Department of Health and Human Services

DEPARTMENTAL APPEALS BOARD

Civil Remedies Division

In the Case of:	
L. John Flage, M.D.,	DATE: November 3, 1995
Petitioner,	Docket No. C-95-064 Decision No. CR399
- v. -	
The Inspector General.	

DECISION

This case is before me on Petitioner's January 30, 1995 request for hearing to contest the determination of the Inspector General (I.G.) of the Department of Health and Human Services (DHHS) to exclude him from participation in Medicare and to direct his exclusion from participation from Medicaid for a period of three years.[1] The parties have stipulated that there exists a basis for the I.G. to impose and direct an exclusion pursuant to section 1156 of the Act. In this Decision, I conclude that the three-year exclusion imposed and directed against Petitioner by the I.G. is reasonable.

BACKGROUND

In a letter dated December 1, 1994, the I.G. notified Petitioner that she had decided to adopt the August 11, 1994 recommendation of the Iowa Foundation for Medical Care, the peer review organization (PRO) for Iowa, to exclude Petitioner from participation in Medicare and Medicaid for a period of three years.

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[1] Petitioner was excluded from participation as a provider in Medicare and any State health care program as defined in section 1128(h) of the Social Security Act (Act). I use the term "Medicaid" in this Decision to include all State health care programs from which Petitioner was excluded.

The PRO's recommendation of August 11 was based on its determination that Petitioner, in 10 cases, "substantially violated" the obligations imposed upon him by section 1156 of the Act: 1) to provide care of a quality which meets professionally recognized standards of health care in a substantial number of cases; and 2) to support the services or items he ordered or provided with evidence of the medical necessity and quality as may reasonably be required by the reviewing PRO. In addition, on the basis of similar violations in certain other cases, the PRO found that Petitioner had demonstrated an inability and unwillingness substantially to comply with his obligations under section 1156(a) of the Act.

In its August 11 letter, the PRO gave Petitioner 30 days to submit to the I.G. any additional material Petitioner believed would affect the PRO's recommendation to exclude him from Medicare and Medicaid. Petitioner submitted no material.

In her December 1 letter, the I.G. informed Petitioner that she agreed with the PRO's conclusion that Petitioner, in his treatment of 10 patients, had "substantially violated" his obligations under section 1156 of the Act. Further, the I.G. informed Petitioner that she agreed with the PRO's conclusion that Petitioner had demonstrated an inability and unwillingness substantially to comply with the obligations imposed upon him by section 1156 of the Act.[2]

By letter dated January 30, 1995, Petitioner requested a hearing, stating that he disagreed with each of the PRO findings relied on by the I.G. in her December 1 letter. The case was subsequently assigned to me for hearing and Decision. During the prehearing conference I conducted in this case on February 28, 1995, I established procedures by which this case was to proceed to an in-person hearing in Des Moines, Iowa, on May 8, 1995.

On May 4, 1995, the parties informed me that they had agreed to file a joint stipulation that would obviate the need for an in-person hearing. I conducted a telephone conference on May 5, 1995, during which Petitioner

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[2] In so doing, the I.G. indicated that she had not relied on some or all of the PRO's findings in six of the cases which it cited to support its conclusion that Petitioner is unwilling or unable to comply with his obligations under section 1156 of the Act. I.G. Exhibit 1 at page 10.

reaffirmed that he was waiving his right to an in-person hearing in this case and declared that he was not disputing the I.G.'s authority to exclude him. Petitioner informed me also that he wanted to proceed by submitting briefs and documentary evidence. Accordingly, in my Order of May 11, 1995, I established a schedule for the parties to submit briefs and documentary evidence, including their joint stipulation.

In his brief (P. Br.), Petitioner requested permission to provide oral argument as well.[3] I granted Petitioner's request. Accordingly, I heard the parties' oral argument in this case on September 6, 1995.

STIPULATION

The parties have stipulated that Petitioner failed in a number of cases substantially to comply with the obligations imposed on him under section 1156(a) of the Act, as cited by the PRO in its August 11, 1994 letter and as restated by the I.G. in her December 1, 1994 letter. The parties further stipulated that the sole remaining issue in this proceeding is the reasonableness of the three-year exclusion imposed and directed by the I.G. against Petitioner. ALJ Ex. 1.[4]

FINDINGS OF FACT AND CONCLUSIONS OF LAW

1. During all times relevant to this case, Petitioner was practicing medicine as a physician in Independence and Buchanan Counties in Iowa. P. Ex. 1.

2. During all times relevant to this case, the Iowa Foundation for Medical Care (IFMC) was the PRO for Iowa. I.G. Ex. 3.

3. On April 17, 1992, the PRO issued Petitioner an initial sanction notice advising him that he had violated

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[3] Petitioner indicated also a desire to file a reply brief. P. Br. at 6. Both parties later waived the opportunity to file reply briefs. Transcript of Oral Argument at 3.

[4] I have received the parties' stipulation into evidence as Administrative Law Judge Exhibit 1 (ALJ Ex. 1). Also, I have received I.G. exhibits (I.G. Ex.) 1 through 34 and Petitioner's exhibit (P. Ex. 1) into evidence.

his statutory obligations under section 1156 of the Act in ten cases. I.G. Ex. 5.

4. After meeting with Petitioner on July 15, 1992, the PRO outlined a corrective action plan (CAP) for Petitioner to follow instead of recommending that Petitioner be sanctioned. I.G. Ex. 6 at 2 - 7.

5. In a response dated August 13, 1992, Petitioner accepted and agreed to follow the PRO's recommended CAP. I.G. Ex. 6 at 1 - 7.

6. On November 12, 1993, the PRO issued a second sanction notice to Petitioner which informed Petitioner that, subsequent to the implementation of the CAP, Petitioner had continued to violate his obligations under section 1156 of the Act. I.G. Ex. 5.

7. On April 20, 1994, the PRO met with Petitioner to discuss its findings of additional violations subsequent to the implementation of Petitioner's CAP. I.G. Ex. 10.

8. On August 11, 1994, the PRO issued a final sanction notice which informed Petitioner that it had found that Petitioner had, in specified cases, substantially failed to comply with his obligations under the Act to assure that the services ordered or provided by Petitioner were: a) of a quality that meets professionally recognized standards of health care; and b) supported by adequate evidence of medical necessity and quality. ALJ Ex. 1; I.G. Ex. 3.

9. The PRO's August 11 letter informed Petitioner also that he had demonstrated an unwillingness and inability to comply with his obligations under the Act and that it was recommending to the I.G. that Petitioner be excluded for three years. I.G. Ex. 3.

10. The I.G. largely accepted the PRO's findings regarding Petitioner and adopted the PRO's recommendation that Petitioner be excluded for three years from Medicare and Medicaid. I.G. Ex. 1.

11. The parties have stipulated that Petitioner violated his obligations under section 1156 of the Act, as stated in the PRO's August 11 letter and as cited also in the I.G.'s December 1, 1994 letter informing Petitioner of his exclusion from Medicare and Medicaid. ALJ Ex. 1.

12. Petitioner has stipulated that he substantially violated his statutory obligation to provide health care of a quality and type which meets professionally

recognized standards of health care in the case of patient I. McG. (admission date March 2, 1991) by failing to: a) repeat abnormal calcium and phosphorus tests; and b) evaluate patient I. McG.'s drop in hemoglobin. ALJ Ex. 1; I.G. Ex. 1, 2, 10 at 27 - 29.

13. Petitioner has stipulated that he substantially violated his statutory obligation to provide appropriate evidence of medical necessity and quality to the reviewing PRO by failing to provide accurate information on patient I. McG's discharge summary. ALJ Ex. 1; I.G. Ex. 1 - 3, 10 at 29 - 30.

14. Petitioner has stipulated that he substantially violated his statutory obligation to provide health care of a quality and type which meets professionally recognized standards of health care by failing to monitor arterial blood gases (ABGs) or oximetry for patient M.S. (admission date June 11, 1991), who had dyspneic chronic obstructive pulmonary disease (COPD). ALJ Ex. 1; I.G. Ex. 1, 2, 10 at 33 - 35.

15. Petitioner has stipulated that he substantially violated his statutory obligation to provide health care of a quality and type which meets professionally recognized standards of health care: a) by inappropriately ordering Valium and morphine for patient D.M. (admitted on June 22, 1991 for neurological observation), specifically by failing to specify a route for the morphine; and b) by failing to obtain adequate information regarding D.M. on admission. ALJ Ex. 1; I.G. Ex. 1 - 3, 10 at 36 - 38.

16. Petitioner has stipulated that he substantially violated his statutory obligation to provide health care of a quality and type which meets professionally recognized standards of health care in the case of E.H. (admitted June 27, 1991) by failing to: a) continue Cardizem during E.H.'s hospital stay; b) obtain ABGs to evaluate E.H.'s dyspnea (labored breathing); and c) appropriately manage E.H.'s fluid therapy. ALJ Ex. 1; I.G. Ex. 1 - 3, 10 at 38 - 40.

17. Petitioner has stipulated that he substantially violated his statutory obligation to provide health care of a quality and type which meets professionally recognized standards of health care in the case of E.G. (admitted May 21, 1991) by failing to: a) adequately evaluate the cause of E.G.'s hematuria (blood in her urine); b) order appropriate laboratory tests on the fluid from both of E.G.'s thoracenteses; c) adequately evaluate E.G.'s abnormal ABGs, aggressively treat E.G.'s

compromised oxygen status, and specify the route and flow rate of the oxygen administration; and d) appropriately manage E.G.'s intravenous fluid therapy. ALJ Ex. 1; I.G. Ex. 1 - 3, 10 at 40 - 49.

18. Petitioner has stipulated that he substantially violated his statutory obligation to provide appropriate evidence of medical necessity and quality to the reviewing PRO by failing to: a) provide an adequate and timely history and physical (H & P) of patient E.G.; and b) complete E.G.'s discharge summary in a timely manner. ALJ Ex. 1; I.G. Ex. 1 - 3, 10 at 49.

19. Petitioner has stipulated that he substantially violated his statutory obligation to provide health care of a quality and type which meets professionally recognized standards of health care in the case of patient O.S. (admitted October 22, 1990) by failing to: a) repeat the white blood count that was elevated; b) obtain blood and sputum cultures before initiating treatment with a broad acting third generation cephalosporin (Cefobid); c) treat O.S.'s pneumonia with a long enough course of antibiotic therapy; d) order an ACE inhibitor for a patient with cardiomegaly and CHF; and e) appropriately manage O.S.'s intravenous fluid therapy. ALJ Ex. 1; I.G. Ex. 1 - 3, 10 at 50 - 52.

20. Petitioner has stipulated that he substantially violated his statutory obligation to provide appropriate evidence of medical necessity and quality to the reviewing PRO by failing to: a) provide an adequate and timely H & P; and b) complete patient O.S.'s discharge summary in a timely manner. ALJ Ex. 1; I.G. Ex. 1 - 3, 10 at 52.

21. Petitioner has stipulated that he substantially violated his statutory obligation to provide health care of a quality and type which meets professionally recognized standards of health care in the case of M.R. (admitted March 12, 1991): a) by failing to adequately evaluate and appropriately treat patient M.R.'s hyponatremia; b) by inappropriately writing an order for "home meds" without specific knowledge of the drugs being ordered; c) by failing to obtain blood cultures before initiating treatment with a broad acting third generation cephalosporin (Cefobid); and d) by failing to appropriately manage M.R.'s intravenous fluid therapy. ALJ Ex. 1; I.G. Ex. 1 - 3, 10 at 53 - 67, 80 - 82.

22. Petitioner has stipulated that he substantially violated his statutory obligation to provide appropriate evidence of medical necessity and quality to the

reviewing PRO by failing to complete patient M.R.'s H & P in a timely manner. I.G. Ex. 1 - 3, 10 at 83.

23. Petitioner has stipulated that he substantially violated his statutory obligation to provide health care of a quality and type which meets professionally recognized standards of health care in the case of patient R.E. (admitted March 19, 1991) by inappropriately: a) ordering oral Lasix, 40 mg twice daily, for a patient without continued signs of heart failure; b) writing an order for "home meds" without specific knowledge of the drugs being ordered; and c) writing an order on March 20 which stated "May use Lanoxin but wait to see chest x-ray results." ALJ Ex. 1; I.G. Ex. 1 - 3, 10 at 85 - 89.

24. Petitioner has stipulated that he substantially violated his statutory obligation to provide appropriate evidence of medical necessity and quality to the reviewing PRO: a) by failing to complete patient R.E.'s H & P in a timely manner; and b) by inappropriately providing inaccurate information in R.E.'s discharge summary. ALJ Ex. 1; I.G. Ex. 1 - 3, 10 at 89 - 91.

25. Petitioner has stipulated that he substantially violated his statutory obligation to provide health care of a quality and type which meets professionally recognized standards of health care in the case of patient M.C. (admitted June 9, 1991) by failing to adequately address the abnormal thyroid study, thus providing inappropriate care to a patient with a history of hypothyroidism. ALJ Ex. 1; I.G. Ex. 1 - 3, 10 at 91 - 94.

26. Petitioner has stipulated that he substantially violated his statutory obligation to provide appropriate evidence of medical necessity and quality to the reviewing PRO by failing to provide accurate information in M.C.'s discharge summary. ALJ Ex. 1; I.G. Ex. 1 - 3, 10 at 91 - 94.

27. Petitioner has stipulated that he substantially violated his statutory obligation to provide health care of a quality and type which meets professionally recognized standards of health care in the case of patient I.C. (admitted July 17, 1991): a) by inappropriately ordering Synthroid for a patient with normal thyroid function studies; and b) by failing to discontinue or lower the Lanoxin dosage in a patient with bradycardia. ALJ Ex. 1; I.G. Ex. 1 - 3, 10 at 94 - 102.

28. Petitioner has stipulated that he substantially violated his statutory obligation to provide appropriate evidence of medical necessity and quality to the reviewing PRO by failing to provide a complete and timely H & P within 48 hours of I.C.'s admission. ALJ Ex. 1; I.G. Ex. 1 - 3, 10 at 94 - 102.

29. Prior to recommending Petitioner's exclusion, the PRO gave Petitioner the opportunity to complete a CAP to remedy the quality of care and medical documentation problems which the PRO had identified in Petitioner's practice. I.G. Ex. 3, 4.

30. In 22 cases involving incidents which occurred after Petitioner agreed to the terms of the CAP, he violated his statutory obligations. I.G. Ex. 3, 4, 6; Finding 5.

31. Petitioner failed to comply substantially with the terms of the CAP. I.G. Ex. 3, 4; Finding 30.

32. Petitioner has demonstrated an inability or unwillingness to comply with the terms of his CAP. I.G. Ex. 3 at 21, 73 - 79, 96 - 97; I.G. Ex. 10 at 6 - 7; Findings 30, 31.

33. Petitioner has placed patients at risk by failing to order or perform appropriate medical tests, or by failing to order repeat testing or monitoring in situations where patients' test results were abnormal. I.G. Ex. 1 - 3; 10 at 87; 12; 13; 15; 16; 17; 18; 20; and 21.

34. Petitioner has placed patients at risk by failing to appropriately evaluate patients' medical conditions or by failing to order appropriate medical treatment for patients. I.G. Ex. 1 - 3; 10 at 38; 14; 15; 16; 17; 18; 19; 20; and 21.

35. Petitioner has admitted that his treatment of 10 patients was not in accordance with professionally recognized standards of health care. I.G. Ex. 10 at 27 - 102; Finding 11.

36. Petitioner has admitted that, in the cases cited by the I.G., he did not provide appropriate evidence of medical necessity and quality to the reviewing PRO . I.G. Ex. 10 at 27 - 102; Finding 11.

37. Petitioner's treatment of the 10 patients identified by the I.G. shows that he failed substantially in his obligation to provide care of a quality which meets professionally recognized standards of health care. See

Findings 12, 14 - 17, 19, 21, 23, 25, and 27; Act, section 1156(a)(2).

38. In a substantial number of cases, Petitioner failed to comply substantially with the obligation imposed upon him by section 1156(a)(2) of the Act to provide care of a quality which meets professionally recognized standards of health care. Finding 37.

39. In a substantial number of cases, Petitioner failed to comply substantially with the obligation imposed upon him by section 1156(a)(3) of the Act to provide appropriate evidence of medical necessity and quality to the reviewing PRO. Findings 13, 18, 20, 22, 24, and 28.

40. Through his treatment of the 10 patients cited by the I.G. as the basis for Petitioner's exclusion, and through the violations he committed while under a CAP, Petitioner has demonstrated that he is unable or unwilling substantially to comply with professionally recognized standards of health care. Findings 12, 14 - 17, 19, 21, 23, 25, 27, 30 - 32.

41. Section 1156 is a remedial, not a punitive statute. Act, section 1156; Dr. Abdul Abassi, DAB CR390 at 3 (1995); Gary E. Wolfe, D.O., DAB CR395 at 5 (1995).

42. Petitioner's violations of his obligations under section 1156 of the Act are serious in nature. Findings 12 - 28, 33, 34.

43. Petitioner's repeated violations of his obligations under sections 1156(a)(2) and (3) of the Act indicate inadequate medical understanding or confusion regarding treatments which endanger the health of patients. Findings 33, 34, 38 - 40.

44. Petitioner's repeated violations of his obligations under section 1156(a)(2) and (3) of the Act indicate a lack of thoroughness in his medical evaluations and treatment of patients which endanger the patients' health. Findings 33, 34, 38 - 40.

45. Petitioner's stipulations and his arguments based on those stipulations do not negate the seriousness of his violations or the risks he currently pose to patients. Findings 36, 37, 43, 44.

46. Petitioner's stipulations and his arguments based on those stipulations do not negate the consequences of Petitioner's inability to evaluate, manage, or treat

relatively basic medical conditions. Findings 11 - 32, 36, 37.

47. Petitioner's stipulations and his arguments based on those stipulations do not negate the consequences of Petitioner's failure or inability to complete his CAP successfully. Findings 29 - 31, 37, 38.

48. Petitioner's arguments in this proceeding do not show that he recognizes the seriousness of his violations or that he is willing and able to comply with the requirements of section 1156 of the Act. See P. Br. at 2.

49. One of the remedial purposes of section 1156 of the Act is to protect the health of Medicare beneficiaries and Medicaid recipients. S. Khalid Hussain, M.D., DAB CR204 (1992); Louis W. DeInnocentes, Jr., M.D., DAB CR247 (1992).

50. A three-year period of exclusion will provide Petitioner with adequate time to: a) improve his medical knowledge; b) prepare him to treat patients in accordance with professionally recognized standards of health care; and c) avoid creating undue risks of harm for patients. See, e.g., Findings 33, 34, 46, 48.

51. A three-year period of exclusion will protect program beneficiaries from being placed at risk by a provider who has demonstrated deficiencies in complying with professionally recognized standards of health care. See, e.g., Findings 48 - 50.

52. A three-year exclusion will provide Petitioner with adequate time to acquire the training to improve the documentation of his prescribed course of treatment, patients' medical history, and the medical necessity and quality of the treatment he provides. See, e.g., Findings 29, 40.

53. A three-year exclusion is necessary, appropriate, and justified in this case. Findings 1 - 52.

DISCUSSION

Section 1156(a) of the Act provides as follows:

> It shall be the obligation of any health care practitioner and any other person . . . who provides health care services for which payment may be made (in whole or in part) under this Act, to assure, to

the extent of his authority that services or items ordered or provided by such practitioner or person to beneficiaries and recipients under this Act --

(1) will be provided economically and only when, and to the extent, medically necessary;

(2) will be of a quality which meets professionally recognized standards of health care; and

(3) will be 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) of the Act provides:

(1) If after reasonable notice and opportunity for discussion with the practitioner or person concerned, and, if appropriate, after the practitioner or person has been given a reasonable opportunity to enter into and complete a corrective action plan (which may include remedial education) agreed to by the organization, and has failed successfully to complete such plan, any organization having a contract with the Secretary under this part determines that such practitioner or person has --

(A) failed in a substantial number of cases substantially to comply with any obligation imposed on him under subsection(a), or

(B) grossly and flagrantly violated any such obligation in one or more instances,

such organization shall submit a report and recommendations to the Secretary. If the Secretary agrees with such determination, and determines that such practitioner or person, in providing health care services over which such an organization has review responsibility and for which payment (in whole or in part) may be made under this Act, has demonstrated an unwillingness or a lack of ability substantially to comply with such obligations, the Secretary (in addition to any other sanction provided under law) may exclude (permanently or for such period as the Secretary may prescribe) such practitioner or person from eligibility to provide services under the Act on a reimbursable basis. In

> determining whether[5] 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.

An excluded individual has a right to a de novo hearing to contest the decision of the Secretary or her delegate (the I.G.) to impose and direct the exclusion. Act, sections 1156(b)(4) and 205(b)(1); Louis W. DeInnocentes, Jr., M.D., DAB CR247 (1992). Only two issues are subject to the de novo hearing: 1) whether there is a basis for the imposition of the exclusion; and 2) whether the length of the exclusion is unreasonable. 42 C.F.R. § 1001.2007(a).

Petitioner has stipulated to the basis for his exclusion. Petitioner stipulated that he violated his obligations under section 1156 of the Act. ALJ Ex. 1. In so stipulating, Petitioner has admitted that, in the 10 cases identified by the I.G., he substantially violated his statutory obligation to provide care of a quality which meets professionally recognized standards of health care. Also, Petitioner has stipulated that, in seven cases, he substantially violated his obligation to provide appropriate evidence of medical necessity and quality to the PRO.

Thus, the only issue is the length of time during which Petitioner should be excluded from participation as a provider in the Medicare and Medicaid programs. The I.G. adopted the recommendation of the PRO and imposed a three-year exclusion, which began in late December of 1994. I.G. Ex. 1 at 13. Petitioner contends that the exclusion should be limited to the period of time that has already elapsed since the exclusion began. P. Br. at 5. I have the authority to review the record and to affirm, increase, or reduce the I.G.'s determination that Petitioner should be excluded for three years. 42 C.F.R. § 1005.20(b).

The regulation relevant to the issue before me specifies the consideration of certain information but does not formulate the period of exclusion. 42 C.F.R. § 1004.90. I am, however, guided by the principles of logic and

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[5] In the Act, this appears as "whehter". I have changed it here for the sake of clarity.

reason, as well as by the remedial purpose of the Act. I have concluded that the three-year exclusion imposed against Petitioner is reasonable for advancing the remedial goals of the Act.

In determining the reasonableness of the exclusion period, I have especially considered the evidence establishing the nature and seriousness of Petitioner's violations. I have concluded from my review of the evidence that Petitioner has serious and recurring deficiencies in his willingness or ability to comply with the requirements set by section 1156(a)(2) and (3) of the Act. Findings 12 to 35. Many of these deficiencies relate to his medical knowledge of the management and treatment of patients, which are evidenced by his failure to 1) order appropriate tests to evaluate the condition of his patients; 2) specify dosage and route for medications; 3) timely obtain or timely report adequate information upon the admission or discharge of his patients; 4) properly monitor his patients' conditions; 5) order appropriate medications for some of his patients; 6) continue to administer medications for a sufficient length of time; and 7) consider or take appropriate actions based on abnormal test results. At the very minimum, Petitioner's acts and omissions deprived each of these 10 patients of a level of care required by statute that was conducive to properly diagnosing or improving their condition.

The evidence provided by the I.G. is replete with details showing that the medical care Petitioner provided to 10 patients was, in each instance, lacking in some basic element of diagnostic or treatment knowledge which also placed the patient's health in unnecessary jeopardy. As correctly pointed out in the I.G.'s Brief (I.G. Br.), examples of such fundamental problems in the record include Petitioner's failure to understand that he should not give morphine and Valium to a patient who was admitted for neurological observation; Petitioner's repeated failure to monitor ABGs in patients who had conditions involving oxygen depletion; Petitioner's failure to address an abnormal thyroid study and provide appropriate care to a patient who had a history of hypothyroidism; Petitioner's inappropriate ordering of oral Lasix for a patient who had no continued signs of heart failure; Petitioner's repeated and inadequate orders for "home meds" for patients without specific knowledge of the drugs the patients received; and Petitioner's repeated failure to properly manage patients' intravenous fluid therapy.

Petitioner relies on the opinions of his professional colleagues who believe that his violations under section 1156 of the Act are not severe, do not evidence deficiencies in his clinical judgment, were errors of omission as opposed to commission, and have not adversely affected his patients' condition. P. Br. at 3 (referring to letters to Petitioner's attorney from Drs. Sutherland and Myers in P. Ex. 1 at 7 - 8). One physician's opinion cited by Petitioner suggests also that Petitioner's recordkeeping problems do not amount to improper patient care. P. Br. at 3 and P. Ex. 1 at 7.
I do not find Petitioner's arguments to be persuasive. Nor do I find Petitioner's reliance on the letters from his colleagues to be appropriate or well founded.

First of all, Petitioner has stipulated that he has "failed in a number of cases substantially to comply with the obligations imposed on him under section 1156(a) of the Act ...." ALJ Ex. 1. Congress has already determined the importance of the obligations specified under section 1156(a) by permitting the Secretary or her delegate, the I.G., to impose an exclusion in the event these obligations are substantially violated in a substantial number of cases. Act, section 1156(b)(1). Even though Petitioner has not specifically acknowledged that his multiple failings in the cases cited by the I.G. establish his violations in a substantial number of cases, this conclusion is self-evident from the evidence of record and the parties' stipulation. See, e.g., Findings 12 - 28, 38, 39.

Petitioner's stipulation and my related conclusion cannot be altered by physicians who formed contrary opinions or who disagree with the importance Congress has attached to a physician's need to fulfill obligations under section 1156(b) of the Act. For an exclusion to be valid, Petitioner's violations of the statutory standard do not have to result in actual harm to patients. Act, section 1156. Nor does the practitioner need to make errors of commission instead of errors of omission, as suggested by one of Petitioner's colleagues. As noted above, the goal of an exclusion is to protect program beneficiaries and recipients from possible harm. Finding 49.

In this case, the I.G. has set the exclusion at three years due to Petitioner's potential for harming patients; there is no allegation that the substandard quality of care rendered by Petitioner actually has harmed patients. I.G. Ex. 1 at 11. The I.G. is authorized to preclude Petitioner from being a source of harm to program beneficiaries and recipients.

I find logical the I.G.'s conclusion that Petitioner's failure to use proper documentation or recordkeeping procedures also could harm patients in that other physicians would not have adequate information for properly treating the same patient. I.G. Ex. 1 at 11. Notwithstanding the belief of one of the physicians who submitted a statement on behalf of Petitioner, there is no adequate or logical basis for accepting that Petitioner was providing proper patient care while Petitioner was unable or unwilling to document the medical necessity or quality of his care. See P. Ex. 1 at 7. Therefore, I do not find persuasive Petitioner's arguments that his violations were not severe because most of them were documentation problems which had no impact on patient care. See P. Br. at 3.

Moreover, Petitioner has not established the proper foundation for the opinions of the doctors who wrote in support of reducing Petitioner's exclusion. For example, Dr. Myers, whose opinion was quoted by Petitioner (P. Br. at 3), specifically noted that he did not know the details of the deficiencies that have resulted in Petitioner's exclusion. P. Ex. 1 at 7; see also letters of other physicians in P. Ex. 1 at 1 - 6. Dr. Sutherland, who did review the PRO's recommendation and summarized his disagreement in a letter also relied upon by Petitioner (P. Br. at 3), did not list his experience or his qualifications for evaluating the significance of deficiencies under section 1156(a) of the Act. P. Ex. 1 at 8.

The letters from Petitioner's physician colleagues are also conclusive in nature and lack the detailed analysis and attention to facts seen in the PRO's reports and in the I.G.'s notice letter. Although Dr. Sutherland, in his letter, does profess to have knowledge concerning the PRO records, nothing in his letter persuades me that he has knowledge of the cases of the 10 patients whose treatment is at issue. Even were I to assume such knowledge on the part of Dr. Sutherland, his one-page letter lacks the detailed and fact intensive analysis of the PRO's reports. Also, I note that Dr. Sutherland agrees that Petitioner was deficient in his care of patients, as cited by the PRO. P. Ex. 1 at 8. Accordingly, I have given no weight to any of the physicians' opinions relied upon by Petitioner.

With regard to Petitioner's unwillingness or inability to comply with his statutory obligation under the Act, I find relevant that, although, since November of 1991, Petitioner has not had a registration number for prescribing a controlled substance, he was convicted of

the offense of dispensing or prescribing a controlled substance on the basis of a post-November 1991 incident. I.G. Ex. 1 at 12. This type of conduct evidences Petitioner's general unwillingness to follow the requirements imposed by law.

I find relevant also that Petitioner argues that the violations cited by the I.G. in her December 1994 letter, to which he stipulated, were "deficiencies" only, and which were "the exceptions and not the rule for his practice." P. Br. at 2. I disagree. The cited violations form a pattern and are not "exceptions" to Petitioner's practice. P. Br. at 2. For example, there is proof of Petitioner's recurring failure to order appropriate medication therapy as evidenced by the cases of: 1) patient R.E., who was placed on Lasix during March 1991 without continued signs of heart failure (Finding 23); 2) patient D.M., who was placed on Valium and morphine during June of 1991 despite his having been admitted to the hospital for neurological observation (Finding 15); and 3) patient O.G., who was not placed on a long enough course of antibiotic therapy for his pneumonia during his hospitalization in October 1992 (Finding 19).

In addition, there were recurring problems with Petitioner's failure to use or to properly interpret laboratory tests, such as in the cases of: 1) patient M.R., who was placed on a broad acting third generation cephalosporin in March 1991 before a blood culture had been obtained and evaluated (Finding 21); 2) patient E.G., for whom there was no adequate evaluation of ABGs or aggressive treatment of the patient's compromised oxygen status in May 1991 (Finding 17); 3) patient E.H., for whom no ABGs were ordered to evaluate dyspnea in June of 1991 (Finding 16); 4) patient M.C., who had a history of hypothyroidism and abnormal thyroid studies but was not provided appropriate care in June 1991; and 5) patient I.C., who was placed on Synthroid in July of 1991 despite normal thyroid study results (Finding 27). There were also recurring failures by Petitioner to provide timely reports of histories and physicals of his patients which, as discussed above, impedes the ability of other physicians to delivery effective treatment to patients. See Findings 13, 18, 20, 22, 24, 26, and 28.

Further evidence that Petitioner has remained unwilling or unable to comply with his statutory obligation is found in Petitioner's failure to live up to the terms of his CAP, and to take advantage of the opportunity to remedy his recurring problems under the statute. As correctly pointed out by the I.G. and the PRO, the same

types of deficiencies in his practice occurred again in 22 cases (each case consisting of multiple violations) after he had agreed to comply with the terms of a CAP. I.G. Ex. 1 - 6; Findings 30, 31. From November 1992 until December 1993, Petitioner continued to exhibit significant problems, such as failing to: 1) adequately evaluate patients; 2) address abnormal test results; 3) order appropriate medication therapy; 4) order appropriate IV therapy; e) provide adequate or appropriate medical orders; and 5) provide timely and adequate documentation, such as H & Ps and discharge summaries. I.G. Ex. 1 - 4. Even after the PRO apprised him of these additional cases in a second sanction notice, Petitioner did not respond. I.G. Ex. 3 at 73.

Petitioner contends that he has successfully completed the CAP. P. Br. at 8. Indeed, during oral argument, counsel for the I.G. admitted that Petitioner had completed the training elements of the CAP. Transcript of September 6, 1995 oral argument at 23 (Tr. at 23). However, while Petitioner has shown that he eventually fulfilled the training requirements in the CAP, the record reflects that, during the time the CAP was in effect, he continued to commit numerous substantial violations of professionally recognized standards of health care. Tr. at 23. The violations that occurred during the period that the CAP was in effect, coupled with Petitioner's established pattern of basic mistakes regarding his treatment of the 10 patients at issue, are very persuasive proof that he is unwilling or unable to comply with his statutory obligations.

Therefore, the record reflects that Petitioner's completion of the CAP courses and paperwork are not persuasive in light of Petitioner's continued violations of the most basic and important elements of the CAP regarding the proper care and treatment of patients and proper and adequate documentation. Petitioner's completion of the CAP coursework is meaningless in view of his continued violations of his obligation under the Act during the CAP period, and certainly does not provide any indication that at present Petitioner is willing or able to comply with his obligations under section 1156 of the Act.

I find equally unpersuasive Petitioner's additional arguments and evidence to support reducing the length of his exclusion. Having already addressed the letters from physicians, I will now discuss the letters of support from some patient and hospital staff members, as well as the petitions signed by local residents. It is obvious

from these submissions that Petitioner is a well-liked physician in his community. P. Ex. 1.

However, as set out in the I.G.'s letter of December 1994, Petitioner's exclusion does not bar him from practicing medicine. The exclusion bars him only from receiving payments under the Medicare and Medicaid programs, so as to protect those whose access to medical care depends on such payments. I.G. Ex. 1. The I.G. has no authority to preclude Petitioner from practicing medicine, having hospital privileges, or treating patients who wish to be treated by him. In fact, Petitioner's exclusion has no potential impact whatsoever on persons who are not Medicare beneficiaries or Medicaid recipients. Yet the letters of support for Petitioner and the petitions signed by local residents fail to indicate an understanding of these distinctions. Some letters ask for reinstatement of Petitioner's hospital privileges. E.g., P. Ex. 1 at 34, 35, 40, 47. Others object to depriving Petitioner of the privilege of practicing medicine. E.g., P. Ex. 1 at 124. The Administrator of a local hospital, for example, notes a physician shortage in the area even though the exclusion from participation in the Medicare and Medicaid programs does not require Petitioner to terminate his medical practice or leave the area. P. Ex. 1 at 9; I.G. Ex. 1.

More importantly, none of the letters from patients or petitions signed by local residents indicates any knowledge of the nature or extent of those violations committed by Petitioner. One individual, for example, appears to assume that Petitioner has been derelict in "the mounds of paperwork required by the government." P. Ex. 1 at 38 (emphasis in original). Nor does the record show that the writers of the letters or signatories of the petitions have the qualifications to evaluate the appropriateness and quality of services rendered by physicians.

The majority of the letters express patient loyalty, contain lay opinions on the quality of medical care, do not show sufficient knowledge of the underlying facts of this case, and are not entitled to any weight. I find it significant that Petitioner has declined the repeated opportunities afforded him by the PRO to address the merits of all the violations alleged by the PRO. E.g., I.G. Ex. 3 at 73. Now, having been unwilling or unable to convince his professional peers familiar with the specific cases that his medical decisions and actions were within professionally recognized standards, Petitioner relies upon the opinions of lay individuals unfamiliar with the PRO's medical findings and the I.G.'s

reasons for excluding him. I do not find that this approach establishes that a three year exclusion is unreasonable.

With respect to the physician shortage alleged by Petitioner and his supporters, I conclude that the evidence relevant to this issue is not sufficient for finding a three year exclusion unreasonable. Petitioner does not contest the I.G.'s determination that other physicians practice in the area (I.G. Ex. 1 at 11), and Petitioner does not allege that his Medicare and Medicaid patients will be rejected by other area doctors. In fact, the physicians who wrote letters in Petitioner's support do not assert that they have full patient loads or will reject Medicare and Medicaid patients. P. Ex. 1 at 1 - 8. Only one doctor has stated in his letter that Petitioner's situation has created "somewhat of a hardship" for other physicians. P. Ex. 1 at 7; P. Br., 4. However, at the time this doctor wrote the letter, many patients of Petitioner's already had changed doctors, and this doctor did not note that any Medicare or Medicaid patient had failed or will fail to find a local physician willing to treat him. Id.. Nor has any Medicare or Medicaid beneficiary or recipient alleged that since Petitioner's exclusion no doctor in the area has been willing to accept her or him as a patient .

Moreover, I do not find that the appropriate method for relieving the physician shortage situation alleged by many local residents and Petitioner is to modify the exclusion period of a physician whose treatment poses serious risks to patient health and who cannot or will not conform the care he renders to professionally recognized standards. It may be true that Petitioner's exclusion causes the other doctors of the community to be "overworked," as alleged by a hospital employee. P. Ex. 1 at 11. Placing Petitioner back in the programs at this time may indeed lessen the workload of other health care professionals in the community. However, doing so will be a disservice to the health of program patients who may be receiving treatment from Petitioner.

I am aware that Petitioner, at least in the proceedings before the PRO and before me, has stipulated to the existence of his violations under the Act. However, his willingness to enter into the stipulation does not negate the seriousness of Petitioner's violations, the risks he creates for patients, or his failure to adequately remedy his deficiencies during the time period that the CAP was in effect. To date, Petitioner continues to minimize the potential harm he created for patients and shirk off the importance of proper medical documentation, as seen by

his reliance upon the letters discussed above. People writing to support a reduction in Petitioner's sanction period may have been given the incorrect impression that the exclusions resulted from hypertechnical and unnecessary paperwork requirements which Petitioner's busy schedule as a good physician did not permit him to satisfy, or from his failure to communicate with the government. E.g., P. Ex. 1 at 2, 13, 38.

The fact that others believe that Petitioner can and will work with the local hospital's Continuing Quality Improvement (CQI) committee to overcome his problems also does not establish that the exclusion period should be decreased. Petitioner is being excluded due to the numerous quality of care and documentation problems that have resulted from his treatment of patients who were admitted to the same hospital with the CQI committee. See, e.g., I.G. Ex. 12 - 34. Petitioner's reliance on letters suggesting the usefulness of the same hospital's CQI committee and his willingness to work with that committee does not amount to a sincere recognition by Petitioner that he has failed to meet his obligations under section 1156 of the Act. Until he understands the nature and significance of his past violations, it is unlikely that he will be able to comply substantially with the statutory requirements.

Based on all of the foregoing considerations and the totality of the evidence, I conclude that a three-year exclusion is reasonable in order to protect the programs' beneficiaries and recipients. A three-year exclusion will give Petitioner the opportunity to understand the manner in which he has violated his statutory obligations and the potentially harmful consequences to his patients. A three year exclusion will also enable Petitioner to obtain the necessary training and instruction which may persuade him to change the types of practices noted by the I.G. and the PRO. The three-year exclusion will provide Petitioner with sufficient time to demonstrate that he can provide medical care to program beneficiaries and recipients in a manner consistent with his obligations under the Act and which will not create undue risk of harm to them.

CONCLUSION

I uphold the three-year exclusion which the I.G. imposed and directed against Petitioner.

/s/

Mimi Hwang Leahy

Administrative Law Judge

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