial that she had done that particular task during that shift." Tr. 419-420.

Further evidence concerning the difficulty in carrying out the 12/2/93 care plan approaches is found in the Social Services notes. The Social Services note dated 12/17/93 indicates that the resident "apparently fell while trying to get more robitussin." It states also that the resident agreed that "she should request help considering her weakened state." Lastly, the resident requested more Pepto Bismol, but could not remember when she had last taken it. P. Ex. 21 at 21.

Once it was ascertained that the 12/2/93 care plan approaches could not be carried out successfully due to resident 1's refusals and her own physical condition, Petitioner should have developed a new care plan which addressed fully resident 1's current needs. There is no evidence of a care plan that mentions the problems of resident 1's refusals and her physical inability to self-administer medicines or addresses how to adequately monitor her taking of medications in light of these problems and difficulties. Petitioner's failure to develop a new care plan on these grounds establishes further that it violated 42 C.F.R. § 483.20(d)(1).

With respect to HCFA's claim that Petitioner didn't start to monitor resident 1's medications (P. Ex. 21 at 31) until December 6, four days after the 12/2/93 care plan was written (Tr. 681), I find that this allegation goes to the implementation of the care plan and not to the development of a care plan. It is the latter which is the focus of the regulation at issue here. Therefore, I do not make any findings on this allegation.

Petitioner argues that "there is no evidence that resident no. 1 was adversely affected because of what was or was not in the care plan document, i.e., no evidence of any adverse outcome." P. Resp. Br. at 21. Petitioner's assertion fails to consider that actual harm to a resident need not be shown to find a deficiency. As Ms. Shekell testified, ". . . the care plan is to reflect at all times the care needs of the patient." Tr. 699. By leaving a misleading and inaccurate care plan in place, thereby representing it to be accurate and up-to-date, Petitioner potentially could have jeopardized resident 1's health, safety, and well-being. Here, Petitioner's difficulty in monitoring resident 1's self-administration of medication could have resulted in the resident "either over- or under-dos[ing] herself." Tr. 2548 (testimony of Ms. Patience). In fact, this potential danger did occur, for resident 1 could not

remember when she had last taken Pepto-Bismol.[74] It is of little consequence that resident 1 may have experienced no actual harm.

The latter part of the alleged deficiency as written in the HCFA 2567 stated: "Medical record review revealed inconsistencies between the assessments, RAPS, and patient care plan indicating a lack of coordination of information collected during the assessment process as well as the evaluation of the care needs from the entire interdisciplinary care team. The patient care plan must reflect the residents care needs as reflected by the ongoing assessment and changing needs." HCFA Ex. 2 at 9. I find that this part of the deficiency also has been proven by HCFA.

As I have described above, resident 1's medical chart establishes that she had changing care needs with respect to self-administration of medication. Her care plan should have been consistent with any physician's orders and should have reflected at all times her current care needs. The fact that Petitioner did not prepare a care plan to implement the February 1993 physician's order contemporaneously with that order and, also, did not develop a new care plan once it became apparent that the care plan approaches could not be successfully carried out, demonstrates a lack of coordination of information and inadequate evaluation of her care needs.

To address further HCFA's claim that there were inconsistencies among the documents, I have reviewed the following: the medication assessment forms (discussed above), which are dated 4/1/93 and 12/2/93; an MDS dated 8/31/93 (P. Ex. 21 at 2-5); an MDS dated 2/15/93 (P. Ex. 21 at 22-25); a quarterly review dated 11/30/93 (P. Ex. 21 at 7-8); and Social Services notes.

HCFA argued that resident 1's assessments, "as contained in the self-medication forms and the MDS, are inconsistent with other information in the record regarding her confusion and forgetfulness." HCFA Resp. Br. at 26. The Social Services notes (see P. Ex. 21 at 17-19) state that the resident exhibited yelling and screaming on 10/4/93, 10/8/93, and 11/15/93, and, also, manifested confusion on 10/8/93 (P. Ex. 21 at 18). The written entry dated 11/29, in addition to mentioning the

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[74] Ms. Patience stated also that "there could also be potential danger to other residents if she's keeping the medication by the bedside and not handling it properly." Tr. 2548.

resident's forgetfulness, stated also "She continues to make most of her own decisions, but experiences a lot of frustration over the process. [The resident] experiences a lot of anxiety. . . and often ends up yelling at the staff . . ." P. Ex. 21 at 19-20. This entry appears to be a summary of the resident's recent behavior as documented in the previous Social Services notes.

Nowhere on the 11/30/93 quarterly review is there any indication that the resident had any mood or behavior problems. P. Ex. 21 at 7-8. I realize that, in accordance with the printed instructions on the quarterly assessment document, the relevant time frame for purposes of assessing resident 1's mood and behavior patterns was the last seven days prior to the date of the quarterly review which, in this case, would be 11/24/93 - 11/30/93. However, in light of resident 1's recently documented behavior of yelling, screaming, and anxiety, this quarterly review is inconsistent with the Social Services notes and does not appear to reflect an accurate assessment of resident 1.[75]

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[75] The testimony elicited from Ms. Patience with respect to F 272 is instructive:

> The quarterly is just to give the facility kind of a check to see if what they've assessed before in the minimum data set has continued with the resident. If it hasn't then a whole new MDS would be indicated, and that's part of what the quarterly is to help the facility decide.
> Q [Counsel for HCFA]: So by doing the quarterly review, does that confine the facility to look only at the prior seven days?
>
> A [Ms. Patience]: . . . For the quarterly you only look at the prior seven days. Overall, what you've got to do is you've got to look at the resident. If the resident is exhibiting a change then there may be a new minimum data set indicated, and that needs to be done if the resident's got a significant change.
>
> Q [Counsel for HCFA]: So, for example, if a resident eight days or ten days prior to a quarterly has a change in mood should that warrant a change in the assessment?

(continued...)

Additionally, both the MDS dated 2/15/93 and the MDS dated 8/31/93, indicate in Section H that resident 1 had exhibited "verbal expressions of distress" during the last 30 days and had demonstrated a "failure to eat or take medications, withdrawal from self-care or leisure activities." P. Ex. 21 at 4, 24.[76] This earlier documentation of resident 1's distress, together with the 10/93 and 11/93 Social Services notes discussed above, further support a conclusion that the accuracy of the 11/30/93 quarterly review is questionable with respect to its assessment that resident 1 had no mood or behavior problems.[77]

I find that resident 1's mood and behavior problems should have been reflected in the 12/2/93 care plan. Petitioner's failure to do so constitutes a further violation of 42 C.F.R. § 483.20(d)(1). Although resident 1 was assessed as being competent to self-administer medications according to the 12/2/93 medication assessment, nevertheless, I find that the care plan should have indicated her mood and behavior problems and addressed them in the context of self-administration of medications. The care plan was thus arguably inconsistent with what was documented in the Social Services notes which I discussed above. A revisiting of the determination that resident 1 was capable of self-

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[75] (...continued)
A [Ms. Patience]: Depending upon how profound the change is, yes . . . .

Tr. 2495-2496.

[76] Pages 4 and 24 of P. Ex. 21 appear to be exact duplicates of each other.

[77] Resident 1's mood and behavior problems, as documented in the Social Services notes, could be described as constituting a "significant change" in her condition that should have resulted in Petitioner completing a new MDS some time in November 1993, at the latest. 42 C.F.R. § 483.20(b)(4)(iv). This was not done. If Petitioner had completed a new MDS for resident 1, such assessment would have indicated, in the appropriate sections, the mood and behavior problems that she had recently manifested. Furthermore, this new MDS, may, in turn, have resulted in an entirely different quarterly review than that which is in the record.

medication may have been warranted in light of the incidents of exhibited distress. The absence of such care plan provisions had the potential to negatively impact this resident since, without addressing these mental problems, the resident was prevented from achieving her highest practicable level of mental and psychosocial well-being. Moreover, failure to treat these mental problems could potentially place this resident in danger of compromising her health from either an overdose or under dose of medication.

I. Set out below is the statement in the HCFA 2567 concerning the alleged deficiency identified as F 297 (HCFA Ex. 2 at 9-11):

> 42 C.F.R. 483.20(d)(2) (ii) Prepared by an interdisciplinary team, that includes the attending physician, a registered nurse with responsibility for the resident, and other appropriate staff in disciplines as determined by the resident's needs, and, to the extent practicable, the participation of the resident, the resident's family or the resident's legal representative;
>
> *****
>
> Based upon observation, interview and medical record review it was determined that staff failed to use an interdisciplinary approach to the evaluation of resident status.
>
> Findings include:
>
> Resident #1 was admitted to the facility 2/1/93. In February, 1993, an order was written by her physician that said sh [sic] could self medicate and have her medications at her bedside. In April, 1993, a "self administration of medication assessment" was completed and she was not found to be a candidate for self-administration of medications.
>
> On 12/2/93 a second "self-administration of medication assessment" was completed and signed by a physician and a licensed nurse. She was found to be a candidate for self administration of medication at that time. The facility failed to follow their own policy and procedure 'Review of bedside medications and self administration' which requires the involvement

> of an interdisciplinary team in the assessment, care planning and monitoring of the resident for self administration and bedside storage of medication.
>
> Cross Reference - F292
>
> It was evident through medical record review that all disciplines did not participate in the evaluation and assessment of each resident on a quarterly basis or as needed.
>
> Cross Reference - F295

42 C.F.R. § 483.20(d)(2)(ii) pertains to the utilization of an interdisciplinary team in the preparation of a resident's care plan. The findings set forth in the HCFA 2567 (re-stated above) in support of this alleged deficiency relate to resident 1's "self-administration of medication" assessments. There is nothing in the findings that identifies Petitioner's conduct in contravention of the requirements of 42 C.F.R. § 483.20(d)(2)(ii), which are limited to a resident's care plan.

The evidence offered by HCFA in the HCFA 2567 relating to Resident 1's assessments is extraneous and goes beyond the regulation at issue. In its brief, however, HCFA discusses resident 1's assessments and her 12/2/93 care plan (HCFA Resp. Br. at 29-30) although this care plan was not mentioned at all in the findings in the HCFA 2567.

In fairness to Petitioner, HCFA's presentation of the evidence in support of this alleged deficiency is an example of the "moving target" approach which Petitioner has accused HCFA of taking at times. I do not accept HCFA's attempt to establish the existence of this deficiency by evidence which is wholly unrelated to the findings set forth in the HCFA 2567. Although the regulation relates to care plans, the basis of the deficiency, as written in the HCFA 2567, concerned resident 1's assessments, not her care plan. While in the course of the hearing I allowed HCFA at times to amplify the factual elements of a deficiency, there was, with respect to those deficiencies, sufficient information given in the HCFA 2567 to put Petitioner on notice of the alleged conduct being challenged which violated the referenced regulation. Here, there are insufficient facts in the deficiency relating to care plans to put Petitioner on notice as to its conduct which was out of compliance with 42 C.F.R. § 483.20(d)(2)(ii).

HCFA goes beyond mere amplification of the facts in the deficiency. It introduces evidence supporting the cited regulatory violation that was not alleged in the HCFA 2567. No amendment of the HCFA 2567 was ever sought by HCFA. Consequently, any attempt by HCFA to go beyond what was charged in the HCFA 2567 is for naught.

Moreover, HCFA relied on the findings set forth in the HCFA 2567, which have no relation to the language of 42 C.F.R. § 483.20(d)(2)(ii), to prove that Petitioner was out of compliance with this regulation. This reliance is misplaced. Resident 1's "self-administration of medication" assessments have nothing to do with her care plans. Further, although F 295 cross-references F 297 (HCFA Ex. 2 at 9), the findings pertaining to F 295, set forth in the HCFA 2567, do not support the existence of a violation of the regulation on which F 297 is based.

The only reference to care-planning in the deficiency related to a general allegation of Petitioner's failure to follow its own internal procedure which requires the involvement of an interdisciplinary team in the assessment, care-planning, and monitoring of the resident for self-administration and bedside storage of medication. The deficiency fails to state with sufficient particularity the care plan in issue, and the make-up of the interdisciplinary team who prepared such care plan and how that grouping was in violation of the cited regulation. The individuals identified in the deficiency pertained to the resident's assessment for self-administration of medication. No information is provided as to individuals who participated in the care plan, nor is there a reference to a specific care plan. Such information is basic to establishing a violation of the cited care plan regulation.

Accordingly, Petitioner did not violate 42 C.F.R. § 483.20(d)(2)(ii).

J. Set out below is the statement in the HCFA 2567 concerning the alleged deficiency identified as F 298 (HCFA Ex. 2 at 11):

> 42 C.F.R. 483.20(d)(2) (iii) Periodically reviewed and revised by a team of qualified persons after each assessment.

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> Based on observation, staff and resident interview, and medical record review it was determined that the careplan did not reflect current assessment of each resident.
>
> Findings include:
>
> Resident 20 was observed on 12/20/93 sitting up in a chair. He had a Linard sitting [sic] system in place, however he was leaning to one side and appeared very uncomfortable. Licensed staff reassessed the resident and changed positional devices, and the resident told this evaluator that he was more comfortable. The plan of care was not updated to reflect this change.

HCFA relies to a great extent on the testimony of Ms. Cox for proof of this deficiency. Ms. Cox stated that she and a staff member observed resident 20 as they walked by him and saw that he was "in very poor bodily alignment. He was slumped forward to the side." Tr. 1061. Ms. Cox stated that she and the staff member "stopped and looked at him." Id. Ms. Cox testified further:

> I talked to the resident. He said -- after I asked him if he would [sic] was comfortable in that position which he certainly appeared not to be, he did say that he was not comfortable. The licensed person with me went and got either an occupational therapist or a physical therapist, had her come, look at him right then when I was there. She said that the system that they were currently using was not working for him and that she would find something else that did work for him.
>
> She in fact did find something else. They changed the chair. They used kind of an -- I'm not sure what it's called but it's a saddle type of thing to keep him from sliding down, and the chair that they replaced kept him sitting more upright.
>
> He himself verbalized that he was more comfortable with the new system that they had given him . . . .

Tr. 1061-1062.

According to Ms. Cox, Petitioner then failed to change the resident's care plan to show that a new system had been started with him. Tr. 1062.[78] Ms. Cox expressed concern that, because Petitioner's staff left the old care plan in place, there was a possibility that the resident would be put back on the old system. Id.

In response to this cited deficiency, Petitioner argues that "the evidence is in sharp dispute as to whether the seating system was changed or whether there was only an adjustment causing the patient to sit more upright." Moreover, "[t]here is a failure of proof to indicate that any modification or change which occurred required a change in the seating system necessitating a change in the plan of care." P. Br. at 83.

HCFA and Petitioner do not dispute that a postural seating system was being used on resident 20 at the time Ms. Cox observed him. This seating system, according to resident 20's medical chart, was instituted pursuant to a physician's order dated September 28, 1993 which states: "Postural seating system when OOB [out of bed] for body alignment and safety in w/c [wheelchair]. DC [Discontinue] previous order for safety bar when in w/c . . ." P. Ex. 23 at 4.[79] Petitioner's staff noted this order in the care plan also. Id. at 12.

Although the care plan does not specify the type of seating system used on resident 20, Ms. Cox has alleged, and Petitioner does not appear to deny, that the seating system which was in place for resident 20 at the time of Ms. Cox's observation was a Linard seating system. Tr. 1308.[80]

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[78] Ms. Cox stated: "When his assistive devices for positioning were changed then his care plan was not changed to reflect that." Tr. 1306-1307.

[79] Ms. Downing testified that there was no indication that the physician ever changed this order for resident 20's seating system. Tr. 1916. She explained that, in long-term care settings, seating systems are primarily used for postural support and body alignment. Tr. 1928.

[80] Ms. Cox testified that the Linard system is "a soft system that's shaped in a semicircle that comes up high on the resident and fastens in front to try and keep them from leaning to one side or the other. Help them sit up straight." Tr. 1458. Ms. Downing testified that

(continued...)

I accept Ms. Cox's testimony relating to this deficiency and find that the scenario involving resident 20 occurred as Ms. Cox described it. Petitioner presented no testimony from anyone on its staff who was present at the time of Ms. Cox's observation of resident 20 to contradict her testimony. Petitioner could have offered the testimony of the staff members who were directly involved in the reassessment of resident 20, but it did not do so. Moreover, while Ms. Downing did testify concerning her review of resident 20's medical chart and about seating restraints in general, she was not present when Ms. Cox observed resident 20 and thus has no first-hand knowledge of this incident.[81]

After resident 20 voiced his discomfort, I find that Petitioner's staff undertook significant steps to maintain resident 20's proper posture and comfort level. Contrary to Ms. Downing's assertion that there was no change in resident 20's seating system, Petitioner's staff did change positional devices to alleviate his discomfort and help him sit upright. Petitioner's staff removed the Linard seating system (Tr. 1308, 1310), put resident 20 in a "saddle type of thing to keep him from sliding down," and replaced his chair with one that "kept him sitting more upright." Tr. 1062. Thus, it cannot be said that resident 20's existing seating system remained the same. I conclude that the changes made by Petitioner's staff were significant and constituted more than a simple re-adjustment of resident 20's existing seating system.[82] As such, Petitioner's staff was

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[80] (...continued)
she was familiar with the Linard seating system and stated that it is a brand of a pre-made, postural seating system that supports a person's upper trunk. Tr. 1914.

[81] Ms. Downing began working for Petitioner on January 17, 1994. Tr. 1687-1688.

[82] At the hearing, both Ms. Downing and Ms. Patience testified as to what kind of "change" in positioning devices or seating systems would warrant revision of the care plan. Ms. Downing testified that a resident who was using a "seating postural support" or any kind of restraint required periodic re-evaluation "every two hours to make sure that. . .they're positioned right, that the support is positioned correctly, to check their circulation, to ensure that their posture is being maintained." Tr. 1924. Ms. Downing stated that these periodic re-evaluations of the resident would not
(continued...)

required to update resident 20's care plan contemporaneously to reflect this change. Ms. Cox testified that she checked the care plan between Dec. 20 and Dec. 23 to see if resident 20's care plan had been updated to reflect the change in positioning devices, and it had not. Tr. 1067. By its failure to revise resident 20's care plan, Petitioner did not comply with 42 C.F.R. § 483.20(d)(2)(iii).

In elaborating on its arguments, Petitioner contends that the saddle is not considered to be part of a seating system and that the addition of a saddle would not constitute a change to the seating system per se. Tr. 1921, 2315-2316; P. Br. at 87-88; P. Resp. Br. at 23-24. Moreover, Petitioner contends, the saddle "was added months after the event in question and not at the time [Ms. Cox] claimed". P. Br. at 85.[83] Petitioner is apparently referring to resident 20's plan of care, which

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[82] (...continued)
necessitate changing his or her care plan. Tr. 1924.

Ms. Patience, like Ms. Downing, had no first-hand knowledge of the incident involving resident 20 which forms the basis of this deficiency. She testified that the readjustment of a slipped pillow or replacement of a fallen pillow would not constitute a change in positioning devices that would require a change in the care plan. Tr. 2814-2816, 2818. Ms. Patience testified also, in response to Petitioner's counsel's questioning, that, if a resident's restraint was made to fit properly upon becoming loosened, this would not require a change in the care plan. Tr. 2818.

According to Ms. Patience, however, the addition or repositioning of pillows could constitute a change which would necessitate reporting it in the care plan if the pillows were being used as a postural support. Tr. 2564-2567; See also Tr. 2816. Ms. Patience, in response to my questioning, testified, "If the pillows need to be in a particular configuration in order to keep the resident in a particular position, then that should be placed on the Care Plan." Tr. 2565; See also Tr. 2566-2567.

[83] Ms. Downing testified that the care plan "doesn't show a change in the seating system", but "shows that a western saddle was added to the seat" on 4/12/94. Tr. 2314, 2316.

does indicate that a "western saddle" was added on 4/12/94 (P. Ex. 23 at 12).[84]

I do not agree with Petitioner that the addition of a saddle device could not have occurred earlier, as Ms. Cox described in her testimony. The existence of the 4/12/94 entry in the care plan does not disprove Ms. Cox's testimony that a saddle was added to resident 20 at the time of the survey in December 1993. It is noteworthy that Petitioner, who had all of resident 20's medical records in its possession, could not produce any care plan entry dealing with seating systems that was made contemporaneously at the time of the December 1993 survey. Petitioner produced only the April 1994 care plan entry, which is irrelevant. Given that I find some sort of a saddle device was added in December 1993, the 4/12/94 entry in resident 20's care plan does not negate the failure on the part of Petitioner's staff to indicate in the care plan in December 1993 that a saddle was added.

Moreover, I cannot conclude whether it was a western saddle that was used on resident 20 in December 1993. Notwithstanding this, whether the western saddle mentioned in the April 1994 care plan is the same device that was used on the resident in December 1993 is irrelevant to the issue of whether resident 20's care plan reflected a current assessment in December 1993.

As further support that there was a change in positional devices, as alleged in the HCFA 2567 ("Licensed staff reassessed the resident and changed positional devices . . ." (emphasis added) (HCFA Ex. 2 at 11), Ms. Downing stated that both the Linard system and the saddle could be described as positional devices (Tr. 2315, 2316). Thus, in light of this statement, the reference in the HCFA 2567 to a positional device could very well be a reference to the addition of a saddle device to resident 20, despite Petitioner's claims that no such event occurred.

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[84] According to Ms. Downing, a western saddle is not a postural seating system or a part of one. Tr. 1921. Ms. Downing described the western saddle as being "a cushion, . . . with a saddle horn to prevent them scooting forward. It's not considered a seating system. . . It's designed to prevent [the individual] from sliding out of the wheelchair." Tr. 2315; see Tr. 1921.

At the hearing, I pointed to the plan of correction submitted by Petitioner in response to this alleged deficiency and noted that it stated, in part, "The resident's care plan has been updated to reflect changes." HCFA Ex. 2 at 11.[85] In response to my inquiry as to whether resident 20's care plan had been updated to reflect the change, Ms. Downing was unable to point to anything in resident 20's care plan which could possibly corroborate this statement. Instead, Ms. Downing interpreted the statement I quoted above as referring to a September 1993 entry in the care plan and stated "that's what they were emphasizing." Tr. 1933-1934. I find Ms. Downing's testimony rather puzzling and confusing in light of the fact that this alleged deficiency involving resident 20 occurred during the survey in late December 1993. Any care plan change dated prior to December 1993, while it could possibly be considered an "update" to the care plan, would not have any relevance to this alleged deficiency nor would it be considered as a remedial action in response to the deficiency. Ms. Downing's statement can be construed only as further proof that Petitioner did not update resident 20's care plan following the change in December 1993 in his positional devices. The statement in

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[85] Petitioner's plan of correction, which is dated 1/31/94, is presumed to contain the corrective actions it has implemented in response to the deficiencies cited in the HCFA 2567 by the survey team.

With respect to resident 20 and this alleged deficiency, the complete text of Petitioner's plan of correction is:

> Residents shall be assessed and their care plan approaches updated to address contracture relative to treatment.
>
> Resident #20 has been assessed by interdisciplinary staff to address his needs for proper positioning to prevent further contracture and instructed staff in his care needs. The residents care plan has been updated to reflect changes.

HCFA Ex. 2 at 11.

Petitioner's plan of correction is apparently uncorroborated by the record before me.[86]

Petitioner contends that there is no evidence to show that resident 20's health or safety was adversely effected. P. Resp. Br. at 24. While this may be true, I find that there existed the potential of harm to resident 20. As I stated earlier, under OBRA, Petitioner is responsible for providing residents with services necessary to attain or maintain their highest practicable physical, mental, and psychosocial well-being as required under 42 C.F.R. § 483.25. In order to maintain resident 20's proper alignment, Petitioner's staff implemented a significant change from his pre-existing seating system. It was necessary for this change to be care-planned to ensure that other caregivers on Petitioner's staff would know that they should implement it on a daily basis to maintain his highest practicable physical well-being. However, because resident 20's care plan did not indicate the change in positional devices that occurred on December 20, 1993, it was likely that other caregivers, not knowing what had been done and assuming the care plan to be up-to-date, would have put him back into his old seating system, which had been determined to be ineffective and uncomfortable. Such a result could have had a detrimental effect on resident 20's health and safety and would have contravened the very purpose of OBRA.

The regulation requires that the comprehensive care plan must be periodically reviewed and revised after each assessment. This was not done here with respect to resident 20's care plan, in violation of 42 C.F.R. § 483.20(d)(2)(iii). Moreover, such failure had the potential to negatively impact this resident recited above. Consequently, HCFA has met its burden of proof in establishing this deficiency.

K. Set out below is the statement in the HCFA 2567 concerning the alleged deficiency identified as F 300 (HCFA Ex. 2 at 11-13):

> 42 C.F.R. 483.20(d)(3) (ii) Be provided by qualified persons in accordance with each resident's written plan of care.

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[86] Ms. Downing testified also that the care plan indicates that there were no changes in positioning devices until 4/12/94. Tr. 2317.

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Based on record review, observation, and interview, the facility failed to provide services by qualified persons in accordance with each resident's plan of care.

Findings include:

Resident 24 has a physician's order for an E-Z boot to be applied by nursing staff daily from 8 P.M. as tolerated. Review of his treatment record revealed that licensed staff was documenting that the boot was not available for use and has not been applied since it was ordered on 12/9/93. Licensed staff was observed by this evaluator when they entered the resident's room to search for the boot. The boot was found in his bedside stand. There was no explanation why the boot had not been used and no monitoring system was in place to insure the plan of care was followed.

Resident 8's plan for care dated 12/1/93 indicates that he requires 1700 CC's of fluid over a 24 hr. period. The resident had a diagnosis of recent pneumonia and current stage 3 decubitus. Review of the intake records from 12/2/93 to 12/19/93 revealed that the resident's intake only met the 1700 cc goal 2 days out of the two week period. The majority of days the resident's intake was less than 1500 cc's over a 24 hr. period and as low as 890 cc on 12/13/93 and 740 cc on 12/19/93. Licensed nurse's notes did not address failure to meet this resident's fluid needs, and in fact stated there was no problem. This resident was at high risk for further skin breakdown and reoccurring pneumonia, if hydration is not monitored and maintained.

1. Resident 24

According to the HCFA 2567, resident 24 had "a physician's order for an E-Z boot to be applied by nursing staff daily from 8 P.M. as tolerated." HCFA Ex. 2 at 12; see P. Ex. 24 at 2. Review of this resident's treatment record revealed that Petitioner's staff documented in this resident's record that the boot was not available for use and had not been applied since it was ordered on December 9, 1993. HCFA Ex. 2 at 12; see P. Ex. 24 at 11, 12. The resident's treatment record

from December 10 through December 23, 1993, provides notations for each day during this period indicating that the E-Z boot was "missing" or "unavailable." P. Ex. 24 at 12. During the survey, Ms. Cox observed that 1) the boot was found in the resident's bedside stand, 2) no explanation was offered as to why the boot had not been used, and 3) no monitoring system was in place to ensure that the plan of care was followed. Tr. 1069-1070.

Ms. Cox described an E-Z boot as "a system that they use to either prevent contracture of the ankle or sometimes they also put them on just to protect the heels or to keep the foot in a certain position. I've seen them used for multiple different things." Tr. 1072. Ms. Cox stated that failure to apply the boot as ordered could have adverse consequences on the resident's health. Id.

Petitioner does not dispute the facts relating to the E-Z boot cited in the deficiency, which were based on Ms. Cox's observations. P. Resp. Br. at 24. Rather, Petitioner argues that proof of a deficiency has not been established in this record. First, Petitioner argues that the surveyor could not state at the hearing what was in the care plan relating to application of the E-Z boot. P. Br. at 90. Second, the plan of care is not in the record and there is no evidence that it covered use of an E-Z boot. P. Resp. Br. at 24-25. Third, Petitioner contends that failure to follow a physician's order is not violative of the cited regulation since the regulation pertains to care plans. Id. at 25. Fourth, Petitioner argues that, even if a deficiency could be found, it was corrected before completion of the survey and, as a result, no deficiency should have been cited. P. Br. at 89. Last, Petitioner argues that HCFA has shown no pattern or negative outcome to the resident. P. Resp. Br. at 25.

I agree with Petitioner that 42 C.F.R. § 483.20(d)(3)(ii) relates to failure to provide services in accordance with the resident's plan of care. HCFA did not place in evidence a plan of care which implements the physician's order requiring use of the E-Z boot. However, such absence does not amount to a failure of proof. While Ms. Cox could not recall at the hearing what the plan of care said about application of the E-Z boot, she did testify that she reviewed the care plan in connection with preparation of her findings.

> This deficiency was written because I did a record review. I observed the resident and I interviewed facility staff and when all after I had looked at the record and the Care Plan

> [emphasis added] and I asked facility staff -- When I observed him he didn't have his easy [sic] boot on as it was ordered by the physician or as it was Care Planned [emphasis added], . . .[she went on to describe the undisputed facts in this deficiency.] . . . So obviously they didn't follow their plan of care and nobody was familiar with the fact that the boot was right in his closet . . . .

Tr. 1069-1070.

Besides such testimony, my review of this resident's records, including the minimum data set, quarterly review, rehabilitation screen and physician's order, leads me to conclude that a care plan was developed for this resident which carried out the physician's order for application of the E-Z boot. P. Ex. 24. These documents establish that the resident had contracture of his lower extremities which would necessitate treatment and which would have triggered preparation of a plan of care which would have included the physician's order for application of the E-Z boot. Id. at 2-4, 6, 9.

Even without the presence of the care plan in evidence, there is sufficient evidence to create a strong inference that such plan existed and was relied on by Ms. Cox in preparing her findings. While Petitioner's counsel may have shown that Ms. Cox had no recollection of the specifics of the care plan at the hearing (Tr. 1327), such failure of recollection does not negate the weight of other evidence in the record suggesting the existence of the care plan and that it implemented the physician's order relating to use of the E-Z boot on this resident. Moreover, I do agree with HCFA's position that, if Petitioner contends that the care plan did not cover the E-Z boot, it should have put the care plan in evidence.[87] HCFA Resp. Br. 35-36. No such care plan was submitted by Petitioner. Therefore, based on the record as a whole, I find that Petitioner failed to carry out the physician's order in accordance with the resident's care plan. This

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[87] I have concluded that HCFA has sufficient evidence of record to support a strong inference of the existence of a care plan which included the physician's order for the E-Z boot. Once such inference is established, Petitioner, who is in possession of the medical records for this resident, has the burden of refuting the inference by offering the care plan into evidence.

failure is precisely the type of conduct that the cited regulation was promulgated to cover.

Petitioner argues that even assuming the regulation was violated, the deficiency was corrected prior to completion of the survey. I do not agree. The violation goes beyond mere placing of the E-Z boot on the resident; it includes also the absence of a monitoring system to ensure that the care plan was followed. See HCFA Ex. 2 at 12; Tr. 2584-2585. Arguably, the failure to have a monitoring system in place led to Petitioner's failure to locate the E-Z boot until the surveyor directed the attention of the staff to its absence. This conclusion is supported by the nurses' treatment notes indicating that, from December 10 through December 21, 1993, the E-Z boot was either missing or unavailable. P. Ex. 24 at 12. It appears that Petitioner's staff did nothing to locate the missing boot nor take steps to get a new boot. Tr. 1069-1070; P. Ex. 24 at 11-12.

Petitioner has not contended nor can I find in this record any evidence that a monitoring system was in place or put in place at the time of the completion of the survey. Without such a system in place, there is no assurance that the circumstances of this deficiency would not be repeated with other residents. Thus, I cannot find that this deficiency was corrected at the completion of the survey.

Lastly, Petitioner argues that there is no evidence of a pattern or negative outcome resulting from this deficiency. Again, I do not agree. The lack of a monitoring system placed this resident and other residents at risk that their treatment would not be provided as ordered by their physicians and implemented in their care plans. The absence of such system goes beyond the treatment of a single resident. The potential for a negative outcome to the health and safety of the residents of Petitioner due to failure to provided necessary treatment cannot be seriously disputed. Such an outcome is contrary to the tenets of OBRA '87 and its implementing regulations.

2. Resident 8

Resident 8's plan of care indicated that he was at risk for fluid volume deficit. P. Ex. 25 at 5. His care plan stated (in the column titled "Measurable and Time Oriented Objectives") that he will have moist oral mucosa and his fluid intake will be at least [emphasis added] 1700 cc's of fluid over a 24-hour period. Id. The resident had been diagnosed with recent pneumonia and

current stage 3 decubitus (pressure sores). HCFA Ex. 2 at 12. The care plan approaches to achieving the goal of 1700 cc's of fluid was to "encourage fluids" and monitor the resident's intake and output. Also, Petitioner's staff was to "[a]ssess for dry oral mucosa & notify MD immediately if present. Monitor labs as ordered."[88] P. Ex. 25 at 5. A surveyor's review of the resident's intake records from December 2 to December 19, 1993 indicated that the resident's intake was 1700 cc's on two days out of this two-week period.[89] HCFA Ex. 2 at 12.

HCFA argues that

> . . . Petitioner's continuing failure to follow its care plan for the resident's fluid intake when the amount of fluid being consumed continued to fall far below the established goal, or to change the plan if necessary, demonstrates a lack of concern and attention to the resident's physical well-being, clearly in contravention of OBRA and its regulations. HCFA Br. at 37.

In response, Petitioner argues that the HCFA 2567 implies that there was a failure to follow the requirements of a plan of care for 1700 ccs of fluid intake. Petitioner contends that "[t]he care plan document itself does not show any such requirement but shows this to be a goal or objective." P. Br. at 93. Further, Petitioner asserts:

> [t]he intake and output records indisputably show that the care plan was followed with respect to the monitoring requirement of the care plan. HCFA failed to put on any proof that the facility did not encourage the fluids as required by the care plan. There is accordingly no evidence indicating a failure to follow the care plan which, contrary to the evidence, did not require that 1700 ccs be achieved in a 24-hour period.

P. Br. at 92.

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[88] There was no evidence offered by HCFA or Petitioner on this lab monitoring action set forth in the care plan. Accordingly, I can make no findings on whether this aspect of the care plan was met.

[89] By actual count, it is an 18 day period, approximately two and one half weeks.

Petitioner takes exception also to the statement in the HCFA 2567 alleging "[l]icensed nurse's notes did not address failure to meet this resident's fluid needs, and in fact stated there was no problem." Petitioner argues that "the allegation that the nurses' notes did not reflect the failure to take in 1700 ccs of fluid is not a violation of the regulation, which requires that care be given in accordance with the written plan of care." P. Br. at 92.

I cannot accept Petitioner's interpretation of this resident's care plan regarding the intake of 1700 ccs of fluid daily. The plain meaning of the care plan -- "fluid intake will be at least 1700 cc/24 hr" -- leaves no doubt that 1700 ccs was the minimum amount of fluid that this resident was to be provided within a 24-hour period. The language is clearly mandatory and not permissive. Even if the 1700 cc amount can be characterized as a goal, the care plan makes clear that this objective was to be met each day.

The record is unambiguous as to Petitioner's failure to have this resident meet this 1700 cc objective on a daily basis as called for in the care plan. During the period of December 2 through December 19, 1993, the resident met the objective only on December 2 and 17, 1993. P. Ex. 25 at 2-4. Although the resident met the objective only once during the period of December 2-8, 1993, there is no notation on his Intake and Outpatient Record that any evaluation of the resident or monitoring of his intake was conducted. Id. at 2. Records for December 9-19, 1993 reflect that the resident met the objective only once and his average 24-hour intake was 1182 ccs for 12/9 - 12/12/93 and 1278 cc's for 12/13 - 12/19/93. Id. at 3-4. These records indicate that Petitioner's staff encouraged the resident to increase his fluid intake and praised him for his efforts. Id. His mucous membrane was noted to be moist. Id.

Ms. Patience testified that "it's a deficient practice if the goal is to be 1700 cc's and they weren't meeting it, that's a deficient practice." She stated also that the goals should have been either updated or reassessed and the care plan should have been revised. Tr. 2590-2591.

I conclude that Petitioner failed to treat resident 8 in accordance with his written plan of care and thereby violated 42 C.F.R. § 483.20(d)(3)(ii). Resident 8's care plan specifically provided that he should have at least 1700 cc's of fluid over a 24-hour period. The evidence shows that the resident did not receive the 1700 cc's of

fluid except for two days out of the 18-day period covered in the record.

Petitioner's argument that "there was no adverse impact to the patient's state of hydration or his health, and the amount actually consumed was adequate for his condition" is flawed. P. Resp. Br. at 91. I have no information on this resident's status for the first week since Petitioner's staff failed to complete its own evaluation form. P. Ex. 25 at 2. I would agree that, if a measuring criteria for lack of hydration is a dry oral mucosa as suggested by the care plan, there is no evidence that this occurred during the period December 9 - 19, 1993.[90] Id. at 3-4. However, I find credible the testimony of Ms. Cox and Ms. Patience that reduction of this resident's fluid intake below the care plan objective could have placed him at risk for pneumonia and skin breakdown. Tr. 1078, 2588-2589. While the resident may have had a moist mucosa, continued repeated failure to adhere to the 1700 cc objective eventually could have placed his health and safety at risk.

I do concur with Petitioner's position that its staff monitored the resident's fluid intake and output. P. Br. at 92. The Intake and Output Records in evidence support this view. P. Ex. 25 at 2-4. But monitoring is not enough. The care plan indicated that the resident was to receive at least 1700 cc's of fluid each day. Petitioner did not ensure that this mandated objective in the care plan was met. Nor did Petitioner's staff's use of encouragement meet this requirement. Id. I do not accept Petitioner's reasoning that monitoring this resident's fluid intake and output and encouraging his increase intake can be substituted for following the specific intake objective contained in the plan of care.

I agree with HCFA's contention that Petitioner was required to take action and reassess the resident where the stated fluid intake objective in the care plan was not achieved except for two isolated days. HCFA Resp. Br. at 37. Notification of the physician would be necessary even when no specific adverse impact on the resident was noted, such as a dry mucosa. I must assume that the physician chose the 1700 cc intake objective for some medically justifiable reason. By not giving the resident the stated amount on a regular basis, Petitioner was in effect altering the specific intake objective in

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[90] The resident's skin turgor was noted to be "warm & dry" or "good," no edema was noted and his mucous membrane was noted to be moist. P. Ex. 25 at 3-4.

the care plan. Considering the potential for adverse consequences resulting from lack of fluids, Petitioner would need to advise the physician of the lower fluid intake and inquire whether the care plan needed to be amended to correspond to the fluid level that the resident was consuming. Despite the fact that Petitioner failed to change the resident's care plan in this case, such failure cannot be a basis for a deficiency, since it is outside of the parameters of the cited regulation.[91]

L. Set out below is the statement in the HCFA 2567 concerning the alleged deficiency identified as F 309 (HCFA Ex. 2 at 13-14):

> 42 C.F.R. 483.25. Each resident must receive and the facility must provide the necessary care and services to attain or maintain the highest practicable physical, mental, and psychosocial well-being, in accordance with the comprehensive assessment and plan of care.
>
> *****
>
> Based on record review, observation, and interview the facility failed to provide the necessary care and services to attain or maintain the highest practicable physical, mental and psychosocial well being of each resident.
>
> Findings include:
>
> Resident 20 was observed eating lunch in his room, in bed. He was attempting to feed himself. Each time he lifted a spoon full of food to his mouth he tipped the spoon, dropping most of the food onto his lap or back onto the plate. Review of the medical record revealed that he has a diagnosis of a stroke with hemiparesis and diabetes. The nursing assessment indicates that he leaves 25% or more of his food and requires supervision while eating. He is below his ideal body weight. This resident was not properly supervised and assessment for the use of assistive devices was inadequate.

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[91] There is no indication in the HCFA 2567 that the facts of this deficiency were to be cross-referenced to another citation, such as F 298, that pertains to the need to revise assessments.

> Review of resident 16's medical record revealed that she was making good progress in her ability to ambulate in June 1993, as documented by Physical Therapy staff. She was referred to the restorative nurse aide program for continued ambulation. She was discontinued from the program for no stated reason and currently is on no routine ambulation program. Observation of this resident throughout the survey revealed that she spends most of her day restrained with a vest in a wheelchair. Cross reference F292.

1. Resident 20

Resident 20 was admitted to the facility on March 30, 1993. P. Ex. 26 at 1. An April 1, 1993 entry in Resident 20's care plan, in the column titled "Patient Problems/Needs" states "Alteration in nutritional needs due to: Dx: DM [diabetes mellitus], CVA [cerebralvascular accident] c Rt. hemiparesis, low wt. c wt. loss" and notes that his ideal body weight range is 133 to 163 pounds. Tr. 229-231; P. Ex. 26 at 10. Resident 20's weight upon admission was 108.4 pounds, well below his ideal weight. P. Ex. 26 at 10. The record indicates that Resident 20 also had Parkinson's disease and difficulty in swallowing (dysphagia).[92] P. Ex. 26 at 1, 10. It is apparent from the record that all of this information was known to Petitioner when it admitted Resident 20. Id.

Resident 20 continued to lose weight during his stay. P. Ex. 26. HCFA contends that resident 20 was attempting to feed himself and was unable to manage the eating utensil, dropping the food onto his lap or onto the plate. HCFA Br. at 59. HCFA contends further that "the resident was

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[92] The transcript contains a reference defining dysphasia as difficulty in swallowing. Tr. 231. However, the definition of dysphasia is "loss of or deficiency in the power to use or understand language as a result of injury to or disease of the brain". Webster's Ninth New Collegiate Dictionary 391 (9th ed. 1990). The word dysphagia is defined as "difficulty in swallowing." Id. Since the witness testifying defined the word as meaning difficulty in swallowing, I can only conclude that the transcript reference at Tr. 231 should read dysphagia and not dysphasia. The rehabilitation screen confirms this conclusion, for, in the "feeding" section, there is a box checked indicating resident 20 had dysphagia. P. Ex. 26 at 3.

not properly supervised and assessment for the use of assistive eating devices was inadequate." HCFA Br. at 60. HCFA argues that Petitioner failed to provide resident 20 with the necessary care and services such that he could maintain adequate feeding. HCFA Br. at 63.

Ms. Shekell testified that from December 16, 1993 through December 31, 1993, resident 20 was assessed by Petitioner as being able to eat independently. Tr. 232; P. Ex. 26 at 13. However, out of the total of 48 meals that were received by resident 20 during this time period, he consumed 75 percent or less on 34 occasions out of the 48. P. Ex. 26 at 13; see Tr. 232-233. Moreover, Ms. Shekell stated that, according to the minimum data set dated 4/12/93, it appears that resident 20 was initially assessed as a "4" (total dependence) in the "Eating" subsection of section E, but the "4" was subsequently crossed out and replaced with a "0", indicating that he was independent. Tr. 233-234; see P. Ex. 26 at 5. Quarterly reviews dated July 14 and October 12, 1993 indicate that resident 20 was able to eat independently without help or supervision. Tr. 234-235; P. Ex. 26 at 8. However, Ms. Shekell testified, the assessments are at odds with other parts of resident 20's record, which indicate that he had impaired range of motion and impaired strength in his upper extremity; was prone to contractures; had motor, memory, and sensory deficits; had impaired cognitive status; and also had Parkinson's disease. Tr. 235-236; see P. Ex. 26 at 3. Ms. Shekell, after describing resident 20's impairments, stated "and yet [resident 20] was allowed to feed himself." Tr. 236.

Petitioner contends that resident 20 "was maintained at his highest practicable level" because he was given a special spoon to assist him in eating independently. P. Br. at 97; see id. at 102. Petitioner contends that resident 20 was offered other nourishment but frequently refused it and that he also refused to eat at all on a number of occasions. Id. at 97, 103. Petitioner notes further that resident 20 rejected more stringent measures, such as tube feedings. Id. at 97, 101, 103. Accordingly, Petitioner contends there were no other alternatives by which it could have given more nutrition to resident 20 and, "given his abilities and his state of willingness to take nourishment," it did maintain the resident at his highest practicable level. Id. at 97, 103.

Contrary to Petitioner's position that no other methods could have been used to assist resident 20 with his eating, the testimony from Ms. Shekell and Ms. Patience is that other assistive devices could have been tried to

assist resident 20 to consume larger amounts at his meal times. Additionally, HCFA avers that Petitioner's staff could have encouraged resident 20 in his efforts. HCFA Br. at 64.

While there is some evidence that resident 20 was offered additional nourishment, the record as a whole reflects that resident 20 was attempting to eat his meals independently, but was unable to do so and was unable to consume sufficient nourishment with the assistance that was being provided by Petitioner. P. Ex. 26; Tr. 233-236. There is no evidence that resident 20 was ever reassessed or that his care plan was adjusted in light of the difficulties he was having in consuming sufficient nourishment. P. Ex. 26.

Petitioner thus failed to maintain resident 20 at his highest practicable level because it failed to address the problems he was experiencing in consuming sufficient nourishment. It would be one thing if Petitioner had tried additional methods and none of these worked. However, the only methods attempted by Petitioner to assist resident 20 were providing him with a special spoon and offering him additional nourishment. The record reflects that both of these methods were ineffective, as resident 20 was observed as not being able to eat independently and was not amenable to accepting the additional nourishment offered by Petitioner. The uncontradicted testimony is that other methods could have been attempted to assist him, but were not. My finding is not that, when a facility encounters a resident who has difficulty eating independently, the facility must exhaustively attempt every conceivable method to get the resident to eat. The facts are that resident 20 was having a large amount of difficulty in consuming sufficient nourishment to maintain his health. The record reflects that Petitioner's approach to solving resident 20's difficulty in eating adequately was to provide him with a special spoon and that this was not working, as the surveyor observed. Also, the chart reflects that he dropped much of his food. It is apparent that Petitioner could have tried other methods, short of tube feeding or force feeding, to enable resident 20 to eat more. Petitioner failed to do so. Accordingly, Petitioner failed to provide resident 20 with the care necessary to maintain or attain his highest

practicable well-being, in violation of 42 C.F.R. § 483.25.[93]

2. Resident 16

HCFA contends that the deficiency with respect to resident 16 "involves Petitioner's failure to maintain [her] . . . at her highest practicable level of ambulation following her discharge from the restorative nurse aide (RNA) program." HCFA Resp. Br. at 40-41. According to HCFA, resident 16's medical record indicates that she was placed in the RNA program for ambulation in June 1993 and that, during June and July 1993, she made significant progress in her ambulation. HCFA Resp. Br. at 41; see P. Ex. 27 at 13-15 (relevant part of medical record). HCFA states that, with no documented reason, the resident was discontinued from the program on August 9, 1993, and that the progress notes stated that staff would continue to ambulate her. HCFA Br. at 66. HCFA contends that, at the time of the survey, there was no evidence that the resident was being routinely ambulated. Id. at 68; HCFA Resp. Br. at 41-42. Further, HCFA notes that the surveyor observed that resident 16 was restrained with a vest in a wheelchair. HCFA Br. at 65.

Petitioner contends that, contrary to HCFA's allegations, resident 16's medical chart indicates that she was routinely ambulated following the conclusion of the RNA program. P. Br. at 103-110. Petitioner alleges that "[t]here is no evidence that her ability to ambulate declined in the slightest." P. Br. at 25. Petitioner contends further that resident 16 "was maintained at the highest practicable physical level with respect to her ability to ambulate." P. Br. at 104.

I find that the record supports Petitioner's position with regard to the ambulation of resident 16. The testimony of HCFA's witnesses on this issue is conflicting and unpersuasive. The record reflects that resident 16 began the RNA ambulation program on June 15, 1993, and that the initial program was for her to ambulate with a front wheel walker 20 feet to 60 feet with the limited assistance of two persons, as tolerated, seven times a week. P. Ex. 27 at 13-14; Tr. 1091-1092. The record further indicates that resident 16 was ambulating from 60 to 100 feet during the period June 15 - June 30, 1993, and from 80 to 100 feet during the

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[93] This resident is now deceased. I have no information which suggests this resident's death was related to the circumstances of this deficiency.

period July 1 - July 31, 1993. P. Ex. 27 at 13, 15. On August 9, 1993, the resident was discontinued from the program. P. Ex. 27 at 17-18. The 8/9/93 progress notes stated "D/C from RNA program . . .able to ambulate 70 ft. this distance can tolerate. Resident made progress toward the program. CNA [certified nurse's assistant] will cont. to ambulate the resident during care." P. Ex. 27 at 18.

On cross-examination, Petitioner's counsel questioned the surveyor regarding certain nurse assistant records (P. Ex. 1 at 14-17) in resident 16's chart. Upon examining these records, the surveyor, who had previously testified that there was no evidence in the chart that resident 16's ambulation continued following the conclusion of the RNA program, conceded that they indicated that resident 16 was ambulated daily throughout November and December 1993. Tr. 1517-1523. Specifically, the November 1993 nurse assistant records contain notations which indicate that resident 16 was ambulated daily, with assistance or a walker. P. Ex. 1 at 14-15. On two occasions, resident 16 ambulated independently. P. Ex. 1 at 15. The December 1993 nurse assistant records also show that resident 16 ambulated daily, either with assistance or a walker. P. Ex. 1 at 16-17.[94]

Absent HCFA establishing that Petitioner's records on this issue were either erroneous or altered in some way to reflect an activity which did not occur, HCFA has failed to meet its burden of proof on this deficiency concerning resident 16's ambulation. HCFA has offered nothing to contradict the evidence in resident 16's records. I find that, contrary to HCFA's allegations, the records reflect that resident 16 was ambulated routinely following the conclusion of the RNA program.

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[94] The following testimony is noteworthy:

> Judge Steinman: In light of what counsel just showed you, in terms of these charts, do they reflect a routine ambulation program, or were you referring to something else?
>
> Witness: I don't know. According to what he just showed me, they would infer that the resident was being ambulate[d]; you're correct. . . .
>
> Tr. 1530.

Additionally, HCFA has offered nothing more than an unsubstantiated allegation that resident 16's ambulation declined. I realize that, while Petitioner's records do establish that resident 16 was ambulated, they are not illuminative regarding the actual distance that resident 16 was ambulated. P. Exs. 1, 27. However, HCFA has not offered anything from which I can conclude that resident 16 was not ambulated such that she was not maintained at her highest practicable level. Moreover, the testimony of the surveyor on this issue was unpersuasive. When pressed on the issue of how it was that she was aware that resident 16's ambulation had declined, the surveyor could only speculate. Tr. 1528-1529.

HCFA argues further that resident 16's care plan did not contain any goals regarding ambulation and that Petitioner should have documented daily the frequency and distances of resident 16's ambulation so that it could be assessed whether the resident was maintaining her highest ambulation level. HCFA Resp. Br. at 41-43. Because I find that Petitioner was not deficient with regard to maintaining the ambulation of resident 16 at its highest practicable level, I do not address these issues.

M. Set out below is the statement in the HCFA 2567 concerning the alleged deficiency identified as F 320 (HCFA Ex. 2 at 14-15):

> 42 C.F.R. 483.25(c)(2) (2) A resident having pressure sores receives necessary treatment and services to promote healing, prevent infection and prevent new sores from developing.
>
> *****
>
> Based upon observation, interview and medical record review it was determined staff failed to provides [sic] services and treatment to prevent development of decubitus and promote healing.
>
> Findings include:
>
> During observation of residents with decubitus and review of records it was noted approximately 35 pressure sores had developed within the facility, indicating a lack of identifying residents prone to skin breakdown, early identification, and inadequate treatment.

> Resident 31 had an order for a Tegaderm dressing to be in place at all times. On 12-22-93 prior to observation of a treatment and change of dressing it was noted that the tegaderm was not in place. Other open areas to be treated did not have dressings in place as ordered by the physician. The treatment sheet indicated the dressings were in place and checked for proper placement. Residents with skin problems were noted to have poor inadequate positioning devices to alleviate pressure to the affected area.

Resident 31's medical record indicates that the dressing was to be changed twice a day. The physician's order dated December 1, 1993 states "cleanse open area coccyx [with] nss [normal saline solution], pat dry and apply Carrington gel and cover [with] Tegaderm dressing BID [twice a day] till clean then d/c [discontinue]." P. Ex. 28 at 17.

Ms. Patience indicated that, in this instance, the purpose of the Tegaderm dressing was to act as a barrier to protect the wound from outside bacteria, as well as to keep the gel in place. Tr. 2620-2621. Ms. Patience explained the consequences to a resident if the Tegaderm were to come off:

> [t]he gel might not stay in place and might leak out of the wound. And, there also is opportunity for infection because of the bacteria. There also could be further skin breakdown because of any contact it may -- the wound may have with the bedding and the bed.

Tr. 2621.

Ms. Patience stated that, in a situation like this, the physician's order would require that the Tegaderm be in place at all times. Tr. 2621.

Further, with regard to resident 31, Ms. Shekell testified:

> I went in to watch the [staff] person change a dressing on a resident and the resident had a physician's order for Tegaderm which is an adhesive-type covering, dressing, to cover the area and when I went in on 12-22 to observe this treatment and change of dressing it was noted that the Tegaderm was not in its place. There was [sic] additional open areas on the patient and they did not have

> dressings as was ordered by the physician. I then went to the treatment record and it indicated that the dressings were in place and had been checked on the previous shift for proper placement.

Tr. 241.

In response to this deficiency, Petitioner argues the following: (1) "there was no evidence of any failure to apply the Tegaderm dressing twice a day," which is all the physician ordered; (2) "assuming there was a failure to comply with the physician's order," the noncompliance was a single instance which was immediately corrected; and (3) the resident's medical record showed that the "pressure sore improved from a stage 3 to a stage 1." P. Br. at 112.

Petitioner's argument that it followed the physician's order to the letter with regard to this resident and that there was no evidence to indicate that it did not apply the Tegaderm twice a day suggests that Petitioner does not understand that merely following a physician's order is not enough. One of the purposes of the Tegaderm is to protect the Carrington gel from oozing out. Without the Tegaderm, the resident is subject to infection from bacteria coming into contact with the pressure sores. This resident had more than one Tegaderm dressing missing which put her at a greater risk for bacterial infection. Even if the medical record indicated that the previous shift had noted that the Tegaderm dressings were in place, Petitioner is responsible for checking on the resident's condition to see that she was not unnecessarily put at risk by the slippage of the Tegaderm dressing. The surveyor observed that the dressings were not in place. The surveyor's observation regarding the treatment of this resident's pressure sores indicates that Petitioner's staff may not have been accurately recording in the treatment records the application of the required treatment. Here, again, Petitioner could easily have substantiated the accuracy. I conclude that Petitioner violated 42 C.F.R. § 483.25(c)(2) with respect to the treatment of resident 31.

Finally, assuming arguendo that resident 31's "pressure sore improved from a stage 3 to a stage 1" (P. Br. at 112), I have no way of knowing if all of resident 31's pressure sores improved or worsened, nor do I know to what extent, if any, this resident was at risk for bacterial infection to other pressure sores. With respect to the HCFA 2567's mention that "approximately 35 pressure sores had developed within the facility" (HCFA Ex. 2 at 15), the record is silent as to how many

residents had pressure sores. HCFA has failed to prove this aspect of the deficiency as set forth in the HCFA 2567.

N. Set out below is the statement in the HCFA 2567 concerning the alleged deficiency identified as F 324 (HCFA Ex. 2 at 15-16):

> 42 C.F.R. 483.25(e)(2) (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.
>
> *****
>
> Based on observation, interview and record review it was determined that staff failed to provide appropriate treatment to increase and/or prevent further decrease in range of motion.
>
> Findings include:
>
> Resident 2 was noted to have as [sic] left hand and arm splint in place. It was noted that the splint was not properly applied to benefit the resident and prevent further decrease in range of motion. Other residents observed in the hallway were observed to have adaptive devices which were not placed properly to provide therapeutic treatment.

HCFA admits, in effect, that the surveyor mistakenly designated resident 2 as the subject. HCFA Br. at 72. However, HCFA proposes that "based on other findings already discussed at length herein, such as the failure to properly position the gentleman found sitting in the Linard seating system, and the failure to apply the E-Z boot as ordered for the resident who suffered from foot drop, it is submitted that this deficiency has been amply supported by the record, and that adaptive devices were often not placed properly, or even at all, to provide the therapeutic treatment for which they were intended." Id.

There was no oral or documentary evidence presented on this alleged deficiency. Since the HCFA 2567 incorrectly identifies resident 2 as the subject of this deficiency, I find that HCFA has not met its burden of proof here. I must agree with Petitioner that, absent the designation of a specific resident as the subject of this deficiency, I do not have a sufficient basis to conclude that "other

residents" were subject also to adaptive devices which were improperly placed. It is not enough for HCFA to offer examples of residents who were discussed in other deficiencies to corroborate the allegations in this deficiency. I might consider evidence of other deficiencies if the deficiency in question had cross references (see HCFA Ex. 2 at 5, 6, 9, 10-11, 14 for citations to deficiencies which cross reference other deficiencies in the HCFA 2567), but there are no cross references cited here. To conclude that I can look to other evidence to support this deficiency would be violative of Petitioner's due process rights since HCFA never identified the resident who is the subject of the deficiency. Thus, Petitioner had no opportunity to defend against this alleged deficiency.

I conclude that HCFA failed to prove that Petitioner was in violation of 42 C.F.R. § 483.25(e)(2).

O. Set out below is the statement in the HCFA 2567 concerning the alleged deficiency identified as F 373 (HCFA Ex. 2 at 16-17):

> 42 C.F.R. 483.35(f)(3) (3) The facility must offer snacks at bedtime daily.
>
> *****
>
> Based on interview of residents and staff, the facility failed to offer snacks at bedtime daily.
>
> Findings include:
>
> Two of four residents interviewed by this evaluator stated that they were [not][95] offered snacks at bedtime. Both stated that they would like to have snacks. Licensed staff interviewed on one station stated that residents only get snacks if they have a physician's order, or if they request it. Resident[s] are not offered snacks on a routine basis. The medical record of one resident documents no snacks were given, while the other has only intermittent snacks documented.

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[95] According to Ms. Cox, who prepared these findings, she inadvertently left out the word "not". Tr. 1102. Petitioner does not challenge this explanation and assumed that was the surveyor's intention. P. Br. at 121.

HCFA relies on the testimony of Ms. Cox for proof of this deficiency:

> I interviewed four residents, and two of the residents stated to me when I asked them about dietary problems or about their meals, . . . that they were not offered snacks at bedtime. . . . [T]hey both stated that they would like to have snacks and they were not getting them, and I talked to the licensed nurse at the station and she said that the residents only get snacks if they have a specific physician's order or if they request it daily[.] . . . [T]he resident[s] should not have to request [snacks] daily because the regulation reads that they must be offered snacks at bedtime daily, and they [i.e. the residents] were deemed interviewable by the facility itself, and so when you're interviewing interviewable residents that the facility says, yes, you know, they understand what you're going to say to them; they participate in their daily care, then I have to take their word for the fact that they were not offered snacks daily and that they would like to have . . . [them].

Tr. 1103.

Petitioner makes several arguments in response to the cited deficiency. First, the two residents surveyed who indicated a failure to receive bedtime snacks represented an isolated circumstance -- two residents out of a resident population of 234. P. Br. at 121. Second, Petitioner had a policy of offering snacks at bedtime and forms existed in each resident's record which could verify that they were offered such snacks. Id. at 122. Third, Ms. Cox testified that she never consulted these resident records in preparing the deficiency. Id. at 123. And last, because Ms. Cox could not identify the residents who she interviewed for this deficiency, Ms. Downing reviewed resident records for all of the identified residents who were listed on the survey team's resident roster (P. Ex. 50) and determined that all residents except for those on tube feeding were offered snacks at bedtime. Id. 123-124.

Ms. Cox had no recollection of the identities of the two residents, although she did examine their resident records which reflected no snacks given to one resident and only intermittent snacks given to the other. Tr. 1366, 1368-1371. However, inasmuch as Ms. Cox could not identify the residents, I find her statement regarding

review of their resident records to be without probative value.

I did review P. Ex. 30 which, according to Ms. Downing, is a compilation of the December 1993 monthly flow sheets for all the residents listed on the sample resident roster used by the surveyors in selecting residents for interviews. Tr. 2039. However, I did not reach the same conclusion as Ms. Downing that all residents except for those on tube feedings were offered snacks at bedtime. I do agree with HCFA's counsel's observation that the notations on the monthly flow sheets contained in P. Ex. 30 are at times inconsistent and confusing.[96] HCFA Resp. Br. at 46. In the applicable block for "HS nourishment offered"[97], some blocks have checks (P. Ex. 30 at 1-2, 5-6, 8-10, 12, 19-20, 32-34, 45-49, 55-56, 58, 69, 71-72); some have "y" marks (id. at 3-4, 24, 65-66, 70); some have "no" (id. at 10)[98]; some have "NA"[99] (id. at 11[100], 14-15[101], 16[102], 22[103], 23[104], 28[105], 37-38[106], 40-41[107],

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[96] Ms. Downing, in response to my inquiries as to the meanings of the different markings in the blocks on the flow sheets, admitted "[t]hat's why we all have problems with these when we -- we need to be working with the staff to understand what they are. And part of our revision of the forms is to attempt the consistent method of interpreting these." Tr. 2050.

[97] Ms. Cox testified that "HS" means hour of sleep which in the context of this form means at bedtime. Tr. 1375.

[98] There is no indication of tube feeding of this patient.

[99] Without a further explanation, I assume "NA" means not applicable.

[100] This resident has "NA", "N" and checks in the various blocks for the month of December 1993. See P. Ex. 30 at 11-12. Again, there is no indication of tube feeding.

[101] This resident apparently was receiving tube feeding for the month of December 1993. This can be discerned from the "GT" notations in meal blocks on the flow sheets. See Tr. 2045.

[102] There is no indication that this resident was receiving tube feeding. P. Ex. 30 at 17.

60[108], 62[109]); some have the letter "N"[110] (id. at 11[111], 18[112], 21[113], 23[114], 25-26[115]); some have dashes[116] (id.

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[103] (...continued)
[103] There is no indication that this resident was receiving tube feeding.

[104] There is no indication of tube feeding.

[105] There is no indication of tube feeding.

[106] There is an indication that this resident was being fed by staff and receiving double portions during December 1993. P. Ex. 30 at 39. There is nothing to suggest that a snack was contraindicated for this resident.

[107] This resident apparently was on regular puree diet and had the ability to feed herself. P. Ex. 30 at 40-42. There is no reason in the record for the lack of snacks at bedtime.

[108] There is a reference to a regular diet but no indication of tube feeding. There is no reason given for the lack of snacks at bedtime. P. Ex. 30 at 61.

[109] There is an indication that this resident was on a regular NAS diet for the entire month of December 1993. P. Ex. 30 at 64. Her flow sheets indicated "NA" for the first half of the month and checks for the latter half. Id. at 62-63. I cannot discern from these flow sheets the reason for the change in snack service or why no snack was provided in the first half of the month.

[110] Ms. Downing indicated that this marking means no snack. Tr. 2049-2050.

[111] This resident has "NA", "N" and checks in the various blocks for the month of December 1993. See P. Ex. 30 at 11-12. Again, there is no indication of tube feeding.

[112] There is no indication that this resident was receiving tube feeding. P. Ex. 30 at 17.

[113] There is no indication that this resident was receiving tube feeding.

[114] There is no indication of tube feeding.

at 16[117], 57[118]); some have numerical markings (id. at 29[119], 35-36); some have a variety of notations on the same page (id. at 7, 11, 16, 21, 23, 28-29, 36, 50, 53[120] 59); and some have "gt"[121] (id. at 43-44, 51-54, 67-68). Ms. Downing explained that a check mark or "y", which means yes, indicates that snacks were offered to the residents. Tr. 2047. She further testified that a dash means that the snack was not accepted. But when I inquired how she knows that the dash does not mean that the snack wasn't offered, she said it would be documented on back of the applicable flow sheet page. She admitted that the backs of the flow sheets were not copied. Tr. 2052-2053.

My review of these flow sheets, particularly those with dashes, "NA", "N", and "no", supports a finding that a number of these residents were not offered bedtime snacks and were not on special diets which would have precluded such food. I do find Ms. Downing's explanation of the meaning of a dash, and, arguably, similar meanings for "N", and "no", to be lacking in credibility. Petitioner assembled this exhibit and, if there was exculpatory information on the back pages of the resident records, I

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[115] (...continued)

[115] This resident apparently was on NAS diet. This diet is not explained in the record. I do note she was an independent eater but had dietary restrictions. There is no suggestion that a snack could not be provided that was consistent with this resident's diet. P. Ex. 30 at 25-27.

[116] Ms. Downing indicated that this marking means no snack. Tr. 2049-2050.

[117] Again, there is no indication that this resident is receiving tube feeding. P. Ex. 30 at 17.

[118] This flow sheet also contains checks.

[119] This resident apparently was receiving a supplementary nourishment. P. Ex. 30 at 31.

[120] This resident apparently was receiving gastric feeding.

[121] Ms. Downing explained that there are three types of tube feedings used at Petitioner. A "GT is for gastrostomy tube. "JT" is for jejunostomy tube which is inserted lower in the intestinal tract. "NT" is a nasalgastric tube which goes through the nose to the stomach of the resident. Tr. 2051-2052.

would expect such documents to be offered in evidence as well. None were provided. The regulation requires the provision of snacks at bedtime. If they were offered to and rejected by the resident, it was incumbent on Petitioner to document this occurrence. Absent records, which are clearly the "best evidence" demonstrating such rejection, I conclude that the bedtime snacks were neither offered or provided.

Other records support that Petitioner did provide special snacks to residents who requested something different from the routine snacks. Tr. 2039-2040; P. Ex. 30 at 73-93. But I read 42 C.F.R. § 483.35(f)(3) to require the facility to offer bedtime snacks to **all** residents unless it is medically contraindicated. This Petitioner did not do.

Petitioner introduced a document which it contends reflects that it had a policy in place that "all residents will be offered a bed time snack to the extent medically possible." P. Ex. 30 at 94-95. Interestingly, the document indicates that it was revised "12/93." Id. at 94. Questioning Ms. Cox, Petitioner's counsel suggested that the snack policy was revised prior to the end of the survey. Tr. 1372. Ms. Cox responded that she had no knowledge of such change in policy. Id. Ms. Cox did testify that the supervisory or charge licensed nurse who indicated that the policy was not to provide snacks to residents unless mandated by their physicians or by a specific resident's requests was responsible for an entire nursing station servicing approximately 60 residents. Tr. 1381. She interpreted the statement of the charge nurse concerning the availability of snacks as representing the "routine of the facility." Tr. 1378.

Ms. Downing testified that the policy was revised in December 1993, and while she had no knowledge of the exact date of the change, she stated that she was advised by the Director of Nursing at that time, Christina Tang, that it occurred "before the survey." Tr. 2040-2041. She testified further that she was not aware of any policy that said that snacks would be offered only upon a physician's order. Tr. 2041.

Petitioner presented no testimony from anyone on its nursing staff who was present at the time of the survey to contradict Ms. Cox's survey findings relating to this deficiency. Contrary to Petitioner's assertion that a revised policy existed at the time of the survey which ensured that residents would be offered snacks at bedtime, there is no explanation of the admission of its charge nurse made during the survey which indicated a

bedtime snack policy different from the revised policy. Moreover, I am dubious of the validity of the assertion by Ms. Downing that the revision occurred before the survey when the snack issue was raised at the time of the survey[122]. The more likely scenario is that Petitioner revised its policy based on the finding of the State surveyor. There is no credible evidence that the policy was revised before the survey was completed. Such a change would have been noted by the State surveyor with the possibility of no deficiency being found. This did not occur. Accordingly, I cannot find that Petitioner implemented the "Procedure for Bed Time (H.S.) Snack" policy reflected in P. Ex. 30 at 94-95 until after the survey was completed and the plan of correction was submitted.

As a last argument, Petitioner asserts that the evidence does not prove that the failure to provide snacks to residents at bedtime represented a pattern at its facility. P. Resp. Br. at 37-38. I reject this argument. My review of P. Ex. 30 and the admission by Petitioner's charge nurse amply demonstrate that a pattern existed at Petitioner of violating the regulation. Moreover, it follows that Petitioner's failure to provide snacks as required by regulation would likely result in a diminishment of the mental and psychosocial well-being of its residents. Such a conclusion can be inferred from the statements of the residents interviewed by Ms. Cox. Petitioner failed to provide bedtime snacks daily to all of its residents, in violation of 42 C.F.R. § 483.35(f)(3).

P. Set out below is the statement in the HCFA 2567 concerning the alleged deficiency identified as F 441 (HCFA Ex. 2 at 17-18):

> 42 C.F.R. 483.65(a)(1) (1) Investigates, controls, and prevents infections in the facility;
>
> *****
>
> Based upon observation and medical record review it was determined that staff failed to provide care to prevent infections in the care of residents.

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[122] The State surveyors indicated that before the end of a survey they generally discuss the deficiencies found with the staff of the facility being surveyed. Here, the charge nurse was put on notice by Ms. Cox that the snack policy was under review.

Findings include:

> On 12/12/93 a licensed nurse was observed taking a container of juice from the medication cart into a resident's room and sitting it on the resident's over-bed table. This resident has a diagnosis of Methcillin [sic] resistant staphylococcal infection and had a sign posted above her bed that indicated that she was on contact isolation. After the resident finished taking her medications, the licensed nurse returned the contained [sic] of juice to the medication cart, increasing the risk of spreading infection.
>
> During observation of care of residents with decubitus open areas it was noted that sterile technique was not observed as per the facility policy and procedure. A sterile tray used was not kept sterile. Sterile gloves, dressings and supplies used in the treatment were not kept sterile to prevent infection in the open wound.
>
> Aseptic technique was not used in the care of the wound.

With respect to the first part of the alleged deficiency, concerning the medication nurse's handling of the juice container, HCFA relies on the testimony of Ms. Cox and Ms. Patience. Specifically, Ms. Cox stated at the hearing that she observed a medication nurse taking a juice container from the medication cart into the room of a resident that had a documented infection and placing the container on the resident's over-bed table. After the nurse poured the juice into the resident's glass, the nurse returned the contaminated juice container to the top of the medication cart. Tr. 1105. Ms. Cox testified that the nurse's action "[was] just not an acceptable standard to follow to prevent infections." Id.; HCFA Br. at 74. Ms. Cox testified further that "a common container used for every patient" should never be taken into the room of a resident with an infection and subsequently returned to a piece of equipment "used by the general population." Tr. 1105-1106; HCFA Br. at 74-75.

In addition, Ms. Patience testified:

> If the resident is supposed to be kept on contact isolation, that means that things are not supposed to be leaving that room that have

> come in contact with surfaces or the resident. And, the fact that the juice container touched the over-bed table and then was taken out, broke that contact isolation.

Tr. 2626.

HCFA states that the resident's infection could have been transmitted on the juice container. Finally, HCFA asserts that, notwithstanding the particular nature of the resident's infection, the action of the medication nurse showed that appropriate precautions were not being taken to prevent the spread of infection to other residents. HCFA Br. at 75.

In response to the first part of the cited deficiency, Petitioner states that HCFA's claim does not comport with the facts. Specifically, Petitioner asserts that the sole occasion where a nurse put a container of juice on the over-bed table of a resident involved a resident who was not isolated but was on "contact isolation." In addition, the infection-spreading characteristics of "non-colonized" residents with methicillin resistant staphylococcal aureaus ("MRSA") differ from those of "colonized" MRSA individuals, and the HCFA witnesses lacked knowledge of the nature of the condition and were unable to state whether the resident in question was colonized. P. Br. at 139-144.

Petitioner further posits that the single act of placing the container on the resident's over-bed table did not risk spreading infection because the container was a vector, and the resident's infection could not have been transmitted by a vector. Rather, the infection could have been carried only through contact with moist secretions, of which there was no evidence. Finally, Petitioner stated that if there was a deficiency, it was corrected prior to the conclusion of the survey and therefore should not have been in the HCFA 2567. P. Br. at 140-141.

The essence of the first part of the alleged deficiency is that the medication nurse's acts of placing a juice container from the medication cart onto the over-bed table of a resident on contact isolation with MRSA, and then returning the container to the medication cart, risked transmitting infection to other residents. Most notably, I find the cornerstone of HCFA's proof, the testimony of Ms. Cox concerning her observation of the medication nurse's specific actions, both persuasive and uncontradicted. Similarly, I note that Petitioner did not specifically challenge the testimony of Ms. Cox that

the nurse's actions were inconsistent with standard protocol. Rather, in response to the allegations in this part of the deficiency, Petitioner submits that the facts relating to the nature of the resident infection at issue reveal that the infection could not have been transmitted by the juice container alone. P. Br. at 140-141.

Notwithstanding its challenges, however, Petitioner indicated that, whether or not the resident was colonized, if any secretions had been transmitted to the container when it was brought into the room and subsequently returned to the medication cart, then the transmission of infection could have occurred. P. Br. at 140. Petitioner nevertheless submits that the deficiency lacks foundation because the HCFA witnesses were unable to present any evidence that moist secretions were present at the time of the observed actions. P. Resp. Br. at 39.

I find this aspect of Petitioner's argument, however, to be inapposite. That is, the issue at hand is not whether moist secretions were actually present, or whether the transmission of infection actually occurred. Rather, the deficiency relates to whether the employee's actions could have increased the risk of infection spreading because the container could have come in contact with moist secretions when it was brought into the room of a resident on contact isolation, placed on that resident's over-bed table and subsequently returned to the medication cart.

Therefore, based on the testimony, strengthened by Petitioner's acknowledgment that the infection of the resident on contact isolation could have been transmitted by contact with moist secretions, I conclude that the record supports the existence of the cited deficiency. Further, while the actions which were the subject of the first part of the findings represent a single incident, I find that the gravity of the breach in acceptable protocol to be a substantial action supporting the deficiency.[123] Accordingly, because the observed actions

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[123] SOM 250 provides support for this conclusion. A strong potential for harm can be a basis for determining that a negative outcome results from a deficient practice. An example is cited relating to the potential for infection when "an observed facility practice is so divergent from accepted principles of practice that a future negative outcome or harm is probable." HCFA Ex. 13 at P-30. These are precisely the circumstances of the cited deficiency.

of the medication nurse could have increased the possibility of transmission of infection, I find that the first part of the cited deficiency represents a failure by Petitioner to control and prevent infections as required by 42 C.F.R. § 483.65(a)(1).

With respect to the second part of the alleged deficiency, concerning whether sterile and/or aseptic technique was used in the care of residents with decubitus open areas, HCFA relies on the testimony of Ms. Shekell:

> in getting the materials necessary to dress that open wound correctly good technique was not used in cleansing and applying the dressing as it should be. In other words, the -- staff person, was a licensed person, contaminated the area during the process of changing that dressing.

Tr. 256.

HCFA relies also on the statement of Ms. Patience that "neither sterile nor aseptic technique was used in caring for [an] open wound. So that the resident was left open to a greater risk of infection." Tr. 2627-2628, 2636; HCFA Br. at 76-77.

In response to the second part of the alleged deficiency, Petitioner avers that it was denied due process because it was not afforded adequate notice of the identities of all but one of the residents that were the subject of the deficiency to confirm or deny the allegations and to defend itself against them. Petitioner further asserts that, while Ms. Shekell initially testified that the deficiency related to resident 31, she later was uncertain whether the alleged deficiency in fact related to that resident. Petitioner stated also that there was a failure of proof with respect to the deficiency as it would relate to resident 31. Tr. 256, 756, 760-766; P. Br. at 127-132.

In addition, Petitioner states that Ms. Shekell later testified that a number of other residents were the subject of the deficiency, but she could identify neither the residents themselves, nor the staff who could provide the names of the residents. Further, while Ms. Shekell stated that the identities of the residents could be ascertained from her notes, those notes had been suppressed pursuant to my prior order. Petitioner argues that HCFA's failure to identify the residents involved in the deficiency not only denied Petitioner due process,

but also constitutes a complete failure of proof on the issue. Finally, Petitioner contends that the deficiency is defective because it is unclear whether HCFA's allegations relate to non-sterile or non-aseptic conditions. Tr. 616-618, 633; P. Br. at 133-138.

With regard to the second part of the alleged deficiency, I find, as a preliminary matter, that the statement as written in the HCFA 2567 is vague and confusing. That is, while the first sentence in the statement speaks of "residents" in the plural, and the failure to use "sterile technique" as required by Petitioner's policy, the last two sentences of the statement refer only to a single "wound" and a failure to use "aseptic technique." Thus, the document did not make clear whether this part of the alleged deficiency related to the observation of the treatment of one resident or more than one resident, and whether the deficiency related to the failure to follow sterile technique, aseptic technique, or both.

While HCFA was provided ample opportunity to submit testimony and documentary evidence to clarify and support this part of the alleged deficiency, it instead relied predominantly on the testimony of Ms. Shekell at the hearing. In her testimony, Ms. Shekell stated that resident 31 was one of the subjects of the alleged deficiency. Tr. 614-616, 751. Initially, Ms. Shekell testified that this resident's wound was open, at risk of infection, and was not dressed correctly. Tr. 256. On cross-examination, however, Ms. Shekell was unable to testify as to whether a sterile tray, sterile gloves, or supplies were used with respect to the identified resident, and she could not state the specific manner in which the dressing used for the resident was not kept sterile. Tr. 757-766. In addition, on cross-examination it was revealed that the resident did not have an open decubitus wound at the time of the survey. Tr. 772.

Further, while Ms. Shekell testified that other residents were also the subject of the deficiency, she could neither identify those residents nor identify the staff nurse who accompanied her during the survey who would know the identities of the residents. Tr. 614-616, 620, 632, 751-52. While Ms. Shekell indicated that her survey notes reflected which residents were seen with respect to the deficiency, those notes were not available because they had been suppressed prior to the hearing. Tr. 639.

As I stated at the beginning of this decision, HCFA had earlier moved to suppress the surveyors' notes in their entirety on the basis of the deliberative process privilege, and, in December 1994, I ruled in favor of

HCFA. It is important to note, however, that HCFA instead could have moved to sanitize the surveyors' notes by redacting information related to the deliberative process privilege and preserving the factual information contained in the notes for use in the proceedings. HCFA, nevertheless, chose not to pursue this opportunity, and it therefore could not use the factual elements of the notes to support the witness' testimony concerning the second part of the alleged deficiency.[124]

As an apparent consequence of the lack of documentation available at the hearing, Ms. Shekell's testimony as a whole emerged confused and contradictory. Further, without her notes, the witness was unable to describe in sufficient detail the facts underlying the stated deficiency as they related to the residents who were

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[124] The somewhat confused state of the testimony of the surveyor illustrates the risk inherent in HCFA's strategy of relying on the privilege of deliberative process and suppressing the surveyors' notes. Because HCFA chose to rely solely on the testimony of the surveyors in proving Petitioner's deficiencies, the surveyors were forced to give testimony on specific factual allegations without having their notes available to assist them. Moreover, to the extent that the surveyors relied on specific resident records when citing Petitioner for a given deficiency during the survey, these documents were withheld also as part of the deliberative process privilege. Consequently, to prove the existence of the cited deficiencies, HCFA was forced to rely on a combination of 1) surveyors testifying without their notes and 2) documents offered by Petitioner. This led to confusing testimony because the documents that would best refresh the surveyor's recollection of the cited deficiency (the surveyors' notes or copies of the specific documents they reviewed) were not available to the surveyors during testimony. In future cases, HCFA might be better served if its surveyors created notes that were strictly factual in nature and devoid of deliberative matters or other information that, if revealed, might compromise HCFA's survey process. This documentation could be used to prove the existence of the cited deficiencies in a clear, direct manner, and serve to refresh the recollection of surveyors who are now forced to testify strictly from memory. Had the surveyors' notes been available to be used by the parties in this case, it may have reduced the acrimony and lengthy argument which, in turn, led to the voluminous hearing record.

observed, the particular nature of the wounds that were treated, or the precise manner in which the residents' wounds were treated. Moreover, HCFA failed to provide any other testimony or documentation concerning the residents and the staff actions observed in connection with the second part of the deficiency. Absent this necessary information, it is impossible to determine what specific policies and procedures Petitioner was required to follow, and did or did not follow, with respect to sterile and/or aseptic treatment of resident wounds.

Accordingly, I conclude that HCFA failed to meet its burden of proof with respect to the allegations contained in the second part of the deficiency. Specifically, the imprecise statement in the HCFA 2567, together with the vague and at times inconsistent testimony presented, failed to establish the existence of facts showing that Petitioner failed to use sterile and/or aseptic technique when required. Thus, with respect to the second part of the alleged deficiency, HCFA did not meet its burden of proving the elements which justify its determination that sterile and/or aseptic technique was not followed when required to control and prevent infection as required by 42 C.F.R. § 483.65(a)(1).

Q. Set out below is the statement in the HCFA 2567 concerning the alleged deficiency identified as F 443 (HCFA Ex. 2 at 18):

> 42 C.F.R. 483.65(a)(3) (3) Maintains a record of incidents and corrective actions related to infections.
>
> *****

On the HCFA 2567, no basis or findings were set forth for this alleged deficiency. HCFA Ex. 2 at 18.

At the hearing, Ms. Shekell admitted that this citation had been inadvertently keyed into the computer. Tr. 257. Accordingly, because this alleged deficiency was cited in error, I find that there is no deficiency here. F 443 has no bearing for purposes of this decision.

R. Set out below, in relevant part, is the statement in the HCFA 2567 concerning the alleged deficiency identified as F 462 (HCFA Ex. 2 at 18-24):[125]

> 42 C.F.R. 483.70(d)(1) (ii) Measure at least 80 square feet per resident in multiple resident bedrooms, and at least 100 square feet in single resident rooms;
>
> *****
>
> Based on observation and record review the facility failed to provide at least 80 square feet per resident in 2/3 of the multiple resident bedrooms.
>
> *****

Neither HCFA nor Petitioner offered any proof relating to F 462 at the hearing or in their briefs. Accordingly, as there is nothing in the record, I find that HCFA has failed to prove the existence of this deficiency.

S. Set out below is the statement in the HCFA 2567 concerning the alleged deficiency identified as F 527 (HCFA Ex. 2 at 25):[126]

> 42 C.F.R. 483.75(l)(1) (1) The facility must maintain clinical records on each resident in accordance with accepted professional standards and practices that are -- (i) Complete; (ii) Accurately documented; (iii) Readily accessible; and (iv) Systematically organized.
>
> *****

Petitioner submitted P. Ex. 32 as being the relevant resident record with respect to F 527. At the hearing, however, HCFA did not present any testimony addressing this alleged deficiency[127], and Petitioner did not present any testimony with respect to P. Ex. 32. Neither HCFA nor Petitioner addressed F 527 in its briefs.

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[125] I do not restate the findings for F 462, which are set forth at HCFA Ex. 2 at 19-24.

[126] I do not restate the remainder of the alleged deficiency, which is set forth at HCFA Ex. 2 at 25.

[127] HCFA's counsel stated that HCFA had not presented any testimony on F 527. Tr. 2065.

Accordingly, I find that HCFA has failed to prove this deficiency.

Conclusion

Petitioner takes issue with HCFA's determination that the date of its certification as a Medicare provider of skilled nursing services was effective on January 31, 1994. This date was based on Petitioner's submittal of an acceptable Plan of Correction for deficiencies contained in the HCFA 2567 which was prepared in connection with an initial survey of Petitioner during the period of December 14 - 23, 1993. Pursuant to 42 C.F.R. § 489.13, the effective date of Petitioner's certification is the earliest date when there is correction of the deficiencies found in the survey or submission of an acceptable plan of correction. Under this regulation, even one deficiency could be the basis for a delay in the effective date of certification. The record supports that deficiencies of 42 C.F.R. § 483 et. seq. were present during the survey of Petitioner, were not corrected at completion of the survey, and were the subject of an acceptable plan of correction submitted on January 31, 1994. Accordingly, I affirm HCFA's determination that Petitioner's certification as a Medicare provider was effective on January 31, 1994.

/s/

Edward D. Steinman
Administrative Law Judge