Department of Health and Human Services

DEPARTMENTAL APPEALS BOARD

Civil Remedies Division

In the Case of:	
Henry A. Peters, D.O.,	DATE: September 24, 1992
Petitioner,	Docket No. C-92-074
- v. -	Decision No. CR232
The Inspector General.	

DECISION

This is a case arising from an action taken by the Inspector General (I.G.) of the United States Department of Health and Human Services (DHHS) against Henry A. Peters, D.O. (Petitioner), pursuant to section 1156 of the Social Security Act (Act). On February 6, 1992, the I.G. notified Petitioner by letter (Notice) that he would be excluded from participating in Medicare and all federally financed State health care programs for a period of one year.1/ The I.G. informed Petitioner that his exclusion was based on the recommendation of the Sentinel Medical Review Organization, the peer review organization of Indiana (PRO) and was authorized by section 1156 of the Act.2/ The I.G. advised Petitioner

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1/ Federally financed State health care programs are defined in section 1128(h) of the Act. There are three types of federally financed programs, including Medicaid. Hereinafter, I use the term "Medicaid" to refer to all State health care programs from which the I.G. proposed to exclude Petitioner.

2/ Sentinel is the successor to the Indiana Medical Review Organization, the PRO which began Petitioner's Quality Review. The Secretary of DHHS contracts with PROs to review the professional activities of physicians to determine whether the physicians are providing services which satisfy their obligations under section 1156 of the Act. If a PRO determines that a physician

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that he had determined that Petitioner had, in two instances "grossly and flagrantly" violated his obligation under section 1156(b)(1)(B) to provide care that meets professionally recognized standards of health care in his treatment of one patient (Patient E.S. -- PRO Case No. 309-07-7091B)).3/ The I.G. asserted that Petitioner had demonstrated an unwillingness and a lack of ability "substantially to comply" with his obligations under the Act.4/ The I.G. alleged that Petitioner's inability is further demonstrated by the problems identified by the PRO in the care Petitioner provided in two additional cases.

In the Notice, the I.G. informed Petitioner that he was entitled to a hearing on the I.G.'s determination to exclude him for one year. Under section 1156, the exclusion would be in effect pending a decision by the Administrative Law Judge (ALJ) on the merits. However, because Petitioner practices in a county with a population of less than 70,000, he was also entitled to a hearing on the related issue of whether Petitioner posed

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2/ (...continued)
has committed a "gross and flagrant" violation, the PRO must submit a report and recommendation to the I.G.

3/ "Gross and flagrant" is defined at 42 C.F.R. § 1004.1 as a violation which represents "an imminent danger to the health, safety or well-being of a Medicare beneficiary or places the beneficiary unnecessarily in high-risk situations."

4/ Section 1156(a) of the Act imposes on health care practitioners a number of duties, among them the duty to provide care of a quality that meets professionally recognized standards of health care. Section 1156(b) authorizes the Secretary of the DHHS to exclude practitioners who commit certain types of violations of their statutory obligations. Section 1156(b)(1)(A) authorizes exclusion of practitioners who substantially violate their obligations in a substantial number of cases. Section 1156(b)(1)(B) authorizes exclusion of practitioners who "grossly and flagrantly" violate their obligations on one or more occasions. In this case, the I.G. alleged in his Notice that Petitioner's proposed exclusion is authorized pursuant to the latter subsection, 1156(b)(1)(B).

a "serious risk" to Medicare patients.5/ As Petitioner timely requested a hearing on both issues, the exclusion did not take effect.6/ See Order and Notice of Prehearing Conference at 1, dated February 25, 1992.

I held the hearing in this case on May 4-8, 1992, in Evansville, Indiana, on both the "serious risk" issue and on the merits. The parties submitted post-hearing briefs.

ISSUES

The issues in this case are:

1. Whether this case must be dismissed by reason of the due process issues raised by Petitioner.

2. Whether Petitioner "grossly and flagrantly" violated his obligations to provide health care which meets professionally recognized standards.

3. Whether Petitioner demonstrated an "unwillingness or lack of ability substantially to comply" with those obligations.

4. Whether the one year exclusion imposed and directed against Petitioner by the I.G. is reasonable.

5/ If the I.G. proves by a preponderance of the evidence that Petitioner poses a "serious risk," within the meaning of section 1156 of the Act, he must be excluded during the pendency of these proceedings.

6/ Section 1156(b)(5) of the Act requires that the effective date of exclusion be stayed for physicians who practice in a county with a population of less than 70,000 or in a rural manpower shortage area, until a preliminary hearing can be held to determine whether the physician poses a "serious risk" to Medicare beneficiaries or Medicaid recipients. In the Notice, Petitioner was advised that the issues at the preliminary hearing would be whether Petitioner: 1) posed a serious risk to persons entitled to participate in the health care programs; and 2) should be allowed to continue to be reimbursed for program items and services pending the outcome of the hearing on the merits.

5. Whether Petitioner presents a "serious risk" to Medicare and Medicaid program beneficiaries and recipients within the meaning of section 1156 of the Act.

SUMMARY OF THIS DECISION

I have considered the testimony and exhibits and the parties' briefs and arguments. I conclude that the evidence establishes that Petitioner "grossly and flagrantly" violated his obligation to provide health care which meets professionally recognized standards with respect to one patient within the meaning of section 1156 of the Act. I conclude further that Petitioner has demonstrated "a lack of ability substantially to comply" with his obligation. Therefore, the I.G. had the authority to exclude Petitioner under section 1156 of the Act. Petitioner was not denied due process. I also conclude that the remedial need for an exclusion, in this case, will be satisfied by the one year exclusion proposed by the I.G. Finally, with respect to the issue of "serious risk," I find that Petitioner poses a "serious risk" to beneficiaries and recipients of the health care programs within the meaning of section 1156 of the Act and must be excluded during the pendency of these proceedings.

FINDINGS OF FACT AND CONCLUSIONS OF LAW

Having considered the entire record, the arguments, and the submissions of the parties, and being advised fully, I make the following Findings of Fact and Conclusions of Law (FFCLs):7/ 8/

7/ The record of this case will be cited as follows:

I.G.'s Exhibits	I.G. Ex. (number) at (page)
Petitioner's Exhibits	P. Ex. (number) at (page)
Transcript	Tr. (page)
I.G.'s Brief	I.G. Br. (page)
Petitioner's Brief	P. Br. (page)
I.G.'s Reply Brief	I.G. R.Br. (page)
Petitioner's Reply Brief	P. R.Br. (page)

8/ Some of my statements in the sections preceding these formal findings and conclusions are also FFCLs. To the extent that they are not repeated here, they were not in controversy. Also, I have used headings in organizing my

(continued...)

Petitioner

1. Petitioner is a physician with a doctor of osteopathy degree from Kansas City, Missouri, College of Health Science. He has practiced medicine in Oakland City, Indiana since 1956 and is on the staff of Wirth Osteopathic Hospital in Oakland. Tr. 891-92.

2. Petitioner has been board certified in family practice medicine by the American Osteopathic Association for about 20 years. Tr. 892.

Procedural History

3. On August 19, 1988, the PRO notified Petitioner that a potential quality issue had been identified in reviewing the chart of Patient E.S., a patient of Petitioner's. Tr. 50; I.G. Ex. 1.

4. On August 29, 1989, the PRO informed Petitioner that, based on a third physician reviewer's review of the chart of Patient E.S., the problem was a assigned a Level II of severity (potential for adverse effects), and the following interventions had been assigned: (1) notice letter and (2) additional focused review of a minimum of 10 cases of patients with infection.9/ Tr. 52; I.G. Ex. 1 at 6.

5. Subsequently, the PRO identified other cases as potential quality of care issues, and on February 12, 1990, the PRO began sending Petitioner notices in these other identified cases. I.G. Exs. 7 at 1, 9, 11, 13, 15, 17, 20, 22, 24, 26, 28, 30, 32, 34, 36.

6. By letter dated May 28, 1990, the PRO notified Petitioner that the Quality Committee had determined that the quality of care issue regarding his treatment of Patient E.S. was a Level III issue (actual adverse effect) and assigned additional interventions as part of a Corrective Action Plan (CAP) which required Petitioner to be reviewed 100 percent, to obtain 24 hours of Continuing Medical Education (CME) on infectious diseases

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8/ (...continued)
FFCLs. These headings are not FFCLs and do not alter the meanings of the FFCLs.

9/ The record includes the use of both Arabic and Roman numerals for the severity levels. For uniformity, I have used Roman numerals throughout this decision.

within six months, and to submit documentation of the CME credits to the PRO. Tr. 53-54; I.G. Ex. 1 at 8.

7. Petitioner responded to the PRO's letter described in FFCL No. 6 by enclosing information on CMEs obtained from 1979-1983. I.G. Ex. 1 at 9-21.

8. By letter dated August 1, 1990, the PRO notified Petitioner that it had concluded that there was a reasonable basis for determining that the case of Patient E.S. represented a "gross and flagrant" violation (within the meaning of section 1156 of the Act) and that he could request a meeting with the Sanction Committee before a final determination was made. Tr. 56, I.G. Ex. 1 at 22-34.

9. The Sanction Committee sent two more requests to Petitioner that he meet with the Committee. I.G. Ex. 1 at 51, 53.

10. Petitioner met with the Sanction Committee on November 20, 1990, and by letter dated November 28, 1990, the Committee affirmed the interventions. I.G. Exs. 2, 43 at 94.

11. At a meeting with Petitioner in September of 1991, Dr. Peter Livingston, Medical Director of the PRO, discussed additional quality of care issues, and asked him to submit the required CME documentation. Petitioner did not submit the documentation. Tr. 63-64.

12. On October 18, 1991, the PRO recommended to the I.G. of DHHS that Petitioner be excluded for six months from participating in Medicare and Medicaid based on its conclusion that Petitioner had "grossly and flagrantly" violated his obligation to provide health care that met professionally recognized standards and that he had demonstrated an unwillingness and inability to comply with his obligation within the meaning of section 1156 of the Act. I.G. Ex. 43 at 2.

13. By letter dated February 6, 1992, the I.G. notified Petitioner that he was being excluded from participating in Medicare and Medicaid for a period of one year. The I.G. stated that in the case of patient E.S., Petitioner had grossly and flagrantly violated his obligation to provide health care of a quality that met professionally recognized standards within the meaning of section 1156 of the Act. The I.G. also determined that Petitioner was unwilling and unable substantially to comply with his obligations. I.G. Ex. 3.

Due Process Issues

14. The regulations require the I.G. to determine whether the PRO is following its procedures. 42 C.F.R. § 1004.90(b)(1).10/

15. In this case, there were some minor and harmless errors made by the PRO in failing to follow its procedures.

16. The PRO notice letters adequately addressed the charges leveled against Petitioner for each review level.

17. The PRO reviewers must forward to the Quality Review Committee those cases in which they have awarded 10 or more points (in severity) to a physician within a three month period. They may also forward other cases to the Quality Review Committee, especially where interventions have been assigned. Tr. 102-03

18. The PRO is not required to specify which CMEs a physician should take to fulfill a CAP. See Tr. 55-56.

19. When reviewing a case, the PRO may increase or decrease its assigned severity level. Tr. 41-42; see Tr. 179.

20. The PRO provided Petitioner with a written explanation of why it increased the severity level of Petitioner's case from Level II to Level III. I.G. Ex. 43 at 7-9.

21. At each level of review, Petitioner was provided with an opportunity to respond to the PRO's charges against him.

22. The PRO did follow its procedures (except for some minor and harmless errors) and did not violate Petitioner's due process rights.

10/ Because the I.G.'s Notice to Petitioner is dated February 6, 1992, I conclude that with respect to the I.G.'s review, the new regulations published January 29, 1992, at 57 Fed. Reg. 3298 et al., are applicable to this proceeding. See Behrooz Bassim, M.D., DAB 1333 at 9 (1992) (substantive provisions of the new regulations may be applied to cases in which the I.G.'s Notice of Intent to Exclude, Notice of Exclusion, or Notice of Proposal to Exclude was dated on or after January 29, 1992). However, with respect to the PRO proceedings, I have relied on the regulations in effect at that time.

23. The I.G.'s Notice, taken in its entirety, is sufficient to apprise Petitioner of the action taken against him by the I.G. and to afford him the opportunity to respond. See I.G. Ex. 3.

24. The I.G. is not bound by the PRO's recommended sanction but properly based its determination of Petitioner's sanction on the factors set forth in 42 C.F.R. § 1004.90(d).

25. As this is a de novo review, the I.G. may introduce evidence not included in the Notice, but, because the I.G. did not provide Petitioner with sufficient notice with respect to the evidence submitted on the 15 additional cases, this evidence may only be used with regard to the issues of the reasonableness of the length of the exclusion, i.e., Petitioner's trustworthiness, and whether he presents a "serious risk" to the program.

26. The I.G. did not violate Petitioner's due process rights.

27. The regulations and their preamble provide for consideration of differences of opinion among experts in that the preamble states that there is no litmus test with respect to the required standard of care. See 42 C.F.R. § 1001.2 (1992); 57 Fed. Reg. 3301 (January 29, 1992).

28. I must assume that the Act and its implementing regulations are constitutional and the determination of an attack on the constitutionality of section 1156 of the Act or its implementing regulations is outside my jurisdiction. See Califano v. Sanders, 430 U.S. 99, 109 (1977).

29. I have the authority to interpret and apply federal statutes and regulations. Francis Schaenboen, DAB CR97 (1990), aff'd DAB 1249 (1991).

"Gross and Flagrant"

30. Under Section 1156 of the Act, the Secretary may exclude a physician from participating in Medicare and Medicaid where the Secretary determines, based on a recommendation by a PRO, that the physician has grossly and flagrantly violated the obligation to provide health care of a quality which meets professionally recognized standards of care, within the meaning of section 1156 of the Act, and has demonstrated an unwillingness or lack of ability "substantially to comply" with the obligation to

provide that care. Sections 1156(a)(2) and (b)(1) of the Act.

31. "Professionally recognized standards of care" (within the meaning of section 1156 of the Act) are those which professional peers of the individual or entity, whose provision of care is an issue, recognize as applying to those peers practicing or providing care within a State. 42 C.F.R. § 1001.2.

32. A "gross and flagrant violation" is defined as the violation of an obligation to provide care 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 a high risk situation. 42 C.F.R. § 1004.1(b).

33. The I.G. proved that Petitioner committed a "gross and flagrant" violation of his obligation to provide health care in accordance with professionally recognized standards of care.

Patient E.S.

34. Patient E.S. was a 72 year old woman who had been hospitalized several times in the last few years of her life with multiple chronic medical problems. Tr. 761-63; I.G. Ex. 1 at 43.

35. Patient E.S., a Medicare beneficiary, was hospitalized at Deaconess Hospital from March 5 to 22, 1988, where she was treated by Dr. William Houser and Dr. Herman Rusche upon referral by Petitioner. Her admitting symptoms were an elevated white blood count (WBC), diarrhea, and abdominal distention.

36. During the hospitalization at Deaconess, Patient E.S. was diagnosed as having pseudomembranous colitis and was treated with Vancomycin and other drugs. Tr. 763-69; I.G. Ex. 1.

37. On March 29, 1988, Patient E.S. was admitted to Wirth Osteopathic Hospital by Petitioner with a provisional diagnosis of septicemia, and the admitting reports listed her complaints as including extreme exhaustion, poor appetite, and white sores on the throat and mouth. I.G. Ex. 6 at 8-9.

38. Petitioner's physical examination of Patient E.S. included findings of poor skin texture, dehydration, and markedly tender and distended abdomen with hyperactive

bowel sounds, and he noted her prior hospitalization for "pseudomembranous ulcerated colitis." I.G. Ex. 6 at 25.

39. During the course of Patient E.S.'s last hospitalization at Wirth, her WBC elevated daily from 12,000 on March 29 to 49,200 on April 4, 1988, the day she died. See I.G. Exs. 1 at 10, 6 at 25-62.

40. After hospitalization, Petitioner ordered a blood count, chemistries, and electrolyte and blood gas studies, but blood cultures were not ordered until April 2 and 4, and a stool culture was not ordered until April 4. I.G. Exs. 1 at 10, 6 at 25-63.

41. During Patient's E.S.'s last hospitalization at Wirth, Petitioner prescribed or continued the prescription of numerous drugs, including Theophylline, Levothyroxine, Berocca-Plus, Naprosyn, Spironolactone, Brethine, Donnatal, Furosemide, Darvocet, Synthroid, Prednisone, Lanoxin, Bicillin, Klotrix, ACTH, Septra, Bactrin, insulin, Immodium, Lomotil, Solumedrol, Gentamycin, Gentian Violet, and Morphine Sulphate. I.G. Ex. 6.

42. Vancomycin was not ordered for Patient E.S. by Petitioner until 11:30 p.m. April 1, 1988, and does not show up on the nurses' record of medications until "Hospital Day 4" (April 2). I.G. Ex. 6 at 30, 46.

43. On March 30, 1988, Dr. Terry Gehlhausen provided a consultation on Patient E.S., and recommended that her multiple medications be reduced and that more lab tests be done. I.G. Ex. 6 at 6-7.

44. Patient E.S. died the evening of April 4, 1988, and the final diagnosis was septicemia, respiratory failure, and pseudomembranous ulcerative colitis. I.G. Ex. 6 at 61.

45. Petitioner failed to timely order tests to permit diagnosis of the cause of the septicemia and determine appropriate treatment or to test for pseudomembranous colitis, and he ignored Dr. Gehlhausen's recommendations for additional testing.

46. Petitioner prescribed Septra and Bicillin for Patient E.S. without diagnosing the cause of her septicemia and which drugs could also have caused or exacerbated a relapse of her pseudomembranous colitis.

47. Petitioner prescribed ACTH, a steroid anti-inflammatory, and two other cortisone drugs, Solumedrol

and Prednisone, without medical indication for Patient E.S. and continued the ACTH even after Dr. Gehlhausen questioned the necessity for repeating it.

48. Petitioner failed to continue to treat Patient E.S's dehydration when he prescribed the diuretics Lasix and Spironolactone and reduced her IV fluids, although she had diarrhea on admittance which increased during her hospitalization, and her intake and outtake rates indicated that she was becoming more dehydrated.

49. Petitioner failed to evaluate or treat Patient E.S.'s abdominal condition by failing to attempt to determine its cause, although hospital records indicate that she had abdominal problems, that her diarrhea steadily increased during her hospitalization, and that Petitioner was aware of her recent treatment for pseudomembranous colitis.

50. Petitioner failed to timely restart Patient E.S. on Vancomycin to treat the suspected pseudomembranous colitis, although it is one of only two drugs useful for this condition.

51. Petitioner administered several drugs which are contraindicated for a someone in Patient E.S's condition and which were potentially harmful to her, including Septra, Bicillin, Lomotil, Immodium, ACTH, and Morphine Sulphate.

52. Petitioner's failure to properly evaluate, test, and treat Patient E.S. was a violation of professionally recognized standards of care.

53. Petitioner's violation of professionally recognized standards of care placed Patient E.S. unnecessarily in a high risk situation and presented serious risk of imminent danger.

54. Petitioner's conduct was a "gross and flagrant" violation of his obligation under section 1156 of the Act to provide health care of a quality which meets professionally recognized standards of care.

Willingness and Ability to Comply

55. The evidence does not support a finding that Petitioner timely or fully complied with the PRO's assigned CAP of completing 24 credits of CME in infectious diseases within six months and forwarding proof to the PRO. See Tr. 64, 916-17; I.G. Ex. 1 at 9; P. Ex. 1.

56. Petitioner has regularly attended medical seminars in excess of that required to maintain his board certification. P. Exs. 1 and 10.

57. The I.G. has not met his burden of proof with regard to whether Petitioner is unwilling substantially to comply with his obligations under the Act.

58. Petitioner's treatment of Patient E.S. demonstrates that he lacks the ability: 1) to evaluate or treat the cause of infectious processes; 2) to understand the proper use of steroids, 3) to prescribe the appropriate and least harmful medications for a patient's conditions; 4) to timely order and evaluate laboratory data or to perform diagnostic tests when indicated; and 5) to manage fluid intake in a patient who requires hydration.

59. Petitioner lacks the ability "substantially to comply" with his obligation to provide care that meets professionally recognized standards.

Authority to Exclude

60. The I.G. has demonstrated by a preponderance of the evidence that Petitioner has violated his obligation to provide health care in accordance with professionally recognized medical standards with regard to Patient E.S.

61. The I.G. had the authority to exclude Petitioner from participating in Medicare and Medicaid pursuant to section 1156 of the Act.

Length of Exclusion

62. Petitioner violated professionally recognized standards of health care by prescribing antibiotics for Patients D.R. and C.H. without first isolating the cause of their elevated WBC or identifying the source of their infections.

63. Petitioner violated professionally recognized standards of health care by failing to identify the source of low hemoglobin in Patients C.H. and B.B. and by failing to diagnose the cause of positive stool for occult blood test results in Patient V.E.

64. Petitioner violated professionally recognized standards of health care by failing to order a computerized axial tomography (CAT) scan of Patient E.R.'s brain to diagnose the cause of her acute neurological unresponsiveness.

65. Petitioner violated professionally recognized standards of health care by failing to control blood glucose levels in Patients D.R. and A.M., who were suffering from diabetes.

66. Petitioner violated professionally recognized standards of health care by failing to either diagnose or definitively rule out a urinary tract infection in Patient A.A.

67. Petitioner violated professionally recognized standards of health care by failing to institute either fluid restriction or sodium infusion to reverse falling serum sodium levels in Patient C.H.

68. Petitioner violated professionally recognized standards of health care by failing to address Patient W.H.'s hypotension, either by treating it or, alternatively, by indicating in her medical record that the low blood pressure readings were inaccurate.

69. Petitioner lacks the ability to diagnose the causes of patients' abnormal laboratory results and to address these results adequately.

70. Petitioner violated professionally recognized standards of health care by prescribing steroids for Patients N.H., W.H., and T.R., who were suffering from illnesses that contraindicated the use of steroids.

71. Petitioner violated professionally recognized standards of health care by prescribing steroids for Patient J.R. without medical justification.

72. Petitioner violated professionally recognized standards of health care by failing to prescribe the recognized steroid treatment for Patient T.P., who was suffering from an illness that did require steroid treatment.

73. Petitioner violated professionally recognized standards of health care by prescribing IV Kefzol, an antibiotic, via an inappropriate route of administration in the case of Patient A.M., and at an inappropriately high dosage in the case of Patient V.E.

74. Petitioner violated professionally recognized standards of health care by discontinuing the drug Tenormin, an antihypertensive, in a dangerous manner for Patient W.H.

75. Petitioner violated professionally recognized standards of health care by prescribing various medications that were contraindicated in the cases of Patients A.M. and J.R.

76. Petitioner lacks the ability to prescribe the appropriate medications for patients' conditions.

77. The I.G. failed to prove that Petitioner violated professionally recognized standards of health care in his treatment of the cardiac conditions of Patients C.H. and J.R.

78. Petitioner violated professionally recognized standards of health care by failing to intervene timely to order an immediate EKG when Patient T.P. experienced severe chest pain, apparently as a result of an acute heart attack.

79. Petitioner violated professionally recognized standards of health care by discontinuing cardiac monitoring of Patient E.G., at a time when abnormal test results indicated that her cardiac condition was still unstable.

80. Petitioner violated professionally recognized standards of health care by failing to perform the necessary and usual tests to evaluate the cause of test results that indicated possible cardiac problems in Patients B.B. and O.B.

81. Petitioner lacks the ability to evaluate and intervene appropriately in patients suffering acute cardiac changes.

82. Petitioner violated professionally recognized standards of health care by failing to order sufficient IV fluids for Patient T.R., whom Petitioner had diagnosed as dehydrated.

83. Petitioner violated professionally recognized standards of health care by failing to order fluid restrictions in the cases of Patients V.E. and E.G., whom he had diagnosed as suffering from congestive heart failure.

84. Petitioner lacks the ability to manage fluid intake in patients who require hydration or fluid restriction.

85. The purpose of section 1156 of the Act is remedial and 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. S. Khalid Hussain, M.D., CR204 at 94 (1992); Evelyn Reyes, M.D., DAB CR131 at 37 (1991).

86. Petitioner has engaged in conduct that endangered the health and safety of Medicare beneficiaries.

87. Petitioner has demonstrated by his "gross and flagrant" violation that he is not trustworthy to treat program beneficiaries and recipients.

88. The I.G. has proven that there is a remedial purpose to exclude Petitioner for one year.

"Serious Risk"

89. The I.G. has proven that Petitioner represents a "serious risk" within the meaning of section 1156 of the Act and should be excluded during his administrative appeals.

90. Petitioner's exclusion shall run prospectively from twenty days from the date of this decision.

DISCUSSION

I. Petitioner Was Not Denied Due Process.

Petitioner has raised a number of due process and constitutional arguments, several of which he asserts are not within my jurisdiction to decide.11/ Petitioner argues that:

1) The Act is unconstitutional.
2) The regulations are unconstitutional.
3) The regulations are not within the Secretary's authority.
4) The PRO involved is not made up of representative licensed doctors of medicine and osteopathy engaged in the practice of medicine or surgery in the area and who are representatives of practicing physicians in the area.

11/ Petitioner notes in his brief that some of these issues have been raised here only to preserve them on appeal. P. Br. at 2; see Papendick v. Sullivan, No. 91-1902 at 7 (7th Cir. July 17, 1992) (due process claims must be raised at the administrative level to preserve them).

5) The regulations do not take into account differences of opinion among physicians regarding practice standards.
6) The regulations do not set out any criteria for imposing sanctions.

P. Br. at 2.

Petitioner has raised additional procedural arguments throughout his brief, the majority of which I shall address in this part of the decision. While I do not have the authority to rule on the constitutionality of the Act and regulations, I do have the authority to interpret and apply federal statutes and regulations. Francis Schaenboen, R.Ph., DAB CR997 (1990), aff'd DAB 1249 (1991). In addition, where there is room to decide how to apply the statute, I have a duty to apply it in a manner that is constitutional and valid. Betsy Chua, M.D., DAB CR76 (1990), aff'd DAB 1204 (1990).

A. The PRO Did Not Violate Petitioner's Due Process Rights.

Congress has determined that federal exclusion actions under section 1156 of the Act originate when a PRO recommends sanctions to the I.G., and the I.G., in reviewing the PRO's report and recommendation, makes certain findings and decides to issue a Notice of Sanction to a medical provider. In addition to these findings, the regulations require the I.G. in its review to determine whether: "The PRO is following its procedures." 42 C.F.R. § 1004.90(b)(1).

Petitioner argues that this case should be dismissed and no exclusion imposed because he was denied due process, alleging that the PRO failed to follow its procedures. The federal regulations governing PRO sanctions provide several layers of due process protection for a medical provider who is the subject of a PRO review. The PRO, which is composed of a cross-section of medical practitioners in a particular state, must, upon identifying potential violations, give the target physician a written notice explaining the obligation violated, the basis for the determination, the recommended sanction, and the physician's appeal rights. 42 C.F.R. § 1004.50. Here, at each step along the way, Petitioner was reviewed by different medical professionals, and Petitioner had the opportunity to, and did, reply to these notices.

Petitioner alleges that the PRO committed numerous errors and demonstrated inconsistencies in processing his quality review. P. Ex. 14. Many of these alleged errors are minor and appear to be more typographical and harmless than intentional or harmful violations of due process. For example, one early PRO document makes a reference to Patient E.S., a female, by using the term "his." Id. at 2. Subsequent documents use the correct gender. Another of Petitioner's allegations regards corrections (white overs) regarding Patient E.S.'s medical condition which were made to some early documents. P. Ex. 14. Petitioner was well aware of each of these errors and called them to the PRO's attention in his responsive letters. Other allegations appear rhetorical, such as Petitioner's questions regarding how the PRO determined that he had not stayed current in medicine, how the I.G. concluded, based on the PRO's recommendation, that Petitioner was unable to comply with his obligations under the Act, or why if Petitioner poses a "serious risk," was he honored by his community. Id. at 92-98, 209. Still others allege bias on the part of members of the PRO and employees of the of the DHHS. Id at 201.

More important than any of the minor harmless errors of which Petitioner has complained, is Petitioner's assertion that the notice letters from the PRO did not adequately address the charges made against him and that these charges changed as the case moved through the several review levels. It is true that the charges increased as the PRO discovered more problems with Petitioner's handling of Patient E.S. However, in each instance, Petitioner was informed of the charges and of his right to be heard, and, in each instance, he responded to the charges. In addition to his written responses, he had an opportunity to be heard before the Sanction Committee at its administrative hearing. This argument appears to stem more from Petitioner's disagreement with the PRO reviewers not agreeing with his explanations than from any lack of due process.

Petitioner also argues that the PRO breached its own statute of limitations and asserts that the PRO was required to decide his case within a three month time frames. This allegation is based on the PRO's procedures, in which points are given depending on the level of the severity of the violation found by the PRO. A Level I issue is assigned one point, a Level II issue has five points, and a Level III issue has 25 points. Tr. 37. Interventions are triggered if a physician accumulates ten points during a three month period. Petitioner's intervention was originally classified as a

Level II and subsequently increased by the PRO Quality Committee to Level III. Dr. Livingston, the Director of the PRO, testified that there are no statutes of limitations as such. If a doctor doesn't accumulate 10 points within a three month period, a case is closed. Tr. 38. Contrary to Petitioner's assertions, this does not mean that the case must be decided in three months, only that if 10 points are accumulated in this time, a case must be referred to the Quality Committee. Tr. 102-03. However, other cases may be referred to the Quality Committee if it is felt to be appropriate. Also, all cases, similar to Petitioner's, in which interventions such as monitoring are imposed, are forwarded to the Quality Committee. Id. Thus, there was no violation of PRO rules because the case did not close after three months, but, rather, it was found to be an appropriate case to refer to the Quality Committee even though Petitioner did not originally accumulate a total of 10 points within that time frame.

Petitioner next asserts that the PRO failed in its mandate to improve health care because it did not respond to his requests for more information on why he had failed in his obligations. P. Br. at 11. This, he claims, is in violation of the PRO's rules. It appears from a review of the PRO's record that there was a significant exchange of written materials between the PRO and Petitioner, and that Petitioner refused to accept the PRO's comments regarding his treatment of Patient E.S. See I.G. Ex. 43. Also, the PRO did attempt to meet its obligation to educate Petitioner by requiring him to take 24 hours of CME in infectious diseases. Contrary to Petitioner's protestations, the PRO was not required to specify which courses, of the many available to physicians, Petitioner should take. See Tr. 55-56.

Lastly, Petitioner argues that the PRO Quality Committee failed to explain why it raised the level of the violation from II (five points) to III (25 points). Dr. Livingston testified that the Quality Committee may re-review a case and adjust the level of severity after discussion among the entire Committee. Tr. 41-42; see Tr. 179. There is nothing in the PRO procedures to prevent it from either upgrading or downgrading an intervention on review. That is the purpose of a review. The Quality Committee voted unanimously for the increase and for the additional assigned interventions. Petitioner asserts that the refusal to respond to his question regarding the upgrading by the Chairman of the Committee is a denial of due process. However, the PRO did provide Petitioner, in writing, with information regarding its decision and the factors upon which it

relied in upgrading the level of severity, including the Quality Committee's determination that "the patient was not adequately evaluated or treated resulting in her death." I.G. Ex. 43 at 7-9 (Sanction Committee Report). The Sanction Committee also voted unanimously that the case was a Level III case.

In summary, I find that the evidence of record shows some very minor irregularities, primarily harmless errors and corrections to the written record. Petitioner has failed to establish that these harmless errors resulted in significant defects in the PRO's procedures. To the contrary, the testimony and documentary evidence relating to these factors shows that the PRO did, as a whole, follow its procedures, and that the procedures provided and available to Petitioner by the PRO afforded him with considerably more than the rudimentary requirements of fair play and due process. See Howard Lifshutz, M.D., DHHS Appeals Council Docket No. 000-44-7020 at 5 (June 1, 1989).12/

B. The I.G. Did Not Violate Petitioner's Due Process Rights.

In addition to due process challenges to the PRO's procedures, Petitioner asserts that the I.G. violated his due process rights because the I.G.'s Notice did not advise Petitioner adequately of the nature of the charges against him. P. Br. at 8-16. Petitioner states that due process requires that he be fully advised, and asserts that the Notice identifies the charges as only: "cultures and antibiotic therapy should have been done sooner" and "the patient was not adequately evaluated or treated." P. Br. at 8, citing I.G. Ex. 3 at 1. The first statement, he maintains, is contrary to the actual charges, while the second is too generic to permit a defense. These statements, however, are summaries and not the full extent of the basis identified by the I.G. for the charges. The PRO's exclusion recommendation

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12/ In fact, contrary to Petitioner's assertions, the record indicates that when it became apparent that the PRO was not accepting Petitioner's explanation's regarding his care of Patient E.S., he became somewhat uncooperative. For example, he was sent several letters with respect to his right to attend the administrative hearing. He was also contacted several times regarding his apparent refusal to complete, within the established time frame, the Corrective Action Program assigned to him by the PRO.

letter to the I.G., which Petitioner received prior to the I.G.'s Notice, contained a three page case synopsis setting forth the factual basis for the "gross and flagrant" finding. The I.G.'s Notice stated that the decision to exclude was based on the PRO recommendation and "incorporated [it] in this notice by specific reference." I.G. Ex. 3 at 1. I conclude that the I.G.'s Notice, taken in its entirety, is of "such a nature as reasonably to convey the required information" and is sufficient to "apprise interested parties of the pendency of the action and afford them an opportunity to present their objections." Mullane v. Central Hanover Tr. Co., 339 U.S. 306, 314 (1949).

Petitioner contends also that the I.G. increased the PRO's proposed six month exclusion to one year without explanation. The key here is that the PRO merely recommends sanctions, but the I.G. must base his determination of an appropriate sanction upon the factors set forth in 42 C.F.R. § 1004.90(d). The PRO recommendation is only one of the factors that the I.G. must consider. The I.G.'s Notice sets forth the I.G's analysis of the regulation's criteria. See I.G. Ex. 3 at 2-3. There is no requirement that the I.G. adopt the PRO's recommendations at all -- let alone be bound to the recommended period of exclusion.13/

Finally, Petitioner claims that the I.G. may not introduce evidence that Petitioner committed violations in addition to those specifically set forth in the Notice. He asserts that due process requires notice of all charges and evidence to be used in arriving at the sanction. Petitioner is correct that certain specific matters alleged by the I.G. to support the "serious risk" issues on the question of the authority of the I.G. to exclude were not referenced in the Notice. However, these specific matters listed by Petitioner were not relied on by the I.G. in determining to impose the exclusion or the reasonableness of its length. Each of the allegations in the "gross and flagrant" portion of the I.G.'s case is included in the charges as noticed. With respect to the additional evidence the I.G. has introduced, this is a de novo review, and I may consider information and evidence not considered or relied on by

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13/ Just as the I.G. is not bound by the PRO's recommendation, I am not bound by the I.G.'s determination. Petitioner is entitled to, and has received, a de novo review here. My analysis of the reasonableness of the length of the proposed exclusion is at part IV of this decision.

the I.G. in his initial determination so long as doing so would not be unfair. Papendick v. Sullivan, No. 91-1902 at 6 n.4 (7th Cir. July 17, 1992); Olufemi Okonuren, M.D., DAB 1319 at 14 (1992).

Petitioner has also challenged the I.G.'s introduction of evidence regarding 15 additional cases which are, or were, on review by the PRO. There were three cases cited in the PRO recommendation and the I.G.'s Notice, although only the case of Patient E.S. was specifically identified. As discussed more fully in part III-B of this decision, this mere reference, without other information, to the other two cases was insufficient to provide adequate notice on the issue of the I.G.'s authority to exclude Petitioner. Also, there was no notice provided Petitioner by the I.G. of his intent to rely also on the additional 13 cases to establish Petitioner's "lack of ability substantially to comply." Therefore, I conclude that it would be unfair to consider evidence on the 15 additional cases (including the two not specifically identified in the Notice) which are not related to the case of Patient E.S. on the issue of the I.G.'s authority to exclude Petitioner (i.e. the issues of "gross and flagrant" and "unwillingness or a lack of ability substantially to comply"). Reyes at 22-23.

Accordingly, I find that the I.G.'s Notice did give adequate notice of the charges with respect to Patient E.S. Also, I conclude that the I.G. may introduce evidence of the 15 additional cases (two of which were included in the Notice) which are, or were, under review by the PRO for the purpose of determining the reasonableness of the length of the exclusion and Petitioner's trustworthiness and on the issue of "serious risk." See Id.

In summary, I find that the I.G.: 1) reasonably found that the PRO had followed its procedures in Petitioner's intervention; 2) adequately advised Petitioner in the Notice of the nature of the charges and the rationale for the one year exclusion; and 3) was permitted to introduce evidence not specifically identified in the Notice only for the purposes of determining the length of the exclusion and the "serious risk" issue.

C. Petitioner's Additional Statutory And Regulatory Challenges Either Do Not Require Dismissal Or Are Not Within My Jurisdiction To Decide.

Petitioner argues that the PRO is not made up of physicians that are similar in practice to Petitioner. Petitioner also argues that the regulations do not take into account differences of opinion among physicians regarding practice standards. Here, I assume that Petitioner is referring to 42 C.F.R. Parts 1000 et al., and, especially, Part 1004 which deals with the imposition of sanctions on health care practitioners and providers of health care services by a PRO. As discussed more fully in part II of this decision, the interpretation of the statutory requirement of standard of care in the preamble to the regulations specifically notes that, with respect to the standard of care, there is no litmus test which can be applied to every case. In this proceeding, Petitioner was able to introduce expert testimony from practitioners of his choice regarding the appropriate standard of care. Further, the question of differences of opinion among experts is not unique to the PRO procedures. In all cases which involve the testimony of experts, it is the duty of the trier of fact to evaluate that testimony. I have done so here, and in doing so, have considered and weighed these differences of opinion in reaching my decision.

Thus, the regulations do address Petitioner's concern regarding consideration of differing medical opinions. Petitioner has not been denied due process on this account.14/

Petitioner has also challenged the constitutionality of both the Act and its implementing regulations. Petitioner recognizes that these constitutional issues are beyond my jurisdiction and raised them solely for the purpose of preserving them for appeal. See, Califano v. Sanders, 430 U.S. 99, 109 (1977) (J. Stewart concurring). Thus, I shall not consider these arguments.15/

14/ Petitioner has intimated that he may not have received fair consideration from the PRO because he is a doctor of osteopathy. I take note of the fact that doctors of osteopathy took part in both the PRO proceeding and these proceedings, and osteopaths testified at the hearing both for Petitioner and the I.G.

15/ Petitioner's assertion that the "regulations are not within the Secretary's authority" is difficult to address

(continued...)

II. Petitioner "Grossly And Flagrantly" Violated His Obligation To Provide Professionally Recognized Standards Of Health Care In The Case Of Patient E.S. Within the Meaning of Section 1156 of the Act.

A. Obligations and "Gross And Flagrant" Violations of Obligations Under The Act.

Section 1156(a)(2) of the Act imposes on physicians an obligation to provide services "of a quality which meets professionally recognized standards of health care." Although section 1156 does not define the term "professionally recognized standards of health care," the regulations provide the following definition:

> Statewide or national standards of care, whether in writing or not, that professional peers of the individual or entity whose provision of care is an issue, recognize as applying to those peers practicing or providing care within a State.

42 C.F.R. § 1001.2 (1992).

The preamble to the above regulation also notes that the definition:

> does not provide a litmus test which can be easily applied in every case. It would be very difficult to formulate a wholly objective standard in the area of medical practice, where a certain amount of subjectivity in judgement is inevitable.

57 Fed. Reg. 3301 (January 29, 1992).

Relying on this preamble, a recent case noted that unanimity of opinion among physicians as to the acceptability of a given treatment is not the standard, and that a physician does not violate his obligation to provide health care that meets professionally recognized standards if the physician pursues a course of treatment

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15/ (...continued)
without more information regarding Petitioner's arguments or to which regulations he is referring. However, 42 C.F.R. Parts 1000-1007, which implement the sanction and civil money penalty provisions of the Act (including section 1156), were authorized by the same legislation which established the Act. See 57 Fed. Reg. 3298 (January 29, 1992) for a list of the relevant legislation.

that has substantial support as proper practice among his or her professional peers. Hussain, at 43.

Petitioner's concerns about the need to consider differences of opinion among physicians regarding practice standards are, therefore, encompassed in this definition. Also, the standard of care is not limited by locality. It is, and has been, a state or national standard. 57 Fed. Reg. at 3301; see also Papendick at 6-7 (ALJ did not err in applying statewide standard of professional care). However, this does not mean, as Petitioner seems to imply, that board certified family practitioners, such as Petitioner, are held to a lower standard of care. For example, a board certified neurosurgeon might be expected to know more about his or her specialty than other physicians. This does not mean that the standard of care would excuse a physician who practiced medicine which had the potential to harm a patient on the ground that he is a general practitioner.

Section 1156(b)(1)(B) authorizes the Secretary to exclude, from participation in Medicare and Medicaid, physicians who have been determined by a PRO to have "grossly and flagrantly" violated their obligation in one or more instances.16/ To justify an exclusion, the Secretary must further conclude that the practitioner has demonstrated an "unwillingness or lack of ability substantially to comply" with his or her obligation under the Act. Id.

"Gross and flagrant violation" has also been defined by regulation as stated in note 3, supra. The term means a violation "which represents an imminent danger to the health, safety or well-being of a Medicare beneficiary or places the beneficiary unnecessarily in high-risk situations." 42 C.F.R. § 1004.1. One court has expanded on this by stating that a "gross and flagrant violation" involves "an especially dangerous deviation from medical norms." Varandani v. Bowen, 824 F.2d 307, 312 (4th Cir. 1987). Another case held that 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).

The I.G. asserts that Petitioner "grossly and flagrantly" violated his obligation to provide services which meet professionally recognized standards of health care in one case, that of Patient E.S. Thus, I must first consider whether Petitioner violated his obligation to provide

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16/ See note 3, supra.

care of the requisite quality and, if so, whether the violation placed Patient E.S. in imminent danger or unnecessarily in a high risk situation. See Hussain at 49-50.

B. Petitioner "Grossly And Flagrantly" Failed to Provide Patient E.S. With Services Which Meet Professionally Recognized Standards Of Health Care.

Patient E.S., a Medicare beneficiary, was a 72 year old female. According to Petitioner, who had treated her for about 20 years, she had multiple chronic medical problems, including a pacemaker, respiratory problems caused by smoking and several bouts with pneumonia, and chronic bronchitis. Tr. 761-62, 897; P. Br. at 3. She was hospitalized several times in both 1987 and 1988. Id.

She had been in Wirth Osteopathic Hospital in Oakland City, Indiana (Wirth) for pneumonia between February 2 and 17, 1988, and treated with antibiotics. She was readmitted on February 29, 1988, released and readmitted on March 1 because of severe diarrhea. I.G. Ex. 1 at 42, 46. On March 5, she was transferred by Petitioner from Wirth to Deaconess Hospital in Evansville, Indiana (Deaconess). There, she was treated by Dr. William Houser, a board certified pulmonary specialist and Dr. Herman Rusche, a board certified internist and gastroenterologist. She was admitted with an elevated white blood count (WBC), diarrhea, and abdominal distention. Tr. 763. Her weight was about 87.4 pounds. At one point her WBC was elevated to 77,000, indicating a serious infection somewhere in the body.17/ She was treated for it with Cefatan, a cephalosporin antibiotic. She also had a nasogastral tube and intravenous fluids. Tr. 763. Dr. Rusche believed that she had ascites and severe hypoproteinemia, cavitary chronic obstructive lung disease, and possible clostridium difficile pseudomembranous colitis. Tr. 763. Pseudomembranous colitis is a condition characterized by diarrhea, dehydration, and usually severe illness. Tr. 220. It is caused when antibiotics are used and the normal bacteria in the bowel are killed off, the result of which leaves leaving the clostridium difficile organism to grow unchecked. Tr. 779. Although a stool test was negative, a flexible sigmoidoscopy indicated evidence of the

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17/ A normal WBC is 6,000 to 10,000. Tr. 763.

organism responsible for pseudomembranous colitis (clostridium difficile).18/ P. Ex. 8 at 4.

At Deaconess, the antibiotics were discontinued and she was treated for the pseudomembranous colitis with Vancomycin for 10 days (including four days after her discharge). Apparently, her colitis responded to the Vancomycin enough so that she was discharged from Deaconess on March 22, 1988, by Drs. Houser and Rusche. Tr. 768. One of her attending physicians testified, however, that he believed there had been a good possibility that she would die during that hospitalization because of her poor general condition and continuing problems. Tr. 764-66. At the time of discharge, her medications included, in addition to the Vancomycin, Atovent and Proventil inhalers, Brethine, and Theodur for breathing, Zantac for stomach acid, Synthroid, a supplement thyroid, Lanoxin, a cardiac medication, Aldactone for swelling, multivitamins, Klotrix, Lasix, a diarrhetic, potassium, and oxygen. Tr. 769; P. Br. at 4-5; I.G. Ex. 1 at 50.19/

On the morning of March 29, 1988, Patient E.S. was readmitted to Wirth under Petitioner's care. I.G. Ex. 6 at 1-2. It is this last hospitalization in which the issue of Petitioner's alleged "gross and flagrant" treatment arises. However, because Patient E.S.'s immediate prior hospitalizations and medical problems are relevant and have been raised and discussed by the parties, they have been summarized briefly above.

Patient E.S. was admitted to Wirth by Petitioner with a provisional diagnosis of septicemia.20/ The admitting nurse noted Patient E.S.'s condition as fair, with complaints of extreme tiredness, no appetite, and white

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18/ Although there was a report from Deaconess indicating that there had been a positive stool culture for pseudomembranous colitis, the doctor who wrote the Deaconess discharge report testified that the report was inaccurate and that the culture had been negative. A stool culture is a different test than the sigmoidoscopy. Tr. 776-77 See I.G. Ex. 1 at 49.

19/ The record shows several spellings of these and other medications. Throughout this decision, I have used those spellings which appear most frequently.

20/ Septicemia refers to the presence of bacteria in the blood stream and an overwhelming infection somewhere in the body. Tr. 230, 476.

sores on her mouth and tongue. I.G. Ex. 6 at 8. The nurse noted that Patient E.S. was alert and able to obey commands but was very emaciated. The nurse report also noted her hospitalization at Deaconess for "ulcerated colitis." Id. at 9. Petitioner, in his physical examination of Patient E.S., noted that her skin texture was poor and she appeared dehydrated. Her heart rate was 100. He noted that her lower lung fields had marked generalized consolidation consistent with the possibility of pneumonia in both lungs. He also noted her abdomen was markedly tender with distension and hyperactive bowel sounds. I.G. Ex. 6 at 5. He noted, on her progress report, that she had been treated at Deaconess for "pseudo membranous ulcerated colitis" with "apparent improvement."21/ I.G. Ex. 6 at 25.

Petitioner saw the patient four times the day she was admitted. Tr. 900. Petitioner stated that her medications included Theophylline, Levothyroxine, Berocca-Plus, Naprosyn, Spironolactone, Brethine, Donnatal, Furosemide and Lanoxin. Tr. 900; I.G. Ex. 6 at 28. He also started her on intravenous (IV) fluids, and began treating her with penicillin. Id. He ordered a blood count, chemistries, and electrolyte and blood gas studies. He did not order cultures. Her WBC was 12,000. I.G. Ex. 1 at 10. After receiving the initial results, he temporarily removed her from the Theophylline. Tr. 900. A chest x-ray showed emphysema but no pneumonia. I.G. Ex. 6 at 24.

On March 30, Petitioner noted that Patient E.S. was not doing well and was "very fragile." Her WBC had increased to 14,800, and there was an increased frequency of stools. I.G. Ex. 6 at 25. She was started on injections of Bicillin. By March 31, the WBC had increased to

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21/ Pseudomembranous colitis (or pseudomembranous enterocolitis), for which Patient E.S. was treated at Deaconess, is not the same disease as that listed by Petitioner in his physical examination report and final report -- pseudomembranous ulcerative colitis. They are different conditions which require different diagnoses and treatments. Tr. 516-18, 663. Also, some of the early PRO reports mistakenly refer to the condition as pseudomonas. However, by whatever name the parties used, it appears that they meant to refer to the disease pseudomembranous colitis. Also, as all parties agree that the condition at issue is "pseudomembranous colitis," that is the term I will use here. None of the parties have argued that they have relied, to their detriment, on the mistaken usage.

20,500. Petitioner noted that she did not feel well, but bowel functions were normal. The records indicate she had four documented stools. He ordered an injection of ACTH, a steroid, and changed her diet from regular to a buttermilk and yogurt diet. I.G. Ex. 6 at 25. There was also a consultation done with Dr. Terry Gehlhausen, and his diagnosis was fever and diarrhea of unknown origins. He recommended that her multiple medications be reduced. His recommendation was to:

> Significantly reduce the patients [sic] [Patient E.S.] medications including Vicon C capsules, Klotrix, Furosemide, Donnatal, Brethine, Spironolactone, Naprosyn, Berocca Plus. Give further consideration to the necessity of Lanoxin in light of an apparent normal size heart and apparent normal sinus rhythm. [C]onsider the absolute necessity of Theophylline in light of her diarrhea and lack of current dyspnea and shortness of breath. Consider the necessity of Levothyroxine in light of the patient's past known history and documented thyroid function test.

He also recommended a thyroid function test if not done recently, a current SMAC, and an electrocardiogram. He questioned the necessity to repeat ACTH injections and suggested consideration of lab tests on the sputum, a urinalysis, and a flat plate of the abdomen if the pain continued. I.G. Ex. 6 at 6-7. The hospital records show that Petitioner did not order any of the tests and did not discontinue the ACTH, Theophylline, Berocca Plus, Brethine, Donnatal, Furosemide, or Lanoxin. See generally, I.G. Ex. 6 at 10-55.

By April 1, Patient E.S.'s WBC was up to 22,700, and she was having more frequent bowel movements -- 13 documented stools in one day. Petitioner discontinued the Naprosyn and Vancomycin was ordered late that evening. On April 2, her WBC increased to 40,600. She was having almost constant bowel movements and complaining of abdominal pain. Petitioner ordered blood cultures and discontinued the Septra and Aldactone. He ordered insulin, Immodium, ACTH, and Vancomycin. On April 3, her WBC was 44,200, and she had three bowel movements. Potassium was eliminated from the IV, and she was given ACTH, a shot of Bicillin, Immodium, and Lomotil. Petitioner noted that her condition was critical, her abdomen distended, and she was in respiratory failure. I.G. Ex. 6 at 25-32.

By April 4, her WBC was 49,200. She had almost constant diarrhea and was in critical condition. Blood and stool

cultures were ordered but the results were not available before her death that evening. Permission for an autopsy was not obtained due to her husband's illness. Petitioner listed the final diagnosis as septicemia, respiratory failure, and pseudomembranous ulcerative colitis. I.G. Ex. 6 at 31-32, 52, 57, 61.

The I.G. alleges that Petitioner "grossly and flagrantly" violated his section 1156 obligation to provide care for Patient E.S. that meets professionally recognized standards of health care. The I.G. asserts that cultures and antibiotic therapy should have been performed sooner, and the patient was not adequately evaluated and treated. In support of his determination to exclude, he introduced four expert witnesses: 1) Peter H. Livingston, M.D., Medical Director of the PRO, Tr. 28; 2) Alan Arkush, D.O., a general surgeon practicing in Indianapolis, Tr. 211-13; 3) Jessie Cooperider, D.O., a general practitioner in Tipton, Indiana, a small city in a county of 16,000, with experience in geriatric care and medical director of three nursing facilities, Tr. 460-62; and 4) Donald Snider, M.D., a surgeon and general practitioner in Vincennes, Indiana, a town of 20,000, Tr. 511-12. Drs. Arkush, Cooperider, and Snider are also associated with the PRO as members of the Quality Committee or Physician Reviewers.

Petitioner asserts that, considering the circumstances of Patient E.S.'s previous hospital admissions and the difficulty in diagnosing and treating pseudomembranous colitis, his treatment of Patient E.S. was within the professional standards for family physicians. Further, he contends that his treatment did not cause her harm because nothing could have saved her life. Petitioner called several witnesses to testify as to the quality of his care with respect to Patient E.S. (and the 15 additional cases discussed later in this decision): 1) Herman F. Rusche, M.D., a board certified gastroenterologist practicing in Evansville, Indiana, who treated Patient E.S. at Deaconess, Tr. 649-50; 2) Bruce Brink, D.O., a family practitioner in Princeton, Indiana, 12 miles from Oakland City, who occasionally shares patients with Petitioner, Tr. 671-72, 682; 3) Terry Gehlhausen, D.O., a board certified family practitioner in Oakland City, Indiana, who fills in for Petitioner when he is unavailable (and performed a consultation on Patient E.S. during the last hospitalization), Tr. 706, 744; 4) Debra Pentz Wayne, D.O., a third year family practice resident at Deaconess and friend of Petitioner, Tr. 749-753; 5) William Charles Houser, M.D., board certified in pulmonary disease, critical care, and internal medicine, who practices in Evansville, Indiana,

and also treated Patient E.S. at Deaconess, Tr. 759-66; 6) Richard John Noveroske, M.D., a radiologist at Wirth. Tr. 789-92; 7) Don V. Elsoff, M.D., a general internist and Vice President of Medical Affairs at St. Mary's Hospital in Evansville, Indiana, Tr. 795-97; and 8) Kevin Young, M.D., a board certified cardiologist practicing in Evansville, Indiana, who treated several of the 15 additional cases, Tr. 841.

The I.G's case is premised on several alleged actions or failures to act on the part of Petitioner with respect to his treatment of Patient E.S. I shall first discuss each of the alleged actions and then consider whether, as a whole, they support a finding that Petitioner's care of Patient E.S. was "gross and flagrant" (that is, whether it was in violation of his obligation to provide care of the requisite quality and, if so, whether the violation placed Patient E.S. in imminent danger or unnecessarily in a high risk situation).

1. Petitioner Failed To Order Cultures At The Time Of Admission.

Petitioner's original diagnosis, on admittance, was septicemia. Tr. 476; I.G. Ex. 1 at 1. Septicemia refers to a condition of having bacteria in the bloodstream and an infection somewhere in the body. Tr. 230, 476. Patient E.S.'s WBC was elevated on admission and rose daily during her last hospital stay. Tr. 480-81. This high WBC indicated septicemia which continued to worsen. Tr. 252-54, 481. Drs. Arkush, Cooperider, Snider, and Houser testified that the first step in treating septicemia is to obtain cultures and sensitivities of the blood, urine, stool, sputum, and any open wound to diagnose the cause and determine the appropriate treatment. Tr. 230-31, 476, 535-36, 771-72. Also, if a lab is not notified to use special handling, test results may be inaccurate if blood cultures are not obtained before beginning antibiotic treatment as the antibiotics may inhibit the growth on the cultures. Tr. 288, 478, 537.

Petitioner immediately started Patient E.S. on antibiotics but did not order cultures of blood, urine, stool, or sputum upon admission, even though he listed septicemia as both his provisional and final diagnosis. I.G. Ex. 6 at 1, 61. Blood cultures were not ordered until April 2 and 4, and a stool culture was not done until April 4. Tr. 287, 477-78, 536; I.G. Ex. 6 at 30-32. None of them showed the presence of pseudomembranous colitis. However, a review of the blood chart did not show special handling to compensate for the antibiotics.

Tr. 537, 904. More importantly, Dr. Cooperider noted that the prime test for pseudomembranous colitis is a titer, not a stool culture. Tr. 479. Just weeks before, the doctors at Deaconess required the results of a flexible sigmoidoscopy to make the diagnosis for pseudomembranous colitis.

Petitioner argues that he did not order cultures upon admission because he had access to the tests and cultures done while Patient E.S. was at Deaconess, and they were negative. Tr. 902-03. Also, he notes that, as the patient had already had extensive antibiotic therapy, any results from blood culture tests would already have been compromised. Lastly, he relies on Drs. Rusche and Houser who commented that studies are not always the first step and may not show anything in circumstances such as these. Tr. 667-69, 772-73.

I do not find these reasons persuasive. As the I.G. notes, reliance on tests taken during a previous hospital stay, in this case between March 5 and 22, may be useful for their history of the patient's illnesses, but are not definitive in diagnosing the problems in the current hospitalization. Also, Petitioner was aware that the flexible sigmoid exam done at Deaconess did indicate the presence of pseudomembranous colitis. In addition, the fact that tests may not always give correct results does not mean that they should not be done or that attempts to determine the source of infection should not be made. As noted, Petitioner did not order the first blood culture until April 2.

Further, Petitioner ignored the March 31 recommendations of Dr. Gehlhausen to obtain a sputum culture and an urinalysis. Petitioner admitted on two occasions that, on hindsight, he should have ordered cultures on the first day and that it was "a good question" as to why he didn't culture the sputum. Tr. 904; I.G. Ex. 2 at 21. Even Dr. Elsoff, one of Petitioner's witnesses testified that he "would have liked to have seen blood cultures done a little earlier . . . ." Tr. 822. The failure to follow up on the initial diagnosis of septicemia with proper testing, especially in light of a recommendation to do so, and Petitioner's admissions that he does not know why he did not test, is a violation of the professionally recognized standards of care. Further, by treating Patient E.S. with several antibiotics for several days before performing any tests to determine the cause and, therefore, the appropriate treatment (and by failing to request special handling), he unnecessarily jeopardized the possibility that these tests would have indicated anything useful.

2. Petitioner Began Empiric Treatment Of Sepsis Without A Diagnosis.

As noted, Drs. Arkush, Cooperider, Snider, and Houser testified that the cause of sepsis should be determined before prescribing antibiotics. This was especially crucial with this patient, because any antibiotic other than Vancomycin or Flagyl could have caused a relapse of her pseudomembranous colitis. Tr. 232-33. Patient E.S. was treated at Deaconess for pseudomembranous colitis, and Petitioner testified that he "was trying to avoid causing a recurrence of the pseudomembranous colitis." Tr. 899. Nevertheless, he prescribed both Septra and Bicillin before ordering any tests. Tr. 235-37, 539. Drs. Arkush, Cooperider, and Snider testified that neither of these antibiotics were indicated and may have been harmful because pseudomembranous colitis is a possible adverse reaction to Septra, a broad spectrum antibiotic, and Bicillin, a penicillin used for specific pulmonary infections. Tr. 235-37, 482, 539. Drs. Arkush and Cooperider testified that there was no indication for them, and thus, it was inappropriate to prescribe these antibiotics. To do so, they continued, was a violation of the professionally recognized standards of care and was potentially harmful to Patient E.S. Tr. 241-2; see Tr. 474.

Petitioner's argument that he prescribed Septra and Bicillin soon after admission because they were the least likely to cause a relapse of pseudomembranous colitis is difficult to reconcile with his argument that he was aware of her previous treatment for this disease and her symptoms on admission. Petitioner's explanation of why he prescribed Bicillin and Septra is illuminating. He told the Sanction Committee that he "hoped they would do some good, and wouldn't cause a relapse of the colitis problem." I.G. Ex. 2 at 12. Therefore, not only did he fail to determine the cause of the sepsis before prescribing the antibiotics, but he prescribed antibiotics which could cause or exacerbate a relapse of pseudomembranous colitis (while believing that they would not). In making this finding, I note that Dr. Houser testified that prescribing these drugs would not necessarily worsen the disease once established, although he acknowledged that it was possible. Tr. 782.

3. Petitioner Used ACTH And Solumedrol In A Septic Patient.

Petitioner prescribed ACTH (adrenal-caricoltropic hormone), an anti-inflammatory agent, throughout Patient E.S.'s last hospitalization. ACTH is a steroid which

stimulates the adrenal cortex to produce cortisol. Tr. 484; I.G. Ex. 6 at 28-31. As Petitioner admits, there was no medical indication for the use of this drug. He explained to the PRO that in older patients, steroids could give the adrenal glands a "a little boost. It seems to work." I.G. Ex. 22 at 6. Dr. Gehlhausen, the consulting physician, even questioned its continued use. Dr. Arkush testified that he disagreed with Petitioner's assertion that ACTH could be useful. He stated that ACTH actually inhibits the body's ability to fight infection and may promote infection. Tr. 257, 332. Drs. Arkush, Cooperider, and Snider testified that prescribing ACTH for Patient E.S. was not appropriate for this patient and was a violation of the professionally recognized standards of care.22/ Tr. 258, 485, 540-41.

Petitioner also prescribed Solumedrol, another type of cortisone, which is also an anti-inflammatory agent, and which is contraindicated in treating sepsis. Tr. 281-82. See I.G. Exs. 6 at 31, 40 at 11 (the PHYSICIANS' DESK REFERENCE (Edward R. Barnhart 1987) (PDR)). The evidence regarding the prescription of these drugs indicates that Petitioner does not understand the effects of, or reasons for steroid use.

4. Petitioner Failed To Treat Patient E.S.'s Dehydration.

According to Petitioner's history and physical examination charts of Patient E.S., she was dehydrated upon admission. I.G. Ex. 6 at 4-5. Although Petitioner started the patient on IV fluids, he decreased the IV fluid rate by half on April 1, at a time when her fluid intake and outtake indicated that she was becoming more dehydrated. Tr. 244-446; I.G. Ex. 6 at 29. This, Drs. Arkush, Cooperider, and Snider testified, failed to meet the professionally recognized standards of care. Tr. 246, 495, 534.

Further, Petitioner continued the prescription of Lasix, a diuretic, upon admission, for a patient whose dehydration was increasing. He also prescribed Spironolactone, another diuretic, for this patient. There is no rationale given for these prescriptions. Drs. Snider and Cooperider stated that Lasix, which is

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22/ Dr. Arkush also stated that the prescription of Prednisone, another anti-inflammatory, would exacerbate the body's inability to fight the infection and its use did not meet professionally recognized standards of care. Tr. 271.

used to eliminate excess fluid from the body, was inappropriate for Patient E.S. Tr. 496; 533-35. They further testified that the use of these prescriptions by Petitioner represented a failure to meet professionally recognized standards of care. Id.23/

5. Petitioner Failed To Evaluate Or Properly Treat the Patient's Abdominal Condition.

The I.G. argues that Petitioner failed to diagnose or properly treat Patient E.S's abdominal condition. On admission, Petitioner noted that Patient E.S.'s abdomen was markedly tender and distended, and bowel sounds were hyperactive. I.G. Ex. 6 at 5. He told the PRO that she "came back to the hospital very weak and with diarrhea." I.G. Ex. 2 at 22. Petitioner stated that he was aware of her recent history of treatment at Deaconess and had access to the tests done there. His physical examination report included "possible relapse of pseudomembranous ulcerative colitis." Tr. 899; I.G. Ex. 6 at 5. Also, Patient E.S. had six stools on March 30. Tr. 485; I.G. Ex. 6 at 37. Thus, Petitioner had ample reason to be aware that there were abdominal problems and their probable cause. Drs. Arkush, Cooperider, and Houser testified that, had they been the admitting physician, their preliminary diagnoses would have been a reoccurrence of the pseudomembranous colitis. Tr. 230, 470, 658. Also, Drs. Arkush, Cooperider, Snider, and Rusche testified that there were several diagnostic tests which could be used to obtain a positive diagnosis of this disease. Tr. 220-21, 487, 517-18, 659.

Petitioner asserts that he did not initially test or treat her for pseudomembranous colitis because: 1) the tests performed at Deaconess were negative; 2) she "presumably had recovered;" and 3) she did not have diarrhea until April 1. P. Br. at 17-19. However, the evidence shows that Petitioner was aware of Patient E.S.'s diarrhea and that it was one of her complaints on admission. I.G. Ex. 6 at 58. Also, as noted above, Petitioner ordered almost no cultures and performed no diagnostic tests to confirm his preliminary diagnoses. Further, if Petitioner had access to her Deaconess hospital records, he should have known that treatment

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23/ Drs. Snider and Cooperider also noted, that although the admitting nurse noted that Patient E.S. had lost fourteen pounds since her prior hospitalization, Petitioner made no attempt to address the patient's increased nutritional needs by using, for example, a feeding tube. Tr. 493-94, 531 See I.G. Ex. 6 at 9.

continued for pseudomembranous colitis after she was dismissed from Deaconess, so presumably she had not fully recovered.24/ Nor is there any evidence that Petitioner made any attempt to contact or consult with either Dr. Rusche or Dr. Houser, who treated Patient E.S. at Deaconess, although he was aware of the prior hospitalization. Tr. 899, 783-84, 905. Also, he did not obtain a gastroenterology consultation, although he admitted to the PRO Sanction Committee that one was available. I.G. Ex. 2 at 32-33.

Based upon the cumulative evidence, Petitioner's assertion that he did not suspect a relapse of pseudomembranous colitis or that Patient E.S. did not have symptoms indicating a relapse on admission is not credible.25/ One chapter of Cecil's Textbook of Medicine, submitted by Petitioner, states that the clinical manifestations of this disease are diarrhea, abdominal tenderness, electrolyte imbalance and dehydration. P. Ex. 14 at 52. According to Drs. Arkush, Cooperider, Snider, Rusche, and Houser, the only effective drugs are Vancomycin and Flagyl. Tr. 226, 467, 517, 661, 779. Petitioner's own witnesses, Drs. Houser and Rusche testified that if they suspected pseudomembranous colitis, they would have restarted Vancomycin right away. Tr. 661, 770. Petitioner did not order Vancomycin until 11:30 p.m. on April 1. Tr. 258-59; I.G. Ex. 6 at 30. Drs. Houser and Rusche also stated further that had the Vancomycin been restarted sooner, it is possible that Patient E.S. might have responded to treatment. Tr. 656, 770. Drs. Arkush, Cooperider, and Snider agreed. Tr. 233, 470, 520. Petitioner's witnesses, Drs. Houser and Elsoff, agreed also that it would have been better if the Vancomycin had been started sooner. Tr. 774, 822.

24/ The I. G. asserts that Petitioner's argument regarding his access to the Deaconess tests should be disregarded because the tests are not in the record. I decline to do so because both parties have submitted evidence and relied on testimony regarding several of these tests.

25/ Petitioner argues also that he relied on the negative results of a Deaconess stool sample and that his April 4 test also was negative. This does not explain why he ignored the results of the flexible sigmoidoscopy, or why the culture for the clostridium difficile bacteria was not included in the testing.

6. Petitioner Administered Potentially Harmful Drugs To Patient E.S..

Instead of testing and treating Patient E.S. for pseudomembranous colitis, Petitioner prescribed several potentially harmful drugs for her. Drs. Arkush and Cooperider testified that giving other antibiotics, such as Septra and Bicillin, to a patient with pseudomembranous colitis, without administering Vancomycin, could worsen a patient's condition because they could kill the friendly bacteria and allow the clustrating difficile bacteria to take over. Tr. 232, 474, 781-82. Dr. Cooperider stated that these drugs are not the appropriate choice for this patient, that they were 20-30 years ago, but are "no longer drug of choice." Tr. 482-83. Dr. Houser agreed, but noted that "once you develop the problem, making it worse is really academic." Tr. 782. Dr. Arkush testified that prescribing Septra and Bicillin for this patient was a violation of professionally recognized standards of care. Tr. 241-42.

Petitioner also prescribed Lomotil and Immodium, antiperistaltic agents. Tr. 237, 489, I.G. Ex. 6 at 31. Dr. Arkush noted that by slowing down the peristalsis with Lomotil, the body keeps the bacteria inside rather than defecating it out. Tr. 238. The PDR indicates that both drugs are contraindicated and potentially harmful for patients with pseudomembranous colitis. Tr. 239-40, 268-69; I.G. Ex. 40 at 5, 9. Drs. Arkush and Cooperider testified that prescribing these drugs for Patient E.S. did not meet professionally recognized standards of care and possibly worsened her condition. Tr. 241, 491-92. See Tr. 268-70, 527-28. Petitioner's witness, Dr. Rusche, also admitted that Lomotil and Immodium theoretically could be harmful to a patient with pseudomembranous colitis. Tr. 665.

Petitioner argues that his prescription of these drugs is not a violation of the standards of care because other physicians also make that mistake.26/ He urges, again, that he should not be held to any standard other than that of a family practitioner. However, I conclude that other physicians' failings do not excuse Petitioner's. Also, although Dr. Houser testified that at a recent medical seminar, he heard that Lomotil may not cause harm in patients with pseudomembranous colitis, there is no other evidence to this effect.

26/ Dr. Rusche testified that as a gastroenterologist, he does not make that mistake, but he indicated that other physicians do. Tr. 664.

Lastly, the record shows that Petitioner prescribed Morphine Sulphate on April 2, 1988, to relieve pain. Tr. 271; I.G. Ex. 6 at 30. There is some testimony and evidence which indicates that Morphine is contraindicated for patients with pseudomembranous colitis because it may make diagnosis more difficult by masking the pain and causing constipation by slowing the intestine down. Tr. 272, 274; I.G. Ex. 40 at 7. Further, Drs. Arkush and Snider testified that the dose was too high in a patient as small as Patient E.S., and that too high a dose can cause respiratory depression and apnea. Tr. 272, 542. The nursing notes indicate that Patient E.S. had periods of apnea after taking the Morphine Sulphate. Tr. 276-77; I.G. Ex. 6 at 49. Dr. Arkush stated that the use of Morphine for this patient was not appropriate, aggravated her condition, and violated professionally recognized standards of care. Tr. 277.

I find that Petitioner's failure timely or adequately to evaluate, test, and treat Patient E.S. was a violation of professionally recognized standards of care. Although his own diagnosis indicated the possibility of a relapse of pseudomembranous colitis, he performed no diagnostic tests for it, only belatedly ordered cultures, ignored the suggestions of the consulting physician, Dr. Gehlhausen, did not obtain a consultation from an available gastroenterologist at the hospital, and failed to contact her physicians at Deaconess regarding her prior hospitalization.

Instead, he relied on results of tests from her prior hospitalization and ordered numerous drugs in an apparently reckless manner, including drugs which are specifically contraindicated and potentially dangerous for a patient in her condition and with her symptoms. Petitioner's protestations that he should be judged under the standards of a family practitioner are misplaced. Petitioner had treated the patient for many years and should have been more aware of her current condition. As Petitioner made a preliminary diagnosis of pseudomembranous colitis and had access to the Deaconess physicians, his failure to adequately evaluate or treat this patient cannot be excused by his status as a family practitioner or the fact that he had not seen this disease before. Family practitioners are able to obtain advice and consultations -- or at least look up in reference books -- diseases which they suspect or have reasons to know their patients may have or are suffering a relapse of. To find otherwise would be a disservice to other family practitioners. As Drs. Cooperider and Snider, who practice in small towns, noted, there is no difference in the standards of care between rural areas

such as Oakland and other parts of Indiana with regard to the treatment of patients with symptoms similar to those of Patient E.S. Tr. 463, 514. Thus, the fault must be Petitioner's failure to follow up on his own diagnosis. If Petitioner was not informed on evaluation and treatment of this disease, he could have asked for a consultation. If he had any concerns over the efficacy of the drugs he was prescribing, he could have consulted a PDR. Petitioner's argument that all drugs in the PDR have adverse effects has no relevance to whether the drugs he prescribed were specifically contraindicated in Patient E.S.'s condition.

Petitioner's arguments that he did not harm Patient E.S. and that nothing could have saved her is not the standard by which section 1156 cases are judged.27/ The I.G. is not required to show actual harm or that Petitioner's actions were a direct cause of Patient E.S.'s death. That is a malpractice standard which is not applicable here. Hussain at 42; cf 57 Fed. Reg. 3301 (in defining term: "professionally recognized standards of health care" agency did not adopt traditional malpractice standards). Rather, the I.G. meets his burden of proof by showing that the treatment placed the patient in imminent danger or unnecessarily in a high risk situation.

I find that the I.G. did meet this burden of proof and that Petitioner's failures placed this patient unnecessarily in a high risk situation and presented serious risk of imminent danger. It is not disputed that Patient E.S. was an extremely ill individual with multiple problems and who had spent quite a bit of time in and out of the hospital during the last several months of her life. Also, people with pseudomembranous colitis appear to have a generally poor prognosis. However, a poor prognosis and no hope for recovery are not synonymous. Dr. Elsoff testified that the death rate on relapses of older debilitated patients with this disease can be as high as 30 percent. Tr. 822. Dr. Cooperider placed survival at 50/50 when patients are well treated. Tr. 492. Dr. Rusche also testified that people do die in spite of being properly treated, but that he couldn't say with any degree of certainty what would have happened had treatment been started earlier. Tr. 655-56. But Dr. Cooperider testified that "by the treatment that he [Petitioner] provided, he virtually guaranteed that she

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27/ Also, Petitioner's witnesses testified that they do not think that Petitioner's treatment caused her any harm. Tr. 766.

would not survive." Id. Again, the standard here is not whether the treatment resulted in Patient E.S.'s death but whether it placed her in an unnecessarily high risk situation or presented serious risk of imminent danger. The key word is risk. I find that: 1) failure over a period of several days to test, evaluate, and treat this patient timely and promptly with at least one of the effective medications for a life-threatening disease; and 2) the prescription of antibiotics and other drugs which are contraindicated for that disease or which could cause a relapse, did unnecessarily place this already weakened patient in imminent danger to her health and safety and placed her unnecessarily in a high risk situation.

Consequently, I find that Petitioner's conduct was a "gross and flagrant" violation of his obligation within the meaning of section 1156 of the Act.

III. Petitioner Is Willing, But Has Demonstrated A "Lack Of Ability Substantially To Comply" With His Obligations Under Section 1156 Of The Act.

As stated earlier, section 1156 authorizes an exclusion where a physician "grossly and flagrantly" failed to provide a service to a Medicare beneficiary which meets professionally recognized standards of health care and that physician has demonstrated either an "unwillingness or a lack of ability substantially to comply" with the obligations placed on that physician by section 1156. In addition, the I.G. does not have authority to exclude unless the PRO first submits a "report and recommendation" to the I.G. and the physician is given "reasonable notice and opportunity for discussion" prior to the issuance of a notice of exclusion by the I.G. 42 U.S.C. § 1320c-5 (b)(1).

I have found that the I.G. proved that Petitioner "grossly and flagrantly" violated his obligation in one instance (the case of E.S.). I also find that the I.G. proved that Petitioner demonstrated "a lack of ability substantially to comply" in one instance (the case of Patient E.S.). In addition, the I.G. introduced evidence showing that Petitioner demonstrated "a lack of ability substantially to comply" in 15 other instances. But, the I.G. cannot rely on these 15 other cases to establish authority to exclude because he failed to prove that the PRO submitted a "report and recommendation" in any of the 15 cases and failed to prove that Petitioner was given "notice and opportunity for discussion" prior to the issuance of the Notice issued in this case. The I.G.'s February 6, 1992, Notice in this case states that the

I.G.'s authority to exclude is based on the case of Patient E.S. and "two additional cases." At the hearing, the I.G. only proceeded to prove the statutory requirements with regard to the case of Patient E.S., not with regard to the "two additional cases." Thus, on the question of whether the I.G. had the authority to exclude Petitioner, I have not relied on the evidence of the 15 additional cases (including the two additional cases mentioned in the Notice). I find that the I.G. did not meet his burden of proof with respect to Petitioner's willingness but that Petitioner lacks the ability "substantially to comply." In summary, the I.G. has proved that he had authority to exclude Petitioner, based solely on the case of Patient E.S.

A. The I.G. Did Not Meet His Burden Of Proof With Respect To Petitioner's "Unwillingness . . . Substantially To Comply."

The I.G. alleges that Petitioner is unwilling "substantially to comply" with his obligations. He states that this determination was based on Petitioner's alleged failure to provide documentation showing that he completed the CAP imposed by the PRO within the established time frames. The I.G. also alleges that Petitioner is unwilling to recognize and modify deficiencies in his medical practice. Petitioner denies both these allegations.

After making a determination that Petitioner's violations were a Level III of severity, the PRO Quality Committee assigned Petitioner additional interventions, including 100 percent review of his practice and 24 hours of CME on infectious diseases. The interventions were assigned by letter dated May 25, 1990, and the CME was to be completed within six months with documentation forwarded to the Quality Committee.28/ I.G. Ex. 1 at 8. By letter dated May 3, 1990, Petitioner wrote to the then Medical Director of the PRO stating that he had "acquired a very adequate knowledge of infectious disease," and attached certificates of seminars he had attended between 1976 and 1983. I.G. Ex. 43 at 76. Despite Dr. Livingston meeting with Petitioner in September 1991 and requesting the documentation, Petitioner did not submit any proof of compliance until December 19, 1991, two

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28/ By letter dated November 28, 1990, the Sanction Committee affirmed the previously assigned CME requirement and gave Petitioner 60 days to comply. I.G. Ex. 43 at 94.

months after the PRO had forwarded the case to the I.G.29/ Tr. 64. That documentation, which was sent to the I.G., consisted of a printout from the American Osteopathic Association (AOA) which shows that Petitioner earned 26 hours of CME on November 25-29, 1990. A review of that printout does not indicate how many of the hours were for the study of infectious diseases.30/

Petitioner does not dispute that the CMEs were taken several days after the end of the six month period, although within the 60 days subsequently allotted by the Sanction Committee, and he has offered no proof that the documentation was ever filed with the PRO.31/ Tr. 54. Thus, the evidence supports a finding that Petitioner did not fully or timely comply with the CAP.

Petitioner asserts, however, that he has kept up to date on medicine and has regularly attended medical seminars. He has submitted certificates and brochures from some past seminars. A printout from the AOA indicates that he attended 206.5 hours of CME credits during a two year

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29/ The PRO did not forward the case to the I.G. until October 13, 1991. The I.G. argues that this documentation may not be considered by me because 42 C.F.R. § 1005.17(j) does not permit me to consider evidence of willingness and ability to enter into and complete a CAP which pertains to matters occurring after the PRO submits the case to the Secretary. As Petitioner points out, the evidence does not concern matters which occurred after the case was submitted. The CMEs, which were the "matter," were taken on November 25-29, 1990, well before the October 13, 1991, PRO submission. Therefore, it is appropriate that I consider this evidence with respect to whether the CMEs were taken. Petitioner does not seriously dispute that he failed to comply with respect to the timely filing of the documentation with the PRO. Tr. 916-17.

30 A brochure of the conference which was submitted by Petitioner indicates that lectures included the topics of sports medicine, consults in clinical medicine, current procedural terminology, and a number of lectures on infectious diseases -- treatments for viral hepatitis and rhinitis, evaluation of fluoroquinoles in infections, and several on HIV infections. P. Ex. 1 at 8.

31/ Another AOA printout submitted here by Petitioner shows that he earned seven more hours of CME during the intervention period, but I am unable to determine all the topics from the titles. See P. Ex. 1 at 8.

time period in which he was required by the AOA to obtain only 150 credits to keep his board certification. P. Ex. 1 at 8; see also P. Ex. 10. Also, Petitioner has taken at least one recent seminar on infectious diseases and others on cardiology issues -- two of the areas in which the I.G. has charged that Petitioner demonstrated an inability to comply with his obligations. P. Ex. 1 at 4. I accept these as evidence of Petitioner's willingness, because they are not related to whether Petitioner completed his CAP, and, thus, fall outside the scope of 42 C.F.R. § 1005.17(j). On that basis, I conclude that Petitioner has regularly attended CME seminars and lectures.

Petitioner also states that his knowledge of medicine is supported by the fact that a University regularly sends physician-students to him for training in family practice. Tr. 893-94. Further, several of Petitioner's witnesses testified that Petitioner is a knowledgeable and caring physician, has an excellent reputation, is a patient advocate, and is loved by his patients. See, e.g., Tr. 657 (Dr. Rusche), Tr. 767 (Dr. Houser), Tr. 682 (Dr. Brink), Tr. 792 (Dr. Noveroske), Tr. 750 (Dr. Wayne).

The I.G. also argues that Petitioner's refusal to recognize quality of care issues in his handling of Patient E.S. and the 15 additional cases indicates his unwillingness to meet professionally recognized standards of care. Petitioner responds that he did not fail in his duty to these patients. As discussed previously in this decision, the evidence regarding the 15 additional cases will not be considered on this issue. However, I have already determined that Petitioner's treatment of Patient E.S., taken as a whole, was "gross and flagrant." Petitioner's refusal to acknowledge that there were any problems in his care of this patient and his delay in responding to the CAP concerns me and indicates a certain reluctance to recognize and correct the deficiencies in his practice. Nevertheless, I find that, in spite of his limitations, he is willing to comply with his obligations. In making this finding, I have not relied on any of the allegations made by either the PRO or Petitioner regarding several of his responses to PRO letters and notices. It appears that Petitioner responded promptly at the early review levels, but as the case progressed there were some problems and miscommunications, and Petitioner apparently became upset and his correspondence became somewhat abusive because the PRO did not agree with his responses or answer all of his questions as he would have wished. However, as a whole, the record shows that Petitioner does regularly attend seminars to update

his medical knowledge and that his reputation among his peers is of a caring family practitioner. Therefore, I find that the I.G. has not met his burden of proof on this issue.

B. Petitioner Has Demonstrated "A Lack Of Ability Substantially To Comply" With His Obligation To Provide Treatment That Meets Professionally Recognized Standards Of Health Care.

The I.G.'s Notice in this case states that Petitioner's inability is demonstrated by his handling of the case of Patient E.S., Petitioner's written responses to the concerns identified by the PRO, and Petitioner's responses during his November 20, 1990, meeting with the PRO about the handling of Patient E.S.

The I.G. argues that Petitioner's treatment of Patient E.S. evidences several examples of mismanagement, which, in turn, betrays Petitioner's lack of knowledge in certain basic areas of medical care.

Petitioner argues that his treatment of Patient E.S. caused no harm. However, even accepting this assertion as true, the lack of harm to a patient does not prove that Petitioner's medical practices conformed to professionally recognized standards, nor does it prove that he is able to conform his practice to that standard.

Based on the evidence in the record, Petitioner's responses to that evidence, and the arguments of the parties, I find and conclude that Petitioner demonstrated a "lack of ability substantially to comply" with his obligation to provide care that meets "professionally recognized standards" in the case of Patient E.S. This finding and conclusion is based on the reasons set forth in part II-B of this decision which analyzes the proof of Petitioner's "gross and flagrant" violation.

Obviously, this is not to say that a finding of "gross and flagrant" would always be sufficient, on its own, to support a "lack of ability substantially to comply" finding. However, in this case, based on the evidence presented by the I.G. as to Patient E.S., I conclude that Petitioner's treatment demonstrates that he lacks the ability: 1) to evaluate or treat the cause of infectious processes; 2) to understand the proper use of steroids; 3) to prescribe the appropriate and least harmful medications for a patient's conditions; 4) to timely order and evaluate laboratory data or to perform diagnostic tests when indicated; and 5) to manage fluid

intake in a patient who requires hydration. In fact, the I.G. proved that Petitioner's treatment of patient E.S. was even inconsistent with Petitioner's own diagnosis.

Although Petitioner has expressed a willingness to comply with his obligations under the Act, and has made an effort to take frequent medical seminars, such willingness is inadequate protection for program beneficiaries and recipients when he lacks either the basic medical knowledge to comply or to recognize his inability to comply. Mere credentials do not demonstrate an ability to comply. Also, as noted previously, I find troublesome Petitioner's refusal to acknowledge that he made any errors in judgement with respect to his treatment of Patient E.S. See William Anderson, M.D., DHHS Appeals Council Docket No. HIX-000-84-7011 at 30 (January 24, 1990). Finally, although Petitioner has introduced evidence consisting of praise from current and former patients, popularity is not relevant to the issues in this case.

For the above reasons, I find that Petitioner is unable to comply with his obligations under the Act. Petitioner has exhibited serious errors in the diagnosis, assessment, and treatment of Patient E.S., which, in turn, indicate a lack of important, fundamental knowledge that is essential in meeting his obligations under the Act. Petitioner has demonstrated a willingness to learn and has begun to take steps to improve his knowledge in areas in which he has particular weaknesses.

IV. The One Year Exclusion Imposed And Directed Against Petitioner Is Reasonable And Comports With The Remedial Purposes Of The Act.

The I.G. is authorized by section 1156 of the Act to impose and direct a sanction against Petitioner. The I.G.'s authority originated with the PRO's recommendations and were based on the evidence which the PRO provided which indicated that Petitioner committed a "gross and flagrant" violation. After reviewing the PRO's recommendation and supporting materials, the I.G. determined to increase the PRO's proposed exclusion from six months to one year.

Pursuant to 42 C.F.R. § 1004.90(d), the I.G. considered the following factors in arriving at the appropriate proposed sanction:

> (1) the recommendation of the PRO (the recommended six month exclusion);

2) the type of offense ("gross and flagrant" violation of obligations in two instances involving one patient);

3) the severity of the offense (the two above instances presented imminent danger to the health, safety, or well-being of the beneficiary or placed the beneficiary unnecessarily in a high-risk situation);

4) the previous sanction record of the practitioner (none known);

5) the availability of alternative sources of services in the community (other physicians practice in the area);

6) any prior problems the Medicare carrier or intermediary has had with the practitioner (none identified);

7) whether the practitioner is "unable or unwilling" to comply substantially with the obligations including whether, prior to the PRO's recommendation, the practitioner entered into a corrective action plan (CAP) and, if so, whether he or she successfully completed that plan (I.G. determined that unwillingness was demonstrated by failure to complete timely the CAP or to provide documentation of completion and inability demonstrated by responses to the PRO and by the PRO's identification of problems of care in two additional cases);32/ and

8) any other matters relevant to the particular case (I.G. unaware of other relevant issues).

I.G. Ex. 3 at 1-2.

While the above factors are those which, by regulation, the I.G. must consider before imposing a sanction and are not binding on me because this is a de novo hearing, they are relevant in determining the reasonableness of the length of the exclusion. Olufemi Okonuren, M.D., DAB 1319 at 14 (1992). I have already determined that the I.G. has met his burden of proof with respect to the

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32/ This subsection (7) was amended January 29, 1992. 57 Fed. Reg. 3350. I have already ruled that these new regulations are applicable to this proceeding. Note 8 supra.

"gross and flagrant" violation, the severity of the offense, and Petitioner's inability "substantially to comply." Also, as noted previously in part I-B, I have determined to consider the evidence presented by the 15 additional cases on the issue of the reasonableness of the exclusion and on the "serious risk" issue. Bernardo G. Bilang, M.D., DAB 1295 at 6-9 (1992); See Robert Matesic, R.Ph., DAB 1327 at 12 (1992). Therefore, the above findings are augmented here by the additional cases which I find establish patterns of inadequate medical care in several areas. As discussed below, these patterns include Petitioner's inability to adequately evaluate and treat patients, specifically with regard to the diagnosis of abnormal laboratory results, the prescription of appropriate medications, evaluation and intervention of patients suffering acute cardiac changes, and the inability to manage fluid intake in patients requiring hydration or fluid management.

A. Petitioner Lacks The Ability To Diagnose The Causes Of Patients' Abnormal Laboratory Results And To Address These Results Adequately.

The I.G. argues that Petitioner's treatment of the additional patients reveals many instances in which he failed properly to diagnose and treat conditions which produced abnormal laboratory test results in the patients. The I.G. alleges that, in several cases, Petitioner either failed to diagnose the cause of an infection or failed to recognize that an infection might be present. In other cases, the I.G. argues that Petitioner failed to identify the source of possible internal bleeding. Finally, the I.G. points to several instances in which Petitioner allegedly failed to institute the appropriate treatment in the face of abnormal test results.

The I.G. presented evidence that Petitioner failed to isolate the cause of elevated WBC counts in the cases of D.R. and C.H. As noted previously, an elevated WBC may be a sign that the patient is suffering from an infection. In both instances, Petitioner prescribed antibiotics without first having identified the source of infection. In the case of D.R., diagnostic tests, such as urinalysis and ultrasound, were negative, Tr. 364-65; in the case of C.H., Petitioner did not perform any diagnostic tests before instituting antibiotic therapy. Tr. 352-53; I.G. Br. at 40. The I.G.'s experts testified that it was inappropriate to prescribe antibiotics as "shotgun therapy" without knowing the source of infection. Tr. 354. Petitioner argues that Patient D.R. had other diagnostic tests prior to his admission to the

swing bed unit and that Patient C.H. was suffering from infection and that his treatment was successful in reducing her WBC and other symptoms, such as fever. P.R. Br. at 8-9. Petitioner does not contend that he, in fact, diagnosed the cause of the patients' infections. I conclude that Petitioner's failure to isolate the source of infection in Patients D.R. and C.H. prior to instituting antibiotic therapy constituted treatment that was not in accordance with professionally recognized standards.

In addition to the cases in which Petitioner failed to identify the source of patient infections, the I.G. argues that, in several cases, Petitioner failed to identify the cause of test results which suggested that patients were experiencing blood loss. For example, the I.G.'s expert, Dr. Arkush, testified that Patient C.H. had a low hemoglobin count throughout her hospital stay. Tr. 349-50. While Petitioner ordered a test of the patient's stool for occult blood, he apparently discharged the patient before obtaining the results of the test. Tr. 351. The test result might have helped to identify the source of the low hemoglobin. Tr. 350. Another of the I.G.'s experts, Dr. Snider, was of the opinion that Petitioner's failure to identify the cause of C.H.'s low hemoglobin placed the patient unnecessarily in a high risk situation. Tr. 558. Petitioner offered no evidence to rebut the I.G.'s contentions.

Petitioner's treatment of Patient V.E. also presents questions involving the results of the stool for occult blood test. V.E.'s medical records showed two positive stool for occult blood test results, indicating that there was blood in the stool. I.G. Ex. 18 at 17, 59. Dr. Snider testified that it would have been appropriate to do further diagnostic tests, such as endoscopy of the stomach and colon or X-ray of the stomach and colon, to determine the source of the blood in the stool. Tr. 585. Petitioner failed to order these diagnostic tests or to make any evaluation of the cause. Id. Petitioner offered no evidence to rebut these contentions.

The I.G. similarly alleges that in the case of Patient B.B., Petitioner failed to perform the appropriate diagnostic tests to determine the cause of the patient's low hemoglobin count. The patient's chart reflects Petitioner's belief that B.B.'s anemia might have been due to gastrointestinal (GI) tract bleeding. I.G. Ex. 31 at 7. Dr. Snider testified that Petitioner failed to order an endoscopy or X-ray of the stomach and duodenum, which, in his opinion, was a violation of professionally recognized standards of care. Tr. 608-11. Petitioner

argues that B.B. could not have tolerated these tests because of her physical handicaps. P. Br. at 37-38. However, Petitioner has not argued that he diagnosed the cause of B.B.'s abnormal test results, nor has he shown that he could not have performed other tests that might have revealed the cause of those results. Therefore, I conclude that by failing to identify the source of the low hemoglobin results in Patients C.H. and B.B. and the cause of the positive stool for occult blood test in V.E., Petitioner failed to provide treatment in accord with professionally recognized standards.

In the case of Patient E.R., the I.G. alleges that Petitioner failed to order the appropriate diagnostic test to determine the cause of the unresponsiveness for which the patient was admitted. The I.G.'s expert, Dr. Snider, testified that the required evaluation in the case of a patient in an acute neurological state is a computerized axial tomography (CAT) scan of the brain. Tr. 602. Petitioner argues that the patient was suffering from digitalis intoxication and not from a cerebrovascular accident (CVA or stroke). P. R.Br. at 9. Petitioner argues that the patient had suffered a CVA some time previously to the admission at issue here. Id. However, given a patient with a history of stroke disease, it does not appear that Petitioner could be certain of the cause of the patient's neurological changes without using a CAT scan to rule out definitively the presence of a stroke or subdural hematoma. Therefore, I conclude that in failing to order a CAT scan of E.R.'s brain, Petitioner failed to provide care that meets professionally recognized standards.

In addition to cases in which Petitioner failed to perform the appropriate tests or take other steps to diagnose the cause of abnormal laboratory results or other clinical symptoms, the I.G. alleges that in several cases Petitioner failed to intervene with appropriate treatments when presented with abnormal test results. In the cases of Patients D.R. and A.M., who both suffered from diabetes, the I.G. alleges that Petitioner failed to address the patients' elevated blood glucose levels. The I.G.'s expert, Dr. Arkush, testified that, as to both patients, their blood glucose levels remained elevated throughout their hospital stays. Tr. 358-59, 378. In the case of D.R., Dr. Arkush opined that insufficient insulin was prescribed. Tr. 369. In the case of A.M., he stated that the diet prescribed by Petitioner was excessive to control blood sugar levels in a diabetic patient. Tr. 380. Petitioner argues that Patient D.R. was extremely noncompliant with his diet and other measures to control his diabetes. P. Br. at 40-41.

However, if Petitioner was aware that this was the case, presumably he should have been aware of the need to prescribe additional insulin. As to Patient A.M., Petitioner did not present any evidence to rebut the I.G.'s contention that the patient's blood sugar was not adequately controlled. Therefore, I conclude that Petitioner's failure to control the blood glucose levels in these patients constitutes a failure to provide care that meets professionally recognized standards.

In the case of Patient A.A., the I.G. alleges that Petitioner failed to diagnose and treat a likely infection. The I.G.'s expert opined that two urinalyses both showed signs of a urinary tract infection because bacteria were present in the urine. Yet Petitioner failed to order a culture and sensitivity on the urine or to institute antibiotic therapy. Petitioner argues that A.A. had a weakness of the bladder known as a cystocele, which could have caused her urine to be contaminated by bacteria even if no infection was present. P. Br. at 35. Petitioner's expert, Dr. Brink, testified that A.A. did not have other signs of a urinary tract infection, such as elevated temperature, chills, painful urination, frequent urination, or elevated WBC. Tr. 677-78. However, Petitioner's contention is not borne out by the medical record, which indicates that A.A. was complaining of frequent urination on admission. I.G. Ex. 25 at 1, 4. As noted, Dr. Brink acknowledged that frequent urination could be symptoms of a urinary tract infection. Therefore, I conclude that Petitioner's failure to either diagnose or definitively rule out a urinary tract infection in Patient A.A. constitutes a failure to provide care that meets professionally recognized standards.

In the case of Patient C.H., the I.G. alleges that Petitioner failed to intervene to correct the patient's low sodium level. The patient's blood chemistry report indicated that the patient had low serum sodium, which continued to fall throughout her hospital stay. Tr. 342-45, 549; I.G. Ex. 35. Dr. Snider testified that the appropriate treatment in such a case was fluid restriction or sodium infusion. Tr. 550. Yet, Petitioner did not institute either of these treatments. Petitioner did not offer any evidence to rebut the I.G.'s contentions regarding his treatment of C.H.'s low serum sodium level. I conclude that Petitioner's failure to institute either fluid restriction or sodium infusion to reverse C.H.'s falling sodium levels constitutes a failure to provide care that meets professionally recognized standards.

The I.G. alleges that Petitioner failed to meet professionally recognized standards of care in his treatment of Patient W.H. because he failed to address the patient's low blood pressure (hypotension). The I.G.'s expert, Dr. Arkush, testified that all but one of five blood pressure readings taken during her hospital admission indicated that the patient was hypotensive. Tr. 422. Petitioner contends that the patient was not hypotensive at all. P. Br. at 30. Petitioner's expert, Dr. Young, testified that he had examined W.H. subsequent to her hospitalization and found that blood pressure readings in the patient's right arm were inaccurate due to a blockage of the subclavian artery, but that blood pressure readings in the left arm were normal. Tr. 843-44. However, if Petitioner was aware that the patient's low blood pressure readings were inaccurate, he failed to document this in the patient's chart. Tr. 429, 875. The I.G.'s expert, Dr. Arkush, testified that Petitioner's failure to address the low blood pressure readings anywhere in the chart was itself inappropriate care. Tr. 429. For this reason, I conclude that, even if Patient W.H. was not in fact hypotensive, Petitioner's failure to document the fact that her blood pressure readings were inaccurate is not in accordance with professionally recognized standards of health care.

The I.G. has proved, as to a number of cases, that Petitioner failed to provide care that meets professionally recognized standards. The I.G. has proved a pattern of practice that indicates that Petitioner lacks the ability to diagnose the cause of abnormal laboratory test results and to intervene when indicated.

B. Petitioner Lacks The Ability To Prescribe Appropriate Medications.

The I.G. argues that Petitioner often prescribes medications that are inappropriate to treat patients' conditions. The I.G. points to a number of cases in which he alleges that Petitioner prescribed steroids inappropriately. In other cases, the I.G. contends that Petitioner failed to use IV antibiotics correctly. Finally, the I.G. cites instances where he alleges that medications were prescribed in a manner which placed the patients at risk.

The I.G. contends that, in addition to Petitioner's treatment of Patient E.S., his treatment of a number of the additional patients supports a conclusion that Petitioner does not understand the proper use of steroids. In the case of Patient N.H., who was suffering from a urinary tract infection, Petitioner prescribed the

steroid Depomedrol. Tr. 569-70; I.G. Ex. 14 at 20. The I.G.'s expert, Dr. Snider, testified that Depomedrol would inhibit the patient's resistance to infection. Tr. 570. Petitioner prescribed the steroid ACTH for Patient W.H. I.G. Ex. 16 at 16. The I.G.'s expert, Dr. Arkush, testified that ACTH was not appropriate because the patient was suffering from fractures. According to Dr. Arkush, the body needs an inflammatory response to such an injury and the steroid would inhibit the inflammatory response. Tr. 424. Petitioner prescribed Depomedrol and ACTH for Patient T.R. Tr. 330; I.G. Ex. 23 at 21. Dr. Arkush testified that Patient T.R.'s laboratory reports indicated he may have suffered a heart attack. Tr. 331. He testified that steroids are not appropriate treatment for a heart attack patient because they cause fluid retention, which may contribute to heart failure. Id.

Petitioner argues that Patients W.H. and T.R. had conditions for which steroids were appropriate treatment. For example, he asserts that W.H. had a muscle strain and T.R. was suffering from arthritis. P. R.Br. 10-11. Taking these assertions as true, nevertheless, Petitioner has failed to show that he could not have treated these conditions with some other medication that would not have posed the risks to these patients identified by the I.G.

The I.G. points to the cases of V.E., J.R., E.R., and O.B., in which he alleges that Petitioner prescribed steroids even though there was no indication for steroid use in these patients. I.G. Br. at 43. Petitioner contends, generally, that it is appropriate to treat elderly patients with steroids to alleviate their arthritis and to stimulate their adrenal glands. P. R. Br. at 10. Dr. Arkush testified that using steroids to boost adrenal glands is not efficacious. Tr. 332. Petitioner contends that steroids were appropriately used in Patient V.E. to treat progressive shortness of breath. P. R.Br. at 11. In the case of E.R., Petitioner argues that steroids were being used to treat cerebral edema. P. R.Br. at 11; I.G. Ex. 26 at 3. As to Patient O.B., Petitioner argues that steroids were appropriate to treat his severe pulmonary problems associated with pneumoconiosis. P. R.Br. at 12. Petitioner did not rebut the I.G.'s contention that there was no indication for steroids in the case of J.R. Thus, accepting Petitioner's justification for prescribing steroids for Patients V.E., E.R., and O.B., it nevertheless appears that he prescribed steroids for Patient J.R. without medical justification.

In another case involving the use of steroids, the I.G. alleges that steroids were indicated but that Petitioner failed to prescribe the treatment of choice. Patient T.P. was suffering from a condition known as idiopathic thrombocytopenia purpura (ITP), which is a low platelet count with bruising and bleeding effects. Tr. 390, 392, 394. Dr. Arkush testified that the standard treatment for ITP is to give Prednisone, a type of steroid. Tr. 394. His testimony is supported by Conn's Therapy, a recognized medical treatise, which also states that ITP is treated with Prednisone. P. Ex. 9 at 3. Petitioner prescribed ACTH and a Medrol Dose Pack for Patient T.P., rather than Prednisone. Tr. 394-95. Petitioner also ordered 10 units of platelets for the patient. Tr. 391. Dr. Arkush testified that this practice is reserved for life-threatening bleeding. Tr. 393. He testified that, in his opinion, Patient T.P. was not bleeding profusely and did not suffer a life-threatening bleed. Tr. 391, 393.

Regarding the use of steroids, the I.G. has proved that Petitioner's prescription practices failed to meet professionally recognized standards in a number of cases. Petitioner prescribed steroids in cases where the use of steroids was contraindicated due to the nature of the patients' illnesses. Petitioner failed to prescribe the recognized steroid treatment in a case where steroids were indicated. And, in at least one case, Petitioner prescribed steroids where there was no medical indication for their use.

The I.G. alleges also that Petitioner's use of other medications does not conform to professionally recognized standards. The I.G. identifies two cases involving the administration of IV antibiotics. In the case of Patient A.M., Petitioner prescribed the antibiotic Kefzol to be administered intravenously. Tr. 374; I.G. Ex. 10. Dr. Arkush testified that, in his opinion, the patient was not suffering from an infection that would respond to Kefzol, and that IV administration was not justified because there was no evidence of an overwhelming infection or that the patient was unable to tolerate oral administration. Tr. 375-76. Petitioner also ordered IV Kefzol for Patient V.E., who was suffering from renal failure. I.G. Ex. 18 at 1, 37. Dr. Snider testified that Petitioner prescribed an inappropriate dosage of Kefzol, because he prescribed it at too high a rate, given the patient's impaired kidney function. Tr. 578-79. Petitioner argues as to Patient A.M. that it was appropriate to prescribe Kefzol because a urinalysis conducted in Petitioner's office prior to the patient's admission indicated that the patient had a urinary tract

infection. P. Br. at 39. However, Petitioner did not rebut the I.G.'s contention that IV administration was not indicated for this patient. Nor did Petitioner offer any evidence to rebut the I.G.'s contentions regarding the dose of Kefzol prescribed for Patient V.E. Therefore, I conclude that in administering IV Kefzol to Patients A.M. and V.E., Petitioner failed to provide care that met professionally recognized standards.

The I.G. relies also on several cases in which he alleges that Petitioner prescribed medications in a dangerous manner or prescribed medications that were contra-indicated. For example, Petitioner prescribed Tenormin, an antihypertensive medication, for Patient W.H. I.G. Ex. 16 at 16. As discussed previously, there was some debate among the experts as to whether W.H. was hypotensive during her hospital admission. Petitioner contends that she was not. However, the I.G. argues that, even if W.H. was not hypotensive, Petitioner prescribed Tenormin in a dangerous manner. I.G. Br. at 53. Petitioner's expert, Dr. Young, testified that it would be "very dangerous" to discontinue Tenormin abruptly in a patient, such as W.H., who was suffering from atherosclerotic heart disease and had a history of a previous heart attack. Tr. 877. Yet, Petitioner discontinued Tenormin on February 22, 1990, and did not restart it until February 25th. Tr. 877-78; I.G. Ex. 16 at 14. I conclude that with respect to Patient W.H. Petitioner did not manage the use of Tenormin in accordance with professionally recognized standards.

In the cases of Patients A.M. and J.R., the I.G. argues that Petitioner prescribed medications that were contraindicated. As discussed previously, Patient A.M. was suffering from diabetes and his blood glucose levels were elevated. Tr. 378; I.G. Ex. 10 at 27. Petitioner ordered hydrochlorothiazide (HCTZ), a diuretic, for Patient A.M. Tr. 383. The I.G.'s expert testified that the use of HCTZ was inappropriate because it can elevate the blood sugar and make it more difficult to control diabetes. Tr. 384. Petitioner also prescribed Normasol M, an IV solution, for Patient A.M. Tr. 376; I.G. Ex. 10 at 27. Dr. Arkush testified that Normasol M is added to an IV solution of dextrose 5 (sugar) and water. Tr. 377. He testified that it was inappropriate to prescribe Normasol M because it would aggravate the patient's diabetes. Tr. 377. Petitioner did not present any evidence to rebut these contentions. Therefore, I conclude that Petitioner's prescription of HCTZ and Normasol M for Patient A.M. did not conform to professionally recognized standards of health care.

In the case of Patient J.R., Petitioner prescribed Donnatal, a stomach sedative. I.G. Ex. 37 at 19. The I.G.'s expert testified that J.R. presented the classic symptoms of prostatism. Tr. 615. Dr. Snider opined that prescription of Donnatal was inappropriate because that medication is contraindicated in patients with prostatism. Tr. 618. Petitioner argues that he successfully treated the patient's stomach condition without an adverse effect on his prostate condition. P. R.Br. 13. Petitioner also argues that he could not treat the patient's stomach problem without using a drug that would have potential impact on the patient's other problems. Id. However, the fact that administration of Donnatal did not actually harm the patient does not change the fact that the patient was placed at risk for harm by the use of an inappropriate drug. Moreover, Petitioner presented no evidence from which I could conclude that there was no drug other than Donnatal which would have been appropriate to treat the stomach condition without aggravating the prostate condition. Therefore, I conclude that by administering Donnatal to Patient J.R., Petitioner failed to provide care that met professionally recognized standards.

The I.G. has proved, in a number of cases, that Petitioner prescribed steroids and other medications in an inappropriate manner. The I.G. has proved a pattern of prescription practices which evidences a lack of knowledge of the effects of various medications on other medical conditions from which patients may be suffering. The I.G. has proved that Petitioner engaged in a pattern of prescribing drugs in a manner that puts patients at risk.

C. Petitioner Lacks The Ability To Evaluate And Intervene Appropriately In Patients Suffering Acute Cardiac Changes.

The I.G. argues that Petitioner's treatment of a number of patients indicates that he lacks knowledge of appropriate intervention in patients whose blood chemistry or EKG test results suggest they may have suffered a heart attack. Both the I.G.'s experts and the Petitioner's expert testified that cardiac monitoring is the standard treatment for patients who may have suffered a heart attack. Tr. 327, 599, 887-88. Cardiac monitoring involves placing electrodes on the patient to constantly determine the behavior of the heart. Tr. 327, 552. Cardiac monitoring enables the physician to respond immediately to an arrhythmia which could result in sudden cardiac death. Tr. 327, 552, 599. The I.G. alleges that Petitioner failed to use cardiac monitoring where

appropriate, and that he discontinued it inappropriately in one instance where he did use it.

According to the I.G.'s experts, Patient C.H. had a number of symptoms and diagnostic test results which indicated that she might be suffering a heart attack. For example, C.H. complained of nausea and vomiting on admission. Tr. 340, 547; I.G. Ex. 35 at 7. Her blood chemistry reports showed an elevated level of CPK enzyme, which may indicate that the patient is suffering a heart attack. Tr. 341-42; I.G. Ex. 35 at 10. Additionally, the patient had two abnormal EKGs and her chest X-ray showed an enlarged heart. Tr. 345-46; I.G. Ex. at 24. The I.G.'s experts testified that Petitioner failed to treat this patient in accordance with professionally recognized standards because he failed to institute cardiac monitoring. Tr. 353. Petitioner's expert, Dr. Young, acknowledged that, if this had been his patient, he might have monitored the patient. Tr. 889.

Petitioner argues that he did not place Patient C.H. on a heart monitor because of the family's desire not to pursue an "aggressive approach." P. Br. at 31; see I.G. Ex. 35 at 3. Dr. Young testified that if the family had requested that the patient not be resuscitated, there would be no need for cardiac monitoring. Tr. 888-89. However, Drs. Cooperider and Snider noted that Petitioner had not adequately documented that the family had requested that the patient not be placed on a monitor or not be resuscitated. Tr. 458, 623-26. I agree that Petitioner should have documented more clearly that the patient's family requested that the patient not be resuscitated. Nevertheless, it appears more likely than not that Petitioner was acting in accordance with the family's wishes in not performing cardiac monitoring on Patient C.H. Therefore, I conclude that the I.G. has not proved that Petitioner failed to treat Patient C.H. in accordance with professionally recognized standards of care.

The I.G. argues that Petitioner failed to provide treatment to Patient T.R. that met professionally recognized standards of care because Petitioner failed to evaluate and treat the patient's cardiac condition. The I.G.'s expert opined that Petitioner should have instituted cardiac monitoring because the patient had two EKGs that showed an anterior myocardial infarction, time undetermined, and because his chest X-ray showed an enlarged heart. Tr. 322-23, 337. According to Dr. Arkush, these test results indicated that the patient may have been admitted with a heart attack. Tr. 325. He also testified that the patient was discharged with

bradycardia (low heart rate) and, thus, was not stable for discharge. Tr. 335-36.

Petitioner relies on the expert testimony of Dr. Young, a board-certified cardiologist, who opined that he could not see any value to cardiac monitoring in this patient, given his age and debilitated condition. Tr. 879. He testified that, in his opinion, monitoring would not reveal any information that would change the treatment options for the patient. Id. He opined that the patient's test results presented no evidence of an acute, evolving heart attack. Tr. 852. The I.G. counters that Petitioner is not a cardiologist and, so, probably would not understand whether or not the abnormal test results were evidence of a heart attack. I.G. R.Br. at 21-22. However, this argument is speculative. I find the testimony of Petitioner's expert more persuasive on this point and therefore conclude that Petitioner did not fail to provide care that met professionally recognized standards by not performing cardiac monitoring on Patient T.R.

The I.G. alleges that Petitioner failed to respond appropriately when Patient T.P. suffered severe chest pain during her hospital admission. The patient had an EKG on admission to the hospital which showed an abnormal result. Tr. 397, 402-403; I.G. Ex. 29 at 16. On the day after admission, the patient complained of severe chest pain. I.G. Ex. 29 at 35. Petitioner ordered Nitroglycerin, Benadryl, and Lasix. Dr. Arkush testified that Petitioner's orders were inappropriate because, in his view, one would have to assume the patient was having a heart attack at that point. Tr. 403. The I.G.'s expert testified that the appropriate intervention would have been an immediate EKG, treatment based on the result of the EKG, and some type of cardiac monitoring. Id. The patient was found dead in her bed later that day. Tr. 404-05; I.G. Ex. 29 at 27.

Petitioner's expert, Dr. Young, also acknowledged that it would have been reasonable to obtain an EKG at the time the patient experienced chest pain. Tr. 863. However, he opined that an EKG or cardiac monitoring would not have altered the outcome for this patient. Id. That is, in his view, the patient would likely have died anyway. In this instance, both the I.G.'s expert and Petitioner's expert agree that the appropriate intervention at the time the patient began suffering chest pain was to at least obtain an EKG, and perhaps institute cardiac monitoring, as well. Petitioner did not do this. The fact that the patient might well have died, even if he had taken the appropriate steps, does not alter the fact

that, as to this patient, Petitioner failed to provide care that met professionally recognized standards.

In the case of E.G., the I.G. alleges that Petitioner discontinued cardiac monitoring at an inappropriate stage of treatment. The patient's laboratory test results showed an elevated CPK level, her chest X-ray showed an enlarged heart, and she had two abnormal EKG reports. Tr. 593-95; I.G. Ex. 21. Petitioner ordered a cardiac monitor on May 11, 1990, and discontinued it on May 12. Tr. 596; I.G. Ex. 21 at 38-39. The patient's CPK level was elevated on the day the monitor was removed and on the following day the CPK level was even higher. Id. Dr. Snider testified that it was inappropriate to discontinue the cardiac monitor when the patient's CPK level was rising. Tr. 597.

Dr. Young, Petitioner's expert cardiologist, testified that, in his opinion, it did not appear that Patient E.G. suffered a heart attack during her admission. Tr. 854-56. He stated that the enzyme results and the EKGs were not indicative of an evolving myocardial infarction. Id. Petitioner argues that, since the patient did not suffer a heart attack, his decision to remove the heart monitor was appropriate. I conclude that it was inappropriate for Petitioner to discontinue cardiac monitoring in the face of test results that suggested the patient's cardiac condition may not have stabilized. Dr. Young testified with the benefit of hindsight. At the time Petitioner confronted the case, he could have been aware only that the patient's CPK level had not yet returned to normal. Therefore, I conclude that Petitioner's care of Patient E.G. failed to meet professionally recognized standards.

The I.G. also alleges that, as to Patients B.B. and O.B., Petitioner failed to perform the necessary and usual tests to evaluate their cardiac conditions, in the face of abnormal test results. I.G. Br. at 63. Patient B.B. had abnormal EKG, chest X-ray, and CPK results. Tr. 608-09; I.G. Ex. 31 at 19-25. Patient O.B. had an elevated CPK level. Tr. 612; I.G. Ex. 33 at 15. The I.G.'s expert testified that Petitioner failed to evaluate these patients properly because he failed to address possible cardiac conditions. Tr. 614. Petitioner argues that Patient B.B. was being treated for anemia, not cardiac problems. P. R.Br. at 16. However, this does not relieve Petitioner of the duty to address the patient's cardiac condition if laboratory results suggest this is necessary. As to Patient O.B., Petitioner argues that his abnormal CPK level was caused by a drug, Cephalosporin. P. Br. at 44; P. R.Br. at 16. However, Petitioner has offered no evidence from which I could

find that elevated CPK is a known side effect of Cephalosporin. For these reasons, I conclude that Petitioner's failure to evaluate the cardiac condition of Patients B.B. and O.B. was not in accord with professionally recognized standards of care.

The I.G. did not prove that Petitioner failed to provide care in accordance with professionally recognized standards to Patients C.H. and T.R. Nevertheless, the I.G. has proved that Petitioner's treatment of possible cardiac problems in Patients T.P., E.G., B.B., and O.B. did not meet professionally recognized standards of care. I am particularly concerned by Petitioner's apparent failure to recognize that Patient T.P. was suffering an acute heart attack and to intervene appropriately.

D. Petitioner Lacks The Ability To Manage Fluid Intake In Patients Who Require Hydration Or Fluid Restriction.

The I.G. argues that in three of the additional cases, as well as in the case of E.S., Petitioner failed to treat patients whose diagnosed conditions required fluid management, either hydration or fluid restriction, in accordance with professionally recognized standards. For example, in the case of Patient T.R., both Petitioner's admitting and final diagnoses included "acute dehydration." I.G. Ex. 23 at 1. The I.G.'s expert, Dr. Arkush, testified that the patient's clinical signs, such as his pulse, temperature, and blood pressure, did not support this diagnosis. Tr. 321. Nevertheless, assuming Patient T.R. was dehydrated, Dr. Arkush testified that Petitioner failed to treat the patient for dehydration. Tr. 336. Petitioner ordered IV fluids for the patient at the rate of 1000 ccs every 12 hours, then reduced the rate to 1000 ccs every 24 hours. Tr. 323; I.G. Ex. 23 at 21. Dr. Arkush testified that the fluids prescribed by Petitioner were insufficient to maintain even a normal-sized person who was not dehydrated. Tr. 323.

Petitioner argues that his diagnosis of dehydration was supported because the patient's digoxin level was 2.6. P. R.Br. at 14; see I.G. Ex. 23 at 2. However Petitioner has offered no explanation as to the meaning of this result nor any evidence that such a result is indicative of dehydration. Petitioner contends that he reduced the rate of IV fluids when the patient's digoxin level returned to normal and the patient became more alert. P.R. Br. at 14. Petitioner did not rebut the I.G.'s contention that the rate of IV fluids was insufficient to treat a patient suffering from dehydration. For this reason, I conclude that Petitioner failed to treat Patient T.R. in accordance with professionally recognized

standards by failing to prescribe adequate fluids for the treatment of dehydration.

The I.G. alleges that Petitioner not only lacks the ability to treat dehydration appropriately, but that he also is unable to treat patients who require fluid restriction. The I.G. points to the cases of V.E. and E.G. in this regard. As to both patients, Petitioner had diagnosed congestive heart failure. I.G. Exs. 18 at 1, 21 at 1. The I.G.'s expert, Dr. Snider, testified that the standard treatment for congestive heart failure would include fluid restriction, diuretics, oxygen, and perhaps digitalis. Tr. 576-77. Petitioner ordered 3000 ccs of normal saline per day, rather than fluid restriction for Patient V.E., which Dr. Snider testified was inappropriate. Tr. 577-78. As to Patient E.G., in addition to Petitioner's diagnosis of congestive heart failure, a chest X-ray on admission revealed that the patient had fluid in her left lung. Tr. 597; I.G. Ex. 21 at 25. Petitioner ordered IV fluids for the patient at the rate of 2000 ccs per day. Tr. 597; I.G. Ex. 21 at 38. In Dr. Snider's opinion, the IV rate was not appropriate, as the patient should have been managed with fluid restriction. Id. Petitioner did not offer any evidence to rebut the I.G.'s contentions regarding Patients V.E. and E.G. Therefore, I conclude that Petitioner failed to provide care that met professionally recognized standards to Patients V.E. and E.G. because he failed to order fluid restriction for those patients.

The I.G. has shown that Petitioner has failed to manage properly the fluid intake of Patients T.R., V.E., and E.G., in addition to the case of Patient E.S. I conclude that the I.G. has shown a pattern of practice by Petitioner that indicates he lacks the knowledge necessary to manage the fluid intake of patients that may be dehydrated or need fluid restriction.

I have concluded that Petitioner failed to practice in accordance with professionally recognized standards of health care in numerous instances. I have further concluded that these instances evidence patterns of treatment which indicate that Petitioner lacks the knowledge to conform his practice to professionally recognized standards of care. Specifically, Petitioner lacks the ability: 1) to diagnose the causes of patients' abnormal laboratory results and to address these results adequately; 2) to prescribe the appropriate medications for patients' conditions; 3) to evaluate and intervene appropriately in patients suffering acute cardiac changes; and 4) to manage fluid intake in patients who require hydration or fluid restriction.

Thus, the weight of the evidence confirms that a one-year exclusion is reasonable in this case. Petitioner's pattern of potentially life threatening judgement errors involving the evaluation and treatment of patients is a serious problem. These recurring patterns and Petitioner's reliance on his status as a family practitioner to excuse these errors is disturbing. However, I do not find that these deficiencies are the consequences of bad faith or of an uncaring physician. Rather, they appear to be deficiencies in judgment, knowledge of current medical procedures, and a failure to consult when presented with unfamiliar medical issues. Petitioner's practice includes a substantial number of elderly patients.33/ All deserve adequate medical care based on current professional standards of practice. It is also possible that Petitioner attempts to see too many patients with severe and complicated problems to adequately treat them all. Petitioner's failure to comply timely or completely with the CME portions of his CAP indicates to me that he did not believe there were any deficiencies in his knowledge or that any changes in his procedures were necessary.

In making the determination to impose the one year exclusion, I must also consider the remedial nature of the exclusion to ensure that its length is the minimum time period needed for Petitioner to demonstrate that he can be trusted to provide medical care to program beneficiaries and recipients in a manner consistent with his obligations. Hussain at 94; Reyes at 37-38. One year is a relatively short exclusion. However, it will balance the needs of the community in which Petitioner works with the needs of the Medicare program to ensure that Petitioner has reestablished his trustworthiness to be a program provider. He will have the opportunity to rectify his deficiencies, as established by the record. At the end of this time, Petitioner may seek reinstatement into the programs pursuant to 42 C.F.R. § 1004.120.34/

33/ Dr. Wayne testified that when she was a student under Petitioner, he would treat 12-14 people over the age of 70 in a morning. Tr. 754.

34/ This is the minimum period of the exclusion as reinstatement is not automatic. The exclusion will remain in effect until Petitioner applies and the I.G. determines that the basis for the exclusion no longer exists. This determination will be based on an evaluation of whether Petitioner has corrected his

(continued...)

V. The I.G. Has Proven That Petitioner Represents A "Serious Risk" To Medicare Beneficiaries And Should Be Excluded During His Administrative Appeals.

The I.G.'s exclusion determination under section 1156 is normally effective pending the outcome of an administrative hearing. However, when, in cases such as this one, the excluded provider is located in a rural health manpower shortage area or in a county with a population of under 70,000, the effectiveness of the exclusion is stayed. The exclusion takes effect only upon an adverse finding in the hearing or if there is a preliminary finding that the provider will pose a "serious risk" to program beneficiaries and recipients. Section 1156(b)(5).

Petitioner requested both a preliminary hearing and one on the underlying issue of the exclusion. The hearings were consolidated, and the I.G. requested an expedited decision of the "serious risk" issue. However, because of the many issues involved in this proceeding, I wanted a full briefing on them before reaching a decision. Also, our procedures encourage prompt and timely decisions, and two decisions in this instance would have resulted in duplication and delays. Therefore, I have consolidated the issues in this decision.35/

"Serious risk," while not defined by statute or regulation, has been interpreted in prior rulings as a "propensity to unreasonably expose a patient to a hazard or danger of serious harm." Louis W. DeInnocentes, Jr., Ruling on Issue of Serious Risk, at 5 (April 20, 1992); Evelyn Reyes, M.D., Ruling on Serious Risk, at 5 (January 9, 1991) (Reyes I). To prove "serious risk," it is not necessary that the I.G. prove repeated episodes of

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34/ (...continued)
practice deficiencies, and, in doing so, the I.G. may request advice from the PRO. 42 C.F.R. §§ 1001.(a)(2) and 1004.120.

35/ Although there may be some question as to the necessity of the "serious risk" finding at this stage, the issue is not completely clear as to whether the exclusion would take effect should Petitioner appeal this decision. It is my understanding that the intent of the statute is that the exclusion should take effect either after a finding in a preliminary hearing or in a decision on the merits. However, as there have been no rulings on this issue, I have decided to address the serious risk issue here.

patient endangerment. Exposure of a patient to a grave hazard in any one case or less grave but serious errors occurring with enough frequency to place beneficiaries and recipients in danger of serious harm is sufficient. DeInnocentes at 6; Reyes I at 5.

Based on the evidence and testimony of record and my previous findings in this decision, I conclude that program beneficiaries and recipients would be exposed to a hazard or danger of serious harm through Petitioner's current practice of medicine. This finding is based not only on the violation found in the case of Patient E.S. but also the 15 additional cases. These 16 cases demonstrate a serious pattern of deficiencies in medical judgment and knowledge. I emphasize that my conclusion on "serious risk" is not based on -- nor do I make any such findings regarding -- whether Petitioner cured any of these patients or whether his treatment resulted, where applicable, in their deaths. This conclusion is based solely on finding that regardless of the prognosis or poor condition of the patient, there were serious deficiencies regarding their treatment. My principal concern is the overall quality of care exhibited by Petitioner.

In this case, the weight of the evidence is against Petitioner. His care and treatment of the 16 patients demonstrates a lack of knowledge of appropriate basic medical responses to problems in both evaluation and treatment of patients.

Finally, as no evidence has been introduced regarding whether Petitioner's exclusion may adversely affect the availability of medical resources in his community, I conclude that it will not. Also, section 1156(b)(5) of the Act contemplates that the existence of "serious risk" to the programs outweighs the possibility of an inadequate supply of medical resources.

Because Petitioner has not yet been excluded from participation, the exclusion will run prospectively from twenty days after the date of this decision, which will allow time for receipt and implementation.

CONCLUSION

Based on the applicable law and the evidence, I conclude that Petitioner "grossly and flagrantly" violated his obligation within the meaning of section 1156 of the Act to provide health care services of a quality that met professionally recognized standards of health care in the

case of E.S. and demonstrated a "lack of ability substantially to comply" with his obligation.

I conclude that the I.G. had the authority under section 1156 to impose an direct and exclusion against Petitioner from participation in the Medicare and Medicaid programs and that a one year exclusion is reasonable. I further conclude that Petitioner represents a "serious risk" to Medicare beneficiaries within the meaning of section 1156 of the Act and must be excluded during the course of these proceedings.

So Ordered.

/s/

Charles E. Stratton
Administrative Law Judge