Department of Health and Human Services

DEPARTMENTAL APPEALS BOARD

Civil Remedies Division

In The Case of:	)	
	)	
Evelyn Reyes, M.D.,	)	DATE: May 31, 1991
	)	
- v -	)	
	)	Docket No. C-302
The Inspector General,	)	
	)	Decsion No. CR131
Respondent.	)	
	)	

DECISION

On August 31, 1990, the Inspector General (I.G.) notified Petitioner that he was excluding her from participating in Medicare and any state health care program for three years.[1] The I.G. advised Petitioner that his authority to impose and direct an exclusion was derived from section 1156 of the Social Security Act (Act). He stated that his exclusion determination was based on a recommendation by the Puerto Rico Foundation for Medical Care, Inc., the peer review organization (P.R.O.) for Puerto Rico. The I.G. further notified Petitioner that she had grossly and flagrantly violated her obligation under section 1156 to provide care to patients that met professionally recognized standards of health care. He concluded that, while Petitioner had exhibited a willingness to comply with her obligations under section 1156, she had demonstrated an inability to substantially comply with such obligations. The I.G. based his conclusions on Petitioner's treatment of three patients

---

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

which he identified, and to which I shall refer hereafter as patients 95883, 39026, and 143127.[2]

The I.G. notified Petitioner that she was entitled to request a hearing before an administrative law judge concerning his exclusion determination. The I.G. also advised Petitioner that, because her practice was located in a county with a population of less than 70,000 or in a rural health manpower shortage area, she was also entitled to a preliminary hearing before an administrative law judge to decide whether the exclusion should be implemented pending a final decision on her hearing request. He informed Petitioner that the issue at the preliminary hearing would be whether Petitioner posed a serious risk to the welfare and safety of program beneficiaries and recipients.

Petitioner timely requested hearings, both as to the preliminary issue of serious risk, and as to the issue of the reasonableness of the I.G.'s exclusion determination. The case was assigned to me for hearings on all issues. Petitioner requested, and the I.G. did not object to, a consolidated hearing on all issues. I held a consolidated hearing in San Juan, Puerto Rico, from December 3 - 6, 1990.

At the completion of the hearing, the I.G. requested that I rule on the serious risk issue prior to issuing my decision in this case. On January 9, 1991, I issued a ruling on the issue of serious risk. I concluded that the I.G. had failed to prove that Petitioner would pose a serious risk to the safety and welfare of beneficiaries and recipients pending my decision in the case. Therefore, I declined to impose an exclusion pending my decision on the merits.

The parties subsequently filed briefs concerning the issues of whether there existed a basis to exclude Petitioner and the reasonableness of the exclusion imposed and directed by the I.G. The parties also filed proposed findings of fact and conclusions of law. I have carefully considered the parties' submissions as well as the record of this case. I conclude that the evidence establishes that Petitioner has grossly and flagrantly violated her obligation to provide care which meets professionally recognized standards and has demonstrated

---

[2] Patients 95883 and 39026 are referred to in the I.G.'s submissions by these designations and as patients "095883" and "039036."

an inability to comply with such obligation. The I.G. therefore had authority to exclude Petitioner pursuant to section 1156 of the Act. Although there is a remedial need for an exclusion in this case, no remedial purpose would be served by excluding Petitioner for three years. Therefore, the three-year exclusion imposed and directed by the I.G. is unreasonable. I modify the exclusion to an exclusion for six months, running prospectively from June 20, 1991 (to allow for receipt and implementation of my decision).

ISSUES

The issues in this case are whether:

1. I may consider evidence that Petitioner committed violations in addition to those which the I.G. specifically identified in his August 31, 1990, notice letter;

2. Petitioner grossly and flagrantly violated her obligation to provide health care which meets professionally recognized standards and demonstrated an inability to comply with her obligation; and

3. the exclusion imposed and directed against Petitioner by the I.G. satisfies the remedial purpose of the Act.

FINDINGS OF FACT AND CONCLUSIONS OF LAW

1. Petitioner is a physician who is licensed to practice medicine in Puerto Rico. P. Ex. 1/1.[3]

2. Petitioner has three years of residency in internal medicine and is board eligible in internal medicine. P. Ex. 1/1, 5/1.

3. Petitioner served as a physician on the staff of Arecibo Regional Hospital (Arecibo Hospital) in Arecibo, Puerto Rico, from 1981 until October 1990. P. Ex. 8/1; Tr. at 885.

4. On April 8, 1987, patient 143127 was transferred to Arecibo Hospital from another hospital, Manati Hospital, intoxicated with the medications phenobarbitol, dilantin, and tegretol. I.G. Ex. 64a/1, 39; 64b/39.

5. Patient 143127 was unconscious on his arrival at Arecibo Hospital. He was in a deep sleep with normal respiration. The pupils of his eyes were fixed with poor response to light. I.G. Ex. 64a/5.

6. Patient 143127 was admitted to Arecibo Hospital under Petitioner's service on April 8, 1987. I.G. Ex. 64a/1; Tr. at 625.

7. When a patient is admitted under a physician's service, that physician assumes responsibility for the management of the care of the patient. Tr. at 625, 851, 884, 897, 911; See I.G. Ex. 22/13-14.

8. Patient 143127 died at Arecibo Hospital on April 12, 1987. I.G. Ex. 64a/1.

9. Petitioner first saw patient 143127 on April 9, 1987, at about 10:35 am. I.G. Ex. 64a/6.

---

[3] I refer to the exhibits and the transcript of the proceedings as follows:

Petitioner's Exhibit	P. Ex. (number)/(page)
Inspector General's Exhibit	I.G. Ex. (number)/(page)
ALJ Exhibit	ALJ Ex. (number)
Transcript	Tr. at (page)

10. The I.G. did not prove that, prior to April 9, 1987, Petitioner was aware that patient 143127 had been assigned to her service.

11. The medical condition of patient 143127 at the time of his arrival at Arecibo Hospital was such that he should have been intubated immediately. I.G. Ex. 22/3; Tr. at 630-631.

12. When a patient is intubated, a tube is placed in the patient's throat in order to create an unobstructed passageway to the patient's trachea. Tr. at 632.

13. A patient is normally intubated in order to assist that patient's breathing, to prevent hypoxemia (deficient oxygenation of the patient's blood), and to prevent inspiration of stomach contents when gastric lavage is performed. Tr. at 632.

14. Patient 143127 was not intubated from the time of his admission until after Petitioner first saw the patient on April 9, 1987. I.G. Ex. 64a/26; Tr. at 630-631; Finding 9.

15. It is standard medical procedure to treat a patient who is intoxicated with medications aggressively during the first 12 hours after that patient's admission. Tr. at 754-755.

16. Aggressive treatment of intoxicated patients should be done in conjunction with monitoring measures which include continued evaluation of vital signs (blood pressure, pulse, and respiration) and urinary output. Tr. at 754.

17. Monitoring measures were not followed with respect to patient 143127 between his admission and April 9, 1987. I.G. Ex. 47/7; Tr. at 755, 762; See I.G. Ex. 64a.

18. Patient 143127 should have been placed in the intensive care unit on his admission to Arecibo Hospital so that necessary monitoring could be performed. I.G. Ex. 22/3, 47/18; Tr. at 767-770.

19. If no beds were available in the intensive care unit, patient 143127 should nevertheless have received care equivalent to what he would have received in the intensive care unit. Tr. at 769-770.

20. Between April 8 and April 9, 1987, patient 143127 was neither placed in the intensive care unit nor did he

receive equivalent treatment at some other location in Arecibo Hospital. See I.G. Ex. 64a.

21. Patient 143127 was first placed in the intensive care unit at Arecibo Hospital on April 9, 1987, on Petitioner's orders. I.G. Ex. 64a/24, 43, 64b/43.

22. Patient 143127 was observed at 8:30 a.m. on April 9, 1987, to be experiencing convulsions of five seconds' duration every minute. I.G. Ex. 64a/42, 64b/42.

23. On April 9, 1987, at 10:45 a.m., Petitioner requested a consultation with a neurologist concerning patient 143127. I.G. Ex. 64a/6.

24. A neurologist examined patient 143127 on April 9, 1987, at 11:30 a.m. I.G. Ex. 64a/6.

25. The neurologist concluded that the prognosis for patient 143127 was very poor. I.G. Ex. 64a/6.

26. The neurologist recommended that if patient 143127 developed seizures, he should be given valium intravenously. I.G. Ex. 64a/6. The neurologist advised against giving patient 143127 anticonvulsant medications. Id.

27. The neurologist also recommended that if patient 143127 developed status epilepticus he should be given depakene. I.G. Ex. 64a/6.

28. The neurologist also recommended that supportive measures for patient 143127 be maintained. I.G. Ex. 64a/6.

29. Status epilepticus is an emergency medical condition in which a patient develops continuous motor convulsions. Tr. at 781-782.

30. When a patient develops status epilepticus, he manifests a muscular movement which is similar to trembling, but with a loss of consciousness. Tr. at 782.

31. Status epilepticus is an emergency condition, because if it persists for more than 30 minutes, it can result in permanent brain damage. Tr. at 782-783.

32. Patient 143127 manifested continuous convulsions after Petitioner consulted with the neurologist. I.G. Ex. 64a/46-50, 64b/46-50; Tr. at 780-783.

the Arecibo Hospital intensive care unit or under equivalent care on April 8, 1987. See Findings 6-7, 9-10, 18-21.

44. The I.G. did not prove that Petitioner failed to follow the consulting neurologist's recommendations for treatment of patient 143127 for status epilepticus. See Findings 23-34.

45. The I.G. did not prove that Petitioner failed to properly assure that good progress notes were made of the condition of patient 143127 between April 8 and 9, 1987. See Findings 6-7, 9-10, 39-40.

46. The I.G. proved that, in contravention of accepted medical practice, Petitioner failed to monitor the level of anticonvulsant medications in the blood of patient 143127. Findings 35-38.

47. On June 5, 1988, at 10:35 a.m., patient 39026 arrived at the Arecibo Hospital emergency room. I.G. Ex. 63a/102.

48. Patient 39026 was admitted to Arecibo Hospital under Petitioner's service on June 5, 1988, at 12:15 p.m. I.G. Ex. 63a/40.

49. Petitioner first examined patient 39026 on June 6, 1988, at 4:00 p.m. I.G. Ex. 63a/35.

50. The I.G. did not prove that, prior to the time she first examined patient 39026 on June 6, 1988, Petitioner was aware that patient 39026 had been admitted under her service.

51. Patient 39026 died at Arecibo Hospital on June 11, 1988. I.G. Ex. 63a/2.

52. Patient 39026 first arrived at Arecibo Hospital on June 5, 1988, suffering from intoxication from the medications luminal (phenobarbitol) and dilantin. I.G. Ex. 63a/4; Tr. at 540-541.

53. Patient 39026 was conscious when he arrived at the Arecibo Hospital emergency room. I.G. Ex. 63a/102.

54. At 1:32 p.m., on June 5, 1988, while still in the emergency room, and after having been admitted to Arecibo Hospital, patient 39026 suffered a cardiac arrest. I.G. Ex. 63a/104; Finding 48.

55. Patient 39026 was resuscitated in the Arecibo Hospital emergency room. I.G. Ex. 63a/106.

56. Patient 39026 was transferred to the Arecibo Hospital intensive care unit at 2:10 p.m. on June 5, 1988. I.G. Ex. 63a/106.

57. On arrival at the intensive care unit, patient 39026 was in a coma. I.G. Ex. 63a/51, 63b/51.

58. In her initial examination of patient 39026 on June 6, 1988, Petitioner found him to be in a deep coma. I.G. Ex. 63a/35.

59. In her initial examination of patient 39026, Petitioner found that the pupils of his eyes were dilated, that his body temperature was 39 degrees centigrade, and that he was not breathing spontaneously. I.G. Ex. 63a/35.

60. Petitioner concluded that patient 39026 was neurologically dead. I.G. Ex. 63a/35.

61. Petitioner's treatment plan for patient 39026 included placement of a nasogastric tube, breathing assistance with a respirator, and intravenous fluids to force diuresis. I.G. Ex. 63a/35.

62. In cases of drug intoxication, the clinical signs of neurologic death may be mimicked by the effects of the drugs. Tr. at 557-561.

63. In cases of drug intoxication, a diagnosis of neurologic death may not be made properly without ruling out the possibility that the signs of neurologic death are drug-induced. I.G. Ex. 88; Tr. at 551-552, 557-561.

64. Petitioner's conclusion that patient 39026 was neurologically dead was contrary to professionally recognized criteria for determining neurologic death. I.G. Ex. 88; Tr. at 551-552, 557-561; Findings 62, 63.

65. The professionally recognized characteristics of phenobarbitol intoxication include drowsiness progressing into coma, hypothermia (low body temperature), and hypotension (low blood pressure). I.G. Ex. 89/313; Tr. at 561-562.

66. Patient 39026 manifested the professionally recognized characteristics of phenobarbitol intoxication on June 6, 1988, when he was first examined by Petitioner. I.G. Ex. 63a/35; Finding 65.

67. The professionally recognized treatment for phenobarbitol intoxication includes monitoring of the patient's fluid intake and output, as well as monitoring of the patient's arterial blood gases. I.G. Ex. 90/316-319; Tr. at 562-565.

68. One reason for monitoring a patient's arterial blood gases is to assure that the patient does not experience hypoxemia (low levels of oxygen in the blood). Tr. at 564-565.

69. Another reason for monitoring a patient's arterial blood gases is to assure that the patient does not experience metabolic acidosis (an excess of acid in the blood). Tr. at 597-598.

70. The consequence of metabolic acidosis is cell impairment leading to cell death, and inefficient delivery of oxygen from the blood's hemoglobin to the body's cells. Tr. at 600.

71. In establishing a treatment plan for patient 39026, Petitioner did not order that the patient's blood gases be monitored for metabolic acidosis or hypoxemia, or that the patient be treated for these conditions. See I.G. Ex. 63a/35.

72. Arterial blood gas studies were made of patient 39026 on June 5, June 7, and June 9, 1988. I.G. Ex. 63a/17-19.

73. The results of the arterial blood gas study performed on June 9, 1988, indicated that patient 39026 was experiencing metabolic acidosis. I.G. Ex. 63a/17; Tr. at 602.

74. The results of the arterial blood gas study performed on June 9, 1988, indicated that patient 39026 was experiencing hypoxemia. I.G. Ex. 63a/17; Tr. at 602.

75. Arterial blood gas studies were not repeated for patient 39026 after June 9, 1988. See I.G. Ex. 63a.

76. Given the results of the June 9, 1988, arterial blood gas studies, studies should have been repeated after June 9, 1988, to monitor patient 39026 for metabolic acidosis and hypoxemia. Tr. at 603-604.

77. The I.G. did not prove that Petitioner failed to properly diagnose the condition of patient 39026 or to properly treat patient 39026 prior to her first examining the patient on June 6, 1988. See Findings 50-57.

78. The I.G. proved that, in concluding that patient 39026 was neurologically dead and in failing to order arterial blood gas studies after June 9, 1988, Petitioner failed to properly identify and order the professionally recognized course of treatment for patient 39026. Findings 62-76.

79. The I.G. proved that Petitioner failed to monitor the respiratory status of patient 39026 in order to prevent hypoxemia and metabolic acidosis. Findings 73-76.

80. On December 21, 1988, patient 95883 was admitted to Arecibo Hospital under Petitioner's service. I.G. Ex. 62a/2.

81. Patient 95883 died at Arecibo Hospital on January 6, 1989. I.G. Ex. 62a/2-3.

82. Petitioner first examined patient 95883 on December 22, 1988. I.G. Ex. 62a/135.

83. In her report of this examination, Petitioner noted that patient 95883 complained of nausea and "coffee ground" vomiting while at Arecibo Hospital. I.G. Ex. 62a/135.

84. Complaints of nausea and "coffee ground" vomiting by a patient are symptoms that the patient is experiencing bleeding from the upper gastrointestinal (GI) tract. Tr. at 275.

85. Petitioner concluded from her initial examination of patient 95883 that the patient was suffering from uncompensated congestive heart failure, chronic obstructive pulmonary disease, and diabetes mellitus. I.G. Ex. 62a/135; Tr. at 134-135.

86. Petitioner expressed concern in her report of her initial examination of patient 95883 that the patient could be suffering intoxication from the drug aminophylline. I.G. Ex. 62a/135.

87. Nausea, vomiting, and upper GI bleeding are signs of intoxication from aminophylline. I.G. Ex. 67; Tr. at 275.

88. Aminophylline intoxication is a medically dangerous condition which may cause a patient to die. I.G. Ex. 67; Tr. at 280-281.

89. A patient who suffers from aminophylline intoxication may experience increased gastric bleeding, seizures, cardiovascular arrhythmias, congestive heart failure, apnea, and coma. I.G. Ex. 67; Tr. at 280-281.

90. The professionally recognized standard for treating a patient who is suspected to be experiencing aminophylline intoxication includes immediately discontinuing administration of aminophylline to that patient. I.G. Ex. 67; Tr. at 279-280.

91. Based on her conclusion that patient 95883 might be suffering from aminophylline intoxication, Petitioner initially ordered that administration of aminophylline to the patient be reduced but not discontinued. I.G. Ex. 62a/135, /160.

92. The I.G. proved that Petitioner's order that administration of aminophylline to patient 95883 be reduced but not discontinued contravened the professionally recognized standard for treating a patient who is suspected to be experiencing aminophylline intoxication. Finding 90.

93. On December 22, 1988, Petitioner ordered that tests be performed immediately to determine the blood level of aminophylline in patient 95883. I.G. Ex. 62a/160.

94. Blood tests were performed on patient 95883 on December 22, 1988, and the results were provided on December 23, 1988. I.G. Ex. 62a/18.

95. Results of the December 22, 1988 tests on patient 95883 established his serum aminophylline level on that date to be 35.9 mcg/ml, which exceeds the professionally recognized maximum therapeutic serum levels for aminophylline of 20 mcg/ml. I.G. Ex. 62a/18, 67.

96. Additional blood tests were performed on patient 95883 on December 27, 1988, and the results were provided on December 28, 1988. I.G. Ex. 62a/30.

97. Results of the December 27, 1988 tests on patient 95883 established his serum aminophylline level on that date to be 53.0 mcg/ml, which exceeds the professionally recognized maximum therapeutic serum levels for aminophylline. I.G. Ex. 62a/30, 67.

98. Although the serum aminophylline levels in patient 95883 exceeded the professionally recognized maximum therapeutic level, aminophylline was administered to

patient 95883 daily between December 22 and 27, 1988. I.G. Ex. 62a/317; Tr. at 289, 486-489.

99. The professionally recognized standard for administration of aminophylline requires that the serum aminophylline level in a patient be monitored to assure that therapeutic levels are achieved and not exceeded. I.G. Ex. 67; See Tr. at 284, 296-298.

100. Petitioner did not order tests to monitor the serum aminophylline levels in patient 95883, aside from those which were ordered on December 22 and 27, 1988. See I.G. Ex. 62a.

101. Between December 22, and 27, 1988, Petitioner did not order that administration of aminophylline to patient 95883 be discontinued, despite the results of the test taken on December 22, which showed the patient's serum aminophylline level to exceed the therapeutic level. See I.G. Ex. 62a.

102. The I.G. proved that Petitioner failed to monitor the serum aminophylline levels in patient 95883 between December 22 and December 27, 1988. Findings 99, 100.

103. On December 27, 1988, patient 95883 experienced tonic focal seizures. I.G. Ex. 62a/140, 62b/140.

104. On December 27, 1988, gastric lavage was performed on patient 95883, and he produced abundant coffee ground aspiration. I.G. Ex. 62a/140, 62b/140.

105. Petitioner did not order that administration of aminophylline to patient 95883 be discontinued on December 27, 1988, despite his development of seizures and production of coffee ground aspiration. See I.G. Ex. 62a.

106. On December 28, 1988, another physician (Dr. Salgado) ordered that administration of aminophylline to patient 95883 be discontinued. I.G. Ex. 62a/169.

107. On the morning of January 3, 1989, another physician whose name is not legible in the medical record ordered that administration of aminophylline to patient 95883 be resumed. I.G. Ex. 62a/174.

108. On the afternoon of January 3, 1989, Petitioner ordered that no aminophylline be administered to patient 95883. I.G. Ex. 62a/175.

109. Petitioner did not order tests for serum aminophylline level for patient 95883 between December 27, 1988, and January 3, 1989, nor were any such tests performed. I.G. Ex. 62a.

110. The I.G. proved that Petitioner failed to monitor the serum aminophylline level of patient 95883 between December 27, 1988, and January 3, 1989.

111. By failing to monitor the serum aminophylline level of patient 95883 between December 22, 1988 and January 3, 1989, Petitioner contravened professionally recognized standards of care for a patient who is suffering from aminophylline intoxication. Findings 93-110.

112. On December 22, 1988, after her initial examination of patient 95883, Petitioner ordered that he be administered the drug tagamet. I.G. Ex. 62a/135.

113. Tagamet (also known as cimetidine) is a medication used to decrease secretion of gastric acid in patients suffering from peptic ulcers, thereby promoting the healing of peptic ulcers. Tr. at 282-284.

114. One consequence of concomitant administration of aminophylline and cimetidine to a patient may be an elevated serum aminophylline level in that patient. I.G. Ex. 67, Tr. at 285-286.

115. The interactions between aminophylline and tagament in patient 95883 resulted in complications that jeopardized this patient's health and may have contributed to his death. Tr. at 298.

116. Petitioner failed to recognize the potentially life-threatening interactions between tagamet and aminophylline in patient 95883, as is demonstrated by her failure to monitor the serum aminophylline level in this patient. Tr. at 298-300; Findings 102, 110, 112-115.

117. Although patient 95883 was suffering from respiratory problems, Petitioner did not consult with a pneumologist or order that the patient be transferred to a facility at which a pneumologist was available. I.G. Ex. 62a.

118. A pneumologist is a practitioner who specializes in respiratory problems. Tr. at 300-301.

119. No pneumologist was available for consultation at Arecibo Hospital. Tr. at 301.

120. Although it may have been in the interests of patient 95883 to have not accepted him for admission at Arecibo Hospital, given the lack of access to a pneumologist at that facility, the I.G. did not prove that Petitioner was consulted or involved in the decision to admit this patient. Tr. at 302; See Findings 80, 82.

121. On December 22, 1988, patient 95883 was examined by a cardiology consultant (Dr. Salgado). I.G. Ex. 62a/132.

122. The cardiology consultant concluded that patient 95883 was suffering from decompensated congestive heart failure and made recommendations as to the patient's treatment. I.G. Ex. 62a/132.

123. The I.G. did not prove that Petitioner failed to follow the cardiology consultant's recommendations concerning the treatment of patient 95883. I.G. Ex. 62a.

124. The cardiology consultant also saw patient 95883 on December 23, 26, 28, 29, 30, and 31, 1988, and on January 3 and 4, 1989. I.G. Ex. 62a.

125. The I.G. did not prove that Petitioner failed to provide cardiology follow up for patient 95883. I.G. Ex. 62a.

126. On December 6, 1989, the P.R.O. told Petitioner that it had found a reasonable basis to determine that Petitioner had grossly and flagrantly violated her obligations to provide care to Medicare beneficiaries that are of a quality that meets professionally recognized standards of care. I.G. Ex. 43.

127. On January 9, 1990, the P.R.O. held an informal hearing in Petitioner's case. I.G. Ex. 47; Tr. at 195.

128. On January 24, 1990, Petitioner submitted a plan of action to the P.R.O. I.G. Ex. 48; Tr. at 197.

129. In her January 24, 1990 plan of action, Petitioner agreed to write daily progress notes and orders for hospitalized patients whom she treated. I.G. Ex. 48.

130. Petitioner agreed to discuss ongoing cases at Arecibo Hospital with interns or "second call" physicians who were assigned to these cases as a work team, and to document the tasks assigned to the work team. I.G. Ex. 48.

131. Petitioner agreed to document all measures taken with the Arecibo Hospital Pharmacy, X-Ray Department, and with laboratories. I.G. Ex. 48.

132. Petitioner agreed to document all patient transfers, out-of-hospital tests, and requests from work team members, along with all errors and omissions in the treatment of patients. I.G. Ex. 48.

133. In a January 24, 1990 plan of action, Petitioner advised the P.R.O. that a conference was being organized at Arecibo Hospital to discuss the management of intoxication by dilantin and luminal. I.G. Ex. 48.

134. The P.R.O. concluded that Petitioner's plan of action did not adequately deal with the deficiencies which the P.R.O identified in Petitioner's treatment of hospitalized patients. Tr. at 201-203.

135. On May 29, 1990, the P.R.O. recommended to the I.G. that Petitioner be excluded from participating in Medicare and Medicaid. I.G. Ex. 52; See I.G. Ex. 51.

136. The P.R.O. based its recommendation on its conclusion that Petitioner had grossly and flagrantly violated her obligations under section 1156 of the Act. I.G. Ex. 52; See I.G. Ex. 51.

137. On August 31, 1990, the I.G. notified Petitioner that he was excluding her from participating in Medicare and Medicaid for three years, pursuant to section 1156 of the Act. I.G. Ex. 57.

138. Based on the P.R.O.'s recommendation, the I.G. concluded that Petitioner had grossly and flagrantly violated her obligations under section 1156 of the Act. I.G. Ex. 57.

139. The I.G. concluded that Petitioner had expressed a willingness to comply with her obligations under the Act, but had demonstrated an inability to substantially comply with her obligations. I.G. Ex. 57.

140. Under section 1156 of the Act, the Secretary of the Department of Health and Human Services may exclude a physician from participating in Medicare and Medicaid where the Secretary determines, based on a recommendation by a P.R.O., that the physician has grossly and flagrantly violated the obligation to provide health care of a quality which meets professionally recognized standards of care and has demonstrated an inability or unwillingness to substantially comply with the obligation

to provide such care. Social Security Act, section 1156(a)(2), (b)(1).

141. A "gross and flagrant violation" is defined by relevant regulation to mean the violation of an obligation to provide care in one or more instances which meets professionally recognized standards which presents an imminent danger to the health, safety, or well-being of a Medicare beneficiary or places the beneficiary unnecessarily in a high risk situation. 42 C.F.R. 1004.1(b).

142. Patients 143127, 39026, and 95883 were Medicare beneficiaries. ALJ Ex. 15; See I.G. Ex. 62a/2, 63a/2, 64a/1; Tr. at 60-63.[4]

143. The I.G. proved that, by failing to monitor the blood levels of medication in patient 143127 on or after April 9, 1987, Petitioner committed a violation of her obligation to provide care to that patient in a manner which presented an imminent danger to his health, safety, or well-being, and unnecessarily placed him in a high risk situation. Tr. at 800; Findings 37, 38, 46.

144. The I.G. proved that, by failing to monitor the arterial blood gases of patient 39026 after June 9, 1988, in order to identify and treat hypoxemia and metabolic acidosis, Petitioner committed a violation of her obligation to provide care to that patient in a manner which presented an imminent danger to his health, safety, or well-being, and unnecessarily placed him in a high risk situation. Findings 67-76.

145. The I.G. proved that, by failing to monitor the serum aminophylline level in patient 95883, Petitioner committed a violation of her obligation to provide care to that patient in a manner which presented an imminent danger to his health, safety, or well-being, and

---

[4] On April 23, 1991, I directed that a letter be sent to the parties advising them that, although there did not seem to be a disagreement as to whether patients 143127, 39026, and 95883 were Medicare beneficiaries, there did not appear to be proof that in fact, these patients were Medicare beneficiaries. Counsel for the I.G. responded with a letter dated May 6, 1991, advising me that she and counsel for Petitioner concurred that patients 143127, 39026, and 95883 were Medicare beneficiaries. I have identified this May 6, 1991 letter as ALJ Ex. 15 and have admitted it into evidence.

unnecessarily placed him in a high risk situation. Tr. at 283, 286; Findings 102, 107, 111.

146. The I.G. proved that, by failing to recognize the potentially life-threatening interactions between tagamet and aminophylline in patient 95883, Petitioner committed a violation of her obligation to provide care to that patient in a manner which presented an imminent danger to his health, safety, or well-being, and unnecessarily placed him in a high risk situation. Tr. at 296-300; Findings 115, 116.

147. The I.G. proved that Petitioner committed gross and flagrant violations of her obligation to provide health care of a quality which meets professionally recognized standards of care. Findings 142-145; Social Security Act, section 1156(a); 42 C.F.R. 1004.1(b).

148. Although Petitioner has manifested a willingness to meet her obligation to provide health care of a quality which meets professionally recognized standards of care, she has not demonstrated the ability to do so. See I.G. Ex. 48; Tr. at 200-203.

149. The I.G. had authority to exclude Petitioner from participating in Medicare and to direct that she be excluded from participating in Medicaid. Findings 146, 147; Social Security Act, section 1156(a).

150. The purpose of section 1156 of the Act is remedial.

151. Section 1156 of the Act is intended to enable the Secretary to protect federally-funded health care programs and their beneficiaries and recipients from health care providers who have demonstrated by their conduct that they are not trustworthy.

152. Petitioner has engaged in conduct that endangered the health and safety of program beneficiaries. Findings 85-92; 141-146.

153. Petitioner has manifested an inability to effectively treat hospitalized patients for drug intoxication. Findings 35-38, 46, 55-76, 78, 79, 82-92, 97-105, 110-116.

154. Petitioner has demonstrated a lack of knowledge of the potentially lethal consequences of drug intoxication in hospitalized patients, and the interactions of drugs in such patients. Findings 35-38, 46, 55-76, 78, 79, 82-92, 97-105, 110-116.

155. Petitioner's deficient treatment of patients occurred in several cases over an extended period of time. Findings 4, 8, 48, 51, 80, 81.

156. Petitioner has demonstrated by her treatment of patients that she is not trustworthy to treat program beneficiaries and recipients. Findings 151-154.

157. The I.G. excluded Petitioner from participating in Medicare, and directed that she be excluded from participating in Medicaid, for three years. I.G. Ex. 57.

158. The I.G. has not proven that there exists a remedial purpose to exclude Petitioner for three years.

159. The remedial purpose of section 1156 will be served by excluding Petitioner from participating in Medicare and Medicaid for six months, running prospectively from June 20, 1991.

ANALYSIS

1. The I.G. may not introduce evidence that Petitioner committed violations in addition to those which the I.G. specifically identified in his August 31, 1990 notice letter.

The August 31, 1990 notice letter which the I.G. sent to Petitioner advised her that a determination had been made to exclude her "pursuant to the authority set out" in section 1156 of the Act. The letter noticed Petitioner that the material which formed the basis for the I.G.'s exclusion determination previously had been provided to Petitioner by the P.R.O. and was "incorporated in this notice by specific reference." The I.G. advised Petitioner that he agreed with the P.R.O. that Petitioner grossly and flagrantly violated her obligation under section 1156 of the Act to provide care that met professionally recognized standards of health care with respect to patients 95883, 39026, and 143127. The I.G. stated that:

> The cases reviewed by the PRO resulted in the following findings, with which the OIG agrees.
>
> Medical Record No. 95883:
>
> - failure to monitor aminophylline levels

- failure to recognize drug interactions which caused complications leading to death

- failure to provide pneumology services

- failure to provide adequate cardiology intervention, and involvement in follow up

Medical Record No. 39026:

- failure to recognize limitations in managing the patient

- failure to monitor respiratory status

- failure to identify and treat metabolic acidosis and resultant hypoxemia

Medical Record No. 143127:

- failure to recognize medication half life in order to review treatment and prevent status epilepticus

Based on these findings, I have determined that you have committed 3 gross and flagrant violations of your quality of care obligations. (Emphasis added)

At the hearing, the I.G. offered evidence as to all of these allegations, in order to establish that Petitioner committed gross and flagrant violations of her obligation to provide health care in accord with professionally recognized standards of care. The I.G. also sought to introduce evidence relevant to additional allegations that Petitioner had not properly treated patient 143127. These consisted of allegations that Petitioner had failed to: immediately intubate the patient on his admission to Arecibo Hospital; monitor the status of the patient from admission on April 8, 1987 to April 9, 1987; immediately admit the patient to the intensive care unit on his admission at Arecibo Hospital; reconsult a neurologist on April 9, 1987, after the patient experienced convulsions; and make appropriate progress notes with respect to the patient's status and treatment.[5]

---

[5] I received this evidence over the objection of counsel for Petitioner. In receiving the evidence, I advised the parties that I might ultimately rule that the evidence was inadmissible to prove that there existed

The issue before me is whether I should permit the I.G. to assert these additional allegations as evidence that Petitioner committed gross and flagrant violations of her obligation to provide health care in accordance with professionally recognized standards of care. I conclude that the I.G. is not entitled to assert that these additional allegations prove that Petitioner committed gross and flagrant violations because he failed to provide Petitioner with adequate notice of these allegations. I conclude further that it would not be fair to Petitioner to permit the I.G. to amend his notice of violations to include these additional allegations.

Under section 1156, the I.G.'s authority to exclude a provider derives from the recommendation he receives from a P.R.O. The Act specifically requires a P.R.O. determination that a provider has failed to meet or has violated his obligations as defined in section 1156(a) as a prerequisite to any exclusion determination by the Secretary. Based on a P.R.O. recommendation, the Secretary (or his delegate, the I.G.) may determine to exclude the provider. Social Security Act, section 1156(b)(1).

The I.G.'s determination that a provider has failed to meet or has violated his obligations may not be based on factors beyond those which form the basis for a P.R.O.'s recommendation. However, the I.G. may make a determination on narrower grounds than those cited by the P.R.O. The Act contemplates that the I.G. will exercise his discretion to evaluate and accept or reject as appropriate a P.R.O.'s recommendation. It is within the realm of reasonable possibility in any case that a P.R.O. may make a recommendation to exclude based on a variety of factors, that the I.G. may accept part of this recommendation and not accept the balance, and that the I.G. may determine to exclude the provider based on that with which he agrees.

The I.G.'s notice to a provider excluded under section 1156 informs that provider of the allegations which the provider must prepare to rebut in any hearing concerning the exclusion. The exclusion notice functions as an administrative complaint. The regulations require that the notice to an excluded provider specify "the legal and factual basis for the determination." 42 C.F.R.

---

authority to exclude Petitioner. I also advised the parties that the evidence might be admissible on the issue of the reasonableness of the three-year exclusion imposed and directed against Petitioner by the I.G.

1004.100(c)(1). Because the I.G.'s determination to exclude may be based on narrower grounds than those recommended by the P.R.O., the exclusion letter serves as notice to an excluded party in such a case that there are some P.R.O. findings which he will not be obliged to rebut at a hearing.

The regulations are silent as to whether the I.G. may amend his notice after having issued it. In the absence of any prohibition against amending the notice, it is reasonable that the I.G. should have such opportunity, providing that no prejudice is caused to the excluded party. Therefore, the I.G. may be permitted to amend an exclusion notice upon a showing of good cause and an absence of prejudice to the excluded party.

The notice in this case did not specify the additional allegations of gross and flagrant violations concerning patient 143127 which the I.G. sought to prove at the hearing. The notice letter specifically enumerated the allegations concerning this patient and these did not include those additional allegations asserted by the I.G. at the hearing. Nor did the notice letter incorporate those allegations in a way which would have reasonably notified Petitioner that the I.G. was relying on them as a basis for his determination. The I.G. in effect stated to Petitioner that he was relying on some, but not all, of the recommendations made to him by the P.R.O. Petitioner could reasonably infer from the notice letter that the allegations against which she must defend were limited to those which were specifically enumerated in the letter. Therefore, the I.G. was not entitled to rely on these additional allegations as an element of his case against Petitioner.

The I.G. argues that, even though the notice in this case did not specify all of the I.G.'s allegations concerning patient 143127, these allegations were incorporated in the notice letter by virtue of the I.G.'s reference to P.R.O. documents which did contain the allegations and which previously had been sent to Petitioner. I conclude that the letter did not provide the Petitioner with reasonable notice that the I.G. was relying on additional unstated allegations as a basis for determining that Petitioner had committed gross and flagrant violations of her duties to patient 143127.

The notice on its face limits the I.G.'s allegations concerning patient 143127 to those listed in the notice. The portion of the notice which I have quoted above states that the determination to exclude Petitioner was based on specifically enumerated findings. A reasonable

individual reading this language would logically conclude that these findings comprised the ambit of the I.G.'s determination as to gross and flagrant violation. Thus, even though the notice incorporated P.R.O. documents by reference, the specific allegations in the notice assert narrower grounds (for finding that Petitioner committed gross and flagrant violations) than those stated by the P.R.O.

It would have been unreasonable to permit the I.G. to amend his notice at the hearing to include the additional allegations against Petitioner. This case turned on complex medical evidence and the opinions of experts. Each party needed time prior to the hearing to evaluate his or her respective affirmative positions and to prepare to rebut the arguments of his or her adversary. Given the complexity of this case, it would be unfair to in effect mousetrap Petitioner by requiring her to defend against charges of gross and flagrant violations which were not specifically alleged by the I.G. prior to the hearing in this case.[6]

2. Petitioner grossly and flagrantly violated her obligation to provide health care which meets professionally recognized standards and demonstrated an inability to comply substantially with her obligation.

At issue in this case is whether Petitioner committed gross and flagrant violations of her statutory obligation to provide health care to program beneficiaries or recipients and demonstrated either an unwillingness or inability to substantially comply with her obligation. I conclude that the I.G. proved that Petitioner committed such violations in each of the three cases in evidence. I conclude further that the I.G. proved that although Petitioner has shown a willingness to comply with her obligation, she has failed to demonstrate an ability to

---

[6] I have made findings of fact concerning the additional allegations which the I.G. asserted at the hearing concerning patient 143127. See Findings 11-21, 39-45. I have done so because it is difficult to properly assess Petitioner's role in treating this patient without considering her services in the context of the patient's entire stay at Arecibo Hospital. See Analysis, Part 2a, infra. I consider that context to be especially important in my evaluation of a reasonable remedy in this case. See Analysis, Part 3, infra. My findings as to the I.G.'s additional allegations concerning Petitioner's treatment of patient 143127 are favorable to Petitioner.

do so. I find, therefore, that the I.G. established that he had authority to impose and direct an exclusion against Petitioner under section 1156 of the Act.

a. Evidence as to gross and flagrant violations of the obligation to provide care which meets professionally recognized standards of care

Section 1156(b)(1)(B) authorizes the Secretary (or his delegate the I.G.) to exclude a health care provider where, based on the recommendation of a P.R.O., he determines that the provider has grossly and flagrantly violated his obligation to provide care of a quality which meets professionally recognized standards of care, and where he determines that the provider is either unwilling or unable to comply with that obligation. The Act does not define the term "grossly and flagrantly." However, there is a regulatory definition of the term at 42 C.F.R. 1004.1(b). The regulation defines a "gross and flagrant violation" to mean that:

> a violation of an obligation has occurred in one or more instances which presents an imminent danger to the health, safety or well-being of a Medicare beneficiary or places the beneficiary unnecessarily in high-risk situations.[7]

A gross and flagrant violation of the obligation to provide care which meets professionally recognized standards must include an element of actual or potential harm to a patient. The regulation defines a gross and flagrant violation to be an especially dangerous deviation from medical norms. Varandani v. Bowen, 924 F. 2d 307 (4th Cir. 1987). A gross and flagrant violation must be found where "substandard medical care unnecessarily places a patient in danger." Doyle v. Bowen, 660 F. Supp. 1484, 1493 (D. Me. 1987).

---

[7] At the time of enactment of the regulation, section 1156 applied only in cases involving patients who were beneficiaries under Title XVIII of the Act (Medicare). Effective September 1, 1987, P.L. 100-93 amended section 1156 to make it applicable to cases involving patients who were beneficiaries or recipients of federally-funded health care programs, including Medicaid. Although the regulation was not revised to conform to the statutory amendment, it is apparent from the language and context of the regulation that the policy of the Secretary is to apply the regulation equally to all cases brought pursuant to section 1156.

The preponderance of the evidence establishes that, in each of the three cases at issue, Petitioner committed acts or omissions that contravened her obligation to provide care which meets professionally recognized standards of care. In each case, Petitioner's failure to meet her obligation presented an imminent danger to the Medicare beneficiary or unnecessarily placed that beneficiary in a high risk situation.[8]

There are common elements to all three of the patient treatment episodes at issue here. Each case involved a patient hospitalized at Arecibo Hospital under Petitioner's service. In each case, the patient was assigned to Petitioner at least several hours prior to Petitioner actually seeing the patient. In each case, the patient was suffering from the effects of intoxication from medication. All three of the patients ultimately died.

The I.G. has alleged, essentially, that Petitioner committed similar judgment errors in each of the three cases. The essence of the I.G.'s case is that Petitioner failed to properly recognize the potential effects of drug intoxication in each of the three cases, and consequently, failed to properly treat or supervise the treatment of the patients. The result, according to the I.G., was that in each case the health and well-being of the patient was imperiled.

Each of these cases involves complicated facts. It is apparent from the evidence that serious judgment errors were committed with respect to all three patients. It is at least arguable that these errors resulted in adverse

---

[8] In my January 21, 1990 ruling, I found that Petitioner did not pose a serious risk to beneficiaries and recipients of federally-funded health care programs and I declined to exclude her pending my decision in this case. I noted then that the serious risk and gross and flagrant abuse standards were not synonymous and that I could ultimately conclude that Petitioner had committed gross and flagrant abuses and sustain an exclusion. I made no specific findings of fact or conclusions of law in that ruling. To the extent that any of my findings and conclusions in this decision differ in any material respect from those in my ruling, that is due to my having had the time to thoroughly review the record in this case and to more carefully reflect on the parties' arguments. The findings of fact that I reach in this decision supersede any fact conclusions that I made in my January 21 ruling.

consequences in each case, possibly leading to the patient's death. In one way or another, personnel at Arecibo Hospital failed to provide care to each of the patients which was consistent with professionally recognized standards of health care.

What is more difficult to discern is the extent to which the errors and omissions that were committed with respect to these patients legitimately can be attributed to Petitioner. Petitioner was not the sole decision maker in any of the three cases. Critical care decisions were made in these cases prior to Petitioner actually becoming involved in the diagnosis and treatment of the patients. Technically, Petitioner bears responsibility for all of the actions taken with respect to these patients after their admission to Arecibo Hospital, because the patients were admitted under her service. The reality is, however, that with respect to two of the three patients, patients 39026 and 143127, serious judgment errors may have been made by staff at Arecibo prior to Petitioner becoming involved in the diagnosis and treatment of the patients. Petitioner cannot reasonably be held responsible for these apparent errors by other staff in view of the fact that they were made prior to her seeing the patients.

Nevertheless, there is a core of truth to the I.G.'s allegations concerning the manner in which Petitioner diagnosed and treated the three patients. The evidence establishes that, in each case, Petitioner failed to diagnose or treat drug intoxication in accord with professionally accepted treatment standards. Although Petitioner is not responsible for the judgment errors that other providers may have made in these cases, she must bear responsibility for her own judgment errors. The evidence establishes that Petitioner failed in these cases to take charge and to manage effectively the treatment of the patients. The consequence was that the patients were to some extent set adrift in the hospital milieu, without effective case management or supervision. Petitioner's judgment errors with respect to these patients unnecessarily placed all of them in danger.

The I.G.'s evidence against Petitioner primarily consisted of the records of the patients' treatment as well as the testimony of expert physicians who had previously evaluated the treatment records on behalf of the P.R.O. (Drs. Gonzalez, Anduze, Arroyo, and de Jesus). Petitioner rebutted this evidence with testimony from physicians who had served with Petitioner on the staff of Arecibo Hospital (Drs. Canavate, Salgado, and Paez). In some respects, the case devolved into a contest of expert

witnesses who offered conflicting opinions based on the treatment records. I have carefully reviewed the transcript of testimony of each of these witnesses. The testimony provided by the I.G.'s experts was more credible than the testimony of Petitioner's experts. The I.G.'s experts presented a more coherent and thorough analysis of the medical records than did Petitioner's experts. The I.G.'s experts' testimony was supported by excerpts from learned treatises, such as the Physician's Desk Reference. See, e.g., I.G. Ex. 67. Petitioner's experts' testimony was not similarly supported and, in fact, often conflicted with the opinions asserted in learned treatises.

My conclusion that the I.G.'s experts were more credible than Petitioner's experts reflects my determination that the I.G.'s experts were unbiased witnesses, whereas Petitioner's experts had an interest in defending Petitioner's reputation. The I.G.'s experts were physicians who were employed by the P.R.O. to evaluate treatment records. None of them had a personal stake in the outcome of this case, aside from vindication of their professional opinions. The I.G.'s experts had not previously worked with Petitioner, and their interactions with Petitioner were limited to their involvement in this case. By contrast, Petitioner's experts had a substantial personal interest in the outcome of the case. All of Petitioner's witnesses were colleagues of Petitioner and were interested in seeing that she be exonerated of the I.G.'s allegations. Petitioner's experts also were individually involved in the diagnosis and treatment of the patients whose care was at issue in this case. To some extent, the allegations of improper treatment made by the I.G. concerning these patients related to diagnoses and treatment by Petitioner's experts. It was apparent from the tone and content of Petitioner's experts' testimony that these witnesses viewed their testimony to be as much in their own defense as that of Petitioner.

In light of these general conclusions, I turn to an analysis of the three treatment episodes on which the I.G. based his determination that Petitioner had grossly and flagrantly violated her obligation to provide care which meets professionally recognized standards of health care. They are discussed here in date order.

i. Patient 143127

This patient first appeared at the Arecibo Hospital emergency room on the evening of April 8, 1987, as a transfer from another facility. The patient had a

history of a seizure disorder. He was admitted at Arecibo Hospital in an unconscious state, having suffered an overdose of the medications phenobarbitol, dilantin, and tegretol. The patient did not regain consciousness prior to his death. Petitioner first saw the patient on the morning of April 9, 1987. The patient died on April 12, 1987.

The records of the patient's treatment prior to April 9 are sparse. Therefore, it is not possible to determine precisely what course of treatment was opted for by staff at Arecibo Hospital, nor is it possible to determine the reasons for the decisions that were made with respect to this patient. However, even from these records it is evident that staff at Arecibo Hospital made treatment errors prior to Petitioner's first seeing the patient. Although the patient was in a state that would normally require immediate intubation (placement of a breathing tube in his air passage), he was not ordered intubated from the time of his admission until 8:36 a.m. on April 9. The patient's condition on admission to Arecibo Hospital was such that he should have been immediately transferred to the intensive care unit or provided with equivalent treatment. The patient was not placed in the intensive care unit until Petitioner ordered that he be transferred to that facility on April 9.

When Petitioner first saw the patient on April 9, 1987, she determined that a consultation with a neurologist was in order. The neurologist concluded that the patient had a very poor prognosis. She recommended that, should the patient develop seizures, he should be treated with intravenous administration of valium. She further recommended that, if the patient developed status epilepticus (continuous motor seizures), the patient should be treated with depakene. She recommended against treatment with anticonvulsant medications, evidently because the patient had overdosed on such medications.

The patient did develop seizures of a continuous nature. Petitioner faithfully followed the neurologist's recommendations by administering both valium and depakene. The response was poor.

The I.G. asserted that Petitioner committed an error in her treatment of this patient in that she failed to order appropriate blood tests to monitor the half-life of anticonvulsant medication in the patient's blood. The weight of the evidence supports this assertion. No blood tests were ordered by Petitioner on April 9 or thereafter. I am convinced from the testimony of the I.G.'s experts that, under professionally recognized

standards of health care, Petitioner should have ordered the appropriate tests and acted in accordance with their results.

Petitioner should have ordered such tests be performed because the results were necessary for her to properly evaluate and treat the patient's status epilepticus. Findings 37-38. The patient had a history of a convulsive disorder and medications had been prescribed to control convulsions. Although the patient had overdosed on those medications, by April 9 and thereafter the levels of those medications in the patient's blood could have been below therapeutic levels. See Finding 38. Petitioner's convulsions were not adequately controlled by the medications recommended by the consulting neurologist. Finding 34. The continuing convulsions experienced by the patient constituted a life-threatening condition. Finding 31. That condition might have been ameliorated by proper administration of anticonvulsant medications to the patient, assuming that the level of such medications in the patient's blood was determined to be below therapeutic levels. Therefore, Petitioner's failure to order and evaluate the appropriate tests in order to determine whether to order that anticonvulsant medications be administered to the patient presented an imminent danger to the patient's health, safety, or well-being, or unnecessarily placed him in a high risk situation.

I am aware, in making this conclusion, that Petitioner became involved in treating this patient only after potentially grievous errors had already been committed by other staff at Arecibo Hospital. I am not holding Petitioner responsible for these errors, even though Petitioner may be accountable for them under prevailing medical ethics standards as the physician in charge of the case.

My conclusion that Petitioner contravened professionally recognized standards of health care by not ordering and evaluating the appropriate tests takes into account the fact that the consulting neurologist recommended that no anticonvulsant medications be administered to the patient. The neurologist made that recommendation at a time when the patient was assumed to be suffering from the effects of an overdose of anticonvulsant medications. However, the level of those medications in the patient's blood would not have been a constant. See Finding 37. Furthermore, as no tests were performed after April 8, neither the neurologist nor Petitioner could have known the actual level of anticonvulsant medications in the patient's blood. See Findings 35, 36. The actual level

of anticonvulsant medications and the need to adjust treatment accordingly could only be determined by ordering and interpreting the appropriate tests.

ii. Patient 39026

This patient arrived at the Arecibo Hospital emergency room shortly after noon on June 5, 1988, having suffered an overdose of the medications phenobarbitol and dilantin. Although the patient was conscious and oriented on arrival, he suffered cardiac arrest while in the emergency room and lapsed into unconsciousness. He was resuscitated while in the emergency room and was transferred to the Arecibo Hospital intensive care unit. The patient never regained consciousness during his stay at Arecibo Hospital. He died on June 11, 1988.

Petitioner first saw and examined the patient on June 6, 1988. She concluded that the patient was neurologically dead. Finding 60. She ordered that the patient be intubated, that his breathing be assisted with a respirator, and that he be administered intravenous fluids to force diuresis. The I.G. asserts that this diagnosis and treatment plan contravened professionally recognized standards of care for an individual in the patient's condition as of the time Petitioner first examined the patient. The I.G. further asserts that Petitioner's judgment errors with respect to this patient unnecessarily placed the patient in a high risk situation and posed an imminent threat to his health and safety. I agree with these contentions.

The weight of the evidence establishes that, as of June 6, Petitioner could not legitimately conclude that the patient was neurologically dead in light of the facts at hand. The I.G. offered impressive and essentially unrebutted evidence that the signs of neurological death can be mimicked in patients who are suffering from drug intoxication. Findings 62, 63. By prematurely concluding that the patient was neurologically dead, Petitioner effectively ruled out treatment measures that might have brought the patient out of his unconscious state, assuming that the state was in fact drug-induced and not the consequence of neurological death.

Petitioner asserted through the testimony of her witnesses that the probability was high in this case that the patient was neurologically dead. Essentially, they asserted that the patient's state on June 6 was the irreversible consequence of his cardiac arrest on the previous day and that no measures by Petitioner would have reversed that state. I do not disagree that, as a

matter of probability, Petitioner's witnesses may be correct. But that does not serve to legitimize Petitioner's diagnosis and subsequent treatment of the patient. The point of the I.G.'s expert testimony, and the weight of the evidence, is that there was a reasonable possibility that the patient was not neurologically dead on June 6, and that accepted medical practice precluded a conclusion of neurological death at that time.

Petitioner's June 6 diagnosis of neurological death had potentially tragic consequences for the patient. One treatment measure that Petitioner could have opted for, had she concluded that a reversible drug-induced coma could not be ruled out, was to monitor the patient's arterial blood gases. Findings 67-68. The purpose of such monitoring, had Petitioner ordered it, would have been to facilitate adjusting oxygen administered to the patient to assure that the patient did not experience hypoxemia (low levels of oxygen in the blood). Another purpose would have been to facilitate administration of medications to the patient to assure that he did not experience metabolic acidosis, a condition which can lead to cell impairment and death. Finding 70. In fact, this patient did suffer from hypoxemia and acidosis. Findings 73, 74. The record does not establish that the patient's death was caused by hypoxemia or acidosis, or that monitoring of the patient's arterial blood gases would have enabled Petitioner to prevent his death. However, Petitioner should not have foregone monitoring until the patient's neurological death was definitively established, due to the potentially life-threatening consequences of hypoxemia and acidosis.

My conclusion that Petitioner grossly and flagrantly violated her obligation to this patient to provide care which meets professionally recognized standards takes into account that the patient's state on June 6, when first seen by Petitioner, was the consequence of events that were beyond Petitioner's capacity to control. Finding 77. It is apparent, as with the case of patient 143127, that serious errors may have been made by other staff at Arecibo Hospital which could have gravely jeopardized the health and safety of the patient. I do not base my finding of gross and flagrant violations by Petitioner on errors which may have been made by other staff at Arecibo Hospital, nor do I find that Petitioner is responsible for those possible errors.

My conclusion also takes into account the fact that physicians other than Petitioner participated in the treatment of this patient after Petitioner first saw the

patient on June 6. See I.G. Ex. 63a. There is nothing in the medical record to suggest that other providers at Arecibo Hospital disagreed with Petitioner's diagnosis and treatment of the patient. That does not excuse Petitioner's errors of judgment, however. As the physician in charge of the patient's care, Petitioner was responsible for the operative treatment decisions for that patient, at least for the time ensuing after Petitioner first saw the patient. See Finding 7.

iii. Patient 95883

This patient was admitted to Arecibo Hospital on the afternoon of December 21, 1988. He died at the hospital on January 6, 1989.

Petitioner first saw the patient on December 22, 1988. She diagnosed the patient to be suffering from uncompensated congestive heart failure, chronic obstructive pulmonary disease, and diabetes mellitus. Finding 85. She also concluded that, based on the patient's history and his complaints of nausea and "coffee ground" vomiting (symptomatic of bleeding from the upper gastrointestinal tract), the patient could be suffering from intoxication from the drug aminophylline. Findings 83, 84, 86. Having reached this conclusion, Petitioner ordered that administration of aminophylline to the patient be reduced. Finding 91.

The I.G. contends that, while Petitioner's suspicion of aminophylline intoxication was well-founded, her treatment plan for the suspected intoxication contravened the professionally recognized standard of treatment for aminophylline intoxication. The I.G. further contends that Petitioner's judgment error in treating the patient caused imminent danger to his health, safety, or well-being, or placed him unnecessarily in a high-risk situation. The I.G. asserts, therefore, that Petitioner grossly and flagrantly violated her obligation to provide care.

I agree with the I.G.'s assertion. The I.G. proved that, in cases of suspected aminophylline intoxication, the professionally recognized standard of care is to immediately discontinue administration of aminophylline. Finding 90. Failure to do so poses a grave threat to the well-being of any patient who may be suffering from aminophylline intoxication, because intoxication from this drug may produce potentially fatal effects, including gastric bleeding, seizures, cardiovascular arrhythmias, congestive heart failure, apnea, and coma. Finding 89.

Petitioner asserted through her witnesses that she reduced rather than discontinued administration of aminophylline to the patient because the patient may have needed the medication to deal with other medical problems, including respiratory problems. Therefore, according to Petitioner, her decision was a rational approach to a complex medical problem. Although I am not challenging Petitioner's good faith in treating this patient, I am not persuaded from the evidence of record that ordering anything other than complete discontinuation of the drug constituted the professionally recognized standard of treatment. I am persuaded by the testimony of the I.G.'s expert, Dr. Gonzalez, and supporting evidence (the I.G. offered an excerpt from the Physician's Desk Reference), that the approach which Petitioner should have followed with this patient was to have discontinued administration of aminophylline. Finding 90. The risk of harm to the patient from aminophylline intoxication was so great that prescribing a reduced dose, rather than discontinuing the drug, was not a professionally acceptable course for the Petitioner to have followed.

The I.G. asserted that Petitioner compounded her judgment error in treating this patient's aminophylline intoxication by failing to adequately monitor the patient's aminophylline blood levels and to undertake appropriate treatment based on the test results available to her. The evidence sustains this assertion. Blood tests for aminophylline levels were performed on the patient twice during his stay at Arecibo Hospital, on December 22 and 27, 1988. Findings 94, 96. The first test result, which was available to Petitioner on December 23, showed an aminophylline level of 35.9 mcg/ml, which exceeds the professionally recognized maximum therapeutic serum levels for aminophylline of 20 mcg/ml . Finding 95. Notwithstanding this first test result, Petitioner neither ordered aminophylline discontinued, nor did she order a follow-up blood test until December 27. The result of that test showed the patient to have a serum aminophylline level of 53.0 mcg/ml, higher than the previous test result, and also above the maximum therapeutic level for the drug.

It is apparent from this evidence that, despite her initial suspicion of aminophylline intoxication, Petitioner was not closely monitoring the patient for that problem. Had she done so, she would have confirmed intoxication no later than December 23, 1988. In fact, Petitioner did not order that aminophylline be discontinued to the patient, despite the fact that, on December 27, the patient experienced seizures and gastric

lavage on that date produced abundant coffee ground aspiration. Findings 103, 104. Administration of aminophylline to the patient was not ordered discontinued until another physician issued the order on December 28, 1988.

Two additional facets of Petitioner's treatment of this patient confirm her failure to recognize and appropriately treat the patient's aminophylline intoxication. First, notwithstanding the patient's seizures on December 27, Petitioner ordered no additional blood tests for aminophylline levels after that date. Finding 111. Second, in her initial assessment of the patient on December 22, Petitioner ordered that cimetidine (tagamet) be administered to the patient. Tagamet is a medication used to suppress secretion of gastric acid and to promote the healing of gastric ulcers. Finding 113. It appears that Petitioner prescribed this medication to treat the patient's complaints of nausea and gastric bleeding. However, tagamet is a drug which can increase serum aminophylline levels in patients. Finding 114. In light of her suspicion of aminophylline intoxication, Petitioner should not have prescribed tagamet to the patient.

The I.G. also alleged, as further evidence of gross and flagrant violations, that Petitioner improperly failed to consult with a pneumologist (a specialist in respiratory problems). He additionally contended that Petitioner failed to provide adequate follow up consultation with a cardiology consultant whom she consulted concerning patient 95883. I do not find that these allegations are supported by the evidence.

Petitioner did not have access to the services of a pneumologist. The I.G. did not prove that, given the patient's condition, the patient could safely be transferred to a facility where a pneumologist's services were available. Given this, it would be unreasonable to hold Petitioner accountable for her failure to consult with a pneumologist. As far as Petitioner's interaction with a cardiologist is concerned, the record shows that a cardiology consultant saw the patient on several occasions and was actively involved in treatment recommendations. Findings 121-124.

b. Evidence as to Petitioner's inability to comply substantially with her obligation

The I.G. contends that Petitioner has expressed a willingness to comply with her obligation to provide health care of a quality which meets professionally

recognized standards. However, according to the I.G., Petitioner has not demonstrated an ability to comply with her obligation. The preponderance of the evidence supports this contention. Petitioner's inability to comply with her obligation is established by her pattern of gross and flagrant violations, coupled with her consistent failure to rectify those violations, despite having been counseled to do so by the P.R.O. The evidence establishes a pattern of judgment errors by Petitioner. Petitioner has on more than one occasion promised to correct these errors. However, she has offered no evidence that she has taken steps to rectify her deficiencies.

The P.R.O. met with Petitioner on at least two occasions to discuss Petitioner's diagnosis and treatment of the three patients. During these sessions, P.R.O. representatives expounded at length on the diagnosis and treatment deficiencies they observed. Petitioner promised to correct these deficiencies.

Petitioner provided two correction plans to the P.R.O. She submitted her first plan in November, 1988. I.G. Ex. 17. She made her most recent submission on January 24, 1990. Finding 128. In her most recent plan, Petitioner promised to: write daily progress notes and orders for hospitalized patients whom she treated, document her interactions with other physicians at Arecibo Hospital, document her interactions with hospital support facilities such as the hospital's x-ray department, and document patient transfers and tests. Findings 129-132. She also advised the P.R.O. that a conference was being organized at Arecibo Hospital to discuss the management of intoxication by dilantin and luminal. Finding 133.

Petitioner's 1990 correction plan demonstrates a recognition by Petitioner of what she needs to do to cure her practice deficiencies. Had she actually implemented this plan, then, arguably, there might not be a basis to exclude her. However, the record of this case is devoid of evidence to show that Petitioner has done more than promise to take corrective steps. Petitioner offered no evidence, either to the P.R.O, or at the hearing in this case, that she had taken concrete steps to rectify the problems identified by the P.R.O.

The three cases on which the P.R.O. based its recommendation that Petitioner had grossly and flagrantly violated her obligation to provide care had occurred over a two year period. Perhaps the most disturbing finding that emanates from Petitioner's involvement in the three cases at issue is that Petitioner has consistently failed

to recognize and treat the consequences of intoxication with prescription drugs. I find it reasonable to conclude from the evidence that Petitioner manifests some deficiencies in her ability to diagnose and to properly treat such conditions. Petitioner's promises in 1988 and 1990 to rectify her deficiencies are not persuasive evidence that she is capable of rectifying her deficiencies, in light of the fact that these deficiencies had been consistently manifested over a protracted period during which they were not corrected by Petitioner. The I.G. points out, correctly, that the deficiencies were originally brought to Petitioner's attention prior to her submitting her November 1988 correction plan. Despite twice promising the P.R.O. that she would rectify her deficiencies, Petitioner has failed to provide any evidence that she has taken the necessary steps to accomplish the desired end.

3. The exclusion imposed and directed against Petitioner by the I.G. fails to satisfy the remedial purpose of the Act.

Petitioner's right to a hearing in this case is established by section 1156(b)(4) of the Act. That section provides that Petitioner is entitled to a hearing to the same extent as is provided in section 205(b) of the Act. Section 205(b) provides for a de novo hearing. Based on the evidence adduced at the hearing, the finder of fact may affirm, reverse, or modify the appealed determination.

I have the authority under this statutory framework to make findings and conclusions both as to the issue of liability under section 1156 and as to the reasonableness of the remedy imposed against a petitioner by the I.G. If I conclude that the I.G.'s remedy is unreasonable, I have the authority to modify it.

The I.G. was authorized by section 1156 to impose and direct a remedy against Petitioner. The I.G.'s authority results from the P.R.O.'s recommendations based on evidence which proves that Petitioner committed gross and flagrant violations of her obligation to provide care which met professionally recognized standards of health care and demonstrated an inability to meet her obligation. However, I do not find that the remedy imposed and directed against Petitioner by the I.G., a three-year exclusion from participation in Medicare and Medicaid, reasonably satisfies the Act's remedial purposes. I conclude that, while the evidence establishes the need for an exclusion, no remedial purpose will be satisfied by imposing and directing an

exclusion of three years against Petitioner. I modify the exclusion to permit Petitioner to apply for reinstatement after six months. Petitioner's eligibility to apply for reinstatement after six months does not constitute an entitlement to be reinstated. If Petitioner does not satisfy the I.G. that she has rectified her deficiencies, then the I.G. is not required to reinstate Petitioner.

Section 1156 is a civil remedies statute. As with other civil remedies sections of the Act (see sections 1128 and 1128A), the purpose of section 1156 is to enable the Secretary to protect federally-funded health care programs and their beneficiaries and recipients from individuals and entities who have proven by their misconduct that they are untrustworthy. Exclusions are intended to protect against future misconduct by providers. See Hanlester Network, et al., Melvin L. Huntsinger, M.D., and Ned Welsh, DAB Civ. Rem. C-186 - C-192, C-208, and C-213 at 93 (1991); Berney R. Keszler, M.D., et al., DAB Civ. Rem. C-167 at 32 (1990).

Federally-funded health care programs are no more obligated to continue to deal with untrustworthy providers than any purchaser of goods or services would be obligated to deal with an untrustworthy supplier. The exclusion remedy allows the Secretary to suspend his contractual relationship with those providers of items or services who are untrustworthy. The remedy enables the Secretary to assure that federally-funded health care programs will not continue to be harmed by untrustworthy providers of items or services. See Hanlester at 93; Keszler at 32-33. The exclusion remedy is therefore closely analogous to the civil remedy of termination or suspension of a contract to forestall future damages from a continuing breach of that contract.

Exclusion may have the ancillary benefit of deterring providers of items or services from engaging in the same or similar misconduct as that engaged in by excluded providers. See Hanlester at 93; Keszler at 33. However, the primary purpose of an exclusion is the remedial purpose of protecting the trust funds and beneficiaries and recipients of those funds. Deterrence cannot be a primary purpose for imposing an exclusion. Where deterrence becomes the primary purpose, section 1156 no longer accomplishes the civil remedies objectives intended by Congress. Punishment, rather than remedy, becomes the end.

> [A] civil sanction that cannot fairly be said solely to serve a remedial purpose but rather

> can be explained only as also serving either retributive or deterrent purposes, is punishment, as we have come to understand the term.

United States v. Halper, 490 U.S. 435, 448 (1989).

Therefore, in order to be adjudged reasonable under section 1156, an exclusion must satisfy the remedial objective of protecting federally-funded health care programs and their beneficiaries and recipients from untrustworthy providers of items or services. An exclusion which satisfies this purpose may also have the ancillary benefit of deterring wrongdoing; however, that ancillary benefit will not sustain an exclusion where the exclusion does not reasonably serve the Act's remedial objective.[9]

The weight of the evidence establishes that an exclusion is reasonable in this case. Petitioner has committed a series of potentially life-threatening judgment errors involving the diagnosis and treatment of patients entrusted to her care. The character of Petitioner's mistakes demonstrates a disturbing pattern of bad judgment. Petitioner manifests deficiencies in her ability to diagnose and treat hospitalized patients who are possibly suffering from drug intoxication. These

---

[9] Section 1156(b)(3) provides that, in lieu of an exclusion, the Secretary may require a party found to have provided or ordered medically improper or unnecessary items or services to pay an amount not in excess of the actual or estimated cost of the improper or unnecessary items or services. The I.G. contends that I have no authority to order this relief as a remedy in lieu of an exclusion. I am inclined to disagree with this contention, because under section 205(b), I am delegated with the authority to act as "the Secretary" in hearings and appeals, and because my delegated authority includes authority to modify any remedy imposed by the I.G. However, I am making no findings on that issue in this case, because I do not believe that substituting a mandatory payment for an exclusion would be a reasonable remedy here. Any exclusion imposed and directed against Petitioner must be premised on the conclusion that she is an untrustworthy provider of care. Requiring Petitioner to make a payment in lieu of an exclusion would not protect beneficiaries and recipients from future untrustworthy acts. Thus, while a payment might serve as a legitimate remedial alternative to an exclusion in some cases, it would not so serve in this case.

deficiencies are compounded by evidence which shows that Petitioner failed to order or supervise monitoring and testing necessary to properly treat intoxicated patients. The pattern of similar errors manifested by Petitioner's handling of the three cases at issue here infers a likelihood that, barring some remedial action by Petitioner, she will repeat her errors in the future. I conclude that, based on the evidence before me, Petitioner is an untrustworthy provider. An exclusion is needed to protect program beneficiaries and recipients from future judgment errors by Petitioner which could adversely affect their health and well-being.

However, I am not persuaded that the three-year exclusion imposed and directed by the I.G. is reasonable. An exclusion of three years does not bear any reasonable relationship to the remedial need established by the evidence in this case.

Petitioner's deficiencies are not the consequence of bad faith or dishonesty. There is no evidence in this case to show that Petitioner is anything other than a dedicated and caring practitioner. See P. Ex. 14-20. Her deficiencies are deficiencies in judgment and, perhaps, training. She possesses the power to cure her deficiencies, either through education or simply by improving her management and treatment of patients. There is no evidence in this case that would show that such self-improvement requires a lengthy period of time. In light of that, a three-year exclusion is excessive.

My assessment of Petitioner's deficiencies also reflects my judgment that, at least with respect to patients 143127 and 39026, Petitioner's judgment errors appear to have been only an aspect of a series of errors which may have led to the demise of the patients. In both of those cases, Petitioner became responsible for the care of the patients after serious damage to those patients' well-being had already been done. Furthermore, my examination of the record of treatment of all three patients convinces me that Petitioner conscientiously sought to provide care to the patients. In each case, she consulted with specialists and ordered care which she intended to benefit the patient.

The history of this case establishes that the P.R.O. was anything but confident in making its exclusion recommendation to the I.G. In June 1989, the P.R.O. determined that Petitioner was capable of adequately treating patients in an office setting, but was unable to cope with the limited facilities available to her at Arecibo Hospital. I.G. Ex. 28a/2. It recommended that

Petitioner be excluded from participation in the Medicare program for a minimum of one year. I.G. Ex. 28a/3, 28b/3.[10]. The recommendation was rejected by the I.G. because the I.G. concluded that the P.R.O. had not complied with the procedural requirements of 42 C.F.R. Part 1004. I.G. Ex. 31.

By letter dated July 14, 1989, the P.R.O. advised the I.G. that recommending a remedy was difficult, alluding in part to problems which Petitioner confronted with the facilities at Arecibo Hospital. I.G. Ex. 33. On July 28, 1989, the P.R.O. recommended, unambiguously, that Petitioner be excluded from participating in the Medicare program for one year. See I.G. Ex. 37. Again, the I.G. rejected this recommendation for procedural reasons. I.G. Ex. 38. On May 21, 1990, after additional proceedings, the P.R.O. recommended to the I.G. that Petitioner be excluded for five years. I.G. Ex. 51.

The P.R.O.'s hesitancy in recommending an exclusion in this case reflects its conclusion that Petitioner's deficiencies related to her ability to diagnose and treat hospitalized patients and not to her overall qualifications as a physician. See I.G. Ex. 40/1. It also reflects its conclusion that Petitioner's deficiencies were in some respects exacerbated by conditions prevailing at Arecibo Hospital. I.G. Ex. 28a/2.

Given the foregoing, I can find no logical remedial basis for the three-year exclusion imposed and directed by the I.G. Three years would not appear to be needed for Petitioner to take the steps necessary to cure the deficiencies in diagnosing and treating patients identified by the P.R.O. and established by the evidence in this case. The P.R.O.'s deliberative processes suggest that three years is longer than it originally felt was necessary. Finally, the I.G. has offered no evidence to show why a three-year exclusion would be needed in this case to satisfy the Act's remedial purposes.

---

[10] It is somewhat unclear from this recommendation whether the P.R.O recommended that Petitioner's exclusion be limited to her claiming reimbursement for treatment of Medicare beneficiaries in a hospital setting. The I.G. seems to have interpreted the recommendation as being for an exclusion limited to claiming reimbursement for treatment of patients in a hospital setting. I.G. Ex. 30.

The Act's remedial purposes would be satisfied in this case by an exclusion of six months, running prospectively. During that period, Petitioner should be able to take all of the steps she identified in her 1990 correction plan. The exclusion also allows Petitioner time to take remedial education in the diagnosis and treatment of patients suffering from drug intoxication.[11]

My decision to modify the exclusion to a term of six months also reflects the fact that any exclusion imposed and directed against a provider under section 1156 sets forth the minimum period that the provider will be excluded prior to becoming eligible for reinstatement by the I.G. Under section 1156 and applicable regulations, the I.G. is not required to automatically reinstate an excluded provider at the end of the exclusion period. At the completion of the exclusion, the excluded provider may apply for reinstatement. However, the exclusion remains in effect until the I.G. determines that "the basis for the exclusion no longer exists and there is reasonable assurance that the problems will not recur . . . ." 42 C.F.R. 1004.120. Therefore, the I.G. may evaluate any application for reinstatement by Petitioner to determine whether Petitioner has corrected her practice deficiencies, prior to determining whether or not to reinstate Petitioner. In deciding whether to approve an application for reinstatement, the I.G. may seek advice from other sources, including the P.R.O. See 42 C.F.R. 1001.130(a)(2).[12]

Because I declined to effect an exclusion against Petitioner in my preliminary ruling, Petitioner has not yet been excluded from participation. The exclusion, as modified by me, will run prospectively from June 20,

---

[11] My decision to impose a six-month exclusion in some respects reflects the fact that nearly six months has already elapsed from the date of the hearing in this case. Presumably, if Petitioner has acted in good faith, she has already taken many of the steps she promised to take in her 1990 corrective plan.

[12] The authority to reinstate an excluded provider lies entirely with the I.G. I have no authority to enumerate conditions pursuant to which the I.G. must grant reinstatement.

1991, which is 20 days from the date of this decision (to allow time for receipt and implementation).[13]

CONCLUSION

Based on the applicable law and evidence, I conclude that Petitioner grossly and flagrantly violated her obligation under section 1156 of the Act to provide care which was of a quality which met professionally recognized standards of health care, and demonstrated a lack of ability to comply substantially with her obligation. I conclude that the I.G. had authority to impose and direct an exclusion against Petitioner from participating in the Medicare and Medicaid programs. I conclude that the three-year exclusion imposed and directed against Petitioner was not reasonable, but that a six-month exclusion will serve the Act's remedial purposes.

/s/

Steven T. Kessel
Administrative Law Judge

---

[13] The I.G.'s exclusion determination under section 1156 is effective pending the outcome of an administrative hearing except in those cases where the excluded provider is located in a rural health manpower shortage area or in a county with a population of under 70,000 and where an administrative law judge declines to make an interim finding that the provider will pose a serious risk to program beneficiaries and recipients. Social Security Act, section 1156(b)(5). In such cases, should the administrative law judge ultimately conclude that there exists a remedial need to exclude the provider, then the exclusion will become effective no earlier than the date of the administrative law judge's decision.