Department of Health and Human Services

DEPARTMENTAL APPEALS BOARD

Civil Remedies Division

In the Case of:	
Anthony G. Corkill, M.D.,	DATE: October 14, 1993
Petitioner,	Docket No. C-93-046
- v.-	Decision No. CR289
The Inspector General.	

DECISION

On January 20, 1993, the Inspector General (I.G.) advised Petitioner, Anthony G. Corkill, M.D., that a determination had been made to exclude him from participating in Medicare and State health care programs for three years.[1] The I.G. told Petitioner that the exclusion was authorized by section 1156 of the Social Security Act (Act). The I.G. based the determination to exclude Petitioner on a recommendation made by California Medical Review Incorporated (CMRI), the peer review organization for the State of California.

CMRI's recommendation that Petitioner be excluded derived from its findings that, with respect to nine Medicare beneficiaries, Petitioner had failed substantially to provide care that was: economical and only when, and to the extent, medically necessary; of a quality that meets professionally recognized standards of health care; and supported by appropriate evidence of medical necessity and quality of services in a form and fashion as may be

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[1] "State health care program" is defined by section 1128(h) of the Social Security Act to cover three types of federally financed health care programs, including Medicaid. Unless the context indicates otherwise, I use the term "Medicaid" hereafter to represent all State health care programs from which Petitioner was excluded.

required. CMRI's recommendation specified, for each of the nine cases at issue, the violations it had discerned.

The I.G. informed Petitioner that CMRI's conclusions had been accepted. The I.G. incorporated CMRI's findings in the notice to Petitioner. Additionally, the I.G. advised Petitioner that the I.G. had determined that Petitioner demonstrated either an unwillingness or an inability to comply with his obligations under section 1156 of the Act. The I.G. noted that CMRI had on more than one occasion offered Petitioner the opportunity to correct his deficiencies by entering into a corrective action plan, and Petitioner had not agreed to do so.

Petitioner requested a hearing and the case was assigned to me for a hearing and a decision. Petitioner moved that the exclusion be held in abeyance pending a ruling by me as to whether he posed a serious risk to the welfare of patients in certain rural communities in which he practiced. On March 5, 1993, I ruled that Petitioner was "located in" a rural area within the meaning of section 1156(b)(5) of the Act and I ordered that the exclusion be held in abeyance until I issued a ruling on the issue of whether Petitioner posed a serious risk to patients.

I held a hearing in San Francisco, California, from May 17 - 19, 1993. The parties agreed that the hearing should consolidate the taking of evidence as to the issues of serious risk, the authority of the I.G. to exclude Petitioner pursuant to section 1156 of the Act, and the reasonableness of the exclusion which the I.G. imposed against Petitioner. On July 1, 1993, I issued a ruling in which I found that Petitioner posed a serious risk to patients. I permitted the exclusion to be in effect pending a final decision in this case. The July 1st ruling did not address the ultimate issues of whether the I.G. had authority to exclude Petitioner or whether the exclusion imposed against Petitioner by the I.G. is reasonable.

With respect to those issues, I have considered carefully the applicable law, the evidence adduced at the hearing, and the arguments raised by the parties in their respective briefs and reply briefs.[2] I conclude that the

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[2] On July 25, 1993, Petitioner moved to supplement the record with exhibits not introduced into evidence at the May 17 - 19 hearing. The I.G. opposed the motion. I denied it. Ruling Denying Petitioner's Motion to Supplement the Record, August 3, 1993.

I.G. proved that authority exists under section 1156 of the Act to exclude Petitioner from participating in Medicare and Medicaid. I find that the three-year exclusion imposed by the I.G. is reasonable.

ISSUES

The issues in this case are whether:

1. The I.G. is authorized to exclude Petitioner pursuant to section 1156(b) of the Act.

2. The three-year exclusion which the I.G. imposed against Petitioner is reasonable.

FINDINGS OF FACT AND CONCLUSIONS OF LAW

I. Petitioner's education, training, work experience, and licensure as a physician[3]

1. Petitioner is a physician. P. Ex. 1, p. 1 (citations to Petitioner's Exhibits are made as "P. Ex.").

2. Petitioner received his medical education at Cambridge University, in England. P. Ex. 1, p. 1.

3. Petitioner is licensed to practice medicine in the State of California. P. Ex. 1, p. 1.

4. Petitioner specializes in neurosurgery and maintains a practice in Redding, California. Tr. at 321. (citations to the Transcript are made as "Tr. at").

5. Petitioner devotes approximately 80 percent of his practice to spinal surgery. Tr. at 324 - 325.

II. Spinal conditions which may cause medical problems for individuals

6. Instability of a vertebral segment of the spine is an abnormal play or motion within that segment. Tr. at 96.

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[3] As a convenience to the parties, I have divided my Findings of Fact and Conclusions of Law (Findings) into sections which are headed by descriptive captions. The captions are not Findings, and they are not intended to augment or substitute for my Findings in this case.

7. Instability of a vertebral segment may be from front to back, from side to side, or rotational. Tr. at 96.

8. Instability may cause a patient to experience pain. Tr. at 197.

9. In some cases, instability may be corrected with surgery. Tr. at 197 - 199; see Tr. at 96 - 97.

10. Spondylolisthesis is an abnormal positioning of a portion of the spinal column. Tr. at 200.

11. Anterior spondylolisthesis (anterolisthesis) is the most common form of spondylolisthesis, and is the abnormal forward shifting of a vertebral body in relation to an adjacent vertebral body. Tr. at 200.

12. The presence of spondylolisthesis indicates potential instability. Tr. at 108.

13. Spondylosis and spurring are overgrowths of bone within the spine. Tr. at 223.

14. The presence of spondylosis or spurring may indicate instability within the spine. Tr. at 223.

15. In the majority of cases, spondylosis or spurring exists without instability. Tr. at 223.

16. Spondylolysis is an interruption of the bony ring which surrounds the spinal canal. Tr. at 226.

17. Spondylolysis may be a congenital or an acquired condition. Tr. at 226.

18. Spondylolysis frequently is a cause of instability. Tr. at 226.

19. Scoliosis is a rotation of the spinal column. Tr. at 233.

20. The presence of scoliosis is an indication of possible instability. Tr. at 233.

21. Paget's disease is a metabolic bone disease where bone is replaced with fibrovascular tissue and bone. Tr. at 124.

22. The bone which develops as a consequence of Paget's disease is structurally relatively poor bone. Tr. at 124.

23. In some patients, Paget's disease produces relatively few symptoms, whereas in others it may produce significant symptoms. Tr. at 124.

24. In most individuals, the soft elements of the spinal column will degenerate over time as a consequence of accumulated stresses and the aging process. Tr. at 193 - 195.

25. Sixty percent of individuals over the age of 60 have demonstrable evidence of degeneration in their spines. Tr. at 194.

26. The vast majority of individuals with degenerative spinal disease live normal lives or have minimal symptoms not requiring surgical intervention. Tr. at 195.

27. Stenosis is a narrowing of the canals through which run the nerves which emanate from the spine. Tr. at 218.

III. Circumstances under which spinal surgery to correct instability may be indicated

28. Surgery to correct spinal instability is justified where there exists clinical evidence of instability coupled with intractable pain. Tr. at 196 - 198, 300.

29. Surgery to correct spinal instability is not normally justified where there exists instability, but where the patient does not complain of intractable pain. Tr. at 197 - 198.

30. Surgery to correct spinal instability is not justified where the patient complains of intractable pain, but where there is not sufficient evidence to establish the presence of instability. Tr. at 198, 291, 300.

31. The presence in a patient of a condition or conditions which might consist of spinal disease or which might be a cause of instability is not normally sufficient to conclude that instability exists in that patient's spine. Tr. at 124 - 125, 214, 217 - 218, 223 - 224, 300 - 301, 358 - 360, 377, 379, 382, 386; see Tr. at 303 - 304.

32. In order to confirm the presence of instability, special studies, such as x-rays taken while the patient is bending, may have to be performed. Tr. at 292, 353 - 354.

33. It may be helpful to temporarily immobilize a patient's spine in order to determine whether the patient's pain is caused by instability. Tr. at 356 - 357.

34. There may exist conditions for which spinal surgery such as decompression or laminectomy is appropriate but for which surgery to correct instability is not appropriate. Tr. at 129; see Tr. at 124 - 126.

35. Decompression is a surgical technique which is intended to relieve pressure on a part of the spinal sac or nerve root. Tr. at 119.

36. Laminectomy is a surgery performed to remove a part of the lamina, which is the covering of the spinal canal. Tr. at 126.

IV. Techniques of surgery performed to correct spinal instability

37. Surgery performed to correct instability of the spine generally consists of an attempt to obtain bony fusion of the unstable part of the spine. Tr. at 96 - 97, 198 - 199.

38. The objective of fusion surgery is to obtain permanent stabilization of the unstable part of the spine. Tr. at 199, 352.

39. Grafting of bone to abnormal segments of the spine is the only way to accomplish a permanent fusion of the spine. Tr. at 202.

40. In order to accomplish bony fusion, the surgeon must graft an adequate quantity of bone to the site which is intended to be fused. Tr. at 204 - 205.

41. Typically, in performing a fusion, the surgeon removes the outer layers of bone from the site which is intended to be fused and grafts to that site bone, which is harvested from the patient's own body. Tr. at 101, 204 - 205.

42. Bone used as grafts in fusion surgery usually includes bone taken from the patient's hip (iliac crest). Tr. at 204 - 205.

43. Bone from a patient's iliac crest is used often for fusion grafts because it may be needed to supply a sufficient quantity of bone to promote fusion. Tr. at 204 - 206.

44. Bone from sources other than a patient's own body, such as from cadavers, can be used to achieve a fusion. Tr. at 101, 205.

45. Bone from a patient's iliac crest often is used for fusion grafts because the patient's own bone is more likely to promote fusion than is bone taken from another source, such as bone taken from a cadaver. Tr. at 205.

46. Fusion surgery may be accompanied by attempts to stabilize the spine mechanically. P. Exs. 11, 15, 16; Tr. at 96 - 97, 202.

47. The purpose of stabilizing the spine mechanically is to immobilize the part of the spine that has had fusion surgery during the period of time that fusion occurs. P. Exs. 11, 15, 16; Tr. at 96 - 97, 202.

48. Devices used to stabilize the spine include both external and internal fixation devices. Tr. at 202.

49. External fixation devices include braces to be worn by patients during the period that fusion is occurring. Tr. at 201 - 202.

50. Internal fixation devices include a variety of systems that are implanted in patients at the time of fusion surgery. P. Exs. 11, 15, 16.

51. Internal fixation devices consist generally of systems of rods or metal plates that are held together with hooks or screws. Tr. at 95 - 97, 204.

52. The Steffee system (sometimes referred to as Steffee plating) is an internal fixation device consisting of a system of metal plates that are fastened to the spine with screws (pedicle screws) that are implanted in the vertebrae. P. Ex. 16; Tr. at 97 - 98.

53. Permanent immobilization of the spine without a bony fusion cannot be obtained by the implantation of an internal fixation device. Tr. at 162 - 1634 203, 352, 389 - 390.

54. In the absence of a bony fusion, an internal fixation device will fail inevitably, either as a result of metal fatigue, or because of loosening of the screws which attach the device to the patient's spine. Tr. at 126 - 127, 162 - 163, 203, 389 - 390.

55. Should an internal fixation device fail in the absence of a fusion, the patient will be put at risk for

recurrence of pain, the need for additional spinal surgery, and damage to tissue (including nerves and blood vessels). Tr. at 116, 123 - 124, 126 - 127, 384.

56. The health of older patients may be placed at risk if they undergo additional spinal surgery to correct for failed internal fixation devices. Tr. at 384.

57. The risks which are attendant to surgery performed on older patients include heart attacks and pulmonary emboli. Tr. at 384.

58. Internal fixation devices should be used without attempts to attain fusion only in cases where there is no need to immobilize the spine for longer than six to twelve months. Tr. at 103, 175 - 176, 250 - 251; see Tr. at 389 - 390.

59. An example of a situation where an internal fixation device may be used to immobilize a patient's spine without performing fusion surgery would be that of a patient with a terminal illness who is not expected to live for more than six to twelve months. Tr. at 250 - 251.

V. Professionally recognized standards of care which govern the performance of spinal surgery utilizing internal fixation devices and the documentation of spinal surgery

60. A professionally recognized standard of health care is a professionally developed norm of care, diagnosis, and treatment which is prevalent in a particular geographic area or nationally. Social Security Act, section 1154(a)(6)(A); 42 C.F.R. § 1001.2.

61. A professionally recognized standard of health care in a particular medical specialty is a consensus among physicians who practice that specialty about how care should be provided to patients. Tr. at 103 - 104, 209 - 210; Finding 60; see Tr. at 398.

62. A professionally recognized standard of health care which governs when to perform spinal fusion surgery requires that the decision to perform such surgery be based on evidence of spinal instability coupled with intractable pain. Tr. at 275, 280 - 282, 300.

63. A professionally recognized standard of health care which governs the use of internal fixation devices to immobilize patients' spines requires that such devices not be used in the absence of attempts to obtain bony

fusion of the spine (except in those circumstances where there is no need to immobilize the spine for more than six to twelve months). Tr. at 102 - 103, 115 - 117, 120, 123 - 124, 126, 129.

64. A professionally recognized standard of health care which governs the performance of fusion surgery requires that the surgeon graft sufficient quantity of bone to a patient's fusion site to assure a reasonable likelihood that the surgery will result in bony fusion. Tr. at 203 - 205, 216; see Tr. at 225 - 226, 232.

65. A professionally recognized standard of health care which governs the manner in which a surgeon documents cases in which he or she performs spinal surgery requires that the surgeon explain in writing his or her diagnosis, medical work up of the patient, and the surgery he or she performs, in sufficient detail so that another surgeon or a third party reviewer can ascertain: (1) the condition or conditions which led to the conclusion that surgery should be performed; (2) whether the patient's condition or conditions justified the surgery that was performed; and (3) the surgery which was performed and the manner in which it was accomplished. Tr. at 111 - 113, 130 - 131, 208 - 209, 398; see Tr. at 214 - 215, 221 - 222, 227.

VI. CMRI's investigation of Petitioner's treatment of Medicare beneficiaries, its recommendation to the I.G. that Petitioner be excluded, and the I.G.'s acceptance of CMRI's recommendation

66. CMRI is a peer review organization within the meaning of section 1154 of the Act. I.G. Ex. 10, p. 1; Social Security Act, section 1154.

67. CMRI's duties as a peer review organization include reviewing the professional activities of physicians in California for the purpose of determining whether the quality of services that physicians provide to Medicare beneficiaries meets professionally recognized standards of health care. Finding 66; Social Security Act, section 1154(a)(1)(B).

68. A physician whose services are reviewed by a peer review organization is obligated to provide the peer review organization with evidence as to the medical necessity and quality of the services that he or she has provided in such form and fashion and at such time as may reasonably be required by the peer review organization. Social Security Act, section 1156(a)(3).

69. On July 8, 1991, CMRI issued to Petitioner an initial notice which advised Petitioner that CMRI had determined that Petitioner had committed substantial violations of his obligations under section 1156 of the Act, in a substantial number of cases. I.G. Ex. 10.

70. CMRI provided Petitioner with a summary of those instances in which it had made initial findings that Petitioner had failed to comply substantially with his obligations under section 1156(a) of the Act. I.G. Ex. 10, pp. 2 - 6, 20 - 62.

71. CMRI offered Petitioner the opportunity to participate in a corrective action plan. I.G. Ex. 10, pp. 6 - 7.

72. CMRI provided Petitioner the opportunity to offer additional information to CMRI and to participate in a meeting with representatives of CMRI. I.G. Ex. 10, pp. 7 - 8.

73. Petitioner requested a meeting with representatives of CMRI, and CMRI scheduled a meeting with Petitioner, which was held on September 27, 1991. I.G. Ex. 12; I.G. Ex. 13.

74. On February 26, 1992, CMRI issued to Petitioner a second notice which advised Petitioner that CMRI had reviewed information supplied to it by Petitioner in response to the first notice, and had determined that such information was not a basis for CMRI to modify its initial determination that Petitioner had failed to comply substantially with his statutory obligations in a substantial number of cases. I.G. Ex. 13, p. 1.

75. CMRI additionally advised Petitioner that it had determined to recommend to the I.G. that the I.G. impose sanctions against Petitioner. I.G. Ex. 13, p. 1.

76. CMRI advised Petitioner also that it had concluded that he had not agreed to accept a corrective action plan at the meeting held on September 27, 1991, and it offered again to enter into a corrective action plan with Petitioner. I.G. Ex. 13, pp. 4 - 5.

77. CMRI afforded Petitioner the opportunity to provide it with additional information or to have an additional meeting with CMRI representatives before CMRI made its recommendation to the I.G. I.G. Ex. 13, pp. 1 - 2.

78. On March 30, 1992, CMRI notified Petitioner that he had not responded to its February 26, 1992 offer to enter into a corrective action plan. I.G. Ex. 14, p. 1.

79. CMRI provided Petitioner with a final offer to enter into a corrective action plan as an alternative to its recommending to the I.G. that sanctions be imposed against Petitioner. I.G. Ex. 14, pp. 1 - 2.

80. Petitioner did not agree to accept the corrective action plan which CMRI offered to him on March 30, 1992. Tr. at 610 - 611.

81. On September 22, 1992, CMRI notified Petitioner that it had determined that he had failed to comply substantially with his obligations under section 1156 of the Act in a substantial number of cases and that it had recommended to the I.G. that he be excluded from participating in Medicare and Medicaid. I.G. Ex. 15, pp. 1 - 2.

82. CMRI advised Petitioner that, within 30 days from his receipt of the notice letter dated September 22, 1992 (receipt was presumed to be five days from the notice date), he could submit to the I.G. any additional information that he had which would affect CMRI's recommendations. I.G. Ex. 15, p. 4.

83. On October 26, 1992, Petitioner submitted additional information to the I.G., which the I.G. considered as part of the final exclusion determination in this case. I.G. Ex. 16, p. 2.

84. On November 12, 1992, Petitioner submitted additional information to the I.G., which the I.G. declined to consider because of its untimely submission. I.G. Ex. 16, p. 2.

85. On January 20, 1993, the I.G. advised Petitioner that the I.G. accepted CMRI's determination that Petitioner had substantially violated his obligations to provide health care under section 1156 of the Act in a substantial number of cases. I.G. Ex. 16, p. 1.

86. The I.G. concluded that Petitioner had, in a substantial number of cases, failed to provide care that was:

> a. economical and only when, and to the extent, that it was medically necessary;

b. of a quality that met professionally recognized standards of health care; and

c. that was supported by evidence of medical necessity and quality in such form and fashion as may reasonably be required by a reviewing peer review organization.

I.G. Ex. 16, p. 1.

87. The I.G. concluded further that Petitioner was either unable or unwilling to comply substantially with his obligations under section 1156 of the Act. I.G. Ex. 16, p. 3.

88. The I.G. determined to exclude Petitioner from participating in Medicare and Medicaid for three years. I.G. Ex. 16, p. 1.

VII. Acts or omissions by Petitioner on which CMRI made its recommendation to the I.G. that Petitioner be excluded and which the I.G. accepted

A. Patient HS[4]

89. HS was hospitalized at Mercy Medical Center, in Redding, California, from May 8, 1989 until May 16, 1989. I.G. Ex. 1, p.1.

90. HS is a Medicare beneficiary. I.G. Ex. 1, p.1.

91. HS was admitted to the hospital under Petitioner's care with a diagnosis of degenerative spondylolisthesis of the lower lumbar spine. I.G. Ex. 1, p.2.

92. During the course of HS' admission, Petitioner performed surgery on HS consisting of decompression, bilateral Steffee plating, and a spinal fusion. I.G. Ex. 1, p. 17.

93. Petitioner used bone obtained from HS' spine during decompression surgery as bone grafts for fusion. I.G. Ex. 1, p. 17; Tr. at 206 - 207.

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[4] The names of each of the patients involved in this case are reported in their hospital records, which are in evidence. However, as a courtesy to these patients, and out of respect for their privacy, I refer to each of them by their initials.

94. CMRI concluded that Petitioner performed unnecessary pedicle fixation (internal fixation) on HS, and the I.G. accepted this conclusion. I.G. Ex. 15, p. 2; I.G. Ex. 16, p. 2.

95. The record of HS' hospitalization does not contain documentation which establishes that HS manifested instability which would justify the performance of fusion surgery or the placement of an internal fixation device. I.G. Ex. 1, pp. 1 - 2, 5 - 6, 17; Tr. at 197, 200 - 201, 352 - 353, 358 - 360.

96. Although the record of HS' hospitalization does not contain documentation which would justify the performance of fusion surgery or the placement of an internal fixation device, it does not demonstrate that such surgery was unnecessary. See Finding 95.

97. The I.G. did not prove that Petitioner performed unnecessary pedicle fixation on HS. Findings 89 - 96.

98. CMRI concluded that Petitioner substantially violated his obligation to furnish care to HS which meets professionally recognized standards of care by failing to supplement internal fixation with an acceptable method of fusion, and the I.G. accepted this conclusion. I.G. Ex. 15, p. 2; I.G. Ex. 16, p. 2.

99. Petitioner's use of bone which was generated from HS' spine during decompression as a basis for a fusion was of inadequate quantity to provide reasonable assurances that HS' spine would fuse. Tr. at 203 - 207, 361 - 362; see Finding 93.

100. Petitioner's use of an inadequate quantity of bone to attempt fusion of HS' spine violated a professionally recognized standard of health care. Findings 64, 99.

101. The I.G. proved that Petitioner substantially violated his obligation to furnish care to HS which meets professionally recognized standards of care by failing to supplement internal fixation with an acceptable method of fusion. Findings 89 - 93, 98 - 100.

102. CMRI concluded that Petitioner substantially violated his obligation to provide it with such evidence of the medical necessity and quality of care that he gave HS as CMRI might reasonably require by failing to document the record of HS' treatment with an adequate history and physical examination, progress notes, an operative note, and indications for the surgery he

performed; the I.G. accepted this conclusion. I.G. Ex. 15, p. 2; I.G. Ex. 16, p. 2.

103. Petitioner failed to explain in the records he created of HS' hospitalization and surgery the reasons why he concluded HS required fusion surgery with internal fixation. Tr. at 197 - 201, 359 - 362; Finding 95; see I.G. Ex. 1, pp. 1 - 2, 4 - 5, 17.

104. The I.G. proved that Petitioner substantially violated his obligation to provide CMRI with such evidence of the medical necessity and quality of care that he gave HS as CMRI might reasonably require. Findings 102 - 103.

B. Patient TS

105. TS was hospitalized at Mercy Medical Center in Redding, California, from May 31, 1989 until June 8, 1989. I.G. Ex. 2, p. 1.

106. TS is a Medicare beneficiary. I.G. Ex. 2, p. 1.

107. TS was admitted to the hospital under Petitioner's care with a diagnosis of lumbar disc disease. I.G. Ex. 2, p. 2.

108. During the course of TS' admission, Petitioner performed surgery on TS consisting of lumbar decompression, Steffee plating, and a spinal fusion. I.G. Ex. 2, p. 15 - 16.

109. CMRI concluded that Petitioner substantially violated his obligation to TS to order or furnish care which meets professionally recognized standards of health care by performing metal stabilization under circumstances where a laminectomy alone would have adequately addressed TS' medical problems; the I.G. accepted this conclusion. I.G. Ex. 15, p. 2; I.G. Ex. 16, p. 2.

110. The record of TS' hospitalization does not contain documentation that establishes that TS manifested instability which would justify the performance of fusion surgery or the placement of an internal fixation device. I.G. Ex. 2, pp. 2, 5 - 6, 15 - 16; Tr. at 214 - 215, 363 - 364.

111. Although the record of TS' hospitalization does not contain documentation which would justify the performance of fusion surgery or the placement of an internal

fixation device, it does not demonstrate that such surgery was unnecessary. See Finding 110.

112. The I.G. did not prove that Petitioner performed metal stabilization on TS under circumstances where a laminectomy alone would have adequately addressed TS' medical problems. Findings 105 - 111.

113. CMRI concluded that Petitioner had substantially violated his obligation to give CMRI such evidence of the medical necessity and quality of care which he provided to TS as CMRI might reasonably require by failing to document in the record of TS' hospitalization the reasons for his decision to perform pedicle fixation; the I.G. accepted this conclusion. I.G. Ex. 15, p. 2; I.G. Ex. 16, p. 2.

114. Petitioner failed to explain in the records he created of TS' hospitalization and surgery the reasons for his decision to perform pedicle fixation and fusion on TS. I.G. Ex. 2, pp. 2, 5 - 6, 15 - 16; Tr. at 214 - 215, 363 - 364; Finding 110.

115. The I.G. proved that Petitioner substantially violated his obligation to provide CMRI with such evidence of the medical necessity and quality of care that he gave TS as CMRI might reasonably require. Findings 113 - 114.

C. Patient IS

116. IS was hospitalized at Mercy Medical Center in Redding, California, from June 7, 1990 until June 13, 1990. I.G. Ex. 3, p. 1.

117. The I.G. asserted, and Petitioner did not dispute, that IS is a Medicare beneficiary. I.G. Ex. 16; see Petitioner's hearing request, January 25, 1993.

118. IS is a Medicare beneficiary. Finding 117.

119. IS was admitted to the hospital under Petitioner's care with a diagnosis of lumbar canal stenosis. I.G. Ex. 3, p. 1.

120. IS was found also to be suffering from anterolisthesis of her spine. I.G. Ex. 3, pp. 91 - 92.

121. During the course of IS' hospitalization, Petitioner performed surgery on IS which included installation of Steffee plating. I.G. Ex. 3, p. 86; Tr. at 118.

122. Petitioner did not perform fusion surgery on IS. I.G. Ex. 3, p. 86; Tr. at 118 - 119.

123. CMRI concluded that Petitioner substantially violated his obligation to furnish care to IS which meets professionally recognized standards of health care by failing to utilize bone graft stabilization (fusion), thereby putting IS at risk for additional surgery; the I.G. accepted this conclusion. I.G. Ex. 15, p. 3; I.G. Ex. 16, p. 2.

124. Petitioner's failure to perform fusion surgery on IS in conjunction with implantation of an internal fixation device created a likelihood that the internal fixation device would fail. Tr. at 116 - 117, 221 - 222, 370 - 371; Finding 54.

125. The risks to IS resulting from likely failure of the internal fixation device could include damage to nerves and blood vessels, and the possibility that additional surgery would be required. Tr. at 116, 374; Findings 55 - 57.

126. Petitioner did not prove that an attempt at fusion of IS' spine would have been futile. See Tr. at 491 - 492.

127. The I.G. proved that Petitioner substantially violated his obligation to provide care to IS that meets professionally recognized standards of health care by implanting an internal stabilization device in IS without performing fusion surgery. I.G. Ex. 15, p. 3; Tr. at 221 - 222, 372; Findings 63, 116 - 126.

D. Patient VK

128. VK was hospitalized at Mercy Medical Center in Redding, California, from July 25, 1989, until August 2, 1989. I.G. Ex. 4, pp. 1 - 2.

129. VK is a Medicare beneficiary. I.G. Ex. 4, p. 1.

130. VK was admitted to the hospital under Petitioner's care with diagnoses which included adult onset scoliosis, spinal canal stenosis, and lumbar spondylosis. I.G. Ex. 4, p. 2.

131. During the course of VK's hospitalization, Petitioner performed surgery on her consisting of laminectomy, installation of Steffee plating, and a bilateral lateral fusion of VK's spine, utilizing a

composite graft of bone from the hospital's bone bank and VK's bone. I.G. Ex. 4, pp. 17 - 18.

132. CMRI concluded that Petitioner violated his obligation to order or furnish only care to VK that is medically necessary by performing a major operation (decompressive laminectomy and metal plating) without clinical justification; the I.G. accepted this conclusion. I.G. Ex. 15, p. 3; I.G. Ex. 16, p. 2.

133. The preoperative work up performed in VK's case by Petitioner established the presence of conditions which may have been a cause of spinal instability, but which did not necessarily cause spinal instability. Tr. at 223 - 224; see I.G. Ex. 4, pp. 2, 5, 17 - 18.

134. The record of VK's hospitalization does not contain evidence which would establish that VK manifested instability which required the surgery performed by Petitioner. Tr. at 224, 227; see Tr. at 377.

135. The I.G. proved that Petitioner violated his obligation to order or furnish care to VK that is medically necessary by performing surgery on VK without adequate medical justification for that surgery. Findings 128 - 134.

E. Patient PW-N

136. PW-N was hospitalized at Mercy Medical Center in Redding, California, from August 28, 1989 until September 7, 1989. I.G. Ex. 5, p. 1.

137. PW-N is a Medicare beneficiary. I.G. Ex. 5, p. 1.

138. PW-N was admitted to the hospital under Petitioner's care with diagnoses that included instability of the lumbar spine and lumbar spondylosis. I.G. Ex. 5, p. 2.

139. During the course of PW-N's hospitalization, Petitioner performed surgery on her which included the implantation of bilateral Steffee plating, bilateral lateral fusion, and excision of a herniated nucleus pulpolsis. I.G. Ex. 5, pp. 2, 35 - 36.

140. CMRI concluded that Petitioner substantially violated his obligation only to order or furnish care to PW-N that is medically necessary by unnecessarily performing a bilateral pedicle fixation and bony fusion; the I.G. accepted this conclusion. I.G. Ex. 15, p. 3; I.G. Ex. 16, p. 2.

141. The record of PW-N's hospitalization does not contain findings which are sufficient to establish that the implantation of Steffee plating and fusion surgery which Petitioner performed was medically necessary. Tr. at 229, 379.

142. Although the record of PW-N's hospitalization does not contain documentation which would justify the performance of fusion surgery or the placement of an internal fixation device, it does not demonstrate that such surgery was unnecessary. See Finding 141.

143. The I.G. did not prove that Petitioner performed unnecessary surgery on PW-N. Findings 136 - 142.

F. Patient JW

144. JW was hospitalized at Mercy Medical Center in Redding, California, from January 12, 1990 until January 19, 1990. I.G. Ex. 6, pp. 1, 4.

145. JW is a Medicare beneficiary. I.G. Ex. 6, p. 1.

146. JW was admitted to the hospital under Petitioner's care with a principal diagnosis of lumbar disc disease. I.G. Ex. 6, p. 6.

147. During the course of JW's hospitalization, Petitioner performed surgery on her which included implantation of bilateral Steffee plating, and lumbar decompression. I.G. Ex. 6, pp. 6, 72 - 73.

148. Petitioner did not perform fusion surgery on JW. I.G. Ex. 6, pp. 6, 72 - 73; Tr. at 118.

149. CMRI concluded that Petitioner substantially violated his obligation to JW only to order or furnish care that is medically necessary by unnecessarily performing pedicle fixation; the I.G. accepted this conclusion. I.G. Ex. 15, p. 3; I.G. Ex. 16, p. 2.

150. Based on the record of JW's hospitalization, it is possible that JW may have had a condition which necessitated fusion surgery to correct. Tr. at 233.

151. It is not possible to conclude from the record of JW's hospitalization that fusion surgery was either necessary or unnecessary. Finding 150; see Tr. at 119.

152. While fusion surgery may have been medically justified by JW's condition, there existed no necessity for implanting an internal fixation device without

performing fusion surgery also. Tr. at 120, 233 - 234; Finding 148.

153. The I.G. proved that Petitioner substantially violated his obligation to JW only to order or furnish care that is medically necessary by unnecessarily performing pedicle fixation. Findings 144 - 152.

154. CMRI concluded that Petitioner substantially violated his obligation to JW to furnish care which meets professionally recognized standards of health care by failing to perform a bony fusion as a necessary adjunct to pedicle fixation; the I.G. accepted CMRI's conclusion. I.G. Ex. 15, p. 3; I.G. Ex. 16, p. 2.

155. Petitioner's failure to perform a fusion on JW as an adjunct to the implantation of an internal stabilization device violated a professionally recognized standard of care. Tr. at 120, 233 - 234, 380 - 381; Finding 63.

156. Petitioner's failure to perform a fusion on JW as an adjunct to the implantation of an internal stabilization device placed JW at risk for complications arising from failure of the device, including nerve damage and pain, and for additional surgery. Tr. at 234 - 236.

157. Petitioner did not prove that JW's medical condition was so frail as to render inappropriate the performance of fusion surgery. See Tr. at 593.

158. The I.G. proved that Petitioner substantially violated his obligation to JW to furnish care which meets professionally recognized standards of health care by failing to perform a bony fusion as an adjunct to the implantation of an internal stabilization device. Findings 147 - 148, 154 - 157.

G. Patient EW

159. EW was hospitalized at Mercy Medical Center in Redding, California, from February 6, 1990 until February 13, 1990. I.G. Ex. 7, p. 1.

160. EW is a Medicare beneficiary. I.G. Ex. 7, p. 1.

161. EW was hospitalized under Petitioner's care with a diagnosis of lumbar disc disease. I.G. Ex. 7, p. 2.

162. During the course of EW's hospitalization, Petitioner performed surgery on him which included lumbar decompression and the implantation of Steffee plating. I.G. Ex. 7, pp. 2, 10 - 11.

163. Petitioner did not perform fusion surgery on EW. I.G. Ex. 7, pp. 2, 10 - 11; Tr. at 123.

164. CMRI concluded that Petitioner substantially violated his obligation to EW to order or furnish only care that is medically necessary by performing a spinal canal exploration and internal fixation without sufficient medical indications for such surgeries; the I.G. accepted this conclusion. I.G. Ex. 15, p. 3; I.G. Ex. 16, p. 2.

165. EW's medical history includes five previous spinal surgeries, and this history created the possibility that spinal fusion was necessary. Tr. at 122.

166. The record of EW's hospitalization does not contain evidence of instability which would establish the need for fusion surgery. Tr. at 123, 382.

167. In the absence of evidence of instability, the fact that EW had five previous spinal surgeries is insufficient to justify performing internal fixation and fusion. Findings 165, 166.

168. Petitioner did not prove that a history of five previous spinal surgeries alone justified the performance of internal fixation surgery on EW. See Tr. at 529.

169. The I.G. proved that Petitioner substantially violated his obligation to EW only to order or furnish care that is medically necessary by performing internal fixation without sufficient medical indications for such surgery. Findings 159 - 168.

170. CMRI concluded that Petitioner substantially violated his obligation to EW to provide care which meets professionally recognized standards of health care by performing metallic fixation without associated bone grafts (fusion surgery); the I.G. accepted this conclusion. I.G. Ex. 15, p. 3; I.G. Ex. 16, p 2.

171. Petitioner's failure to perform fusion on EW as an adjunct to implantation of Steffee plating put EW at risk for future complications. Tr. at 123, 239 - 240, 384.

172. Petitioner's failure to perform fusion on EW as an adjunct to implantation of Steffee plating violated a professionally recognized standard of care. Tr. at 384; Finding 63.

173. Petitioner did not prove that implantation of Steffee plating in EW without fusion surgery was an added

benefit to EW beyond that which EW obtained from decompression. See Tr. at 595 - 596.

174. The I.G. proved that Petitioner substantially violated his obligation to EW to provide care which meets professionally recognized standards of health care by performing metallic fixation without associated bone grafts. Findings 162 - 163, 170 - 173.

H. Patient LH

175. LH was hospitalized at Mercy Medical Center in Redding, California, from February 16, 1990 until February 25, 1990. I.G. Ex. 8, pp. 1 - 2.

176. LH is a Medicare beneficiary. I.G. Ex. 8, p. 1.

177. LH was hospitalized under Petitioner's care with diagnoses of unstable lumbar spine and Paget's disease. I.G. Ex. 8, p. 2.

178. During the course of LH's hospitalization, Petitioner performed surgery on her consisting of lumbar laminectomy and the implantation of Steffee plating. I.G. Ex. 8, pp. 2, 10 - 11.

179. Petitioner did not perform fusion surgery on LH. I.G. Ex. 8, pp. 2, 10 - 11; Tr. at 125 - 126, 242.

180. LH was hospitalized again in January 1991, under the care of a physician other than Petitioner. I.G. Ex. 21.

181. Fusion surgery was performed on LH during the January 1991 hospitalization. I.G. Ex. 21.

182. CMRI concluded that Petitioner substantially violated his obligation to LH to order care which meets professionally recognized standards of health care by failing to perform a fusion in conjunction with installation of metal plating; the I.G. agreed with this conclusion. I.G. Ex. 15, p. 4; I.G. Ex. 16, p. 2.

183. By failing to perform a fusion on LH as an adjunct to the implantation of Steffee plating, Petitioner placed her at risk for complications, including the need for additional surgery. Tr. at 126 - 127, 387; see Findings 180 - 181.

184. Petitioner violated a professionally recognized standard of health care by not performing a fusion on LH as an adjunct to the implantation of Steffee plating. Tr. at 387; Finding 63.

185. Petitioner did not prove that fusion would have been futile in this case due to LH's Paget's disease. See Tr. at 598 - 600.

186. The I.G. proved that Petitioner substantially violated his obligation to LH to order care which meets professionally recognized standards of health care by failing to perform a fusion in conjunction with the implantation of Steffee plating. Findings 175 - 185.

I. Patient WB

187. WB was hospitalized at Mercy Medical Center in Redding, California, from April 9, 1990 until April 15, 1990. I.G. Ex. 9, pp. 1 - 2.

188. WB is a Medicare beneficiary. I.G. Ex. 9, p. 1.

189. WB was hospitalized under Petitioner's care with a diagnosis of lumbar disc disease (although the Discharge Summary recites that WB suffered from "cervical disc disease" it is apparent from its context that, in fact, the diagnosis was of lumbar disc disease). I.G. Ex. 9, p. 2.

190. During the course of WB's hospitalization, Petitioner performed surgery on him consisting of lumbar canal decompression and the implantation of Steffee plating. I.G. Ex. 9, pp. 2, 10 - 11.

191. Petitioner did not perform a fusion on WB. I.G. Ex. 9, pp. 2, 10 - 11; Tr. at 129.

192. CMRI concluded that Petitioner substantially violated his obligation to WB to order or furnish only care that is medically necessary by unnecessarily performing metallic fixation; the I.G. accepted this conclusion. I.G. Ex. 15, p. 4; I.G. Ex. 16, p. 2.

193. Although the record of WB's hospitalization established that he needed decompression, the record does not establish that WB needed fusion. Tr. at 128 - 129.

194. While it is possible that fusion surgery may have been medically justified by WB's condition, there existed no necessity for implanting an internal fixation device without performing fusion surgery also. Tr. at 129 - 130, 249 - 251, 389 - 390; Finding 190.

195. The I.G. proved that Petitioner substantially violated his obligation to WB to order or furnish only care that is medically necessary by unnecessarily

performing metallic fixation in the absence of fusion. Findings 187 - 194.

196. CMRI concluded that Petitioner substantially violated his obligation to WB to furnish care which meets professionally recognized standards of health care by failing to supplement the implantation of metallic plating with a bone graft; the I.G. accepted this conclusion. I.G. Ex. 15, p. 4; I.G. Ex. 16, p.2.

197. Petitioner's failure to perform a fusion on WB as an adjunct to implanting Steffee plating put WB at risk for complications in the future. Tr. at 249, 389 - 390.

198. Petitioner's failure to perform a fusion on WB as an adjunct to implanting Steffee plating violated a professionally recognized standard of care. Tr. at 129, 389; Finding 63.

199. Petitioner did not prove that implantation of Steffee plating in WB absent a fusion was medically justified. See Tr. at 542 - 547.

200. The I.G. proved that Petitioner substantially violated his obligation to WB to furnish care which meets professionally recognized standards of health care by failing to supplement the implantation of metallic plating with a bone graft. Findings 190 - 191; Tr. at 196 - 199.

201. CMRI concluded that Petitioner substantially violated his obligation to provide evidence of medical necessity and the quality of care of services which he provided to WB as CMRI may reasonably require by failing to provide it with adequate documentation to justify the implantation of Steffee plating without performing a fusion; the I.G. accepted this conclusion. I.G. Ex. 15, p. 4; I.G. Ex. 16, p. 2.

202. Petitioner failed to explain in the records he prepared concerning WB's hospitalization and surgery why the implantation of Steffee plating in WB was medically necessary. Tr. at 129 - 131, 247.

203. The I.G. proved that Petitioner substantially violated his obligation to provide to CMRI evidence of the medical necessity and the quality of care of the services which he provided to WB as CMRI may reasonably require. Findings 201 - 202.

VIII. Additional acts or omissions by Petitioner which violate professionally recognized standards of care

A. Patient HS

204. A finding of spondylolisthesis in HS, even coupled with complaints by HS of intractable pain, is not a medically sufficient basis for performing fusion surgery (with or without implantation of an internal fixation device), absent findings of instability. Tr. at 197, 200 - 201, 352 - 353; Findings 95 - 96; see I.G. Ex. 1, pp. 1, 5 - 6.

205. Petitioner did not develop evidence that demonstrated that HS suffered from instability. Tr. at 201, 358 - 360; see I.G. Ex. 1, pp. 1, 5 - 6.

206. Petitioner's performance of fixation surgery on HS in the absence of evidence establishing that HS manifested instability violated a professionally recognized standard of health care. Findings 62, 204 - 205; see Tr. at 508.

B. Patient TS

207. A finding of stenosis and lumbar disc disease in TS, even coupled with complaints by TS of intractable pain, is not a medically sufficient basis for performing fusion surgery (with or without implantation of an internal fixation device), absent findings of instability. Tr. at 214 - 215, 363 - 364; Finding 110; see I.G. Ex. 2, pp. 2, 5 - 6.

208. Petitioner did not develop evidence that demonstrated that TS suffered from instability. Tr. at 214 - 215, 363 - 364.

209. Petitioner's performance of fusion surgery on TS with implantation of an internal fixation device, in the absence of evidence establishing that TS manifested instability, violated a professionally recognized standard of health care. Findings 62, 207 - 208; see Tr. at 510.

C. Patient VK

210. In performing fusion surgery on VK, Petitioner utilized bone that he obtained from VK's spine along with cadaverous bone which he obtained from Mercy Medical Center's bone bank. I.G. Ex. 4, pp. 17 - 18; Tr. at 377 - 378.

211. It cannot be determined from the records which Petitioner prepared of VK's hospitalization and surgery whether he used adequate bone in the fusion surgery he performed on VK to obtain fusion. Tr. at 225 - 226, 377 - 378; see I.G. Ex. 4, pp. 17 - 18.

212. Petitioner violated a professionally recognized standard of health care by failing to document adequately the quantity of bone which he used to attempt fusion in VK. Findings 65, 210 - 211.

D. Patient PW-N

213. Although PW-N was diagnosed by Petitioner to be suffering from lumbar instability, the medical evidence developed by Petitioner and documented by him fails to support that conclusion. Tr. at 229, 379; Finding 141; see I.G. Ex. 5, pp. 1, 5, 35 - 36.

214. Petitioner violated a professionally recognized standard of health care by failing to document adequately the necessity for performing fusion surgery on PW-N. Findings 65, 213.

E. Patient JW

215. Although JW was diagnosed by Petitioner to be suffering from dextroscoliosis of the lumbar spine, the medical evidence developed by Petitioner and documented by him does not establish that JW suffered from instability sufficient to justify fusion surgery or the implantation of an internal fixation device. I.G. Ex. 6, pp. 4 - 6; Tr. at 119, 223; Findings 150 - 151; see Tr. at 527.

216. Petitioner violated a professionally recognized standard of health care by failing to document adequately the necessity for implanting an internal fixation device in JW. Findings 65, 215.

IX. The I.G.'s authority to impose an exclusion against Petitioner based on Petitioner's substantial violation of his statutory obligations in a substantial number of cases and his unwillingness to provide health care of a quality which meets professionally recognized standards of care

217. A provider of care or practitioner is obligated to assure that items or services which he or she provides to Medicare beneficiaries and Medicaid recipients are:

a. provided economically and only when, and to the extent, medically necessary;

b. of a quality which meets professionally recognized standards of health care; and

c. supported by evidence of medical necessity and quality in such form and fashion and at such time as may reasonably be required by a reviewing peer review organization in the exercise of its duties and responsibilities.

Social Security Act, section 1156(a); Finding 68; see Findings 60 - 65.

218. The Secretary, or her delegate, the I.G., may exclude a provider or practitioner from participating in Medicare and Medicaid where, based on the recommendation of a peer review organization, she or the I.G. determines that the party has, in a substantial number of cases, substantially violated his or her obligations under section 1156(a) of the Act, and where that party is unable or unwilling substantially to comply with his or her statutory obligations. Social Security Act, section 1156(b)(1).

A. Petitioner's substantial violation of his statutory obligations in a substantial number of cases

219. A practitioner commits a substantial violation of his or her statutory obligations under section 1156(a) of the Act where the pattern of care he or she provides in a substantial number of cases is inappropriate, unnecessary, does not meet professionally recognized standards of care, or is not supported by necessary documentation of care as required by a peer review organization. 42 C.F.R. § 1004.1(b).

220. Petitioner provided unnecessary and inappropriate care, or care which failed to meet professionally recognized standards of health care, or care which was not supported by necessary documentation of care, in nine cases of surgeries which he performed on Medicare beneficiaries. Findings 89 - 203.

221. The I.G. proved that Petitioner committed 13 violations of his statutory obligations in nine cases of surgeries which he performed on Medicare beneficiaries. Findings 101, 104, 115, 127, 135, 153, 158, 169, 174, 186, 195, 200, 203; Social Security Act, section 1156(a).

222. The violations of statutory obligations committed by Petitioner occurred between May 8, 1989 and June 13, 1990. Findings 89, 105, 116, 128, 136, 144, 159, 175, 187.

223. In a substantial number of cases, the I.G. proved that Petitioner engaged in a pattern of care that is inappropriate, unnecessary, did not meet professionally recognized standards of health care, or was not supported by necessary documentation as was required by CMRI. Findings 220.

224. In a substantial number of cases, the I.G. proved that Petitioner substantially violated his obligations under section 1156(a) of the Act. Findings 219 - 223; Social Security Act, sections 1156(a), (b)(1).

B. Petitioner's inability or unwillingness to demonstrate that he is complying substantially with his obligation to provide care in accordance with his obligations under section 1156(a) of the Act

225. Petitioner has refused to enter into a corrective action plan with CMRI which would enable CMRI to determine whether Petitioner is complying with his obligations under section 1156(a) of the Act. I.G. Ex. 14; Tr. at 610; Findings 71 - 80.

226. Petitioner has not provided CMRI with credible evidence that he is complying with his obligations under section 1156(a) of the Act. See Finding 225.

227. The I.G. proved that Petitioner is unable or unwilling to comply substantially with his obligation to provide care in accordance with his obligations under section 1156(a) of the Act. Findings 225 - 227; Social Security Act, sections 1156(a), (b)(1).

X. The remedial need for an exclusion

228. The remedial purpose of an exclusion imposed pursuant to section 1156 of the Act is to protect the welfare of program beneficiaries and recipients from parties who are untrustworthy to provide health care of the requisite quality. Social Security Act, section 1156(b)(1).

229. Petitioner's repeated violations of his obligations under section 1156(a) of the Act, and his additional acts or omissions which violate professionally recognized standards of care, constitute serious and repeated violations of Petitioner's duty as a physician to provide

health care of a quality which meets accepted medical standards. Findings 89 - 216; 42 C.F.R. § 1004.90(d)(2), (3).

230. Petitioner's repeated violations of his obligations under section 1156(a) of the Act, and his additional acts or omissions which violate professionally recognized standards of health care, establish an unwillingness or inability by Petitioner to conform his practice to those standards which are recognized commonly by his peers as applying to the items or services which Petitioner provides. Findings 60 - 65, 89 - 216; 42 C.F.R. § 1004.90(d)(7).

231. Petitioner's assertions that he now performs fusion in all surgical cases in which he implants fixation devices and that he generally provides sufficient documentation of his surgeries to satisfy the criteria of reviewers is not credible in light of his refusal to enter into a corrective action plan with CMRI. See Findings 71 - 80.

232. Petitioner did not rebut evidence as to his untrustworthiness. See Finding 231.

233. The I.G. proved that Petitioner is an untrustworthy provider of care. Findings 229 - 231.

234. A three-year exclusion is reasonable in this case. Findings 228 - 233.

ANALYSIS

There are two principal issues in this case. The first issue is whether, based on CMRI's determination and recommendation to the I.G., the I.G. had authority to exclude Petitioner. The second issue is whether the three-year exclusion imposed and directed against Petitioner by the I.G. is a reasonable remedy.

The I.G. proved by a preponderance of the evidence that authority exists to exclude Petitioner. The evidence in this case strongly supports CMRI's recommendations, as adopted by the I.G., that Petitioner engaged in a pattern of substantially inappropriate treatment of his patients, in contravention of professionally recognized standards of care, and in violation of his obligations to his patients and to CMRI under section 1156(a) of the Act. The credible evidence proves that Petitioner performed spinal fixation surgeries without documenting a sufficient medical basis for performing such surgeries.

Petitioner performed these surgeries on elderly individuals where it appears, from the evidence of record, that it is possible that less drastic and less taxing measures might have sufficed. The evidence proves further that Petitioner implanted internal fixation devices in patients without attempting to perform fusions on those patients, a procedure which contravenes professionally recognized standards of health care, is of dubious or no medical benefit to patients, and puts patients at risk for future complications, including additional surgery.

Petitioner is either unwilling or unable to comply with his obligations under section 1156(a) of the Act. Petitioner refused to enter into corrective action plans which would assure that he did not repeat his improper conduct. He continues to deny that the procedures which he performed contravened professionally recognized standards of health care or jeopardized the welfare of his patients, despite strong evidence to the contrary.

The I.G. proved that the three-year exclusion which was imposed and directed against Petitioner is reasonable. Petitioner's pattern of inappropriate surgeries coupled with additional violations by him of professionally recognized standards of health care establishes Petitioner to be an untrustworthy provider of care. Petitioner's assurances that he is no longer engaging in inappropriate medical practices are unpersuasive, given his refusal to enter into a corrective action plan, his unwillingness to accept that his medical practices have been inappropriate, and his failure to present credible evidence that his practice now conforms to professionally recognized standards of health care. The exclusion which the I.G. imposed against Petitioner is justified to protect program beneficiaries and recipients from the possibility that Petitioner might fail to treat them properly.

1. The I.G. had authority to exclude Petitioner under section 1156(b)(1) of the Act.

The I.G. excluded Petitioner pursuant to section 1156(b)(1) of the Act. The I.G.'s authority to impose an exclusion under section 1156(b)(1) derives from a peer review organization's determination and recommendation that a party be excluded. In any hearing conducted under section 1156(b)(1), the judge must resolve whether: (1) evidence adduced by the peer review organization and relied upon by it in making its recommendation to the I.G. supports its recommendation that a party be excluded; and (2) the peer review organization's

recommendation is in accord with one of the statutory grounds on which an exclusion recommendation may be based.

Section 1156(a) of the Act defines three professional obligations of parties who provide items or services to program beneficiaries and recipients. These are that health care will be: (1) provided economically and only when, and to the extent, medically necessary; (2) of a quality which meets professionally recognized standards of health care; and (3) supported by evidence of medical necessity and quality in such form and fashion and at such time as may reasonably be required by a reviewing peer review organization in the exercise of its duties and responsibilities. Section 1156(b)(1) provides that a peer review organization may recommend that a party be excluded if it determines that the party has either failed in a substantial number of cases to comply substantially with any of these three obligations, or if that party has grossly and flagrantly violated any of these obligations in one or more instances.[5]

CMRI based its exclusion recommendation to the I.G. on its conclusion that Petitioner had in a substantial number of cases substantially violated his three statutory obligations under section 1156(a)(1) of the Act. The I.G. accepted CMRI's conclusion. The I.G. found also that Petitioner was either unable or unwilling to provide health care of a quality which meets professionally recognized standards of health care.[6]

Section 1156(b)(4) of the Act provides that a party who is subject to an exclusion determination pursuant to section 1156(b)(1) is entitled to an administrative hearing. This section expressly confers on excluded

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[5] The term "substantial violation in a substantial number of cases" is defined by regulation to mean a pattern of care that is inappropriate, unnecessary, does not meet professionally recognized standards of care, or is not supported by the necessary documentation of care as required by a peer review organization. 42 C.F.R. § 1004.1(b).

[6] Section 1156(b)(1) provides that, in order to exclude a party based on a recommendation by a peer review organization, the Secretary must find that the party has demonstrated either an inability or an unwillingness to comply substantially with his or her obligations to provide care consistent with the requirements of section 1156(a).

parties those rights to a hearing which inure to parties under section 205(b) of the Act. Section 205(b) provides for a de novo hearing. Bernardo G. Bilang, M.D., DAB 1295 (1992); Eric Kranz, M.D., DAB 1286 (1991). Thus, parties excluded pursuant to section 1156(b)(1) are entitled to de novo hearings. Louis W. DeInnocentes, Jr., M.D., DAB CR247 (1992).

My obligation in conducting a de novo hearing under sections 205(b) and 1156(b)(1) on the issue of the I.G.'s authority to exclude a party is to allow each party to the hearing the opportunity to offer evidence concerning the sufficiency of the facts on which a peer review organization's recommendation and the I.G.'s ultimate determination are based.[7] Inasmuch as the I.G.'s authority to exclude under section 1156(b)(1) derives from a determination and a recommendation made by a peer review organization, I must limit the evidence I receive on the issue of authority to exclude to evidence which establishes whether there exists a basis in fact for: (1) the peer review organization's determination and recommendation to the I.G.; and (2) the I.G.'s finding that the excluded party is unable or unwilling to meet

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[7] In her opening statement at the hearing of this case, counsel for Petitioner asserted that the de novo hearing which I conducted should not be an adversary hearing, but, rather, should be conducted according to the procedures utilized in Social Security disability hearings. In such hearings, the Secretary is not represented by counsel and only the disability claimants and their representatives generally appear personally before administrative law judges in order to advocate the claimants' entitlement to disability benefits. See 20 C.F.R. § 404.932. Petitioner has not repeated this argument in his posthearing briefs and may have abandoned it. I conducted the hearing in this case pursuant to regulations published by the Secretary which explicitly provide for hearings, including hearings in cases of exclusions imposed pursuant to section 1156(b)(1), in which both the Petitioner and the I.G., and their respective representatives, may appear. 42 C.F.R. § 1005.2(a), (b). I note, furthermore, that section 205(b) of the Act does not prescribe the form that administrative hearings are to take. Therefore, the fact that the Secretary may have opted to conduct "non-adversary" hearings in Social Security disability cases does not suggest that Congress mandated that all hearings conducted pursuant to section 205(b) be "non-adversary" in character.

his or her statutory obligation to provide care. DeInnocentes at 33.[8]

In hearing the issue of whether the I.G. has authority to exclude a party under section 1156(b)(1), deriving from a peer review organization's recommendation, I may not permit the I.G. to offer evidence as to facts which were not considered by the peer review organization in making its determination and recommendation, even if those facts might support the I.G.'s determination to exclude a party.[9] Also, I must permit the excluded party the opportunity to challenge and to rebut the factual basis for the peer review organization's determination and recommendation. However, I may not allow an excluded party to offer evidence proving facts which exceed the

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[8] Regulations which govern the process by which a peer review organization makes an exclusion recommendation, and the I.G. determines to accept or not accept such recommendation, enable a provider to present both the peer review organization and the I.G. with any facts relevant to the items or services at issue which should be considered by the peer review organization or the I.G. 42 C.F.R. §§ 1004.40(c)(6), 1004.50(b)(6), 1004.60(b)(2).

[9] At the hearing, the I.G. offered the opinions of three experts -- Kent Michael Patrick, M.D. (Tr. at 94 - 176), Russ P. Nockels, M.D. (Tr. at 186 - 306), and Frances K. Conley, M.D. (Tr. at 346 - 399) -- as to whether there existed professionally recognized standards of health care which governed Petitioner's treatment of his patients, and as to whether Petitioner's acts or omissions violated the standards of care which they identified. Petitioner did not object to the testimony given by these experts. The experts confined their analysis of Petitioner's conduct to records which were reviewed by CMRI. The experts did not address facts which were not considered by CMRI, inasmuch as they confined their opinions to commenting on facts considered by CMRI in making its recommendation, and on the appropriateness of the criteria employed by CMRI in making its recommendation. Thus, the I.G.'s use of experts on the authority to exclude issue did not contravene the proscription against offering facts on that issue which exceed the scope of a peer review organization's review of a party's items or services.

scope of the peer review organization's review, determination, and recommendation.[10]

As I shall discuss infra, at Part 2 of this Analysis, the de novo hearing requirements of section 205(b) permit a broader evidentiary presentation in section 1156(b)(1) exclusion cases on the issue of whether an exclusion of a particular length is reasonable, than on the issue of whether the I.G. has authority to exclude a party. On the remedy issue, I may accept evidence from either party which relates to an excluded party's trustworthiness to provide care, even if that evidence exceeds the boundaries of that which was considered by the peer review organization in making its determination and recommendation to the I.G.

My decision on the issue of whether the I.G. had authority to exclude Petitioner is based on evidence which relates to CMRI's findings that Petitioner substantially violated his statutory obligations under section 1156(a) in a substantial number of cases. On this issue, I have not considered evidence offered by the I.G. concerning other instances in which Petitioner is

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[10] Petitioner introduced the written and live testimony of an expert, J. Abbott Byrd, III, M.D., to prove that the surgeries he performed were in accord with professionally recognized standards of health care. P. Ex. 35; Tr. at 497 - 522. In contrast to the testimony offered by Drs. Patrick, Nockels, and Conley, Dr. Byrd's testimony was based on facts that had not been reviewed by CMRI and, therefore, not considered by CMRI in making its recommendation to the I.G. Tr. at 504. I considered Dr. Byrd's testimony to be relevant to the preliminary issue of whether Petitioner posed a serious risk to his patients, and relevant also to the issue of whether the exclusion imposed by the I.G. is reasonable. In my July 1, 1993 ruling as to serious risk, I gave no weight to Dr. Byrd's testimony because Petitioner provided no foundation for his opinions. The materials on which Dr. Byrd based his opinions were not only not provided by Petitioner to CMRI, but were not offered by Petitioner as exhibits at the hearing which I conducted. Petitioner did not contend that he had been deprived of the opportunity to present these materials to either CMRI or to the I.G. See n.8, supra. However, while Dr. Byrd's testimony may be relevant to the issues of serious risk and remedy, I am precluded from considering it on the issue of the I.G.'s authority to exclude Petitioner because it is based on facts which were not before CMRI. See n.9, supra.

alleged to have violated professionally recognized standards of health care. See Findings 204 - 216. Nor have I considered as relevant to this issue evidence offered by Petitioner concerning his practice of medicine subsequent to the events upon which CMRI based its recommendation to the I.G. However, I have considered such evidence as relevant to the issue of whether the three-year exclusion imposed by the I.G. is reasonable. On this latter issue, I have also considered evidence relating to CMRI's findings that Petitioner violated his obligations under section 1156(a) of the Act. See Findings 89 - 203.

a. Petitioner did not prove that CMRI denied Petitioner due process in investigating Petitioner's conduct and in making its recommendations to the I.G.

Petitioner contends that CMRI denied him due process in investigating his conduct and in making its recommendations to the I.G. He asserts that, consequently, CMRI's recommendation to the I.G. was defective, and the I.G. cannot rely on that recommendation as authority for excluding Petitioner. This contention subsumes two arguments. First, Petitioner asserts that CMRI was required by the Act to publish in writing the professionally recognized standards of care to which it held Petitioner accountable. CMRI's failure to publish such standards, according to Petitioner, was a denial of due process which renders invalid CMRI's entire review of Petitioner's items or services. Second, Petitioner argues that he was entitled to confront the medical reviewers whom CMRI employed to evaluate Petitioner's items or services, prior to CMRI making any recommendations to the I.G. in his case, so that he could refute their conclusions, explain his practice, or establish that the reviewers were biased against him. Petitioner contends that CMRI denied him that right, thus denying him due process and invalidating its recommendations to the I.G.

Neither the Act nor regulations require CMRI to publish or otherwise disseminate to the medical community the professionally recognized standards of health care to which it holds providers accountable. However, the record of this case proves that Petitioner received notice from CMRI of those standards to which he was held accountable. There is no right for parties under review by peer review organizations to confront the individuals who review their items or services. CMRI afforded Petitioner that to which he was entitled, which was to meet with a representative of CMRI. Furthermore, Petitioner has not proven that CMRI deprived him of the

opportunity to present CMRI and its reviewers with information which was pertinent to his case and to CMRI's recommendations to the I.G.

The Act contains no requirement that peer review organizations codify and publish the criteria which they use to review providers' items or services. See Social Security Act, section 1154. Neither do regulations governing the activities of peer review organizations. See 42 C.F.R. Part 1004.

The Act provides that, in discharging their duties, peer review organizations must apply professionally developed norms of care, diagnosis, and treatment, based upon typical patterns of practice within the geographic areas served by such organizations. Social Security Act, section 1154(a)(6)(A). On its face, this section does not apply specifically to peer review organizations' discharge of their duties under section 1156 of the Act. However, it does appear to establish a general obligation for peer review organizations to use professionally recognized standards of health care of either national recognition or of a unique local character in discharging their statutory duties. It is evident from this language that a professionally recognized standard of health care in a given medical specialty constitutes a consensus among the physicians practicing that specialty about how items or services should be provided. Finding 61.

However, the statutory requirement that peer review organizations evaluate physicians according to a consensus of their peers as to how medicine should be practiced does not mean that peer review organizations must publish or disseminate every criterion for evaluation that they use in every case. Congress' directive to peer review organizations in section 1154(a)(6)(A) is that they should use criteria for evaluating physicians' practices which are so widely accepted in the community of physicians that they need not be published. Furthermore, given the diversity of medical practice and the rapidity with which technology changes in medicine, it probably would be impossible for peer review organizations to publish and disseminate such criteria.

The Act's requirements are mirrored in regulations adopted by the Secretary. Regulations define professionally recognized standards of health care to be:

> Statewide or national standards of care, whether in writing or not, that professional peers of the individual or entity whose

> provision of care is an issue, recognize as applying to those peers practicing or providing care within a State.

42 C.F.R. § 1001.2 (emphasis added).[11]

That is not to suggest that peer review organizations are under no duty to advise individual providers whose practices they review of the standards by which their practices are being evaluated. A peer review organization is required to give a provider whose items or services it reviews written notice of its determination of violations under section 1156(a) of the Act, which includes a statement of any statutory obligation the provider has been found to have violated, along with a basis for the peer review organization's finding of violation. Social Security Act, section 1154(a)(14); 42 C.F.R. §§ 1004.40(b), (c), 1004.50(a). However, Petitioner has not demonstrated that CMRI failed to comply with its duty to provide him with such notice. In fact, the notices which CMRI sent to Petitioner articulate in considerable detail the specific

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[11] In his posthearing reply brief, Petitioner suggests that a codification requirement might be in regulations contained in 42 C.F.R. Part 466. These are regulations which govern peer review organizations' review of utilization and quality under sections 1154, 1866(a)(1)(F), and 1886(f)(2) of the Act, and which do not appear to have relevance to the functions exercised by CMRI in reviewing Petitioner's items or services for possible violations under section 1156(a) of the Act. 42 C.F.R. § 466.70(a). However, even if these regulations are of direct relevance, they do not contain a requirement that peer review organizations codify and publish all professionally recognized standards of health care. The regulations require that, for the conduct of a review, a peer review organization must:

> Establish written criteria based upon typical patterns of practice in the PRO [peer review organization's] area, or use national criteria where appropriate. . . .

42 C.F.R. § 466.100(c)(1). This section gives the reviewing peer review organization the option to use national criteria for review or to establish its own special criteria for review. It does not obligate a peer review organization to codify and publish professionally recognized standards of health care which are recognized nationally.

deficiencies which CMRI found in Petitioner's items or services and the standards which CMRI considered Petitioner to have violated. I.G. Exs. 10, 13, 15.

The Act does not provide for a face-to-face meeting between a provider whose items or services are being reviewed and the persons who conduct the review on behalf of a peer review organization. It provides only that, before a peer review organization determines a violation of professionally recognized standards of health care, it must provide the affected provider with "reasonable notice and opportunity for discussion." Social Security Act, section 1154(a)(14).

Nor do regulations provide for a face-to-face meeting between a provider and reviewers. Where a peer review organization initially identifies what it believes to be a substantial violation of statutory obligations in a substantial number of cases, it must afford the provider under review the option to submit more information to the peer review organization, or to have a face-to-face meeting with a "representative" of the peer review organization. 42 C.F.R. § 1004.40(c)(6). Where a peer review organization determines that a violation has occurred, it must afford the provider under review the opportunity both to submit additional information and to have a face-to-face meeting with the peer review organization. 42 C.F.R. § 1004.50(b)(6). Neither of these regulations imposes on a peer review organization the duty to have a specific individual or individuals present at meetings between the peer review organization and providers whose items or services are under review. Rather, these regulations require only that the peer review organization designate a representative to meet with an affected provider. The regulations give the peer review organization the discretion to decide who will represent it.

CMRI discharged its duty under the Act and regulations to give Petitioner the opportunity for face-to-face discussions with a representative of CMRI. In its initial sanction notice to Petitioner, CMRI advised him of the opportunity to have a face-to-face meeting with a CMRI representative. I.G. Ex. 10, pp. 1, 7 - 8; Finding 72.[12] CMRI afforded Petitioner the opportunity for a

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[12] CMRI advised Petitioner that "you may request that the physician(s) at the . . . [peer review organization] who determined that there is a reasonable basis for concluding that you have violated one or more obligations under the Medicare program appear at the

meeting with a CMRI representative in the notice it sent to him advising him of its determination that he had violated his obligations under section 1156(a). I.G. Ex. 13, pp. 1 - 2; Finding 77. Petitioner met with a representative of CMRI on at least one occasion. Findings 73, 76.

Furthermore, Petitioner has not shown that, but for being deprived of the opportunity to meet with the individual or individuals who reviewed his items or services, he would have presented CMRI with information that would have changed the outcome of CMRI's review. He has argued that he should have been provided the opportunity to meet with a reviewing physician who had the same specialty training and expertise as does Petitioner. However, he has not explained why he could not have furnished information in writing in a form which CMRI could transmit to specialists who might have been involved in reviewing Petitioner's items or services. Furthermore, Petitioner has not demonstrated that the representative of CMRI who met with Petitioner was incapable of understanding Petitioner's explanations for his items or services.

Petitioner contends also that, by not being permitted a face-to-face meeting with the individuals who reviewed his items or services, he was unable to determine whether such individuals were biased against him. Therefore, according to Petitioner, he was unable to exercise his right to have reviewers disqualified for bias. Petitioner has not cited any requirement in the Act or in regulations that a peer review organization furnish a provider whose items and services are under review with the names of reviewers, or offer a face-to-face meeting between the provider and the reviewers, so that the provider may ascertain possible bias and challenge the review on that ground. Indeed, regulations which govern reviews by a peer review organization prohibit the organization from disclosing the names of individuals who conduct reviews. 42 C.F.R. § 476.139(b).

Although CMRI did not offer Petitioner a face-to-face meeting with the individuals who reviewed his items or

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meeting to discuss the basis for the determination, although CMRI does not have to grant that request." I.G. Ex. 10, p. 8. CMRI thus presented Petitioner with the opportunity to request something that was not required either by the Act or regulations. However, CMRI never waived its right to have a representative of its choice present at the meeting. Id.

services, it offered to provide Petitioner with the names of the members of its Monitoring Committee and its Board of Directors. I.G. Ex. 11, p. 2. These are the individuals who bear responsibility for making determinations concerning possible violations of statutory obligations by providers and recommending exclusions to the I.G. CMRI invited Petitioner to advise it whether he considered any of these individuals to be biased against him. There is nothing of record to suggest that Petitioner ever asserted that any of CMRI's Monitoring Committee or Board of Directors members were biased.

Finally, the experts whom the I.G. called as witnesses at the hearing acknowledged that they had been involved in the review of Petitioner's items or services. Tr. at 140 - 142, 252 - 255, 391. Petitioner was provided the opportunity to cross-examine each of these experts and to establish either bias or lack of knowledge through cross-examination and impeachment. There was no evidence of bias adduced at the hearing, and Petitioner has not asserted that any of the experts were biased against him. As I discuss at Part 1 c. of this Analysis, these experts are knowledgeable and dispassionate witnesses.

b. The I.G. is not estopped from excluding Petitioner.

In his request for a hearing, Petitioner contended that the I.G. was without authority to exclude him because an administrative law judge had found the items or services at issue in this case to be reasonable. Petitioner was alluding to an administrative law judge decision dated June 25, 1992, in which the administrative law judge found that certain surgical items or services provided by Petitioner, including, apparently, many of the items or services at issue here, were medically necessary and appropriate covered care reimbursable under Part B of the Medicare program. P. Ex. 32.

This decision was vacated subsequently by the Appeals Council of the Social Security Administration's Office of Hearings and Appeals, which dismissed the request for hearing on which the administrative law judge's decision was premised. I.G. Ex. 20. The Appeals Council found that Petitioner had no right to a hearing before an administrative law judge, because he had not exhausted his administrative remedies within the Department of Health and Human Services prior to requesting a hearing. Id. The order of the Appeals Council became the Secretary's final administrative action in the case. Therefore, the Secretary's final administrative action in

that case was to nullify the findings made by the administrative law judge and to vacate his decision. That administrative law judge's decision does not estop the I.G. from imposing an exclusion in this case.[13]

Petitioner has now filed a suit in the United States District Court for the Eastern District of California in which, among other things, he requests the court to vacate the Appeals Council's dismissal of the administrative law judge's decision under Part B of the Medicare program. P. Ex. 37. Petitioner has not averred that the District Court has issued any orders or decisions in that case which reverse the Appeals Council.

c. Petitioner committed substantial violations of his obligation to provide care in compliance with section 1156(a) of the Act in a substantial number of cases.

The I.G. proved that Petitioner engaged in a pattern of acts or omissions which contravened his obligations under section 1156(a) of the Act. The I.G. thus proved that Petitioner substantially violated his obligations under section 1156(a) in a substantial number of cases. 42 C.F.R. § 1004.1(b).

At issue in this case are nine surgeries that Petitioner performed on Medicare beneficiaries between May 8, 1989 and June 13, 1990. I.G. Exs. 1 - 9. CMRI determined that in these nine cases Petitioner committed 18 violations of his obligations under section 1156(a)(1) of the Act.[14] I find that the I.G. proved that Petitioner committed 13 violations of his obligations under section 1156(a), and that these violations comprise a pattern of care which violates statutory obligations. Findings 221, 223.

Each of the cases at issue involve common features. All nine of the beneficiaries in question had documented medical problems involving their lower spines. In each of the nine cases, Petitioner performed surgery

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[13] It is not apparent that the I.G. would have been estopped by the administrative law judge's decision even had it remained in effect. The facts and legal issues in the Medicare Part B reimbursement case do not appear to be identical to those in this case.

[14] On close review, it appears that CMRI determined that Petitioner had committed 16 violations, and not 18 violations, as was alleged by the I.G. I.G. Ex. 15, pp. 2 - 4.

consisting of implanting an internal fixation device (Steffee plating) in the patient's spine, in order to immobilize a portion of the spine. In five of the nine cases, Petitioner implanted a fixation device without attempting to attain bony fusion of the patient's spine. Findings 89 - 203.

The I.G. offered expert opinion testimony about these surgeries which was credible and which strongly supported CMRI's recommendations and the I.G.'s determinations. Drs. Patrick, Nockels, and Conley concurred that there were professionally recognized standards of health care which governed the surgeries performed by Petitioner, and which were utilized by CMRI in recommending that Petitioner be excluded. They agreed, first, that spinal fusion surgery is justified only in those cases where there exists medically demonstrated instability of the spine coupled with complaints of intractable pain that reasonably could be found to be caused by the instability. Finding 62. Second, they agreed that, in performing fusion surgery, an adequate quantity of bone must be grafted to the fusion site by the surgeon, or the fusion attempt would fail. Finding 64. Third, they concurred in finding that the implantation of internal fixation devices, such as Steffee plating, in patients without a concurrent attempt at fusion is justified in only the most extraordinary cases. Finding 63. That is so because the stresses imposed on patients' spines, coupled with wear and tear on the fixation devices, will cause such devices to fail inevitably. Failure of fixation devices can put patients at risk for future surgery and for complications, including nerve and blood vessel damage. Finally, the experts concurred that surgeons must document adequately the work that they do so that other providers and reviewers can understand their work and the reasons for it having been performed. Finding 65.

Drs. Patrick, Nockels, and Conley offered testimony which was based on the record adduced by CMRI and which supported CMRI's conclusions that Petitioner had violated his obligations under section 1156(a)(1) of the Act. Based on these experts' testimony, and on the exhibits offered by the I.G. and reviewed by CMRI, I make the following findings. First, Petitioner performed surgeries which were not medically necessary, by implanting internal fixation devices in patients where medical evidence developed by Petitioner either did not justify surgery to stabilize the patients' spines, or did not justify implantation of fixation devices without concurrent fusion surgery. Findings 135, 153, 169, 195; Social Security Act, section 1156(a)(1). Second,

Petitioner performed surgeries which contravened professionally recognized standards of care, either by failing to utilize an adequate quantity of bone in attempting to perform spinal fusion, or by implanting internal fixation devices in patients without even attempting to perform spinal fusion. Findings 100, 127, 158, 174, 186, 200; Social Security Act, section 1156(a)(2). Finally, Petitioner violated his obligation to provide CMRI with such information as CMRI might reasonably require, by failing to document adequately the reasons for performing surgeries on some patients, or the surgeries he actually performed. Findings 104, 115, 203. Social Security Act, section 1156(a)(3).

In three instances, CMRI determined, and the I.G. found, violations which I conclude were not proven by a preponderance of the evidence. Each of these alleged violations involved determinations that Petitioner had performed unnecessary spinal surgery on Medicare beneficiaries. In each case, I find that the record of the patient's hospital stay is unclear as to whether the surgery Petitioner performed was necessary. Findings 96 - 97, 111 - 112, 142 - 143. However, the evidence in these cases establishes also that Petitioner did not provide adequate medical justification, in accord with professionally recognized standards of health care, for the surgeries he performed. Had CMRI made the determination that Petitioner performed these surgeries without justification, instead of determining that the surgeries were unnecessary, then I would have concluded that Petitioner had violated his obligation in these three cases to provide items or services in accordance with professionally recognized standards of health care. See Social Security Act, section 1156(a)(2).

Petitioner attacks the testimony of the I.G.'s experts by asserting it to be "conclusory" and without foundation. I disagree with this assertion. These experts based their testimony on the exhibits introduced by the I.G., consisting of the treatment records of the nine Medicare beneficiaries whose surgeries are at issue, and on the professionally recognized standards of health care which they identified. They identified clearly and unequivocally the professionally recognized standards of health care and the acts or omissions by Petitioner on which they based their conclusions. Petitioner offered no evidence, aside from his own testimony, to support his argument that the standards identified by the experts are not professionally recognized standards of health care. The I.G.'s experts' opinions were supported to some extent by the expert opinions on which Petitioner relied. I.G. Ex. 13, pp. 47 - 48; P. Ex. 13, p. 11; P. Ex. 31,

p. 2; Tr. at 519 - 521. Petitioner offered no treatment records as evidence which had been reviewed by CMRI and which would establish that the items or services he provided comported with professionally recognized standards of health care.

Petitioner relied on Dr. Byrd's opinion for the conclusion that implantation of internal fixation devices was justified in at least eight of the nine cases. However, Dr. Byrd's opinion is of no relevance to the issue of the I.G.'s authority to exclude Petitioner because it is based on facts which were never presented by Petitioner to CMRI or to the I.G. See n. 10, supra. Petitioner has not asserted that he was precluded from presenting these facts either to CMRI or to the I.G.

Petitioner asserts that fixation alone or fixation accompanied by fusion was justified in some of these cases because the patients manifested degenerative spinal conditions which in and of themselves justified such surgeries, without further proof of instability. Petitioner contends, specifically, that instability, and, hence, the need for fusion surgery, can be inferred from the presence of certain medical conditions in patients, such as spinal stenosis, without further proof of instability (such as motion studies of the patients' spines). Tr. at 412 - 414, 483 - 485. He therefore disputes the conclusion of the I.G.'s experts that the presence of degenerative conditions, such as stenosis, absent additional proof of instability, is not a sufficient basis for performing fixation and fusion.

The weight of the evidence does not support this contention by Petitioner. I conclude that the opinions expressed by Drs. Patrick, Nockels, and Conley are more authoritative than that expressed by Petitioner. These three physicians are extremely well-qualified and dispassionate experts. By contrast, Petitioner's assertion was motivated by his self-interest. Furthermore, Petitioner did not support his assertion with credible, dispassionate expert testimony that rebutted the opinions expressed by the I.G.'s experts. Indeed, one of the treatises that Petitioner cites to support his contention (that the presence of stenosis, by itself, justifies performance of fusion surgery) appears to support the opposite conclusion. See P. Ex. 13, p. 11; Tr. at 424.[15]

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[15] In discussing the appropriate surgery to perform on older individuals with spinal stenosis, this text provides:

Petitioner argues that the advanced age and frailty of the patients justifies his performing fixation surgeries without concurrent fusion attempts. This contention is without support and is contradicted by the opinions of all of the experts who testified in this case, including Petitioner's expert, Dr. Byrd. Tr. at 519 - 521. Dr. Steffee, the physician whose fixation system Petitioner utilized, advised CMRI that his system was not intended to be used without concurrent fusion surgery. I.G. Ex. 13, pp. 47 - 48. He stated:

> The plates were designed to help obtain a fusion. Considering the continuous lumbar motion taking place and forces at the lower end of the lumbar spine which are so great, there is no hardware in existence that would tolerate the stress and strain put on the screws without breaking. As you know a broken screw is an attorney's delight, and therefore I would say there is zero indication for the use of plates and screws without also doing a fusion operation.

Id. Dr. Steffee later advised Petitioner that, in over 1200 surgeries, he had performed "one or two" cases of stabilization without concurrent fusion. P. Ex. 31, p. 2. The one case he specifically recalled consisted of an 89-year-old individual who was not expected to survive long enough to obtain a solid fusion. Id. Petitioner made no showing that any of the nine cases at issue was equivalent, medically, to the one case cited by Dr. Steffee.

Petitioner did not offer affirmative proof to counter the opinions of the I.G.'s experts as to the adequacy of the documentation he provided for the surgeries at issue, aside from asserting that, in his opinion, the documentation was adequate. I find that this testimony by Petitioner is outweighed by the testimony offered by Drs. Patrick, Nockels, and Conley. Petitioner did offer

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> A fusion procedure is generally not performed on the older patients in this age group (usually about 60 to 70 years old), because decompression is already an extensive operation. The motion segments in question are usually rather immobile with significantly diminished disk heights and osteophytes limiting the danger of future instability.

P. Ex. 13, p. 11.

an exhibit to prove that, generally, his documentation of his items and services is of good professional quality. P. Ex. 33. The exhibit is a liability and risk assessment performed by the Medical Insurance Exchange of California on 85 hospital records of patients who were hospitalized under Petitioner's care at Mercy Medical Center in Redding, California, and who were discharged between January 1990 and the end of June 1991. Id. at 5. This exhibit is, at best, of questionable relevance to the issue of the I.G.'s authority to exclude Petitioner. Petitioner did not aver that he had provided the exhibit to CMRI. Assuming, however, that the exhibit was provided to CMRI, there is no evidence to show that Petitioner provided CMRI with the underlying medical records from which the study described in the exhibit was made. There is no evidence to show that any of the nine cases at issue were included in those records.

Petitioner argues that the I.G.'s experts based their opinions on incomplete and inadequate documentation of the surgeries which he performed. He contends that the I.G. ought to have introduced into evidence everything which CMRI reviewed concerning Petitioner's items or services. He intimates, without elaboration, that had the experts based their opinions on all of these materials, their opinions might be different.

Petitioner has not identified a single document in CMRI's records which he contends would have affected the opinions expressed by Drs. Patrick, Nockels, and Conley, or impeached these experts' credibility. Rather, he relies on his general contention that the experts should have been shown more than they reviewed and should have been questioned about these additional materials at the hearing. At bottom, Petitioner is contending merely that the experts might have changed their opinions, or their opinions might have been impeached, had the record contained some unspecified additional materials. Petitioner had the opportunity to cross-examine Drs. Patrick, Nockels, and Conley, and could have questioned them about any of the additional materials which ostensibly would have affected their opinions. Petitioner did not avail himself of that opportunity. Petitioner could have offered as exhibits at the hearing any materials which he provided to CMRI and which the I.G. did not present as part of the I.G.'s case-in-chief.

Petitioner did not avail himself of that opportunity either.[16]

Petitioner contends also that the nine cases at issue represent only a small fraction of the spinal surgery cases he performed during the period at issue. He argues that it is not reasonable to find a pattern of inappropriate treatment from the nine cases, because they comprise only a small sample of his total work product. Notwithstanding this contention, the evidence supports a finding of a pattern of violations. The nine cases comprise surgeries performed over a brief period of time. The five cases in which Petitioner performed internal fixations without concurrent fusion surgery all occurred between January and June, 1990. I.G. Ex. 3, 6 - 9. All of the cases involved similar surgeries. The violations of statutory obligations found by CMRI and the I.G. have common features.

Arguably, a pattern of inappropriate treatment would have been less evident had these cases been evaluated in the context of all of the surgeries performed by Petitioner during the time period at issue. However, the burden shifts to Petitioner to show that the conduct at issue did not constitute a pattern of inappropriate treatment, in light of the evidence presented by the I.G. Petitioner's assertion that the cases at issue comprise only a small part of his total practice does not rebut

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[16] Subsequent to the hearing, and after Petitioner had rested his case, he moved to supplement the record by offering as evidence the entire record of materials reviewed and considered by CMRI. I denied that motion, because the offer was untimely, because Petitioner did not prove any extraordinary circumstances as required by regulation, because the I.G. would have been prejudiced by my admitting the materials into evidence, and because the hearing process would be disrupted by my admitting the materials into evidence. Ruling Denying Petitioner's Motion to Supplement the Record, August 3, 1993. Petitioner filed his initial posthearing brief on July 23, 1993 before I denied his motion. Large portions of that brief consist of arguments based on the materials which I refused to admit into evidence. I cannot identify any materials cited in that brief which Petitioner contends would have affected the I.G.'s experts' opinions, had they been shown them, or would have impeached these experts' credibility.

effectively the evidence of a pattern of misconduct which emerges from the nine cases.[17]

d. Petitioner is unable or unwilling to comply substantially with his obligation to provide health care of a quality which meets professionally recognized standards of health care.

The I.G. determined that Petitioner was unable or unwilling to comply substantially with his obligation to provide health care of a quality which meets professionally recognized standards of health care. The I.G. made this determination in accordance with the Act, which as a prerequisite to the imposition of an exclusion against a party requires that the Secretary determine whether that party is able or willing to comply substantially with his obligation to provide health care as specified by the Act. Social Security Act, section 1156(b)(1).[18]

The I.G.'s determination is supported by the preponderance of the evidence. It is supported by Petitioner's unwillingness to enter into a corrective action plan with CMRI. It is supported also by Petitioner's continued failure to understand that his decisions to perform stabilization and fusion surgery in some cases do not comport with professionally recognized standards of health care.

The Act provides that the Secretary may infer that a provider is unable or unwilling to comply substantially with his obligation under the Act, based on the provider's unwillingness or inability to enter into a corrective action plan with a peer review organization.

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[17] Furthermore, Petitioner did not prove that he had presented to CMRI evidence about the surgeries he performed, other than the nine surgeries at issue, which should have changed CMRI's recommendation to the I.G.

[18] The Act does not require that the I.G. determine that a party is both unable and unwilling to provide health care of a quality which meets professionally recognized standards of health care, as a prerequisite to excluding that party. The Act's criteria for exclusion will be met if the I.G. determines either that a party is unable to provide health care of a quality which meets professionally recognized standards of health care, or that a party is unwilling to provide such health care. Social Security Act, section 1156(b)(1).

Social Security Act, section 1156(b)(1).[19] I infer that Petitioner's refusal to enter into any corrective action plan with CMRI, including the last plan which CMRI offered to him, was motivated by his unwillingness to conform his surgical practice with the professionally recognized standards of health care which CMRI found him to have contravened. I draw this inference from the fact that the last plan which CMRI offered to Petitioner was calculated reasonably to address the deficiencies in Petitioner's practice. I draw it also from Petitioner's failure to articulate a cogent reason for his refusal to accept the plan.

Petitioner refused to accept any corrective action plan which CMRI offered to him. Findings 76, 79 - 80. Petitioner has offered no explanation for his refusal other than to state that "I had no faith in their corrective action plan and they never enunciated the terms in a manner that we felt we could comply with." Tr. at 610 - 611.

The final corrective action plan which CMRI offered to Petitioner would have required Petitioner to: document patient records sufficiently so that reviewers could determine the need for surgeries which Petitioner performed; perform internal fixations only with concurrent fusion attempts; and provide CMRI with a monthly list for six months of patients on whom Petitioner performed surgeries consisting of spinal fixation or decompression, so that CMRI could evaluate Petitioner's patient care. I.G. Ex. 14, pp. 1 - 2. This plan did not necessarily comprise CMRI's non-negotiable stance as to what it would be willing to accept from Petitioner. CMRI advised Petitioner that: "should you

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[19] This provision applies to peer review organization determinations made after November 5, 1990. It states:

> In determining whether a practitioner or person has demonstrated an unwillingness or lack of ability substantially to comply with such obligations, the Secretary shall consider the practitioner's or person's willingness or lack of ability, during the period before the organization submits its report and recommendations, to enter into and successfully complete a corrective action plan.

Social Security Act, section 1156(b)(1).

wish to submit an alternate corrective action plan you may do so; . . ." I.G. Ex. 14, p. 1.

Petitioner has not asserted that any of the requirements of this plan are unreasonable. In fact, the terms that CMRI sought to have Petitioner accept are calculated reasonably to address the deficiencies which CMRI observed in Petitioner's surgical practice. Petitioner has not provided any explanation for his refusal to execute the plan or to offer CMRI an acceptable alternative, beyond his assertion that he had no faith in CMRI. See Tr. at 610 - 611.

Petitioner contends that he is willing to comply with appropriate professionally recognized standards of health care. He asserts that he no longer performs internal fixations without concurrent attempts at fusion. He asserts also that he now documents his surgical procedures in a manner which third-party reviewers would find to be acceptable. These assertions do not rebut the inference of unwillingness to comply which I draw from his refusal to enter into any of the corrective action plans which CMRI offered to him. The corrective action plans would have required Petitioner to demonstrate that his surgeries complied with professionally recognized standards of health care. That stands in contrast with his unsupported assertion that he is doing so on his own. I find Petitioner's assertions of voluntary compliance with professionally recognized standards of health care to be not credible, in light of his refusal to enter into a corrective action plan.

I conclude also that Petitioner's refusal to accept that his surgeries did not comply with professionally recognized standards of care demonstrates that he is unable to comply with such standards. Petitioner continues to assert that the criteria he uses to judge when to perform fusion surgery are acceptable medically. In fact, as I discuss at Part 1 c. of this Analysis, Petitioner continues to insist that fusion surgery is appropriate in cases where there is not medically sufficient evidence of instability causing intractable pain. This contention is contrary to professionally recognized standards of health care. Finding 62. The inference which I draw from this is that Petitioner continues to be unable to discern the appropriate case in which to perform fusion. Petitioner continues also to insist that it was appropriate medically for him to have performed fixation surgeries in five cases, without concurrent attempts at fusion. This contention is contrary to the overwhelming weight of the evidence in this case.

2. The three-year exclusion which the I.G. imposed and directed against Petitioner is reasonable.

The final issue which I must resolve is whether the remedy which the I.G. imposed and directed against Petitioner -- a three-year exclusion from participating in federally funded health care programs -- is reasonable. That question is not answered automatically by my finding that the I.G. had authority to exclude Petitioner under section 1156(b)(1), because the Act does not direct that an exclusion of any particular duration is per se reasonable in a given case.

Section 1156 is a remedial statute. As with other sections of the Act which authorize the imposition of an exclusion as a remedy, the purpose of an exclusion under section 1156 is not to punish a party for past wrongful conduct, but to provide a remedy against possible wrongful conduct by that party in the future. DeInnocentes at 48; see Narinder Saini, M.D., DAB 1371, at 6 (1992). Evidence of past wrongful conduct by a party may serve as an important predictor of that party's propensity to engage in wrongful conduct in the future. For that reason, evidence about Petitioner's violations of his obligations under section 1156(a) is highly relevant to the question of whether the exclusion imposed by the I.G. is reasonable. However, I may not limit legitimately the evidence which I receive on the remedy issue to that which was considered by CMRI in making its determination that Petitioner had violated his statutory obligations to provide care. Because section 1156 is remedial, and because of the de novo nature of the hearing which I conduct in a section 1156 case, I must consider evidence offered either by the I.G. or by Petitioner concerning his propensity or lack of propensity to engage in wrongful conduct in the future.

Evidence which I received from the I.G. which relates to the issue of remedy includes evidence concerning the violations of statutory obligations on which CMRI based its recommendation to the I.G. Findings 89 - 203. It includes evidence also concerning additional acts or omissions committed by Petitioner in his treatment of the nine Medicare beneficiaries whose cases are at issue here, which violated professionally recognized standards of health care. Findings 204 - 216. Evidence which I received from Petitioner which relates to the issue of remedy includes the testimony of Petitioner's expert, Dr. Byrd, concerning the appropriateness of the care which Petitioner provided to the nine Medicare beneficiaries. It includes Petitioner's testimony concerning the nature of his medical practice in the time subsequent to the

dates of the nine cases at issue. It includes also evidence from Petitioner concerning continuing medical education and training which he has received since the dates of the nine cases at issue. P. Ex. 34.

I am convinced from the weight of the evidence that the three-year exclusion which the I.G. imposed and directed against Petitioner is reasonable. Petitioner's treatment of the nine Medicare beneficiaries whose cases are at issue demonstrates a serious misunderstanding by him of the professionally recognized standards of health care which govern spinal surgery. His evaluation and treatment of these beneficiaries establishes a propensity to perform major surgeries in instances where there is insubstantial evidence that such surgeries are necessary and appropriate. Furthermore, he manifests a tendency to perform surgeries which his professional peers agree may endanger the welfare of his patients.

Petitioner refuses to concede that his judgments were incorrect, or that he engaged in practices which violated professionally recognized standards of health care. Most disturbing, Petitioner refuses to acknowledge that the standards which Drs. Patrick, Nockels, and Conley identified as governing the surgeries which Petitioner performs in fact exist or govern his surgeries. Thus, Petitioner continues to insist incorrectly that the presence of certain medical conditions alone, such as spinal stenosis, justifies the performance of fusion surgery without the need for additional evidence of instability. Petitioner also continues to contend against the weight of expert testimony that the performance of internal fixation without concurrent fusion surgery is appropriate in cases of elderly patients who do not suffer from terminal illness. From all of this, I infer the possibility that Petitioner will continue in the future to engage in conduct which violates professionally recognized standards of health care.

Petitioner did not rebut evidence which establishes his treatment of patients to have been inappropriate, or which shows that he continues to refuse to accept the judgments of experts concerning the existence of, and his adherence to, professionally recognized standards of health care. Petitioner relied on Dr. Byrd's opinions to prove that the surgeries Petitioner performed were appropriate medically. I do not question Dr. Byrd's professional qualifications or his expertise. However, his opinions were presented without any foundation, inasmuch as Petitioner did not offer as evidence any of the materials which Dr. Byrd consulted in offering his

opinions.[20] The I.G. had no opportunity to rebut these underlying materials or to cross-examine Dr. Byrd from them. I am not prepared to accept as credible Dr. Byrd's opinions in the absence of foundation evidence which could either support or refute those opinions.

Petitioner contends that the I.G.'s experts' opinions as to the potential for harm to patients resulting from the surgeries he performed is refuted by the allegedly excellent results the patients obtained, including relief from pain. The record in this case does not, in fact, demonstrate that these patients all received the benefits which Petitioner contends they received. In one instance, a patient was hospitalized again and underwent fusion surgery shortly after Petitioner installed a fixation device in that patient's spine without a concurrent attempt at fusion. Findings 177 - 181. However, the possibility that some or even most of the beneficiaries on whom Petitioner performed surgery may be satisfied with the results of that surgery begs the question of whether Petitioner's services were provided in accordance with professionally recognized standards of health care. What Drs. Patrick, Nockels, and Conley established is that these surgeries did not comport with professionally recognized standards of health care and that there existed a serious potential for harm to the beneficiaries.

Furthermore, in at least some cases, Petitioner performed fusion surgery without evidence that would justify the performance of such surgery. Findings 95, 110, 134, 141, 166, 193, 204 - 209, 213 - 216. The fact that Petitioner's patients may have recovered from the surgery and even experienced relief from their symptoms does not refute evidence that equally good results might have been obtained from less drastic and risky surgery.

Petitioner's completion of continuing medical education in spinal surgery does not rebut the evidence which establishes a need for an exclusion. I do not question the quality of the courses which Petitioner completed. See P. Ex. 34. However, notwithstanding his training, Petitioner continues to espouse practices which do not conform to professionally recognized standards of health care. It does not appear that the courses which Petitioner completed have affected Petitioner's

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[20] The materials consisted of x-ray films and other diagnostic studies which Petitioner never provided to either CMRI or to the I.G.

assessment of the criteria for performing spinal fusion surgery and internal fixation.

Petitioner's assertions that he now complies with professionally recognized standards of health care in the performance of spinal surgery, and in his documentation of that surgery, are not persuasive in view of his refusal to acknowledge that he has contravened such standards in the past, or to execute a corrective action plan with CMRI. In effect, Petitioner is demanding that the Secretary trust him to comply with professionally recognized standards of health care, but at the same time is refusing to acknowledge the existence of these standards, or to offer any verifiable assurances that he will comply with them. I do not find that to be a reasonable position, in view of the record of Petitioner's pattern of violations of his obligations under the Act.

Furthermore, Petitioner did not offer convincing proof at the hearing that he now is complying with professionally recognized standards of health care. He had the opportunity to present evidence demonstrating that spinal fusion surgeries which he now performs are performed only where the professionally recognized criteria for performing such surgeries are met. He offered no evidence which would prove that.

Even if I were to find true Petitioner's assertion that he no longer implants fixation devices in patients absent concurrent attempts at fusion, that would not obviate the need for an exclusion. While this asserted change in Petitioner's surgical practice addresses one major deficiency identified by CMRI, it does not address other problems. CMRI's recommendation to the I.G. was based to a large extent on Petitioner's pattern of performing fusion surgeries in cases where the medical evidence did not indicate a need for such surgeries. Even if Petitioner is now attempting fusion in every case where he implants a fixation device, he may be continuing to implant fixation devices and to attempt fusions where fixation devices and fusions are not needed.

In deciding the issue of remedy, I have taken into consideration Petitioner's education, training, and experience as a surgeon. He is an individual who is well-trained and who has had a successful professional career. Findings 1 - 5. Petitioner's background suggests that he should be fully aware of the professionally recognized standards of health care which govern his specialty. That conclusion makes it all the

more troubling that Petitioner refuses to acknowledge that they exist, or that he should be bound by them.[21]

CONCLUSION

I conclude that the I.G. had authority to impose and direct an exclusion of Petitioner pursuant to section 1156(b)(1) of the Act, based on the recommendation of CMRI. The three-year exclusion which the I.G. imposed and directed is reasonable.

/s/

Steven T. Kessel
Administrative Law Judge

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[21] Subsequent to the hearing, my office received three letters from individuals who are not parties to this case, supporting Petitioner and urging that he not be excluded. I did not admit these letters into evidence and I did not consider them in deciding this case. I referred the letters to Petitioner's counsel and I provided her with the opportunity to move that they be admitted into evidence. Had Petitioner moved to admit the letters, I would have considered any opposition that the I.G. might have offered, and I would have decided whether to admit them. However, Petitioner never moved to admit the letters into evidence.