Department of Health and Human Services

DEPARTMENTAL APPEALS BOARD

Civil Remedies Division

In the Case of:	
Bernard J. Burke, M.D.,	DATE: December 8, 1995
Petitioner,	
- v. -	Docket No. C-94-380 Decision No. CR406
The Inspector General.	

DECISION

On May 3, 1994, the Inspector General (I.G.) issued a letter (Notice) advising Petitioner that, effective May 23, 1994, he would be excluded from participation in Medicare and State health care programs for five years, pursuant to authority under section 1156 of the Social Security Act (Act).[1] The I.G. based the determination to exclude Petitioner on a recommendation made by Island Peer Review Organization, Inc. (IPRO), the peer review organization (PRO) for the State of New York.

The Notice stated that IPRO based its recommendation that Petitioner be excluded for five years on its determination that, in a substantial number of cases, Petitioner failed substantially to comply with the obligations imposed on him by section 1156(a) of the Act. This determination derived from IPRO's findings that in 20 cases, Petitioner substantially violated the obligations imposed on him by section 1156(a) of the Act.

The Notice stated that, after careful review of all the evidence of record, including rebuttal information submitted by Petitioner, the I.G. agreed with IPRO's

---

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

findings that, in a substantial number of cases, Petitioner substantially violated his obligations under section 1156(a) of the Act. Of the 20 cases identified by IPRO, the I.G. agreed with IPRO's findings in 14 cases. The I.G. determined that 11 of the 14 cases involved violations of the obligation to provide care of a quality that meets professionally recognized standards of health care[2] and that three of the 14 cases involved violations of the obligation to provide appropriate evidence of medical necessity and quality in a form and fashion as may be required.

Additionally, the I.G. determined that Petitioner has demonstrated an unwillingness and an inability substantially to comply with the obligations imposed on him by section 1156(a) of the Act. The I.G. alleged that this is demonstrated by the seriousness and multiplicity of problems with Petitioner's care as identified by IPRO.

In addition, the I.G. stated that a corrective action plan (CAP) established in 1989, and an education intervention undertaken in 1990, had not altered Petitioner's pattern of practice.[3]

---

[2] A provider of care is obligated to assure that items or services which he or she provides to Medicare beneficiaries and Medicaid recipients are "of a quality which meets professionally recognized standards of health care." Act, section 1156(a)(2). For the sake of brevity, I refer to these standards as "professionally recognized standards of care", "professional standards of health care", "professional standards of care" or "professional standards." In addition, the conduct which formed the basis of the exclusion occurred in 1991 and the applicable professionally recognized standards of health care are those which were in effect in 1991. Unless the context indicates otherwise, I use the term "professionally recognized standards of health care" to refer to the standards in effect in 1991.

[3] The I.G. alleged also in the Notice that 18 additional cases, while not being used as the basis on which the exclusion is imposed, demonstrate Petitioner's continuing inability to meet his obligations under section 1156(a). During a prehearing conference held by me on September 7, 1994, counsel for the I.G. stated that the I.G. would not rely on these 18 additional cases in this proceeding. September 8, 1994 Order and Notice of Hearing at 3 - 4. At the hearing, the I.G. reiterated

(continued...)

The Notice stated also that, in arriving at the determination to exclude Petitioner for a period of five years, the I.G. had considered specific factors in accordance with 42 C.F.R. § 1004.90(d).[4]

Petitioner requested a hearing and the case was assigned to me for hearing and decision. By letter dated August 31, 1994, the I.G. stated that the best evidence available indicated that the population of the county in which Petitioner practices medicine is less than 70,000. Therefore, before an exclusion could be effected, Petitioner was entitled to a preliminary hearing on the issue of whether he poses a serious risk to the welfare of program beneficiaries and recipients. Based on this, the I.G. informed Petitioner that the I.G. was reinstating Petitioner's eligibility to be reimbursed for items and services provided to program patients, retroactive to May 23, 1994.[5]

---

[3] (...continued)
this position. The I.G. stated that, even though there has been an ongoing review of Petitioner's medical practice, the I.G. is not relying on any of the cases which have been the subject of this ongoing review in this proceeding. Transcript (Tr.) at 32 - 33. At the hearing, I ruled that I will not make any inferences based on the fact that there is an ongoing review of Petitioner's medical practice, nor will I rely on any evidence pertaining to any case which is the subject of the ongoing review in reaching a decision on any issue before me in this case. Tr. at 34.

[4] Once the I.G. has determined that there is a basis for an exclusion, she must consider the specific factors contained in 42 C.F.R. § 1004.90(d) in determining the appropriate length of the exclusion. The I.G. is to consider these factors: (1) the recommendation of the PRO; (2) the type of offense; (3) the severity of the offense; (4) the previous sanction record of the practitioner or other person; (5) the availability of alternative sources of services in the community; (6) any prior problems the Medicare carrier or intermediary has had with the practitioner or other person; (7) whether the practitioner or other person is unable or unwilling to comply substantially with the obligations; and (8) any other matters relevant to the particular case.

[5] Petitioner attached a copy of this letter to his initial posthearing brief for my convenience.

I held a hearing in New York, New York, from February 14 through 16, 1995. The parties agreed that the hearing should consolidate the taking of evidence as to the issues of serious risk, the authority of the I.G. to exclude Petitioner pursuant to section 1156 of the Act, and the reasonableness of the length of the exclusion which the I.G. imposed on Petitioner. The parties agreed to address these issues also in posthearing briefs.

The parties submitted posthearing briefs, response briefs, and reply briefs. In addition, I notified the parties that I would take judicial notice of the Merck Manual, an authoritative medical treatise, in considering certain issues in this case. The parties submitted supplemental briefs on the applicability of information contained in the Merck Manual to issues in this case.

The I.G. did not offer any evidence pertaining to Case # 10, referred to at page four of the Notice, nor did the I.G. make any arguments pertaining to this case in the posthearing submissions. Accordingly, my decision is based on the evidence and arguments pertaining to the 13 other cases referred to in the Notice.

I have considered carefully the applicable law, the evidence adduced at the hearing, and the arguments raised by the parties. I conclude that the I.G. proved that authority exists under section 1156 of the Act to exclude Petitioner from participation in Medicare and Medicaid. I conclude also that the five-year exclusion is reasonable. Lastly, I conclude that Petitioner poses a serious risk to program beneficiaries and recipients within the meaning of section 1156(b)(5) of the Act. In order to allow time for receipt and implementation of this decision, the exclusion will become effective 20 days after the date of this decision.

FINDINGS OF FACT AND CONCLUSIONS OF LAW (FFCLs)[6]

Petitioner's professional background

1. Petitioner graduated from Syracuse Medical School in 1943. I.G.'s Exhibit (I.G. Ex.) 6 at 6.

---

[6] As a convenience to the parties, I have divided my FFCLs into sections which are headed by descriptive captions. The captions are not FFCLs, and they do not alter the meaning of my FFCLs.

2. Petitioner has been licensed to practice medicine in the State of New York since 1943. Tr. at 183 - 184.

3. Upon graduating from medical school, Petitioner was an intern at Methodist Hospital in Brooklyn, New York. Tr. at 184.

4. After completing his internship, Petitioner served in the military. Following his military service, Petitioner completed two years of postgraduate training in general pathology at Methodist Hospital. I.G. Ex. 6 at 6; Tr. at 184.

5. Petitioner is not board-certified in any specialty. I.G. Ex. 6 at 6.

6. Petitioner has practiced general medicine in Little Falls, New York continuously from approximately 1947. Tr. at 184 - 185.

7. Petitioner is affiliated with Little Falls Hospital in Little Falls, New York. Tr. at 184.

Procedural history

8. The duties of a PRO under contract with the Secretary of the United States Department of Health and Human Services (the Secretary or DHHS) include reviewing the professional activities of physicians for the purpose of determining whether the quality of services that physicians provide to program beneficiaries and recipients meets professionally recognized standards of health care. Act, section 1154(a)(1)(B).

9. In December of 1988, the Empire State Medical, Scientific and Educational Foundation, Inc. (ESMSEF) was under contract with the Secretary to be a PRO in the State of New York. Petitioner's Exhibit (P. Ex.) 14.

10. On December 15, 1988, ESMSEF notified the I.G. that Petitioner had grossly and flagrantly violated his obligations under section 1156 of the Act and recommended that Petitioner be permanently excluded. P. Ex. 14.

11. The I.G. determined that there was insufficient evidence to support ESMSEF's recommendation. The I.G. returned the case to ESMSEF without prejudice. P. Ex. 14.

12. On June 16, 1989, ESMSEF issued an initial sanction notice advising Petitioner that it had made an initial determination that Petitioner had failed to comply

substantially with his obligations under section 1156 of the Act in 14 cases. ESMSEF offered Petitioner the opportunity to provide additional information to ESMSEF and to participate in a meeting with representatives of ESMSEF. I.G. Ex. 7.

13. Petitioner met with representatives of ESMSEF on August 17, 1989. Petitioner was represented by counsel at this meeting. I.G. Ex. 8.

14. During the August 17, 1989 meeting, Petitioner and ESMSEF agreed that Petitioner would participate in a CAP. The CAP had three elements: (1) ESMSEF would review all of Petitioner's hospital admissions for the previous three-month period; (2) Petitioner would take a continuing medical education (CME) course approved by ESMSEF; and (3) Petitioner would improve the quality of his documentation. I.G. Ex. 8, 9.

15. On approximately December 1, 1989, IPRO was awarded the New York State PRO contract. As a result of this contract, IPRO assumed responsibility for monitoring the implementation of Petitioner's CAP. Tr. at 25 - 26; I.G. Ex. 10.

16. By letter dated January 29, 1990, IPRO asked Petitioner to report on his progress in complying with the CAP requirement that he take a CME course. I.G. Ex. 10.

17. By letter dated March 29, 1990, IPRO acknowledged that it had received Petitioner's response to its request for information regarding Petitioner's CME compliance. IPRO informed Petitioner that it would review all of Petitioner's Medicare medical records for a period of three months. P. Ex. 15.

18. By letter dated October 1, 1990, IPRO instituted an educational intervention. IPRO asked Petitioner to provide information regarding the educational program established at Little Falls Hospital and stated that it would evaluate the information to ascertain whether the program met IPRO's educational intervention requirements. I.G. Ex. 31 at 65.

19. By letter dated October 10, 1990, the administrator of Little Falls Hospital provided information regarding the hospital's efforts to fulfill IPRO's educational intervention requirements for Petitioner. The hospital administrator reported that the hospital had purchased tapes produced by the Network for Continuing Medical Education Program, that Petitioner was watching these

tapes, and that a hospital secretary would keep a record of the tapes which Petitioner watched. I.G. Ex. 31 at 64.

20. By letter dated October 19, 1990, Petitioner agreed to enter into the educational intervention program. I.G. Ex. 14 at 3.

21. By letter dated January 18, 1991, IPRO informed Petitioner that IPRO accepted the educational intervention program that had been submitted. IPRO requested Petitioner to submit documentation on a monthly basis listing the CME programs he completed. I.G. Ex. 31 at 63.

22. Petitioner subsequently submitted to IPRO regular reports on the CME tapes he watched and the CME lectures and conferences he attended. I.G. Ex. 31.

23. On June 19, 1992, IPRO issued an initial sanction notice advising Petitioner that it had made an initial determination that Petitioner had failed to comply substantially with his obligations under section 1156 of the Act in 26 new cases. IPRO offered Petitioner the opportunity to provide additional information to IPRO and to participate in a meeting with representatives of IPRO. I.G. Ex. 11.

24. By letter dated August 7, 1992, IPRO informed Petitioner that its continuing review of Petitioner's cases revealed additional cases in which Petitioner failed to substantially comply with his obligations. I.G. Ex. 14 at 1.

25. In view of the continuing deficiencies in Petitioner's medical care identified by IPRO, IPRO made the decision to withdraw its June 19, 1992 initial sanction notice and to proceed directly to a second sanction notice. I.G. Ex. 14 at 1, 4, I.G. Ex. 15 at 13.

26. On August 7, 1992, IPRO issued a second sanction notice advising Petitioner that there was a reasonable basis for determining that Petitioner had failed to substantially comply with his obligations under section 1156 in a substantial number of cases. IPRO identified 24 cases which formed the basis for this determination. IPRO offered Petitioner the opportunity to provide additional information to IPRO and to participate in a meeting with representatives of IPRO. I.G. Ex. 14.

27. By letter dated October 6, 1992, IPRO notified Petitioner that it was adding another case to the 24

cases identified in the August 7, 1992 second sanction notice. I.G. Ex. 15 at 2 - 12.

28. Petitioner met with representatives of IPRO on November 10, 1992. Petitioner was represented by counsel at this meeting. I.G. Ex. 6.

29. On December 18, 1992, IPRO's Board of Directors voted to recommend to the I.G. that Petitioner be excluded for five years. I.G. Ex. 1 at 2.

30. On January 26, 1993, IPRO issued a final sanction notice advising Petitioner that it had determined that Petitioner had failed to comply substantially with his obligations in 23 cases and that it had recommended to the I.G. that Petitioner be excluded for five years. P. Ex. 16.

31. In a letter to IPRO dated March 31, 1993, the I.G. determined that IPRO failed to follow regulatory requirements, because it had not provided Petitioner with three notices and two hearings on the same cases. Based on this procedural defect, the I.G. returned IPRO's recommendation without prejudice. I.G. 1 at 2.

32. On June 4, 1993, IPRO issued a second sanction notice advising Petitioner that it had reviewed the additional information provided by Petitioner in response to the August 7, 1992 notice, and that this information did not modify IPRO's determination that there was a reasonable basis to conclude that Petitioner has failed to substantially comply with his obligations under section 1156 in a substantial number of cases. IPRO offered Petitioner the opportunity to provide additional information to IPRO and to participate in a meeting with representatives of IPRO. I.G. Ex. 2.

33. IPRO identified 20 cases which formed the basis for its June 4, 1993 notice. All 20 of these cases were identified also in the August 7, 1992 notice. I.G. Ex. 2.

34. Petitioner met with representatives of IPRO on September 28, 1993. Petitioner was represented by counsel at this meeting. I.G. Ex. 3.

35. On December 20, 1993, IPRO's Board of Directors again voted to recommend to the I.G. that Petitioner be excluded for five years. I.G. Ex. 1 at 10.

36. On January 13, 1994, IPRO issued a final sanction notice advising Petitioner that it had determined that

Petitioner had failed to comply substantially with his obligations under section 1156 of the Act in 20 cases and that it had recommended to the I.G. that Petitioner be excluded for five years. I.G. Ex. 1 at 4 - 8.

37. IPRO advised Petitioner that, within 30 days from his receipt of the final sanction notice letter dated January 13, 1994, he could submit to the I.G. any additional information he had which could affect IPRO's recommendation. I.G. 1 at 8.

38. On February 16, 1994, Petitioner submitted rebuttal information to the I.G., which the I.G. considered as part of the final exclusion determination in this case. I.G. Ex. 31; Notice at 2.

39. On May 3, 1994, the I.G. advised Petitioner that the I.G. accepted IPRO's determination that Petitioner had substantially violated his obligations under section 1156(a) of the Act in a substantial number of cases. Notice at 1.

40. The I.G. concluded that in 11 cases Petitioner had failed to provide care that met professionally recognized standards of health care. The I.G. concluded also that in three cases Petitioner had failed to provide appropriate evidence of medical necessity and quality in a form and fashion as may be required. Notice at 9.

41. The I.G. concluded further that Petitioner demonstrated an unwillingness and inability substantially to comply with the obligations imposed by section 1156(a) of the Act. Notice at 7.

42. The I.G. determined to exclude Petitioner from participation in Medicare and Medicaid for five years, pursuant to section 1156(b)(1) of the Act. Notice at 8, 10.

Right to a hearing

43. A party who is subject to an exclusion determination pursuant to section 1156(b)(1) of the Act is entitled to an administrative hearing. Act, section 1156(b)(4).

44. Petitioner's right to a hearing is a right to a de novo hearing. Act, sections 1156(b)(4) and 205(b).

45. The exclusion imposed by the I.G. must be supported by the preponderance of the evidence. S. Khalid Hussain, M.D., DAB CR204 (1992).

The I.G.'s authority to impose an exclusion

46. A provider of care is obligated to assure that items or services which he or she provides to program beneficiaries and recipients are:

> a. provided economically and only when, and to the extent, medically necessary;
>
> b. of a quality which meets professionally recognized standards of health care; and
>
> c. supported by evidence of medical necessity and quality in such form and fashion and at such time as may reasonably be required by a reviewing PRO in the exercise of its duties and responsibilities.

Act, section 1156(a).

47. The Secretary, or her delegate, the I.G., may exclude a provider where, based on the recommendation of a PRO, she or the I.G. determines that the provider has, in a substantial number of cases, substantially violated his or her obligations under section 1156(a) of the Act, and where that provider is unable or unwilling substantially to comply with his or her statutory obligations. Act, section 1156(b)(1).

Acts or omissions by Petitioner related to his obligations under section 1156 of the Act on which the I.G. based the determination to exclude Petitioner

Patient 031409[7] (Discussion begins on page 42)

48. Patient 031409, a 73-year old female, presented to Little Falls Hospital on July 29, 1991, with back and shoulder pain that had lasted for several hours. I.G. Ex. 16 at 9, 13.

49. The patient was admitted to the hospital for observation, with admitting diagnoses of arteriosclerotic heart disease, possible anginal syndrome, and diabetes mellitus with diabetic retinopathy. I.G. Ex. 16 at 11.

---

[7] The names of each of the patients involved in this proceeding are reported in their medical records, which are in evidence. However, as a courtesy tho these patients, and out of respect for their privacy, I refer to each of them by the number assigned to their medical record.

50. A gallbladder sonogram was done to rule out gallbladder colic as a cause of the patient's recurrent pain. I.G. Ex. 16 at 10.

51. The sonogram of the patient's gallbladder revealed evidence of cholelithiasis (gallstones) with thickened gallbladder walls suggesting cholecystitis (gallbladder infection). I.G. Ex. 16 at 59; Tr. at 39 - 40.

52. Petitioner's discharge diagnosis for this patient was thoracic pain, probably secondary to cholecystolithiasis. I.G. Ex. 16 at 7, 10.

53. Cholecystolithiasis is a term which refers to the presence of gallstones and the thickening of the gallbladder wall. Tr. at 409.

54. Professionally recognized standards of care for a physician presented with a sonogram indicating possible gallbladder disease would require the physician promptly to order tests to determine the patient's complete blood count (CBC), and levels of serum amylase, alkaline phosphatase, bilirubin, and transaminase (also referred to as SGOT). Tr. at 39, 43, 310 - 311, 315 - 316.

55. The CBC would show whether the patient's white blood cell count was elevated, which might indicate ascending cholangitis, that is, that the infection from the gallbladder has traveled up the common bile duct, and is in the liver. Tr. at 42 - 43.

56. Abnormal bilirubin and transaminase results would be indicators of jaundice or liver damage. Tr. at 43.

57. The alkaline phosphatase level would indicate whether there is an obstruction in the patient's common bile duct. Tr. at 43.

58. The serum amylase would indicate whether the patient is suffering from acute pancreatitis, which may be associated with cholecystitis. Tr. at 43.

59. During the patient's July 29, 1991 hospitalization, Petitioner did not order a CBC, nor tests to determine levels of serum amylase, alkaline phosphatase, bilirubin, or transaminase. See I.G. Ex. 16 at 2, 4.

60. Petitioner testified that he did not order the blood tests for this patient because he concluded that the sonogram results and his physical examination of the patient, which did not reveal local abdominal pain, led him to conclude that the patient's gallbladder disease

was chronic, rather than acute, and was not likely the cause of her pain. Tr. at 334 - 335.

61. Petitioner did not note in the patient's medical record his reasons for concluding that her gallbladder disease was likely chronic and, thus, that there was no need for additional laboratory tests. Tr. at 408. See also I.G. Ex. 16.

62. Petitioner's failure to note in the medical record his reasons for concluding that further laboratory tests were unnecessary was not in accord with professionally recognized standards of health care. Tr. at 405 - 407.

63. Petitioner's testimony that the patient's gallbladder disease was not likely the cause of her pain is inconsistent with his discharge diagnosis of thoracic pain, probably secondary to cholecystolithiasis. I.G. Ex. 16 at 7.

64. Petitioner's testimony that the patient's gallbladder disease was not likely the cause of her pain is inconsistent with his statement to IPRO on November 10, 1992, that the patient's pain was consistent with gallbladder colic. I.G. Ex. 6 at 13.

65. Petitioner's expert testified that the patient had no clinical symptoms referable to her gallbladder. Tr. at 405.

66. The testimony of Petitioner's expert is entitled to little weight because it is contradicted by the patient's medical record and by Petitioner's statement to IPRO.

67. During a previous admission, on July 25, 1991, Petitioner ordered a CBC and SGOT for this patient, the results of which were within normal limits. In addition, bilirubin results were negative. P. Ex. 48 at 1, 3; Tr. at 339 - 340.

68. The test results for the July 25, 1991 admission do not indicate that any tests were done to ascertain the patient's serum amylase or alkaline phosphatase levels. P. Ex. 48; Tr. at 341 - 342.

69. There is no indication in the patient's medical record that Petitioner relied on the test results from the July 25, 1991 admission in determining not to repeat the tests done during the July 29, 1991 admission. I.G. Ex. 16; Tr. at 342.

70. In his initial written response to IPRO, Petitioner did not claim to have relied on test results from a previous admission in deciding not to order tests during the patient's July 29, 1991 admission. I.G. Ex. 16 at 4.

71. Petitioner's failure to cross-reference the patient's previous admission leaves me with no basis to conclude that her condition remained unchanged from the previous admission.

72. Petitioner consulted a gastroenterologist regarding the treatment of this patient. I.G. Ex. 16 at 20 - 21; Tr. at 312.

73. The gastroenterologist's report does not mention gallbladder disease as a possible diagnosis. Tr. at 312; I.G. Ex. 16 at 21.

74. At the November 10, 1992 meeting with IPRO, Petitioner stated that he recalled that he had consulted the gastroenterologist before he defined gallstones. I.G. Ex. 6 at 15.

75. At the hearing before me, Petitioner could not recall whether he discussed the findings of the gallbladder sonogram with the gastroenterologist. Tr. at 333.

76. A consulting gastroenterologist would be expected to comment in the consultation report on the results of a gallbladder sonogram if the consultant were aware of such results. Tr. at 314.

77. It is more likely than not that the consulting gastroenterologist was not aware of the results of this patient's gallbladder sonogram when he dictated his consultation report. Tr. at 312.

78. The fact that the consulting gastroenterologist did not suggest a diagnosis of gallbladder disease in his report did not relieve Petitioner of the duty to obtain the required blood tests or, at a minimum, to discuss the need for such tests with the gastroenterologist. Tr. at 313 - 315.

79. Petitioner's failure to obtain the patient's CBC, and blood levels of serum amylase, alkaline phosphatase, bilirubin, and transaminase during the July 29, 1991 admission was a substantial violation of his obligation to provide care of a quality that meets professionally recognized standards of health care.

Patient 031943 (Discussion begins on page 47)

80. Patient 031943, a 67-year-old female, was admitted to Little Falls Hospital on August 27, 1991, with a complaint of chest pressure. I.G. Ex. 17 at 13, 15.

81. The patient had a family history of stomach cancer. I.G. Ex. 17 at 13.

82. The results of blood tests performed at the time this patient was admitted to the hospital in 1991 met the criteria for a diagnosis of anemia. I.G. Ex. 17 at 15; Tr. at 77.

83. Physical examination at the time of admission revealed the stools to be dark and to be "4+" for blood. The "4+" result is strongly positive for bleeding. I.G. Ex. 17 at 15; Tr. at 288 - 290.

84. On August 29, 1991, the patient was transfused with two units of blood, in response to the anemia. I.G. Ex. 17 at 33; Tr. at 347.

85. On September 1, 1991, the stools were "+1" for blood. This result indicated that the bleeding had essentially stopped. I.G. Ex. 17 at 34; Tr. at 436 - 437.

86. On September 3, 1991, a colonoscopy was performed on the patient. The colonoscopy examined the patient's anus, rectum, colon and cecum. I.G. Ex. 17 at 31.

87. The consulting physician who performed the colonoscopy diagnosed diverticulosis of the sigmoid colon. No other lesion was identified. I.G. Ex. 17 at 31.

88. The patient was discharged on September 3, 1991. Petitioner's final diagnosis was anemia secondary to bleeding from a hiatus hernia. Petitioner based this diagnosis on the fact that the patient had the same condition approximately three years earlier. I.G. Ex. 17 at 4, 11 - 12; Tr. at 349 - 350.

89. At the time of discharge, Petitioner recommended that the patient be observed over a period of time. In addition, he instructed her to lose weight, to elevate the head of her bed, and to take medication (Zantac and Maalox). I.G. Ex. 17 at 12.

90. The presence of darkened stool suggests bleeding from the upper gastrointestinal (GI) tract. The darkened

stool is caused by blood from the upper GI tract that has been digested by bacteria in the gut. Tr. at 290, 412.

91. There are many possible causes of upper GI bleeding. Tr. at 290.

92. Professionally recognized standards of care for a patient with an unexplained upper GI bleed requires that a physician perform either an endoscopy or an upper GI series, provided that neither is contraindicated for the patient. Tr. at 78 - 79, 290, 297.

93. An endoscopy (also known as an esophagogastroduodenoscopy) is a diagnostic procedure which involves placing a tube down the esophagus and then passing it under direct vision into the stomach. It can be used to rule out the presence of an ulcer, cancer of the stomach or esophagus, gastritis in the stomach, or esphogeal varices. Tr. at 81 - 83; I.G. Ex. 33.

94. An upper GI series involves the patient taking a barium swallow followed by an x-ray. The upper GI series is not as accurate as an endoscopy, but it is a viable alternative for diagnosing the cause of an upper GI bleed. Tr. at 83, 89 - 90, 291.

95. The patient did not have any contraindications for either an endoscopy or an upper GI series. Tr. at 298.

96. Petitioner did not obtain an endoscopy or an upper GI series in the course of evaluating the patient. I.G. Ex. 17.

97. Petitioner's failure to obtain an endoscopy or an upper GI series to investigate an upper GI bleed is a substantial violation of professionally recognized standards of care.

98. Petitioner's failure to obtain an endoscopy or an upper GI series exposed the patient to the serious risk of having a gastric malignancy go undetected and untreated. It exposed her also to the serious risk of rebleeding. Tr. at 292.

<u>Patient 039837</u> (Discussion begins on page 53)

99. Patient 039837, an 89-year-old female, had been a long-term patient in the chronic care ward of Little Falls Hospital. On September 28, 1991, she was transferred to the active floor of the hospital due to a serious change in her condition. At the time of the

transfer, she had a temperature of 104, some cough, and ongoing diarrhea. I.G. Ex. 18 at 4, 11, 14, 16.

100. At the time of her initial examination, the patient was very ill. Her skin was mottled, as if she was about to die, and she was bathed in cold perspiration. She was unresponsive. Tr. at 211 - 212.

101. Petitioner diagnosed her as being in a septic state. He also diagnosed possible pneumonia or enteritis, acute, with vascular collapse. I.G. Ex. 18 at 14.

102. Petitioner did not take a urine culture. However, he did take blood and sputum cultures. I.G. Ex. 18 at 5.

103. Results of a chest x-ray taken on September 28, 1991 revealed a large amount of fluid in the patient's right chest. I.G. Ex. 18 at 4, 48; Tr. at 213.

104. On September 28, 1991, Petitioner performed a thoracentesis, a procedure that involves inserting a needle in the chest cavity to remove the accumulation of fluid. I.G. Ex. 18 at 12; Tr. at 95.

105. The thoracentesis was accomplished with difficulty, since the patient could not sit up due to the fact that she had no palpable blood pressure. In order to perform the procedure, it was necessary for her to be placed with her right side down and her head slightly elevated. I.G. Ex. 18 at 4.

106. A follow-up chest x-ray was not taken until the day following the thoracentesis. Tr. at 103, 215.

107. A chest x-ray taken on September 29, 1991 revealed a pneumothorax, which is air in the chest cavity. The bottom half of the patient's right lung was collapsed. The upper lobe of the right lung adhered to the chest wall. Tr. at 95, 215; I.G. Ex. 18 at 12, 49.

108. On October 1, 1991, a chest x-ray was taken which revealed that the patient's right chest had again filled up with fluid. Tr. at 217; I.G. Ex. 18 at 50.

109. On October 1, 1991, Petitioner performed a second thoracentesis. A chest tube was inserted which drained fluid for a few days. I.G. Ex. 18 at 12; Tr. at 217 - 218.

110. As a result of the chest tube, the patient's lung re-expanded and the pleural effusion decreased. I.G. Ex. 18 at 4, 51.

111. On October 4, 1991, the patient died. I.G. Ex. 18 at 13.

112. Professionally recognized standards of care require a chest x-ray to be taken immediately after a thoracentesis is performed. The reason for taking a chest x-ray immediately after a thoracentesis is to ascertain whether all the fluid is removed from the chest and whether the thoracentesis damaged the lung. Tr. at 96, 466 - 467.

113. Petitioner's failure to obtain a chest x-ray immediately after the September 28, 1991 thoracentesis was a substantial violation of his obligation to provide care in accordance with professionally recognized standards of care.

114. Petitioner's delay in obtaining a chest x-ray after the September 28, 1991 thoracentesis delayed diagnosis and put the patient at serious risk for developing complications related to her ability to breathe. Tr. at 96 - 99.

115. Professionally recognized standards of care require a urine culture be taken of a patient who is in a septic state. I.G. Ex. 18 at 5; Tr. at 462.

116. Petitioner admits that his failure to obtain a urine culture was an oversight. I.G. Ex. 18 at 5.

117. Petitioner's failure to obtain a culture of this patient's urine was a substantial violation of professionally recognized standards of care for a septic patient.

Patient 058705 (Discussion begins on page 59)

118. Patient 058705, a 73-year-old male, was admitted to Little Falls Hospital on July 8, 1991, after having been found lying on the floor of his apartment. I.G. Ex. 19 at 12 - 13.

119. At the time of admission, Petitioner noted that the patient had blisters on his buttocks. Petitioner attributed this to the fact that the patient had been on the floor of his apartment for a considerable period of time. I.G. Ex. 19 at 14, 25.

120. Examination revealed that the patient had a considerable amount of dried feces around the rectum and the patient's family reported that he had a history of incontinence of the bowel. I.G. Ex. 19 at 16.

121. Petitioner stated in the admission report that the patient's incontinence was probably explained by chronic impaction. Petitioner stated also that the patient probably had chronic organic brain syndrome. I.G. Ex. 19 at 17.

122. The nursing notes written on the date of admission describe the patient's buttocks as reddened with skin breakdown. I.G. 19 at 54.

123. On July 11, 1991, Petitioner's progress notes indicated that the patient's cellulitis had gotten smaller. The nursing notes of that date described the patient's lesion on his left buttock as a yellow central area surrounded by a red area six inches in diameter and indicated that there was no drainage. I.G. Ex. 19 at 26, 60.

124. On July 12, 1991, the nursing notes reported that the lesion on the left buttock was smaller and less red than it had been on July 11, 1991. I.G. Ex. 19 at 62.

125. On July 15, 1991, the nursing notes reported that the skin lesion was much smaller than it had been on July 12, 1991. The notes stated that it was a small open area near a large white patch surrounded by a small red margin. I.G. Ex. 19 at 68.

126. On July 16, 1991, Petitioner's progress notes described the skin lesion as healing and indicated that it was about six centimeters in size. The nursing notes of that dated described the lesion as yellow with dry skin at the margins. I.G. Ex. 19 at 26, 70.

127. On July 21, 1991, the nursing notes stated that the skin lesion was healing and that it was clean with clear edges. I.G. 19 at 80.

128. On July 22, 1991, the nursing notes described the lesion as an open area with a small amount of yellow drainage. I.G. Ex. 19 at 82.

129. On July 23, 1991, the nursing notes described a small amount of red drainage. I.G. Ex. 19 at 84.

130. On July 24, 1991, the nursing notes stated that there was no change in the patient's skin lesion. I.G. Ex. 19 at 86.

131. On July 29, 1991, Petitioner's progress notes indicated that the patient had an unhealed ulcer on his buttock which was four centimeters in size. I.G. Ex. 19 at 27.

132. On July 30, 1991, the nursing notes stated that the skin lesion appeared to be healing, and described it as an open area. I.G. Ex. 19 at 98.

133. On July 31, 1991, the nursing notes described the lesion as a dry, open area and indicated that the patient did not complain of pain. I.G. Ex. 19 at 103.

134. On July 31, 1991, Petitioner telephoned an order that the patient's skin lesion be treated with Neosporin, a topical antibiotic. I.G. Ex. 19 at 24; Tr. at 261.

135. On August 2, 1991, the patient was discharged to the County Home for ongoing care. I.G. Ex. 19 at 13, 15.

136. Petitioner's final diagnoses included cellulitis of the buttock and decubitus ulcer. I.G. Ex. 19 at 10.

137. The patient's discharge instructions included application of Neosporin ointment to the buttock. I.G. Ex. 19 at 107.

138. The July 8, 1991 nursing notes indicated that the nurses moved the patient from side to side at regular intervals. The patient was ambulating by July 10, 1991, and the nurses encouraged him to ambulate regularly after that. The nurses applied "A&D" ointment repeatedly, changed his linens when they were wet, and monitored his eating throughout his hospital stay. I.G. Ex. 19 at 54 - 103.

139. A decubitus ulcer is an erosion or ulceration of tissue that has been subjected to prolonged pressure. Tr. at 255.

140. The stages of decubitus ulcer formation correspond to tissue layers. The first stage consists of skin redness that disappears on pressure. The second stage shows redness, edema, and induration, at times with blistering. In the third stage, the skin becomes necrotic, with exposure of fat. In the fourth stage, necrosis extends to the muscle. Further fat and muscle necrosis characterizes the fifth stage. In the sixth

stage, bone destruction begins. Merck Manual (15th ed. 1987) at 2298.

141. This patient had an ulceration of tissue that was caused by prolonged pressure. I.G. Ex. 19 at 14, 25.

142. This patient had a decubitus ulcer.

143. Professionally recognized standards of care require an attending physician to initiate a written plan of care to address skin conditions caused by prolonged pressure. Tr. at 255, 272.

144. The only written documentation of a physician order pertaining to the treatment of this patient's skin condition was made on July 31, 1991, when Petitioner telephoned an order for Neosporin. I.G. Ex. 19 at 24.

145. Petitioner admits, and I find, that this patient's chart does not contain a written plan of care to address the treatment of the patient's skin condition. Tr. at 486, 489 - 490.

146. Petitioner's failure to document a plan of care to address this patient's skin condition is a substantial violation of professionally recognized standards of care.

147. There is no indication in this patient's chart that Petitioner instructed the nurses orally to take specific measures to care for this patient's skin condition. I.G. Ex. 19.

148. Petitioner's unsubstantiated testimony that he initiated a plan of care orally to address this patient's skin condition is not credible.

149. Petitioner's failure to initiate a plan of care orally to address this patient's skin condition is a substantial violation of professionally recognized standards of care.

150. Petitioner was informed about this patient's skin condition, and he participated in the treatment of it. I.G. Ex. 19 at 24 - 27.

151. While the patient's skin condition did not heal completely during the course of his hospital stay, there were documented periods of improvement. At no point did the condition progress to the stage where it affected muscle and bone tissue. I.G. Ex. 19.

152. The fact that this patient was continually soiling himself could hinder the quick healing of this patient's skin condition. Tr. at 263, 580.

153. Dr. Kops' testimony that the care received by this patient hampered the healing of his skin condition is not persuasive. Tr. at 258, 262, 274.

154. The weight of the evidence fails to establish that the patient suffered any adverse consequences as a result of Petitioner's care of the patient's skin condition.

Patient 032141 (Discussion begins on page 67)

155. Patient 032141, a 70-year-old female, was admitted to Little Falls Hospital on July 25, 1991. The patient's chief complaint was intractable pain of the left lateral thigh of two weeks' duration. I.G. Ex. 20 at 14 - 15.

156. The patient had a history of recurrent pains in the abdomen and chest of an unknown etiology. In addition, she had a history of a suspected dependency on medication. I.G. Ex. 20 at 14 - 15.

157. A few days prior to admission, the patient had been treated as an outpatient with injections of medication that gave her relief from the pain for about an hour, and then it recurred. I.G. Ex. 20 at 15.

158. Physical examination of the patient at the time of admission revealed that the patient had point tenderness at the insertion of the fascia lata into the greater trochanter on the left side. I.G. Ex. 20 at 15.

159. At the time of admission, Petitioner again treated the patient with injections of medication which gave the patient relief from the pain for a short period before it recurred. I.G. Ex. 20 at 15.

160. Petitioner diagnosed pain, left lateral thigh, either trochanteric tendinitis with fascia lata syndrome or diabetic neuropathy. I.G. Ex. 20 at 14.

161. Petitioner referred the patient to a physical therapist. In a report dated July 26, 1991, the physical therapist described the patient as having discomfort during hip flexion and external rotation. I.G. Ex. 20 at 24.

162. During the course of the patient's hospital stay, she was treated with a combination of ultrasound, moist

heat, a "TENS" unit, anti-inflammatory medication, and a series of active exercises. I.G. Ex. 20 at 27.

163. Petitioner obtained a psychiatric consultation. In a report dated July 30, 1991, the consultant opined that, while the patient did not appear to suffer from any major psychiatric illness, there was a possibility that the patient's pain could be symptomatic of a major depression. I.G. Ex. 20 at 22 - 23.

164. The patient was not examined by an orthopedist or neurologist during the course of the hospital stay. In addition, no x-rays or "CAT" scans were taken of the patient's hip and thigh. Tr. at 643; I.G. Ex. 20.

165. The patient complained of intermittent pain throughout her stay at the hospital. On August 1, 1991, the day that she was discharged, she complained of pain and became more comfortable after a new patch was applied to the "TENS" unit. I.G. Ex. 20 at 42 - 56.

166. At the time of discharge, the patient was independent in ambulation and was able to bear weight in her left leg. Petitioner reported that the patient's pain had improved during the hospital stay, but that it had not completely resolved. I.G. Ex. 20 at 13, 27.

167. The patient was discharged with instructions to take medication, and she was advised to see Petitioner for a follow-up examination. I.G. Ex. 20 at 13, 62.

168. The principal diagnosis at the time of discharge was left trochanter tendinitis with fascia lata syndrome. I.G. Ex. 20 at 8.

169. On August 4, 1991, the patient again was admitted to the hospital with the complaint of severe pain in the left thigh. I.G. Ex. 20 at 80.

170. The patient was injected with medication in the tender area of the left trochanteric area. The pain remained intractable and she was admitted to the hospital for care and possible additional diagnostic procedures. I.G. Ex. 20 at 80.

171. At 9:00 p.m. on the day the patient was admitted to the hospital, the patient had achieved complete relief of her pain. The following morning, the patient did not have any pain, and she was discharged that day. I.G. Ex. 20 at 80, 95.

172. During the second hospital admission, no x-rays or "CAT" scans were taken, and no orthopedic or neurologic consultations were obtained. Tr. at 645 - 646; I.G. Ex. 20.

173. On August 7, 1991, the patient was readmitted to the hospital with the same complaint. I.G. Ex. 6 at 118.

174. The patient's pain symptoms improved or completely diminished prior to each discharge. I.G. Ex. 20.

175. The patient's physical examination and her response to Petitioner's injections is suggestive of the diagnosis of tendinitis. Tr. at 631 - 632.

176. Tendinitis is a condition known to produce intermittent pain, and a person suffering from this condition might continue to experience intermittent pain even after discharge from a hospital setting. Tr. at 636 - 638.

177. Petitioner properly considered the patient's history of fixating on pain and her history of possible drug dependency in making the decision to manage her condition conservatively, without extensive diagnostic testing. Tr. at 638 - 640.

178. The record is devoid of expert medical opinion evidence establishing that professionally recognized standards of care require that this patient should have been free of pain for a specific period of time before she was discharged from the hospital.

179. The record is devoid of expert medical opinion evidence establishing that this patient's readmission to the hospital for the same complaint within a few days establishes that a prior discharge had been premature.

180. The record is devoid of expert medical opinion evidence establishing that professionally recognized standards of care required Petitioner to perform radiologic tests and to obtain additional consultations under the circumstances of these hospital admissions.

181. The I.G. did not prove that Petitioner's treatment of this patient violated professionally recognized standards of care.

<u>Patient 060460</u> (Discussion begins on page 73)

182. Patient 060460, a 76-year old male, was brought by ambulance to the emergency room at Little Falls Hospital

on August 22, 1991, following a sudden episode of weakness, slurred speech, and confusion. I.G. Ex. 22 at 11 - 12.

183. He was admitted for observation with a preliminary diagnosis of a transient ischemic attack (TIA). I.G. 22 at 13.

184. A TIA is a cerebral dysfunction of vascular origin, which usually lasts between several minutes and several hours with no permanent neurological damage. I.G.'s Brief at 39.

185. Patients who experience a TIA are at risk for developing another TIA or a stroke. Tr. at 495.

186. A common cause of TIAs is the formation of arteriosclerotic plaques in the carotid arteries. Tr. at 111, 610.

187. Arteriosclerotic plaques may narrow the carotid arteries, restricting blood flow to the brain. Tr. at 111.

188. Patients who have stenosis, or narrowing, of the carotid artery of more than 25 percent have an increased risk of both stroke and coronary heart disease. I.G. Ex. 34 at 4.

189. Patients who have suffered TIAs related to stenosis of the carotid arteries may be treated medically, using anticoagulant drugs, or surgically, by carotid endarterectomy, to remove the arteriosclerotic plaques. P. Ex. 50 at 1 - 2, P. Ex. 51; Tr. at 111.

190. Conn's Current Therapy is a professionally recognized medical text. Tr. at 117.

191. The risk of stroke in symptomatic patients with stenosis of the carotid arteries of 70 percent or more is reduced by carotid endarterectomy. P. Ex. 50 at 3, P. Ex. 51.

192. Physical examination alone does not yield precise information about carotid artery function or blood flow to the brain. Tr. at 499 - 500.

193. Professionally recognized standards of health care in diagnosing carotid artery stenosis require a physician to first assess the status of the carotid arteries non-invasively, using Doppler ultrasound. P. Ex. 51; Tr. at 113, 134, 500.

194. If the Doppler ultrasound indicates a potentially serious lesion, that is stenosis of more than 30 percent, professionally recognized standards require that the patient be further evaluated. P. Ex. 51.

195. The preferred method for accurately measuring the degree of stenosis of a patient's carotid arteries is direct cerebral angiography, an invasive procedure that involves injecting dye into the carotid arteries, and which itself involves approximately one percent risk of stroke. P. Ex. 50 at 3, P. Ex. 51; Tr. at 113, 496, 500.

196. Carotid endarterectomy is clearly indicated only for those patients whose carotid arteries are at least 70 percent occluded, as demonstrated by angiography. P. Ex. 51.

197. It is not in accord with professionally recognized standards of health care to recommend carotid endarterectomy on the basis of Doppler ultrasound studies without confirming the degree of stenosis by angiography. P. Ex. 51; see also P. Ex. 50 at 3 - 4.

198. Petitioner did not order a Doppler ultrasound of this patient's carotid arteries.

199. Petitioner failed to meet his obligation to provide care in accordance with professionally recognized standards by failing to order a Doppler ultrasound for this patient.

200. Petitioner treated this patient by prescribing the medical treatment appropriate for a patient with a diagnosis of TIA who was not a surgical candidate. Tr. at 136.

201. Petitioner testified that this patient did not wish to consider surgical treatment under any circumstances. Tr. at 494, 500 - 501.

202. Professionally recognized standards of health care require the physician to note in the medical record a patient's refusal of surgical treatment. Tr. at 616.

203. Petitioner failed to document in the medical record that this patient did not wish to consider surgical treatment. Tr. at 616.

204. Petitioner's failure to document that this patient refused surgical treatment violated Petitioner's obligation to provide care in accordance with professionally recognized standards of health care.

205. Petitioner's testimony that this patient refused surgical treatment is not completely consistent with his written response to IPRO, in which he stated: "On the basis of the man's clinical presentation, I could not suggest to this man that he have an operation on his carotid system." I.G. Ex. 22 at 4.

206. Because Petitioner failed to obtain a Doppler ultrasound of this patient's carotid arteries, Petitioner could not meaningfully have advised the patient of the risks and benefits of carotid endarterectomy surgery.

207. Petitioner violated his obligation to provide health care that meets professionally recognized standards by ruling out surgery for this patient without obtaining the results of a Doppler ultrasound of the patient's carotid arteries.

Patient 060717 (Discussion begins on page 76)

208. Patient 060717, a 69-year-old male, was admitted to Little Falls Hospital on December 2, 1991 with the complaint of acute dyspnea. I.G. Ex. 23 at 11.

209. At the time of the patient's admission to the hospital, Petitioner diagnosed him as having arteriosclerotic heart disease with acute severe pulmonary edema, severe chronic obstructive pulmonary disease, and mild renal insufficiency. I.G. Ex. 23 at 11.

210. At the time of his admission, the patient had been taking Capoten. On December 3, 1991, the patient's medication was switched from Capoten to Vasotec. Vasotec and Capoten are both medications which are ACE (angiotensin converting enzyme) inhibitors which are used in the treatment of hypertension and congestive heart failure. I.G. Ex. 23 at 19, 41; Tr. at 243 - 245.

211. Petitioner prescribed five milligrams of Vasotec twice a day on December 3, 1991. He increased the dosage later that day to five milligrams in the morning and 10 milligrams at night. I.G. Ex. 23 at 19; Tr. at 244.

212. On December 4, 1991, Petitioner increased the dosage again to ten milligrams twice daily, which was continued until the day of discharge. I.G. Ex. 23 at 20; Tr. at 244.

213. The patient was discharged on December 9, 1991. Petitioner's progress notes of this date state that the patient was to go home with a prescription for five

milligrams of Vasotec to be taken twice a day. I.G. Ex. 23 at 21, 25; Tr. at 244 - 245.

214. Petitioner did not document his discharge instructions on his physician order sheet. I.G. Ex. 23 at 21.

215. A discharge summary which was dictated by Petitioner on December 30, 1991, 21 days after the patient was discharged from the hospital, indicates that the patient was discharged with a prescription for five milligrams of Capoten to be taken twice a day. I.G. Ex. 23 at 14.

216. The patient's chart does not include a discharge instruction sheet containing written instructions that had been given to the patient prior to his discharge from the hospital. Tr. at 248, 251.

217. Petitioner's testimony that he discharged the patient with oral instructions to take five milligrams of Vasotec twice a day is credible. Tr. at 503 - 504, 506.

218. The I.G. did not prove that the patient was discharged with instructions to take the higher dosage of ten milligrams of Vasotec twice a day. I.G. Ex. 23.

219. The I.G. gave Petitioner sufficient notice that she was alleging that Petitioner inaccurately documented his treatment of the patient on the discharge summary, and that this documentation error was a basis for the I.G.'s determination to exclude Petitioner. Notice at 5.

220. Petitioner admits that the discharge summary incorrectly states that this patient was discharged on five milligrams of Capoten twice a day. Tr. at 509 - 510.

221. Petitioner admits that the discrepancy between his December 9, 1991 progress notes and his December 30, 1991 discharge summary might be confusing to a physician attempting to treat the patient if he was readmitted to the hospital. Tr. at 507.

222. Petitioner's failure to accurately document his discharge instructions on the December 30, 1991 discharge summary was a substantial violation of his obligation to provide care which is supported by the necessary documentation.

223. The I.G. did not prove that professionally recognized standards of care require Petitioner to write

the discharge instructions in the progress notes and on the physician order sheet. Tr. at 623 - 624.

224. The I.G.'s contention that Petitioner's documentation of his treatment of this patient is deficient because the patient's chart does not include a written discharge instruction sheet is not encompassed by the allegations in the Notice. Notice at 5.

225. The absence of a written discharge instruction sheet in this patient's chart is not a valid basis for Petitioner's exclusion in this case.

226. The I.G.'s contention that Petitioner's documentation of his treatment of this patient is deficient because Petitioner failed to explain the reasons for the changes in the patient's cardiac medication is not encompassed by the allegations in the Notice. Notice at 5; Tr. at 246 - 247, 249.

227. The I.G.'s allegation that Petitioner failed to explain the reasons for the changes in the patient's cardiac medication is not a valid basis for Petitioner's exclusion in this case.

Patient 030053 (Discussion begins on page 82)

228. Patient 030053, a 76-year old male who suffered from diabetes mellitus, was brought by ambulance to the emergency room at Little Falls Hospital on December 27, 1991, after an episode of coma induced by his overdosing himself with 70 units of insulin that morning. I.G. Ex. 24 at 12 - 13.

229. The normal range for blood sugar values is 80 to 120 mg/dL. Tr. at 140.

230. The emergency medical technicians who transported the patient had found that his blood sugar was 33 mg/dL, and they administered 50 percent Dextrose. I.G. Ex. 24 at 10.

231. By the time the patient arrived at the emergency room, the patient's blood sugar was 180 mg/dL, and he was alert and oriented. I.G. Ex. 24 at 10.

232. The patient suffered another episode of hypoglycemia in the emergency room and was admitted to the hospital for observation. I.G. Ex. 24 at 12.

233. On December 27, 1991, the nursing staff checked the patient's blood sugar at 4:30 p.m., when his blood sugar

level was 77; at 9:30 p.m., when his blood sugar level was 26; and at 9:45 p.m., when his blood sugar level was 57. I.G. Ex. 24 at 32 - 33.

234. On December 27, 1991, at 10:15 p.m., the nursing staff noted a telephone order from Petitioner to "change IV solution to Dextrose 10% -- run at rate to obtain blood sugar above 80 then slow IV down to KVO [keep vein open] for the n[ight]." I.G. Ex. 24 at 14.

235. On December 27, 1991, at 10:30 p.m., the nursing staff noted that the patient's blood sugar level was 108. I.G. Ex. 24 at 32 - 33.

236. There is no record that the patient's blood sugar level was monitored again until 6:30 a.m. on December 28, 1991, when the patient's blood sugar level was 134. I.G. Ex. 24 at 32 - 33, 35.

237. Professionally recognized standards of health care require that the attending physician specify a rate for administering IV Dextrose to a hypoglycemic patient. Tr. at 137, 139.

238. Professionally recognized standards of health care require the attending physician to establish a plan of care for a hypoglycemic patient that would specify regular monitoring of the patient's blood sugar. I.G. Ex. 3 at 119 - 120; Tr. at 138.

239. Petitioner's orders for this patient failed to specify a rate of administration for IV Dextrose and failed to specify regular monitoring of the patient's blood sugar levels.

240. Even if Petitioner's order to administer 10 percent Dextrose at a KVO rate once blood sugar was normal was sufficient, the fact that this patient's blood sugar was not monitored between 10:30 p.m. on December 27, 1991 and 6:30 a.m. the next morning would represent care that failed to meet professionally recognized standards.

241. Petitioner's failure to order a rate for administering the IV Dextrose, and his failure to order regular monitoring of the patient's blood sugar, are substantial violations of his obligation to provide care of a quality that meets professionally recognized standards of health care.

Patient 030344 (Discussion begins on page 85)

242. Patient 030344, a 76-year-old male, was admitted to Little Falls Hospital on August 15, 1991 with complaints of dyspnea, weakness, and intermittent chest pain. Petitioner diagnosed auricular fibrillation. I.G. Ex. 25 at 7, 13, 15.

243. On August 20, 1991, Petitioner ordered that the patient be placed on Heparin, an intravenous anticoagulant medication. I.G. Ex. 25 at 11, 19; Tr. at 277.

244. On August 25, 1991, the patient was discharged. I.G. Ex. 25 at 9.

245. Petitioner's handwritten progress notes, dated August 25, 1991, and his typewritten progress notes, dated September 18, 1991, indicate that Petitioner discharged the patient with instructions to follow a low sodium diet, to take various medications (Vasotec, Lasix, and Isosorbide), and to come in for a follow-up visit. I.G. Ex. 25 at 11, 25.

246. The discharge instruction sheet, prepared by the nurse who discharged the patient, repeated the instructions given by Petitioner in his progress notes. I.G. Ex. 26 at 76.

247. Professionally recognized standard of care requires the attending physician to write his discharge instructions in the medical chart. The nurse who discharges the patient will include the attending physician's instructions in the discharge instruction sheet which is given to the patient. Tr. at 285 - 287.

248. Neither Petitioner's handwritten nor his typewritten progress notes indicate that the patient was instructed to take Coumadin, an anticoagulant medication, at the time that he was discharged. The discharge instruction sheet, prepared by the nurse in response to Petitioner's progress notes, did not include an instruction for the patient to take Coumadin. I.G. Ex. 25 at 11, 25, 76; Tr. at 277.

249. After IPRO reviewed this chart and requested a response, Petitioner stated for the first time that the patient was treated with Coumadin as an outpatient after his discharge from the hospital. I.G. Ex. 25 at 4.

250. Petitioner admits that his failure to document his intent to treat this patient with Coumadin on discharge

was a documentation error. Petitioner's Brief at 56 - 57.

251. Petitioner's failure to document his intent to prescribe Coumadin to this patient on discharge is a substantial violation of his obligation to provide necessary documentation of his care.

Patient 039069 (Discussion begins on page 88)

252. Patient 039069, a 76-year-old male, was admitted to Little Falls Hospital on September 22, 1991, complaining of vertigo and nausea. I.G. Ex. 26 at 9 - 10.

253. Petitioner's initial examination of this patient revealed that he had generalized arteriosclerosis with acute episodes of vertigo, mild organic brain syndrome, and arteriosclerotic heart disease with ongoing auricular fibrillation and cardiac prominence. I.G. Ex. 26 at 9.

254. Petitioner noted in his progress notes that the patient had been under the care of several cardiac and orthopedic physicians, but there is no mention of any contact with these physicians during the patient's admission. I.G. Ex. 26 at 9.

255. A CBC was performed on the patient approximately seven days before admission. A CBC was not performed at the time of admission. I.G. Ex. 3 at 23; I.G. Ex. 6 at 82.

256. A CBC was necessary at admission. I.G. Ex. 26 at 4, I.G. Ex. 6 at 182 - 183, I.G. Ex. 30 at 11.

257. Petitioner did not indicate on the chart that he did not perform a CBC and he did not explain why a CBC was not performed on admission. In addition, the results of the prior CBC are not documented on the patient's chart. I.G. Ex. 26.

258. Petitioner's failure to document that he did not perform a CBC on this patient at the time he was admitted, his failure to explain why a CBC was not performed on admission, and his failure to document the results of the CBC performed prior to admission is a substantial violation of his obligation to provide the necessary documentation of care. I.G. Ex. 26, I.G. Ex. 29 at 7.

Patient 037680 (Discussion begins on page 91)

259. Patient 037680, an 85-year-old female, was admitted to Little Falls Hospital on August 21, 1991. Her chief complaint was that she was having hallucinations. Although the patient had some insight into her problem, the hallucinations had a considerable reality to the patient and disturbed her. I.G. Ex. 27 at 5 - 6.

260. The patient had a brother who lived nearby. I.G. Ex. 27 at 5.

261. At the time of the patient's admission to the hospital, Petitioner diagnosed organic brain syndrome with hallucinatory and delusional state. I.G. Ex. 27 at 5.

262. Physical examination of the patient revealed evidence of bilateral arthritis of both knees, and that the right knee was acutely inflamed. I.G. Ex. 27 at 6.

263. From August 21, 1991 through August 23, 1991, the patient alternated between being disoriented and being lucid. At times, she did not realize that she was in the hospital, and, at other times, she was oriented and gave appropriate responses. I.G. Ex. 27 at 56, 59 - 61.

264. On August 23, 1991, Petitioner performed an arthrocentesis of the patient's right knee. I.G. Ex. 27 at 61; Tr. at 149, 223.

265. Arthrocentesis is an invasive procedure which involves inserting a needle into the patient's knee and withdrawing fluid. I.G. Ex. 27 at 61; Tr. at 149 - 151, 223.

266. Petitioner's progress notes describe the procedure and its results as follows: "Tapped Rt [right] Knee - Old Blood - Hemarthrosis." I.G. Ex. 27 at 19.

267. Within 45 minutes after the arthrocentesis was performed, the patient began to cry and stated that she saw snakes coming out of a box containing needles. The patient stated that, although she knew the snakes were not real, she still could see them. The patient reported seeing snakes the next day. I.G. Ex. 27 at 61, 65.

268. During the course of the patient's hospital stay, she was treated with insulin, and her hallucinations improved. At the time of her discharge on September 10, 1991, the patient had achieved mental equilibrium. I.G. Ex. 27 at 25, 26.

269. Professionally recognized standards of health care require that a physician obtain informed consent prior to performing an invasive procedure. Tr. at 150.

270. Arthrocentesis is an invasive procedure. Tr. at 149.

271. Professionally recognized standards of health care regarding the process for obtaining informed consent require the physician to explain the purpose of the procedure, how it will be performed, the possible benefits of the procedure, and the possible complications of the procedure. The patient should be given the opportunity to ask questions of the physician. Tr. at 300.

272. The patient's chart does not contain a consent form for the arthrocentesis. I.G. Ex. 27.

273. If the patient is incapable of understanding information pertaining to the procedure, it should be explained to an adult who is the closest relative to the patient. Consent for performing the procedure should be obtained from that individual. Tr. at 151.

274. Petitioner did not make any attempt to contact the patient's brother in order to obtain consent. Tr. at 231.

275. The fact that the patient was delusional does not necessarily mean that she was incapable of giving informed consent for the arthrocentesis. Tr. at 561.

276. Petitioner's assertion that the patient gave informed consent orally is not corroborated by the evidence. Petitioner's Brief at 70.

277. Petitioner's self-serving assertion that he obtained informed consent is not credible.

278. Petitioner did not obtain informed consent from this patient.

279. The right of a patient to be fully informed about the treatment being recommended and to refuse that treatment is a basic right which is codified in the New York State Patients' Bill of Rights. Tr. at 563; I.G. Ex. 27 at 111.

280. Petitioner's failure to obtain informed consent from this patient shows a disturbing indifference to the fundamental rights of patients and it is a substantial

violation of Petitioner's obligation to provide care that meets professionally recognized standards of care.

281. Professionally recognized standards of care require a physician to document that oral consent has been obtained. Tr. at 563 - 565.

282. Even if Petitioner had obtained valid consent orally, Petitioner's failure to document that such consent was obtained is a substantial violation of his obligation to document the quality of his care.

283. Hemarthrosis is a diagnostic term indicating that blood was found in the knee joint. Tr. at 160, 557.

284. Petitioner diagnosed the patient's medical condition based on his observations of the fluid withdrawn from the patient's knee and he documented this diagnosis in the patient's chart. I.G. Ex. 27 at 19.

285. Professionally recognized standards of care require a physician to write a procedure note for invasive procedures, such as arthrocentesis, performed at bedside. The procedure note should contain a comprehensive description of the indication for the procedure, the procedure itself, and the results. Tr. at 160 - 161, 301 - 302.

286. Petitioner's August 23, 1991 entry in the chart documents that arthrocentesis was performed and that old blood was obtained, but it does not describe the procedure and the results in sufficient detail to comport with professionally recognized standards of care. Tr. at 160 - 161.

287. Petitioner substantially violated a professionally recognized standard of health care by failing to document adequately the procedure performed on this patient.

288. Professionally recognized standards of care require that fluid withdrawn from a knee in the course of arthrocentesis should be sent for laboratory analysis. Tr. at 162 - 163.

289. Petitioner failed to prove that the fluid withdrawn from this patient's knee had degenerated to the point that sending it for a laboratory analysis would yield meaningless results.

290. The purpose of sending the withdrawn fluid to a laboratory for analysis is to obtain information

necessary to reach a final and complete diagnosis. Tr. at 163.

291. While hemarthrosis was a properly documented diagnosis based on the available information immediately following the arthrocentesis, it is not a final or complete diagnosis based on all tests that should have been performed.

292. Petitioner's discarding the withdrawn fluid without obtaining the necessary tests to make a final diagnosis is a substantial violation of professionally recognized standards of care.

Patient 034026 (Discussion begins on page 103)

293. Patient 034026, a 75-year old female, was admitted to Little Falls Hospital on July 24, 1991 with a diagnosis of renal colic. I.G. Ex. 28 at 8 - 11.

294. A laboratory test conducted on July 24, 1991 indicated that this patient had a blood glucose level of 232 mg/dL, an abnormally high result. I.G. Ex. 28 at 12.

295. Another blood test (SMA 18) was ordered on July 26, 1991. I.G. Ex. 28 at 21.

296. The results of that blood test are not recorded in the patient's medical record. I.G. Ex. 28.

297. This patient was discharged from the hospital on July 26, 1991. I.G. Ex. 28 at 8.

298. Petitioner admitted that there was no follow-up value for blood glucose in the patient's medical record. I.G. Ex. 28 at 4.

299. Petitioner admitted that results of the follow-up blood test should have been in the medical record. I.G. Ex. 28 at 4; Petitioner's Brief at 91.

300. The I.G. did not prove that Petitioner's care of this patient represented a quality of care violation.

301. Petitioner's failure to document the follow-up blood test result represents a substantial violation of his obligation to provide necessary documentation of the quality of his care.

Petitioner's substantial violations of his statutory obligations in a substantial number of cases

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

303. The I.G. proved that Petitioner engaged in a pattern of care that is inappropriate, unnecessary, did not meet professionally recognized standards of care, or was not supported by necessary documentation as required by IPRO.

304. The I.G. proved that Petitioner substantially violated his obligations under section 1156(a) in a substantial number of cases.

Petitioner's inability and unwillingness

305. The I.G. proved that Petitioner has demonstrated an unwillingness and lack of ability substantially to comply with his obligation to provide care in accordance with his obligation under section 1156(a) of the Act.

The remedial need for an exclusion

306. The remedial purpose of an exclusion imposed pursuant to section 1156 of the Act is to protect the welfare of program beneficiaries and recipients from providers who are untrustworthy to provide health care of the requisite quality.

307. The I.G. proved that Petitioner is an untrustworthy provider of care.

308. A five-year exclusion is reasonable in this case.

Serious Risk

309. The I.G. proved that Petitioner is a serious risk within the meaning of section 1156 of the Act.

RATIONALE

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

a. Section 1156 of the Act imposes obligations on health care providers.

The I.G. excluded Petitioner pursuant to section 1156(b)(1) of the Act. The I.G.'s authority to impose an exclusion under section 1156(b)(1) derives from a PRO's determination and recommendation that a party be excluded. In any hearing conducted under section 1156(b)(1), the administrative law judge must determine whether the PRO's recommendation is in accord with one of the statutory grounds on which an exclusion recommendation may be based.

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

In this case, IPRO based its exclusion recommendation to the I.G. on its conclusion that Petitioner had in a substantial number of cases substantially violated his statutory obligations under section 1156(a)(1) of the Act. The I.G. accepted IPRO's conclusion.

Section 1156(b)(1) states that, in order to exclude a provider based on a recommendation by a PRO, the Secretary (or the Secretary's delegate, the I.G.) must find that the party has demonstrated either an inability or an unwillingness substantially to comply with the obligations to provide care consistent with the requirements of section 1156(a). In this case, the I.G. found that Petitioner was unable and unwilling to comply

substantially with the obligations imposed on him by section 1156(a) of the Act.

Section 1156(b)(4) of the Act provides that a provider who is subject to an exclusion determination pursuant to section 1156(b)(1) is entitled to an administrative hearing. This section expressly confers on excluded providers those rights to a hearing which inure to parties under section 205(b) of the Act. Section 205(b) provides for a de novo hearing. Thus, parties excluded pursuant to section 1156(b)(1) are entitled to de novo hearings. My obligation in conducting a de novo hearing under sections 205(b) and 1156(b)(1) on the issue of the I.G.'s authority to exclude a provider is to allow each party to the hearing the opportunity to offer evidence concerning the sufficiency of the facts on which a PRO's recommendation and the I.G.'s ultimate determination are based.

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

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

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

42 C.F.R. § 1001.2.

The term "substantial violation in a substantial number of cases" also has been defined by regulation. The term means "a pattern of care that is inappropriate, unnecessary, does not meet professionally recognized

standards of care, or is not supported by the necessary documentation of care as required by a peer review organization." 42 C.F.R. § 1004.1(b).

It is apparent from this regulatory definition that a provider has violated his obligations under section 1156(a) of the Act in a "substantial number of cases" if there is a showing that the provider has engaged in a pattern of acts or omissions which substantially violate his statutory obligations.

While it is clear that there must be a pattern of substantial violations in order to meet this standard, the regulatory definition does not explicitly define what is meant by "substantial violation." In the absence of a regulatory definition of substantial violation, I give the word substantial as used here its common and ordinary meaning. "Substantial" is defined in the American Heritage Dictionary, 2d College Edition, as "5. Considerable in importance, value, degree, amount, or extent . . ." I conclude from this common definition that Congress intended the statutory term substantial violation to mean any violation that is not minor or trivial.

With these observations as background, I turn now to an examination of the individual cases which the I.G. relies on to support the I.G.'s allegation that Petitioner substantially violated his obligations under section 1156(a) in a substantial number of cases.

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

The I.G. Notice alleged that Petitioner substantially violated his obligations under section 1156(a) of the Act in 14 cases. During the course of this proceeding, the I.G. withdrew one of the cases involving a violation of the obligation to provide care of a quality that meets professionally recognized standards of health care. Two of the remaining 13 cases involve the same patient. Thus, at issue in this proceeding are 13 cases involving 12 different patients. My decision on the issue of whether Petitioner substantially violated his statutory obligations in a substantial number of cases is based on evidence which relates to IPRO's findings in these 13 cases.

The record shows that, on December 15, 1988, IPRO's predecessor, ESMSEF, notified the I.G. that Petitioner

had grossly and flagrantly violated his obligations under section 1156 of the Act and recommended that he be permanently excluded. The I.G. concluded that there was insufficient information to support this recommendation, and returned the case to ESMSEF without prejudice. P. Ex. 14.

On June 16, 1989, ESMSEF made an initial determination that Petitioner had failed to comply substantially with his obligations under section 1156 of the Act in 14 cases. Petitioner met with representatives of ESMSEF on August 17, 1989 to discuss these 14 cases. During that meeting, Petitioner and ESMSEF agreed that Petitioner would participate in a CAP. I.G. Ex. 7, 8, 9.

On June 19, 1992, IPRO issued an initial sanction notice advising Petitioner that it had made an initial determination that Petitioner had failed to comply substantially with his obligations under section 1156 of the Act in 26 new cases. That notice, including the cases referred to therein, was subsequently withdrawn by IPRO. I.G. Ex. 11, 14, 15.

In reaching my decision on the issue of whether Petitioner substantially violated his obligations in a substantial number of cases, I have not considered the cases which formed the basis for ESMSEF's December 15, 1988 recommendation, nor have I considered the 14 cases which formed the basis for its June 16, 1989 initial determination. In addition, I have not considered the 26 cases which formed the basis for IPRO's June 19, 1992 initial determination.

At the hearing, the I.G. offered the testimony of two expert witnesses, Herbert Sperling, M.D. and Richard Kops, M.D. Dr. Sperling, a board-certified surgeon, was the chairman of the IPRO Sanction Committee from 1989 to 1992. I.G. Ex. 32. Dr. Kops is board-certified in both gastroenterology and internal medicine. In addition, he has been a consultant to IPRO for 11 years. Tr. at 239 - 241. Petitioner offered the testimony of Peter Nicholas, M.D. Dr. Nicholas is board-certified in both internal medicine and infectious diseases. Tr. at 366. All three of these individuals are highly qualified practitioners whose credentials were not disputed by the opposing party.

The experts whom the I.G. called as witnesses at the hearing have been involved in the review of Petitioner's treatment of patients during the peer review process conducted by IPRO. While Petitioner has not disputed the professional qualifications of these witnesses, he

contends that IPRO is biased against him and that it is "unwilling and unable to fairly assess" his practice. Petitioner's Brief at 100 - 101. In particular, Petitioner contends that Dr. Sperling has demonstrated a bias against him. Petitioner's Brief at 97. In support of these allegations, Petitioner points to parts of Dr. Sperling's testimony in which he disagrees with Dr. Sperling's opinions and characterization of the facts. Petitioner argues that Dr. Sperling's bias, combined with IPRO's "effort to taint the record with . . . unsupported allegations and unilateral findings" against him, cast doubt on IPRO's ability to assess his performance as a medical practitioner in accordance with the requirements of due process. Petitioner's Brief at 97.

I find that Petitioner's allegations of bias are not supported by the record. Petitioner's attempt to bootstrap his disagreement with the IPRO's conclusions into allegations of bias is not persuasive. Petitioner has not adduced credible evidence that Dr. Sperling or other members of IPRO are biased against him. I find Dr. Sperling and Dr. Kops to be knowledgeable and dispassionate experts. By contrast, Petitioner's assertion of bias is motivated by self-interest.

Moreover, Petitioner's argument that he was not provided due process during the sanction process is unavailing. In this regard, the exhaustive administrative record in this case speaks for itself. Petitioner was offered many opportunities to provide information that he thought might convince the reviewers of the propriety of his practices. He took advantage of these opportunities. That IPRO did not make the desired determination is not evidence that due process was denied.

I have evaluated the evidence pertaining to the I.G.'s allegations. I do not find that the I.G. proved that Petitioner violated his obligations under the Act in each of the 13 cases. However, in every instance that I find that the I.G. proved that Petitioner violated an obligation under the Act, I find also that the violation is substantial. Moreover, I find that there are a sufficient number of cases where Petitioner substantially violated his obligations under the Act to prove that Petitioner engaged in a pattern of acts or omissions which substantially contravened his obligations under section 1156(a) of the Act. The I.G. thus proved that Petitioner substantially violated his obligations under section 1156(a) in a substantial number of cases.

I will now proceed to an analysis of the 13 cases at issue in this proceeding. For each case, I will quote

verbatim the PRO Findings, the I.G. Analysis, and the I.G. Decision as set forth in the Notice. I will follow this with my analysis of the evidence pertaining to that case.

Patient 031409

> PRO Findings: Failure to order complete blood count, bilirubin, alkaline phosphatase, SGOT or amylase on a patient.
>
> [I.G.] Analysis: Patient admitted with chest and abdominal pain. Sonogram shows cholelithiasis and cholecystitis. Practitioner's failure to order appropriate tests constituted a failure to evaluate gallbladder and liver function in a patient with diagnosed cholelithiasis.
>
> [I.G.] Decision: The medical records support the PRO findings, and the findings are upheld. (Quality of care violation)

My Analysis: This patient was a 73-year old female who was admitted to Little Falls Hospital on July 29, 1991 complaining of pain in her back and shoulders. I.G. Ex. 16 at 9, 13. Because the patient had a history of heart disease, it first appeared that her symptoms might be related to her heart, but her pain did not respond to nitroglycerin. I.G. Ex. 16 at 13; Tr. at 325. A gallbladder sonogram was done to rule out gallbladder colic as a cause of her pain. I.G. Ex. 16 at 10. The sonogram revealed evidence of cholelithiasis (gallstones) and suggested cholecystitis, an infection of the gallbladder. I.G. Ex. 16 at 59; Tr. at 39 - 40.

Dr. Sperling testified that professionally recognized standards of health care for treating a patient with possible gallbladder disease would be to order blood tests to determine the extent of the gallbladder infection and to determine whether the liver and pancreas were involved. Tr. at 39 - 43. This opinion was corroborated by Dr. Kops. Tr. at 310 - 311, 315 - 316. Neither Petitioner nor his expert testified that a different professionally recognized standard was applicable.[8] Therefore, I conclude that professionally

---

[8] At the meeting with IPRO on November 10, 1992, Petitioner stated that the tests would be appropriate for a patient presenting purely with gallbladder colic. I.G. Ex. 6 at 12. Petitioner's expert did not suggest that

(continued...)

recognized standards of health care required Petitioner to order a CBC, and serum amylase, alkaline phosphatase, bilirubin, and transaminase (SGOT) tests.

Petitioner acknowledges that he did not order these tests during the July 29, 1991 hospitalization of this patient. However, Petitioner offers a number of explanations as to why such tests were not needed in this particular case. First, Petitioner contends that the tests were not needed because the patient's physical symptoms indicated that her gallbladder disease was likely chronic, rather than acute, and, in any event, she was not a candidate for surgery. Petitioner's Brief at 4 - 5. Alternatively, Petitioner contends that, if the tests were needed, they had been done four days earlier, during a previous admission, with normal results. Petitioner's Brief at 5 - 6. Finally, Petitioner contends that he consulted a gastroenterologist, who did not recommend that the patient undergo further gallbladder studies. Petitioner's Brief at 7, 9. I do not find any of Petitioner's explanations sufficient to overcome the I.G.'s showing that Petitioner violated professionally recognized standards of health care.

Petitioner contends that the CBC and enzyme studies were not required, because his physical examination of the patient did not reveal local tenderness or right upper quadrant pain and she did not have fever or chills. Tr. at 334 - 335. Petitioner contends that these physical symptoms would have been present had the patient been suffering acute gallbladder complications. In essence, Petitioner is contending that whether the patient's gallbladder disease is chronic or acute would dictate the course of her diagnostic testing. While it can be argued that a chronic gallbladder condition might not require new diagnostic tests, this would occur only after those tests had been done previously and ruled out the need for more invasive treatment. However, nowhere in the medical record does Petitioner document a conclusion that the gallbladder sonogram and physical examination suggested chronic, rather than acute, gallbladder disease, and that, therefore, no further studies were warranted. Tr. at 408.

---

[8] (...continued)
the tests were not required in treating gallbladder disease; instead, he opined that the tests were not needed in this case because the patient did not have clinical symptoms related to her gallbladder. Tr. at 404 - 405.

Moreover, the testimony of Dr. Nicholas goes even farther than Petitioner's testimony. He opined that the tests were unnecessary because the patient did not have any clinical symptoms referable to her gallbladder. Tr. at 405. However, Dr. Nicholas' opinion is contradicted by Petitioner's discharge note, which gives a final diagnosis of thoracic pain probably secondary to cholecystolithiasis. I.G. Ex. 16 at 10.[9] Further, at the November 10, 1992 IPRO meeting, Petitioner stated that the patient's pain was consistent with gallbladder colic. I.G. 6 at 13. Therefore, Dr. Nicholas' conclusion that the patient's pain was not referable to gallbladder disease must be given little weight, since it assumes findings and conclusions which are contrary to those documented in the patient's medical record.

Similarly, Petitioner's testimony must be given less weight when compared with his documented findings in the patient's chart. As his note indicates, at the time he discharged this patient, Petitioner apparently concluded that her symptoms most likely were related to gallbladder disease. Petitioner's discharge note and his statement to IPRO were made closer in time to his treatment of the patient than his testimony in these proceedings. Therefore, I find the discharge note and the IPRO statement more probative of his thinking at that time than explanations he has produced after the fact which are not supported by documentation in the medical record. Therefore, I conclude Petitioner considered it likely that this patient was suffering pain due to gallbladder disease, yet did not order a CBC and enzyme tests, or give any explanation for the absence of such tests, tests that are required in accordance with professionally recognized standards of health care.

Petitioner argues that, even if a CBC and other enzyme tests were required, it was unnecessary to perform them during this patient's July 29, 1991 admission because similar tests done during a previous admission just four days earlier were within normal limits. Petitioner offered P. Ex. 48, which shows that during the July 25, 1991 admission, Petitioner ordered a CBC and SGOT for this patient, the results of which were within normal limits. In addition, the bilirubin results were negative. P. Ex. 48; Tr. at 339 - 340. I conclude that the fact that these tests were performed during a prior admission does not justify Petitioner's failure to order

---

[9] The term "cholecystolithiasis" refers to the presence of stones and the thickening of the gallbladder wall. Tr. at 409.

them during the July 29, 1991 admission, for three reasons. First, not all the required enzyme tests were performed during the July 25, 1991 admission. Second, there is no indication in the patient's medical record that Petitioner relied on the earlier tests in ruling out acute gallbladder disease as a cause of the patient's pain. Third, since he did not reference her prior admission, there is no way of determining whether her gallbladder symptoms as of July 29, 1991 demonstrated a worsening of her condition which would have required additional diagnostic tests to determine whether her condition had changed from chronic to acute, thus requiring a change in her treatment.

As to the first point, I have concluded that professionally recognized standards of health care would require a physician to evaluate possible gallbladder disease by ordering a CBC, as well as measuring bilirubin, alkaline phosphatase, transaminase (SGOT), and amylase levels. There is evidence that Petitioner ordered the CBC, SGOT, and bilirubin during the July 25, 1991 admission. P. Ex. 48. There is no indication in the record that Petitioner ever ordered tests to determine this patient's alkaline phosphatase or amylase levels. Id.; see also Tr. at 341 - 342. Therefore, even if I were to conclude that Petitioner properly relied on earlier test results in evaluating this patient, I would find that the tests which Petitioner ordered during the July 25, 1991 admission did not completely satisfy his duty to provide care in accordance with professionally recognized standards.

Second, Petitioner failed to document in the medical record that he was relying on earlier test results as a basis for ruling out acute gallbladder disease as a cause of her pain. I.G. Ex. 16; Tr. at 342. As I previously noted with regard to Petitioner's explanation that the patient's clinical symptoms were more consistent with chronic, rather than acute, gallbladder disease, the absence of contemporaneous documentation suggests to me that this explanation, too, may be an after-the-fact justification. Petitioner's present reliance on the previous test results, like his explanation of the clinical symptoms, fails to account for his failure to address this issue in his discharge summary.

Third, the absence of any discussion in Petitioner's discharge summary of this patient's prior history with gallbladder disease, including a description of her earlier symptoms, does not provide me with any basis to conclude that her symptoms of July 29, 1991 were merely a continuation of her chronic symptoms and not a new acute

phase of her gallbladder disease. The latter condition would require diagnostic studies that were not performed by Petitioner during this patient's July 29, 1991 admission.

For these reasons, the test results from the patient's July 25, 1991 admission do not alter my conclusion that Petitioner violated his duty to provide care in accordance with professionally recognized standards.

Finally, Petitioner argues that he did not violate professionally recognized standards of health care because he justifiably relied on the opinion of a consulting gastroenterologist, who did not recommend further diagnostic studies, other than endoscopy, nor suggest a diagnosis of gallbladder disease. See I.G. Ex. 16 at 21. I conclude that Petitioner's consultation of a gastroenterologist did not relieve him of the duty to either order the required tests or, at a minimum, to discuss the results of the patient's gallbladder sonogram with the gastroenterologist. Dr. Kops opined that it would be standard practice for a consulting gastroenterologist to comment on the results of a gallbladder sonogram, if the consultant were aware of such results. Tr. at 314. Because the consultant's report in this case did not mention the gallbladder sonogram, the I.G.'s expert suggested that the consultant may not have been aware of the results at the time he dictated his report. Tr. at 312, 314 - 315. He stated further that professionally recognized standards of health care would require the family practitioner to discuss the results of the sonogram with the specialist and that they jointly would decide on the future course of treatment for the patient. Tr. at 313. At the hearing, Petitioner could not recall whether he discussed the results of the sonogram with the consultant. Tr. at 333.[10] Nor is there any reference to such communication in the patient's medical record. I.G. Ex. 16. The consultant's report does not say that gallbladder disease was considered and ruled out, it simply does not mention gallbladder disease. I find that the consultant's report is insufficient to justify Petitioner's failure to order further diagnostic studies.

For these reasons, I conclude that the I.G. proved that Petitioner's failure to order a CBC, and blood levels of serum amylase, alkaline phosphatase, bilirubin, and

---

[10] At the November 10, 1992 IPRO meeting, Petitioner stated, "I had Dr. Wong look at her I think before I defined gall stones." I.G. Ex. 6 at 15.

transaminase during the July 29, 1991 admission was a substantial violation of his duty to provide care of a quality that meets professionally recognized standards.

Patient 031943

> PRO Findings: Failure to properly evaluate and follow-up a patient with abnormal laboratory findings (anemia and blood in stools) and positive family history for gastrointestinal malignancy.
>
> [I.G.] Analysis: Patient admitted with chest pressure. Patient had guaiac positive stool and a Hgb of 8.2. Patient with hiatus hernia had colonoscopy performed, which showed diverticulosis, but not esophagogastroduodenoscopy or upper GI [series], for anemia requiring transfusion of two units of blood.
>
> [I.G.] Decision: The medical records support the PRO findings, and the findings are upheld. (Quality of care violation)

My Analysis: On August 27, 1991, this patient, a 67-year-old female, was admitted to Little Falls Hospital with complaints of chest pressure. I.G. Ex. 17 at 13, 15. The patient had a family history of stomach cancer. I.G. Ex. 17 at 13. Blood tests met the criteria for a diagnosis of anemia. I.G. Ex. 17 at 15; Tr. at 77. A stool sample was noted as being 4+ for occult blood. This result was strongly positive for bleeding. I.G. Ex. 17 at 15; Tr. at 288 - 290. On August 29, 1991 the patient was transfused with two units of blood, in response to the anemia. I.G. Ex. 17 at 33; Tr. at 347. A second stool sample taken on September 1, 1991 produced a +1 result. I.G. Ex. 17 at 34. Petitioner's expert, Dr. Nicholas, testified that a +1 occult blood test result indicated that the patient's bleeding had essentially stopped. Tr. at 436 - 437.

On September 3, 1991, Petitioner ordered the patient to undergo a colonoscopy. The colonoscopy examined the patient's rectum and lower GI tract. The doctor who performed the procedure, Dr. Sodhi, determined that the patient had diverticulosis of the sigmoid colon.[11] I.G.

---

[11] Diverticulosis is "the presence of pouches or sacs in the colon, which are caused by herniation of the mucosa of the colon through the muscular layers of the bowel wall." I.G.'s Brief at 18, footnote 3.

(continued...)

Ex. 17 at 31. Dr. Sodhi noted in his "Report of Operation" that "[a]lthough the diverticulosis could cause a GI hemorrhage, I don't [sic] it would give anemia of this significance." Id. Dr. Kops commented on Dr. Sodhi's statement. He suggested that the source of the bleed in this case was not the diverticulosis, since patients who bleed from diverticulosis generally bleed with bright red blood and the patient here had a dark stool. Tr. at 293. Petitioner acknowledged that, although the patient had diverticulosis, her anemia was relatively severe for that condition. Tr. at 348. He testified that he did not obtain an endoscopy or upper GI series to investigate the upper GI bleed because: 1) he did not do any defensive medicine; and 2) based on this patient's dislike of the colonoscopy, Petitioner concluded she would not "enjoy" the endoscopic procedure of her upper GI tract. Tr. at 348 - 349.

Petitioner diagnosed the cause of the patient's bleeding as a hiatus hernia. He based this diagnosis on the fact that she had this condition approximately three years earlier.[12] I.G. Ex. 17 at 4, 11 - 12; Tr. at 349. On the basis of his diagnosis and his determination that the patient did not exhibit progressive anemia, Petitioner discharged her with the recommendation that she be observed over a period of time. Tr. at 349. In addition, he told her to elevate the head of her bed, take Zantac and Maalox, and lose weight. I.G. Ex. 17 at 12.

All three experts who testified about this particular patient stated that the bleed in this case was most likely due to an upper GI bleed. Dr. Kops testified that the 4+ stool test and the presence of darkened stool was indicative of bleeding from the patient's upper GI tract. Tr. at 289 - 290. Dr. Sperling testified also that the presence of dark stool signified upper GI tract bleeding. Tr. at 78, 93. Dr. Nicholas stated that he believed that the bleed had come from the upper tract and explained that darkened stool is caused by blood from the upper GI tract that has been digested by bacteria in the gut. Tr. at 412 - 413. However, Petitioner did not order any examination of the patient's upper GI tract and relied

---

[11] (...continued)

[12] A hiatus hernia is "a herniation of the abdomen through the diaphragm." I.G.'s Brief at 18, footnote 3.

instead upon the hiatus hernia diagnosis which he had made approximately three years earlier. Tr. at 349 - 350.

Both Dr. Kops and Dr. Sperling testified that professionally recognized standards of care for a patient with an unexplained upper GI bleed are to perform either an endoscopy or an upper GI series, provided that neither was contraindicated for the patient. Tr. at 78 - 79, 290, 297. An endoscopy is a procedure used to examine the upper GI region, and involves placing a tube down through the esophagus and then passing it under direct vision into the stomach. The procedure is also known as esophagogastroduodenoscopy and can be used to rule out the presence of an ulcer, cancer of the stomach or esophagus, gastritis in the stomach, or esphogeal varices. Tr. at 81 - 83; I.G. Ex. 33. Dr. Kops testified that an endoscopy allows the clinician to visualize the bleeding and, in most cases, spot the exact source of the bleeding. Tr. at 291. An upper GI series test involves the patient taking a barium swallow and then having an x-ray taken. Tr. at 89. Both Dr. Sperling and Dr. Kops indicated that the upper GI series is not as accurate as the endoscopy, in that it cannot identify gastritis, ulcerations, or small lesions, but it is another viable alternative for diagnosing an upper GI bleed. Tr. at 83, 89 - 90, 291. Dr. Kops testified that there were no contraindications for doing either an endoscopy or an upper GI series on this patient, and both he and Dr. Sperling stated that Petitioner's failure to rule out upper GI tract bleeding with an upper GI workup was a digression from professional standards of care. Tr. at 79 - 84, 298.

In support of the argument that professionally recognized standards of care dictate that an endoscopy or upper GI series should be used to diagnose an upper GI bleed, the I.G. relied on Harrison's Principles of Internal Medicine. I.G.'s Brief at 23. However, Petitioner contended, through his expert Dr. Nicholas, that there is considerable controversy about the role of routine endoscopy in upper GI bleeding. Tr. at 417. Dr. Nicholas opined that, based on a study showing no increase in the number of further hospital admissions, surgeries, or death for patients who did not have an endoscopy, and who were treated only with antacid therapy, endoscopy should not be a routine procedure in patients with upper GI tract bleeding that ceases during

treatment.[13] Tr. at 417 - 418. Dr. Nicholas testified that since the bleeding in this case had essentially stopped, as evidenced by the +1 occult blood test result, an endoscopy was not necessary.

I do not find Petitioner's reliance on this controversy about the efficacy of endoscopy in evaluating the source of GI bleeds to be persuasive. The presence of a controversy relating to the need for endoscopy does not justify the conclusion that endoscopy examinations or upper GI x-ray series should not be done when upper GI bleeding occurs which ceases after the initial bleeding. Moreover, Dr. Nicholas acknowledged that, despite the existence of the controversy "some people [physicians] do endoscopies for all upper GI bleeds." Tr. at 424. Furthermore, Petitioner has failed to demonstrate that the existence of the controversy in 1991 altered professionally recognized standards then in effect to do endoscopic or upper GI x-ray examinations.

Petitioner did not offer any evidence to prove that he relied upon the controversy cited by his expert in making

---

[13] The "Routine Early Endoscopy in Upper-Gastrointestinal-Tract Bleeding" study relied on by Dr. Nicholas indicates that an endoscopy is useful if the patient experienced prior episodes of bleeding or if the presence of a malignant disease is possible. P. Ex. 53 at 4 - 5.

Even if we were to accept Dr. Nicholas' assertion and find that the standards of care do not require an immediate endoscopy for a patient presenting with an upper GI bleed that ceases during treatment, this case falls within an exception to the standards. The study on which Petitioner relies states that there are situations where an endoscopy may be necessary in order to make a specific diagnosis, and this includes a patient who has had prior episodes of bleeding. P. Ex. 53 at 5. The patient here did have recurrent bleeding in that she had bled back in 1987, and, if the source of the present bleed wasn't discovered, she was at risk of bleeding again. Moreover, another exception to the general conclusion made in this study is that an early endoscopy should be used if there is a suspicion of malignancy. P. Ex. 53 at 4. Thus, even though the bleeding in this case had essentially stopped by September 1, the fact that the patient here had prior episodes of bleeding and was at risk of having a malignancy (due to her family history) makes this an exception to Petitioner's cited rule.

his decision to forego doing an endoscopy on this patient.[14] To the contrary, he testified that he based his decision on his dislike of defensive medicine and this patient's dislike of undergoing uncomfortable procedures. Interestingly, the colonoscopy that Petitioner ordered for this patient is considered to be a more strenuous test than an endoscopy. Tr. at 298. A colonoscopy takes longer and requires more sedation than does an endoscopy. Id. Moreover, it appears that Petitioner's belated reference to this controversy is an attempt to use post hoc rationalizations as an explanation for his actions. Thus, I find that, absent any evidence that the controversy regarding the use of endoscopies had been resolved in Petitioner's favor in 1991, and absent any evidence that Petitioner was even aware of the controversy and relied on it to support his treatment of this patient, the expert testimony regarding the standard of care in 1991 should be applied in this case.[15]

Petitioner belatedly argued also that an endoscopy was not done during the hospitalization, due to the unavailability of an endoscopist, and that further GI evaluation would have been performed subsequent to her discharge if she had not adequately recovered as an outpatient. Tr. at 353; I.G. Ex. 17 at 4. He made this argument in April 1992, in response to IPRO's challenge of the treatment of this patient. I.G. Ex. 17 at 4. Again, such reasoning is suspect, since Petitioner's

---

[14] Petitioner acknowledged that an endoscopic examination would have been the most accurate means to diagnose the reason for the upper gastrointestinal bleed. Tr. at 353.

[15] The I.G. attempted to introduce an article which contradicts the one relied on by Petitioner. The I.G. asserts that this article, which is written by one of the same authors of the article cited by Petitioner, indicates that the standards of care for upper GI bleeds requires early endoscopies. I.G.'s Brief at 23 - 24. I do not accept this article into evidence because it was submitted untimely. The I.G. had the opportunity to request an extension of time to submit the article after the hearing in this case and failed to do so. Moreover, in light of my conclusion that the existence of a controversy in 1991 does not alter the professional standard of care to examine the patient's upper GI tract in instances of bleeding from that area, the new article offered by the I.G. is not relevant.

hospital progress notes for the patient (which were completed shortly after her discharge in 1991) contain no references to consideration of an endoscopy examination. I.G. Ex. 17 at 9 - 12. In response to my questions, Petitioner indicated that the progress notes contain the summarization of his treatment of the patient.[16] Tr. at 357. He further indicated that "all of the information that [he] thought ... was important to the patient that [he] discussed with her" would be included in his summary. Tr. at 358. When I inquired at the hearing why he did not include in his summary the circumstances regarding the endoscopic examination that were contained in his response to IPRO, he replied that this was a "simple omission." Tr. at 361. I do not find this to be a credible response. I conclude that Petitioner did not consider conducting an endoscopic examination of this patient either as part of her hospitalization or part of her aftercare.

Petitioner's failure to perform either an endoscopy or upper GI series examination was a substantial violation of professionally recognized standards of care. Petitioner's violation of professionally recognized standards of care is serious. Petitioner never definitively determined the source of the bleeding. Without doing appropriate diagnostic testing, he concluded that the bleeding resulted from an hiatus hernia. Dr. Kops testified that Petitioner's failure to do an upper GI examination of this patient exposed her to the serious risk of having a gastric malignancy go undetected, thus delaying necessary treatment. Petitioner's failure exposed this patient to the additional risk of rebleeding. Tr. at 292. Petitioner acknowledges that the endoscopic examination is the most accurate tool in diagnosing upper GI bleeds and that, if the patient rebled, such test would have been ordered. There is no credible evidence in the record to support Petitioner's assertion that an endoscopic examination could not be performed on this patient during her hospitalization. Nor do professionally recognized standards of care support Petitioner's apparent medical judgment to await a future GI bleed before conducting an upper GI examination of this patient.

---

[16] Petitioner testified that the progress notes reflect "the chief complaint, the physical findings that are pertinent, the laboratory work that's relevant and the final diagnosis and what happened to the patient." Tr. at 357.

Patient 039837

> PRO Findings: Failure to obtain a post-procedure x-ray resulting in delay of diagnosis, and failure to properly evaluate and work-up a septic patient.
>
> [I.G.] Analysis: Patient had a 40% collapse of a lung due to air between the lung and the chest wall. This followed an attempt to remove fluid from the chest, and required insertion of a chest tube to attempt to re-expand the lung by removing the aid compressing the lung. A chest x-ray should have been obtained to determine the status of the chest after the first procedure. Also, urine cultures were not obtained on this septic patient.
>
> [I.G.] Decision: The medical records support the PRO findings, and the findings are upheld. (Quality of care violation)

My Analysis: On September 28, 1991, this patient, an 89-year-old female, was transferred from the chronic care ward to the active floor of Little Falls Hospital. At the time of the transfer, her skin was mottled, as if she was about to die, and she was bathed in cold perspiration. She was unresponsive. She had a temperature of 104 degrees, a cough and diarrhea. I.G. Ex. 18 at 4, 11, 14, 16; Tr. at 211 - 212. Petitioner diagnosed her as being in a septic state. I.G. Ex. 18 at 14. Petitioner did not take a urine culture. However, he did take blood and sputum cultures. I.G. Ex. 18 at 5.

An x-ray revealed a large pleural effusion, a large amount of fluid in her right chest. I.G. Ex. 18 at 4, 48; Tr. at 213. This problem had appeared previously and it had been treated; however, it recurred rapidly. Tr. at 213. Petitioner performed a thoracentesis on the patient that day.[17] I.G. Ex. 18 at 12. The thoracentesis was accomplished with difficulty, since the patient could not sit up due to the fact that she had no palpable blood pressure. In order to perform the procedure, it was necessary for her to be placed with her right side down and her head slightly elevated. I.G. Ex. 18 at 4. A follow-up chest x-ray was not taken until the day following the thoracentesis. Tr. at 103, 215. On the second hospital day, September 29, a chest x-ray was performed which revealed a partial pneumothorax on the

---

[17] A thoracentesis is a procedure involving the insertion of a needle into the chest cavity to drain out fluid. Tr. at 95.

right side of the chest.[18] The patient had a partial collapse of her right lung. The upper lobe of the right lung adhered to the chest wall. I.G. Ex. 18 at 12, 49; Tr. at 95, 215. The partial collapse of the upper right lung meant that she had only the use of the lower right lung and the left lung to breathe. Tr. at 215.

On the third hospital day, September 30, Petitioner reported that her condition appeared to have improved. I.G. Ex. 18 at 12. Petitioner did not perform a chest x-ray. On the fourth hospital day, October 1, the nurses at the hospital summoned Petitioner and told him that the patient did not look well. Petitioner reported that she had some shallow respirations and that she appeared somewhat stuporous. Tr. at 217; I.G. Ex. 18 at 12. An x-ray was performed which revealed that her right chest had again filled up with fluid. I.G. Ex. 18 at 50; Tr. at 217. Another thoracentesis was performed. A chest tube was inserted which drained fluid for a few days. I.G. Ex. 18 at 12; Tr. at 217 - 218. As a result of the chest tube, her right lung re-expanded and the pleural effusion decreased. I.G. Ex. 18 at 4, 51. On October 4, 1991, the patient died. I.G. Ex. 18 at 13.

The I.G. contends that Petitioner violated his duty to provide care that meets professionally recognized standards of health care by failing to take an x-ray of the patient immediately after performing the September 28, 1991 thoracentesis and by failing to take a urine culture from the patient. Notice at 3. Petitioner did not deny that professionally recognized standards of care required him to perform a chest x-ray immediately after the September 28, 1991 thoracentesis. Tr. at 215. He also acknowledged that it was not done until the following day. Id. Moreover, Petitioner did not deny that professionally recognized standards of care required that he obtain a urine culture for the patient, who was in a septic state upon arrival at the active floor of this hospital. Petitioner admitted that his failure to take a urine culture was an oversight. I.G. Ex. 18 at 5.

With regard to the failure to take an x-ray immediately after performing the thoracentesis, Petitioner's arguments focused primarily on his decision to delay the insertion of the chest tube. He asserted that he elected to wait to insert the chest tube until two days after he

---

[18] Dr. Sperling testified that a pneumothorax exists when air has accumulated in the chest cavity. Petitioner did not contest this definition, therefore, I accept it as true. Tr. at 95.

discovered the pneumothorax because he thought that if it was left alone it would reabsorb and the lung would re-expand. Tr. at 216. He testified also that another reason he waited until the fourth hospital day was that her oxygen saturation was good on the third hospital day and a physical examination indicated that she had air in her chest. Tr. at 217.

Dr. Sperling's testimony focused primarily also on Petitioner's insertion of the chest tube. He indicated that the chest tube should have been inserted on the first hospital day, immediately after discovering the first pleural effusion. Tr. at 97. He indicated that Petitioner's delay in inserting the chest tube compromised the patient's care and put her at risk for developing a tension pneumothorax, and an inability to breathe, which would lead to a mediastinum flutter and cardiac arrest.[19] Tr. at 98 - 99. He testified that these risks were "directly due to a thoracentesis that was done inadequately, and should not have been done, other than for a smear, and then should have been followed up immediately by a chest x-ray." Tr. at 98. As to the timing of the x-ray, he testified that it is necessary to take a chest x-ray immediately after doing the thoracentesis, at the patient's bedside, in order to make sure that no damage was done during the thoracentesis and to determine whether all the fluid had been removed. Tr. at 96.

Petitioner's expert witness, Dr. Nicholas, stated that Petitioner inserted the chest tube at the appropriate time, since the need for the chest tube was the re-accumulation of fluid in her chest, and not the pneumothorax, and that this pleural effusion did not appear until the fourth hospital day. Tr. at 455. Dr. Nicholas testified also that there would be controversy among "reasonable doctors" as to the timing of the chest tube insertion in this patient. Tr. at 456. He indicated that this was a peculiar case, since the patient's right lung had only partially collapsed and she was still able to breathe and she was doing well clinically. Id.

As for the chest x-ray, however, Dr. Nicholas admitted that the standard of care is for a chest x-ray to be taken on the same day that thoracentesis is performed, and he indicated that Petitioner violated the standard by

---

[19] In his testimony, Dr. Sperling defined a pneumothorax. He explained that the term means that there is air in the chest cavity. Tr. at 95.

failing to do so. Tr. at 466 - 467. Yet, he testified that the delay in obtaining a chest x-ray did not compromise the patient's care in this case. Tr. at 452. In support of his position, he cited to IPRO's second physician's review, which states that "It [the x-ray] should have been done no matter what the clinical improvement was but it would not have prevented the pneumothorax or changed the course." Dr. Nicholas noted also that the second IPRO physician who reviewed Petitioner's medical records and the findings of the first reviewing physician, reduced the quality determination from a level three violation to a level two violation.[20]

I find that Petitioner's conduct was a substantial violation of professionally recognized standards of care. By delaying the x-ray, Petitioner delayed the diagnosis of this patient. At the 1992 hearing before IPRO, Dr. Sperling asked Petitioner if he considered "getting a portable x-ray up and putting the chest plate under her" in order to determine whether the thoracentesis procedure caused the pneumothorax. I.G. Ex. 6 at 46. Dr. Sperling indicated that an x-ray immediately after the thoracentesis was necessary because Petitioner performed the thoracentesis with the patient on her side, and therefore, he "violated a closed space with a needle." Id. If an x-ray had been taken right after the thoracentesis, Petitioner could have immediately determined whether his needle had caused the pneumothorax which was discovered a day after the thoracentesis was performed. In addition, during the 1992 hearing before IPRO, Petitioner essentially admitted that the pneumothorax had probably resulted from the difficulty he encountered in doing the thoracentesis. I.G. Ex. 6 at 55.

Furthermore, at the hearing before me, Dr. Sperling testified that a portable x-ray should have been taken after the thoracentesis:

---

[20] Dr. Sperling explained the significance of the Level I, II and III determinations made by the PRO:

> Level 1 is incurring a disability to the patient that is not life-threatening. Level 2 is developing a severe disability to the patient that is life-threatening. Level 3 is a life-threatening situation which did or did not cause a mortality.

Tr. at 100.

> to make certain that you've gotten the fluid out, that you haven't clipped the lungs and now developing a pneumothorax, a tension pneumothorax, which would directly affect the patient's cardiac status, you just have to do it just to make certain that you haven't caused any damage. After all you're going in blindly. You don't know where you're putting that needle or trochar, so you have to see what you've done.

Tr. at 96. Thus, the significance of taking an x-ray immediately after the thoracentesis is to ensure that the thoracentesis was done properly, that all of the fluid was removed from the patient's chest, and that no damage was done to the lung.

Petitioner's failure to follow the standard procedure upon completion of a thoracentesis delayed diagnosis, in that a pneumothorax and a partial collapse of the right lung was discovered the day after the thoracentesis, and a second pleural effusion appeared two days after the pneumothorax was discovered. Tr. at 215 - 218. Petitioner indicated, at both the 1992 and 1993 hearings before IPRO, that as a result of this case he now routinely takes x-rays immediately after doing a thoracentesis. I.G. Ex. 6 at 55; I.G. Ex. 3 at 308.

I find also, as Dr. Sperling asserts, that Petitioner's violation contributed to the risk of the patient developing a tension pneumothorax and an inability to breathe which could lead to cardiac arrest. Petitioner's failure to x-ray the patient until the day after the thoracentesis delayed discovery of the pneumothorax. According to professionally recognized standards of care, his failure to monitor his patient's condition put her at risk of developing further complications. Indeed, the patient developed a pleural effusion two days after the pneumothorax was discovered.

Dr. Sperling's opinion with regard to the risks he cited was based not only on Petitioner's failure to immediately obtain a chest x-ray, but also upon his opinion that Petitioner inadequately performed the thoracentesis and waited too long to insert the chest tube. Tr. at 97. I do not consider the significance of these additional allegations, since they are not relevant to the issue of whether he violated professionally recognized standards of care in this case. IPRO cited Petitioner for his failure to obtain a post-thoracentesis x-ray, and not for the adequacy of his thoracentesis or his alleged delay in inserting the chest tube. Accordingly, I do not consider these other allegations of wrongdoing, and my

determination that Petitioner substantially violated professionally recognized standards is based only on his failure to obtain a post-thoracentesis x-ray. I do find, however, that Petitioner's failure to obtain an immediate post-thoracentesis x-ray contributed to the risk of this patient developing an inability to breathe as a result of the pneumothorax, and possibly led to cardiac arrest, as stated by Dr. Sperling. These are serious risks which possibly could have been avoided had Petitioner followed professionally recognized standards of care in this case. The reduction by the IPRO physician of the level of care violation from three to two does not negate the conclusion that Petitioner's conduct placed this patient at serious risk, albeit it may not have caused her death.

IPRO found also that Petitioner failed to properly evaluate and work-up a septic patient. Notice at 3. Upon initial examination of the patient, Petitioner diagnosed her as being in a septic state. I.G. Ex. 18 at 14. He performed blood and sputum cultures, but failed to do a urine culture. I.G. Ex. 18 at 5. When questioned about his failure to perform a urine culture, Petitioner admitted that he simply forgot to do it. Id. Moreover, Petitioner did not rebut the I.G.'s finding that Petitioner's failure to take a urine culture was in violation of professionally recognized standards of care for a patient who is in a septic state.

Dr. Nicholas testified that, since it was determined from the serum culture that the patient in this case had influenza, and since the patient did not have any urinary symptoms, it was not unreasonable for Petitioner to have foregone a urine culture. Tr. at 458 - 459. He stated also that it is possible that the patient was not truly septic, within the proper meaning of the word. Tr. at 459. Finally, he asserted that, at the time the patient was first examined, she was "essentially suffocating," and the urine culture was not the first priority. Tr. at 460. These arguments are unpersuasive, however, since Petitioner indicated that he did not make a conscious decision to forego a urine culture for this patient, rather he simply forgot to do it. I.G. Ex. 6 at 43, I.G. Ex. 3 at 86, I.G. Ex. 18 at 5. Moreover, Dr. Nicholas did not deny that the professionally recognized standard of care for a patient who the examining doctor believes is in a septic state is to obtain a urine culture. Tr. at 462. On the basis of all of the testimony and medical records in this case, I find that Petitioner's failure to obtain a urine culture of this patient was a substantial violation of professionally recognized standards of care for a septic patient.

Patient 058705

PRO Findings: Failure to initiate treatment of local skin lesions resulting in a decubitus ulcer.

[I.G.] Analysis: Patient noted to have blisters on buttocks and be debilitated. No plan of care or treatment was initiated and patient developed a 4 cm. decubitus ulcer. Practitioner states that local treatment with ointment, daily, as well as systemic antibiotics were given for therapy of ulcer which became a decubitus. The medical record shows an order for 'neosporin ointment to decubiti Lt. Buttock BID' by telephone order 7/31/91, for patient admitted 7/8/91 and discharged 8/2/91. Nurses note abrasion left buttock on admission. Yellow central area with surrounding 6" red area on buttock noted 7/14/91, treated with A & D ointment.

[I.G.] Decision: The medical records support the PRO findings, and the findings are upheld. (Quality of care violation)

My Analysis: This patient was a 73-year-old man who was admitted to Little Falls Hospital on July 8, 1991, after being found lying on the floor of his apartment. I.G. Ex. 19 at 12 - 13. In his progress notes, written on the date the patient was admitted, Petitioner noted that the patient had blisters on his buttocks. Petitioner attributed this to the fact that the patient had been on the floor of his apartment for a considerable period of time. I.G. Ex. 19 at 14, 25.

On examination, the patient had a considerable amount of dried feces around the rectum. His family reported that he had a continuing problem with bowel incontinence. I.G. Ex. 19 at 16. In his admission report, Petitioner opined that the patient's incontinence was probably explained by chronic impaction, and he indicated that he would attempt to relieve the impaction. I.G. Ex. 19 at 17. Petitioner stated also that the patient probably had chronic organic brain syndrome. Id.

On July 11, 1991, Petitioner's progress notes indicated that the patient's cellulitis on his buttock was "involuting." I.G. Ex. 19 at 26. His progress note entered on July 16, 1991 indicated that the patient's ulcer on his left buttock was "[h]ealing." Id. That note indicated also that the lesion was six centimeters in size. On July 29, 1991, Petitioner's progress notes state that the patient had an unhealed ulcer on his

buttock that was four centimeters in size. I.G. Ex. 19 at 27.

On July 31, 1991, Petitioner telephoned an order that the lesion be treated with Neosporin, a topical antibiotic. I.G. Ex. 19 at 24; Tr. at 261. On August 2, 1991, the patient was discharged to the County Home for ongoing care. I.G. Ex. 19 at 13, 15. Petitioner's final diagnoses included cellulitis of the buttock and decubitus ulcer. I.G. Ex. 19 at 10. The patient's discharge instructions included application of Neosporin ointment to the buttock. I.G. Ex. 19 at 107.

The nursing notes contained in the chart describe the patient's buttocks on the date of admission as reddened with skin breakdown. The nursing notes indicated also that the patient was being moved from side to side at regular intervals. I.G. Ex. 19 at 54. On July 9, 1991, the nurses applied A&D ointment to the left buttock. I.G. Ex. 19 at 56. The nursing notes reported that on July 10, 1991, the patient ambulated from the bed to the chair with some assistance. I.G. Ex. 19 at 58.

On July 11, 1991, the nursing notes described the patient's lesion on his left buttock as a "yellow central area surround[ed] by 6" diameter red area" and indicated that there was "no drainage."[21] The nurses applied A&D ointment, and reported that the patient ambulated well with a walker. I.G. Ex. 19 at 60. The following day the nursing notes reported that "Red area on L[eft] buttock seems smaller (approx 5 [inches] diam) & less red than 7/11." On that day, the patient ambulated in the hall with a walker. I.G. Ex. 19 at 62.

On July 15, 1991, the nursing notes indicated that the left buttock abrasion was "much smaller" than it had been on July 12, 1991. The notes stated that it was a "small open area near large white patch surrounded by small red margin." In addition, the notes stated that A&D ointment was applied and that the patient was moved out of bed to his chair. I.G. Ex. 19 at 68. On July 16, 1991, the nursing note described the abrasion as yellow with dry skin at the margins. A&D ointment was applied. The patient was reported as tolerating activity well. I.G. Ex. 19 at 70.

---

[21] The I.G. Analysis in the Notice incorrectly states that the nursing notes give this description of the lesion on July 14, 1991 rather than on July 11, 1991.

On July 21, 1991, the nursing notes stated that the patient's wound on his left buttock was "healing" and that it was clean with clear edges. I.G. Ex. 19 at 80. The following day the nursing notes described the abrasion as an "open area" with a "small amount of yellow drainage." A&D ointment was applied. I.G. Ex. 19 at 82. The next day the nurse noted a "small amount of red drainage." A&D ointment was applied. I.G. Ex. 19 at 84. The nurse stated that there was "no change" to the patient's buttock condition the following day. I.G. Ex. 19 at 86.

On July 30, 1991, the nurse noted an open area on the left buttock and stated that it "appears to be healing." I.G. Ex. 19 at 98. The following day the nurse reported that the lesion was a "dry, open area" and that the patient did not complain of pain. I.G. Ex. 19 at 103.

The undisputed expert medical evidence shows that prolonged pressure can result in a breakdown of the skin and a diminished blood supply to the affected area. As the tissue breaks down, it can develop into an infection that erodes the layers of skin and affects the muscle and bone. In addition, it is undisputed that professionally recognized standards of care require an attending physician to initiate a written plan of care to address skin conditions caused by prolonged pressure. Tr. at 255, 272.

Petitioner admitted during the hearing that he did not adequately document a plan of care. Tr. at 486, 489 - 490. This admission is supported by the patient's chart, which shows that the only written documentation of a physician order pertaining to the treatment of this skin condition was made on July 31, 1991, when Petitioner telephoned an order for Neosporin. I.G. Ex. 19 at 24.

In view of the foregoing, I find that Petitioner failed to document a plan of care to treat this patient's skin condition and that this was a substantial violation of his obligation to provide care in accordance with professionally recognized standards of care.

The I.G. argues that this case is not simply a matter of poor documentation. The I.G. contends that Petitioner failed to properly address and follow up on the patient's need for skin care and that this is demonstrated "by the fact that his condition worsened over the course of his hospitalization, and that there were no physician's orders expressly addressing this condition until July 31, 1991, some 23 days after admission." I.G.'s Reply at 6.

Petitioner alleges that he initiated a plan of care to address this patient's skin condition and that he directed the nurses to carry it out orally. He contends that his care did not cause the patient's condition to worsen. He asserts also that the patient did not ever have a true decubitus ulcer, as the I.G. alleges.

I find that the evidence establishes that this patient suffered from a decubitus ulcer. This patient's medical chart shows that the final diagnoses of this patient's medical condition made by Petitioner included a decubitus ulcer. Petitioner's diagnosis of a decubitus ulcer is supported by Dr. Kops' testimony. Dr. Kops defined a decubitus ulcer as an erosion or ulceration of tissue caused by prolonged pressure. He indicated that decubitus ulcers can vary in their severity. As the decubitus ulcer becomes more severe, it can erode muscle and bone tissue. Tr. at 255.

The July 11, 1991 nursing notes described this patient's skin lesion as a yellow central area surrounded by a red area six inches in diameter. Dr. Kops testified that this description of the condition of this patient's skin is consistent with the formation of a decubitus ulcer. Tr. at 257. In addition, Dr. Kops opined that this patient had a decubitus ulcer on July 22, 1991, when the nursing notes described the affected area as open with small amounts of yellow drainage. Dr. Kops testified that this description suggested the drainage of pus. On July 23, 1991, the nursing notes described red drainage, and Dr. Kops testified that this suggested that the drainage was mixed with blood. Tr. at 259 - 260.

I find this evidence to be persuasive, and it establishes that this patient had a decubitus ulcer during the course of his hospital stay. The Merck Manual provides additional support for this finding. It defines a decubitus ulcer as ulceration of tissues that have been subjected to prolonged pressure. It states that the stages of decubitus ulcer formation correspond to tissue layers. The first stage consists of skin redness that disappears on pressure. The second stage shows redness, edema, and induration, at times with blistering. In the third stage, the skin becomes necrotic, with exposure of fat. In the fourth stage, necrosis extends to the muscle. Further fat and muscle necrosis characterizes the fifth stage. In the sixth stage, bone destruction begins. Merck Manual (15th ed. 1987) at 2298.

Dr. Nicholas testified that this patient never developed a "true" decubitus ulcer. He defines a decubitus ulcer as an ulcer which has penetrated through all the layers

of the skin "into underlying structures and then even deeper down into facia, muscle and bone." Tr. at 568. He states that, using that definition, this patient did not have a decubitus ulcer. Tr. at 569. Dr. Burke's testimony echoed that of Dr. Nicholas. He stated that, while this patient developed a superficial infection in the affected area, the lesion was not a decubitus ulcer because it did not affect the tissue underlying all the layers of the skin. Tr. at 488.

Neither Dr. Nicholas or Dr. Burke dispute that this patient had an ulceration of superficial tissue which was caused by prolonged pressure. They disagree with the I.G. only on nomenclature. While it may be true that the patient did not have a decubitus ulcer according to their definition of that term, I do not accept their definition. The definition advocated by Dr. Nicholas and Dr. Burke is not consistent with the definition contained in the Merck Manual. That medical treatise indicates that an ulcer which affects only superficial tissue is a decubitus ulcer in its early stages of formation.

Moreover, the definition of a decubitus ulcer offered by Petitioner and Dr. Nicholas at the hearing is not consistent with Petitioner's contemporaneous diagnosis of a decubitus ulcer. Petitioner has consistently maintained that only superficial layers of tissue were affected by the ulcer, and there is nothing in the descriptions of this patient's buttock in the chart which indicate that deep layers of tissue were affected. Petitioner diagnosed a decubitus ulcer for a condition that he maintains affected only superficial tissue. His attempt to now redefine the term decubitus ulcer in a self-serving manner is not persuasive.

In addition, I find that Petitioner did not prove that he initiated a plan of care to treat this patient's skin condition which Petitioner communicated to the nurses orally.

Petitioner testified that he became aware that this patient had a blister on the buttock when the patient was admitted and that he discussed the treatment of the patient's skin lesion with the nurses at that time. He stated that he emphasized to the nurses that the patient should be kept as dry as possible. In addition, he stated that, since the patient was relatively inactive due to a fever, he instructed the nurses to turn the patient from side to side and to protect the affected area from continuous pressure. Petitioner stated also that he instructed the nurses to keep the affected area

lubricated and to try to maintain the patient's nutrition. Tr. at 480 - 481, 485 - 486.

Petitioner's testimony that he was aware that this patient had a blister on his buttock at the time the patient was admitted is corroborated by his July 8, 1991 progress note. However, there is no corroboration for his testimony that he instructed the nurses to take specific measures to care for this condition at the time the patient was admitted.

Petitioner's progress notes and his orders do not mention these instructions. While the nursing notes show that the care the nurses gave to this patient was consistent with the instructions Petitioner testified he gave to the nurses, there is no indication in the nursing notes that this care was given pursuant to instructions from Petitioner. Indeed, Petitioner testified that the "problem of pressure sores and the problems of infection are a day by day problem for the people who are nurses." Tr. at 486. This comment suggests that Petitioner relied on the nurses to provide routine treatment for this type of condition.

Moreover, a nurse did document Petitioner's July 31, 1991 telephone order for Neosporin. I.G. Ex. 19 at 24. This suggests that, had Petitioner ordered the nurses to follow a designated treatment plan, they would have documented that plan in the patient record. Also absent from the record is the testimony of the nurse who would have received the oral instructions Petitioner asserts he gave. In view of the foregoing, I am not convinced by Petitioner's unsubstantiated testimony that he initiated a plan of care to treat this patient's skin condition which he communicated to the nurses orally at the time the patient was admitted. I find also that Petitioner's failure to orally initiate a plan of care to treat this patient's skin condition is a substantial violation of professionally recognized standards of care.

While I find that Petitioner's failure to initiate a plan of care is a substantial violation of professionally recognized standards of care, this does not mean that I conclude that Petitioner ignored this patient's skin condition. The record shows that treatment was provided by the nurses from the beginning. The patient was turned from side to side at regular intervals. The patient was ambulating within days of his admission, and he was encouraged to ambulate regularly after that. The nurses applied A&D ointment repeatedly. The patient's linens were changed when they were wet, and the nurses monitored his eating. I.G. Ex. 19 at 54 - 103.

This treatment was provided by the nurses in coordination with Petitioner's visits to attend to the patient. It is reasonable to conclude that, while Petitioner did not explicitly order the nurses to provide this treatment, he was aware of it and he did nothing to show that he disapproved of it. In addition, Petitioner made periodic notations in his progress notes regarding this patient's skin condition, which shows that he was monitoring it. He was, therefore, in the position to intervene and alter the treatment if he thought it was necessary. In fact, he did intervene on July 31, 1991 when he ordered Neosporin for this patient. Petitioner testified that the reason he ordered Neosporin at this time was that he wanted the patient to have it to treat his unhealed ulcer after he left the hospital. Tr. at 488. Thus, I find that, although Petitioner did not explicitly initiate a plan of care, he nevertheless was informed about the patient's condition and he was involved in the treatment of it.

Moreover, I find that the evidence fails to establish that Petitioner's care of this patient's skin condition resulted in adverse consequences to this patient, as the I.G. alleges.

The I.G.'s assertion that this patient's condition worsened over the course of the hospitalization implies that the patient's skin condition steadily deteriorated during the course of his hospital stay. While the descriptions of the patient's decubitus ulcer in the chart demonstrate that Petitioner's skin ulcer never healed completely during the course of the hospitalization, they do not show that his condition consistently worsened over time.

On the contrary, the chart entries show that the condition had periods of healing during his hospital stay. The patient was admitted on July 8, 1991 with a blister on his buttocks. This finding on admission suggests that, under the Merck Manual description of the staging of decubitus ulcers, the patient had a decubitus ulcer in its early stages. Three days later, Petitioner noted that it had gotten smaller.[22] Nursing notes on July 12 and 15, 1991 reported that the lesion was getting smaller. Petitioner's July 16, 1991 note described the lesion as "healing." The nursing note entry on July 21,

---

[22] Petitioner's July 11, 1991 progress note describes the condition as "involuting." The American Heritage Dictionary, 2d College Edition, defines "involute" as "[h]aving the margins rolled inward."

1991 also described the lesion as "healing." While some drainage was noted for the first time by the nurses on July 22 and 23, 1991, the notes described it as a "small amount" and there is no indication that the lesion affected deep layers of tissue such as bone or muscle. It is at this point in the record of the patient's hospitalization that his decubitus ulcer is arguably at its worst stage. But, again using the Merck Manual as a reference, the evidence fails to establish that the decubitus ulcer affected deep tissue layers and advanced beyond the third stage. The I.G. concedes that the medical records' description of the patient's decubitus ulcer is "consistent with the lesion progressing through the early stages of a decubitus." I.G.'s Supplemental Brief at 3. On July 30, 1991, the nursing notes indicate that the lesion "appears to be healing." On July 31, 1991, the nurses describe the lesion as dry and the patient did not complain of pain.

Dr. Kops provided testimony which suggests that Petitioner failed to treat this condition adequately. The nursing notes state that there was a breakdown of skin on the date of admission. Dr. Kops opined that, once the skin breaks down, the application of A&D ointment is inappropriate because it traps moisture and may cause further breakdown of the skin. Tr. at 258. Dr. Kops stated also that a topical antibiotic should be applied as soon as the skin breaks down. In addition, he stated that dressings should be changed daily. Tr. at 262. While Dr. Kops criticized the care this patient received, he then contradicted himself and testified that the nursing care, including the application of ointment, was in accordance with professionally recognized standards. He testified that the deficiency here was just a lack of documentation and a lack of specific order to the nurses. Tr. at 274. Dr. Kops' testimony is confusing and contradictory, and, therefore, I find that it does not establish that Petitioner's care was inadequate.

On the other hand, Dr. Nicholas testified that the measures which were taken to treat this skin condition were in accordance with professionally recognized standards of care. Tr. at 581. He indicated that relieving the pressure on the lesion is imperative and that this was done when the nurses moved the patient from side to side and encouraged the patient to get out of bed. In addition, he stated that it is important to attend to the patient's nutrition and that this was done here. Tr. at 566 - 567, 586 - 587. He acknowledged that, while the application of A&D ointment may have some drawbacks, it has the substantial benefit of decreasing

the likelihood that the condition will be aggravated by sheet burns. He explained that a week of healing can be destroyed with "one yank across the sheet." Tr. at 573. Dr. Nicholas opined also that the use of dressings is "optional." He indicated that the use of dressings for superficial lesions has the disadvantage of making the skin "sort of water logged and fragile." Tr. at 573 - 574. He indicated also that antibiotics generally are not necessary to treat superficial lesions. Tr. at 575.

The record fails to demonstrate that any of the treatments employed had a significant adverse effect resulting in the worsening of the patient's ulcer during his hospitalization. As previously conceded by the I.G., this patient's ulcer never progressed beyond the early stages.[23]

Also Dr. Nicholas expressed the view that the reason this patient's condition persisted was not due to the care he received, but instead it was due to the fact that he was impacted and incontinent. The unfortunate consequence of this condition was that the patient sometimes was lying in liquid diarrhea. Tr. at 580. Even Dr. Kops acknowledged that the fact that this patient was continually soiling himself would impede the quick healing of this patient's skin condition. Tr. at 263.

Dr. Nicholas' opinion on the adequacy of Petitioner's treatment of this patient is well-rationalized and persuasive. I find that the evidence does not establish that this patient suffered any adverse consequences as a result of Petitioner's care of his skin condition.

Patient 032141

This patient involves two cases referred to in the I.G. Notice (Cases 6 and 7 at page 4 of the Notice). The first case pertains to Petitioner's treatment of the

---

[23] As indicated in the Merck Manual at 2299, "[u]lcers that have not advanced beyond the 3rd stage may heal spontaneously if the pressure is removed and the area is small." The record supports that this patient was turned from side to side at regular intervals and was encouraged to ambulate as soon as he was capable of doing so. This reference from the Merck Manual suggests that early staged decubitus ulcers are not particularly significant, as long as they are not allowed to worsen to a later stage (stages four to six) where there is muscle necrosis and bone destruction, neither of which occurred in this case.

patient after she was admitted to Little Falls Hospital on July 25, 1991. The second case pertains to Petitioner's treatment of the patient after she was admitted to Little Falls Hospital on August 4, 1991.

First case: (Admission date 7/25/91)

> PRO Findings: Failure to evaluate severe pain in a patient resulting in premature discharge and readmission for the same complaint within 72 hours.
>
> [I.G.] Analysis: Patient discharged without evaluation of complaint (severe left thigh pain). Patient was discharged but readmitted for the same complaint within 72 hours. Patient complaining of pain on day of discharge.
>
> [I.G.] Decision: The medical records support the PRO findings, and the findings are upheld. (Quality of care violation)

Second case: (Admission date 8/4/91)

> PRO Findings: Failure to evaluate severe pain in a patient resulting in premature discharge and readmission for the complaint with 48 hours.
>
> [I.G.] Analysis: Patient hospitalized and discharged without evaluation of complaint (severe left thigh pain). This resulted in premature discharge and subsequent readmission within 48 hours. There is not an extended period of pain relief.
>
> [I.G.] Decision: The medical records support the PRO findings, and the findings are upheld. (Quality of care violation)

My Analysis of both cases: The medical record pertaining to these two cases shows that the patient, a 70-year-old female, was initially admitted to Little Falls Hospital on July 25, 1991. In a medical report written at the time of the patient's admission, Petitioner described the patient's chief complaint as "Intractable pain, left lateral thigh, two weeks duration." Petitioner noted that "[t]his patient is no stranger to intractable pain" and that she had a history of recurrent pains in the abdomen and chest of an unknown etiology. Petitioner noted also that in the past the patient "has been suspected of dependency on Darvon." I.G. Ex. 20 at 14 - 15.

Petitioner reported also that his physical examination of the patient at the time of admission revealed that the patient had "point tenderness at the insertion of the fascia lata into the greater trochanter on the left side." He noted that the patient had been treated as an outpatient three to four days prior to admission with injections of medication. This had given her relief from the pain for about an hour, and then the pain recurred. Upon admission, Petitioner again injected the patient with medication at the base of the trochanter on the left side. Again, this injection gave the patient relief from the pain for a short period, and then it recurred. I.G. Ex. 20 at 15. At the time of admission, Petitioner diagnosed "Pain, left lateral thigh, either trochanteric tendinitis with fascia lata syndrome or diabetic neuropathy." I.G. Ex. 20 at 14.

Petitioner referred the patient to a physical therapist for treatment. In a report dated July 26, 1991, the physical therapist reported that the patient had discomfort during hip flexion and external rotation. During the course of the patient's hospital stay, she was treated with a combination of ultrasound, moist heat, a "TENS" unit, anti-inflammatory medication, and a series of active exercises. I.G. Ex. 20 at 24, 27.

In addition, Petitioner obtained a psychiatric consultation. In a report dated July 30, 1991, the consulting physician opined that, while the patient did not appear to suffer from any major psychiatric illness, there was a possibility that the patient's pain could be symptomatic of a major depression. I.G. Ex. 20 at 22 - 23. During this admission, the patient was not examined by an orthopedist or neurologist, nor were any x-rays or "CAT" scans taken of the patient's hip and thigh. Tr. at 643.

The patient complained of intermittent pain throughout her stay in the hospital. Ex. 20 at 42 - 56. On August 1, 1991, the day that she was discharged, she complained of pain and became more comfortable after a new patch was applied to the "TENS" unit. At the time of discharge, she was independent in ambulation and was able to bear weight on her left leg. I.G. Ex. 20 at 27. In the discharge summary, Petitioner reported that the patient's "pain problem had improved, but it had not been completely relieved." The patient was discharged with instructions to take medication, and she was advised to see Petitioner for a follow-up examination. I.G. Ex. 20 at 13, 62. She was discharged with a diagnosis of left trochanter tendinitis with fascia lata syndrome. I.G. Ex. 20 at 8.

On August 4, 1991, the patient was again admitted to the hospital for the same complaint of severe pain in her left thigh. She was injected with local anesthetics in the tender area of the left trochanteric area. The pain remained intractable, and she was admitted to the hospital for care and "perhaps additional diagnostic maneuvers." However, at 9:00 p.m., the patient had achieved complete relief of her pain. I.G. Ex. 20 at 80. The following morning the patient reported no pain and was discharged. I.G. Ex. 20 at 95. As with the previous admission, no x-rays or "CAT" scans were taken, and no orthopedic or neurologic consultations were obtained. Tr. at 645 - 646. On August 7, 1991, she was readmitted to the hospital with the same complaint. I.G. Ex. 6 at 118.

The I.G. did not offer any direct testimony at the hearing in support of the PRO findings. Instead, the I.G. contends that the record substantiates the PRO findings set forth in the Notice.

The I.G. argues that, during these two admissions, Petitioner did not take the necessary steps to accurately diagnose this patient's condition, but attempted only to treat her symptoms. In support of this argument, the I.G. relies on the fact that, during both admissions, no radiologic studies were done and no consults from a neurologist or orthopedist were requested by Petitioner. The I.G. points out also that, although the patient's pain was addressed during the first admission with injections and a "TENS" unit, the entries on the chart do not reflect any consistent alleviation of her condition. According to the I.G., Petitioner's failure to adequately evaluate this patient during the first admission resulted in a readmission of the patient within 48 hours of her first discharge. The I.G. argues that, even after the second admission, Petitioner lacked the information needed to make a definitive diagnosis and points out that the patient was readmitted within 48 hours. The I.G. contends that Petitioner prematurely discharged the patient on August 1, 1991, after the first admission and that the second discharge, on August 5, 1991, was premature as well.

I find that in these cases the weight of the evidence fails to establish the PRO Findings contained in the Notice.

I agree with the I.G. that the evidence establishes that Petitioner did not perform any radiologic studies and that he did not obtain medical consultations, other than a psychiatric consultation, during the two hospital

admissions at issue. However, I do not agree with the I.G. that, based on this, I must conclude that Petitioner failed to evaluate the patient's pain in accordance with professionally recognized standards of care.

The I.G. has not presented any expert medical opinion evidence setting forth what tests and consultations would be necessary to meet professionally recognized standards of care under the circumstances of this case. The I.G. did not offer any direct testimony at the hearing on this issue, nor did the I.G. cite any documents in the record which address this issue. Absent medical evidence establishing that Petitioner's failure to perform radiologic studies and obtain additional consultations violated professionally recognized standards of care, I do not have a basis to make this finding.

In addition, the I.G. relies on the fact that the patient's pain symptoms had not been consistently alleviated during her hospital stays and on the fact that the patient was readmitted within days after being discharged to support the PRO finding that the patient was prematurely discharged in these cases. However, the record is devoid of expert medical opinion evidence establishing that professionally recognized standards of care require that the patient should have been free of pain for a specific period of time before she was discharged from the hospital. Similarly, the record is devoid of expert medical opinion evidence establishing that the patient's readmission to the hospital for the same complaint within a few days establishes that a prior discharge had been premature.[24]

On the other hand, Dr. Nicholas offered expert medical testimony in which he opined that Petitioner's care of the patient in these cases was in accordance with professionally recognized standards of care. Tr. at 642, 652. Dr. Nicholas pointed out that the patient had a history of fixating on pain and a history of dependence on drugs. He indicated that these were important considerations in Petitioner's decision to manage the patient's care conservatively. Tr. at 630 - 631, 638 - 640.

---

[24] At the November 10, 1992 IPRO hearing, Dr. Nicholas mentioned in passing that he had read a regulation that provided that "readmissions resulted in automatic Level 3 citations." I.G. Ex. 6 at 140. However, the I.G. did not mention or rely on any regulatory criteria to support the PRO finding that Petitioner prematurely discharged this patient.

Dr. Nicholas noted that Petitioner's physical examination of the patient at the time of the first hospital admission revealed point tenderness. According to Dr. Nicholas, this is often due to tendinitis. Dr. Nicholas testified that, based on this, Petitioner proceeded to inject the patient with medication. He indicated that this procedure is both diagnostic and therapeutic because, if the injection relieves the pain, it makes a diagnosis of tendinitis very likely. Dr. Nicholas opined that Petitioner appropriately evaluated the patient's pain symptoms. He stated that the fact that the clinical examination revealed point tenderness together with the fact that the patient experienced relief of pain with the injection was highly suggestive of a diagnosis of tendinitis. Tr. at 631 - 632. Dr. Nicholas testified that, under these circumstances, radiologic tests and additional medical consultations were not necessary to evaluate the patient's condition during the two hospital stays. Tr. at 652.

Dr. Nicholas opined that the patient was not discharged prematurely after either of the two hospital stays. He stated that tendinitis is a condition known to produce intermittent pain, and that it would be reasonable to expect a person suffering from this condition to experience intermittent pain even after discharge from a hospital setting. According to Dr. Nicholas, the patient showed a therapeutic response to treatment during both hospitalizations, and she was appropriately sent home to be followed as an out-patient. Tr. at 636 - 638.

Dr. Nicholas expressed the view that the wisdom of Petitioner's evaluation and treatment of the patient was demonstrated by the fact that the patient was subsequently admitted to two other area hospitals for over 56 days for the same pain complaint. During those 56 days, the patient had an extensive array of tests and her final treatment was the conservative treatment advocated by Petitioner. In addition, at the end of the 56 days, the patient was suffering from the adverse effects of morphine. Dr. Nicholas stated that, since Petitioner was privy to the patient's history of fixating on pain and drug dependence, he had astutely tried to avoid lengthy hospitalizations and exposure to addictive drugs. Tr. at 638 - 641.

Dr. Nicholas' testimony regarding Petitioner's care of this patient is well-rationalized and persuasive. In addition, the I.G. has not adduced any expert medical evidence to rebut Dr. Nicholas' opinion. In view of this, I find that the I.G. did not prove that Petitioner

rendered care to this patient which did not meet professionally recognized standards.

I have reviewed the transcript from the IPRO hearings involving this patient. While it is difficult to discern with specificity the deficiency cited by the IPRO physicians, it is clear that they were concerned that Petitioner admitted this patient on several occasions to evaluate her pain, but he did not perform sufficient diagnostic tests to evaluate the pain. In addition, IPRO was concerned that this failure led to two premature discharges and a need for subsequent readmissions. The I.G. relies almost exclusively on the lack of diagnostic tests being performed during the hospitalizations in issue. However, Dr. Nicholas' testimony establishes that, under the circumstances of this case, Petitioner's conservative treatment of this patient without performing extensive diagnostic tests was meritorious. In reaching this conclusion, Dr. Nicholas took into account the chronicity of the patient's pain complaints, her psychiatric history, her possible drug dependency, and the hospital records showing improvement or complete diminishment of her pain prior to each discharge. The I.G. offered no proof that professionally recognized standards of care would require different treatment under the circumstances of these several admissions.

Patient 060460

> PRO Findings: Failure to properly evaluate and treat patient with changing neurological status.
>
> [I.G.] Analysis: Patient admitted with questionable transient ischemic attacks. No diagnostic work-up obtained, i.e., carotid studies, doppler or ultrasound.
>
> [I.G.] Decision: The medical records support the PRO findings, and the findings are upheld. (Quality of care violation)

My Analysis: This patient, a 76-year old male, was brought by ambulance to the emergency room at Little Falls Hospital on August 22, 1991, following a sudden episode of weakness, slurred speech, and confusion. I.G. Ex. 22 at 11 - 12. He was admitted for observation with a preliminary diagnosis of a transient ischemic attack ("TIA"). I.G. Ex. 22 at 13. The I.G. contends that Petitioner violated his duty to provide care that met professionally recognized standards of health care by failing to order a Doppler ultrasound study of the patient's carotid arteries.

TIAs may be caused by the build-up of arteriosclerotic plaques in the carotid arteries which restrict blood flow to the brain. Tr. 111, 610. Patients with stenosis, or narrowing, of the carotid arteries of 25 percent or more are at increased risk for both stroke and coronary heart disease. I.G. Ex. 34 at 4. A Doppler ultrasound is a non-invasive study which can help to measure the degree of stenosis of the carotid arteries. Tr. at 113. It is not possible, based on a physical examination alone, to diagnose the degree of carotid stenosis. Tr. at 499 - 500.

Stenosis of the carotid arteries may be treated surgically or medically. The professionally recognized standard for medical treatment is to give anti-coagulant drugs, such as aspirin. P. Ex. 50 at 2, P. Ex. 51. The surgical treatment is carotid endarterectomy, in which the arteriosclerotic plaques are surgically removed from the carotid artery or arteries. Id. Medical research has demonstrated that, in patients with severe stenosis, that is occlusion greater than 70 percent, carotid endarterectomy reduces the risk of stroke. P. Ex. 50 at 3, P. Ex 51. Medical research has not demonstrated that carotid endarterectomy benefits patients with less severe occlusion. P. Ex. 51.

The professionally recognized standard for evaluating the degree of a patient's carotid stenosis is to perform a Doppler ultrasound of the carotid arteries, as a first step. P. Ex. 51; Tr. at 113, 134, 500. If the Doppler ultrasound indicates significant occlusion of the carotid arteries, professionally recognized standards would require that the precise degree of occlusion be confirmed by angiography. P. Ex. 50 at 3, P. Ex. 51; Tr. at 500. Angiography is an invasive procedure in which a contrast material is injected into a patient's carotid arteries. Tr. at 113, 496.

Petitioner does not dispute that professionally recognized standards of care for a patient with TIA possibly related to carotid stenosis require Doppler ultrasound, followed up by angiography. Tr. at 500. Instead, Petitioner argues that there was no reason to do the Doppler ultrasound in this case because this patient did not wish to consider surgical treatment. Petitioner's Brief at 39 - 40.

As an initial matter, the record in this case is equivocal as to whether the patient refused surgery or whether Petitioner ruled out surgery. Petitioner testified at the hearing that the patient refused surgical treatment. Tr. at 494, 500 - 501. However,

Petitioner's written response to IPRO suggests that Petitioner made the decision to rule out surgery. See I.G. Ex. 22 at 4.[25] Nevertheless, whether it was Petitioner or the patient who did not wish to consider surgery, I would still conclude that Petitioner's failure to order the Doppler ultrasound violated his duty to provide care in accordance with professionally recognized standards.

The standards of care are that carotid endarterectomy surgery is the preferred treatment for patients with carotid stenosis of 70 percent or more. P. Ex. 51. This does not mean that every patient with 70 percent stenosis will have surgery. Undoubtedly, there will be cases in which patients refuse consent or surgery is ruled out for other medical reasons. However, both the patient and the physician need information about the degree of stenosis in order to make a rational decision about the need for surgery. Obviously, the calculus of risks and benefits of surgery is different depending upon whether the patient's carotid arteries are 20 percent or 90 percent occluded. To make an informed choice, a patient with severe stenosis of the carotid arteries needs to know that the best chance to avoid a future stroke would be to have surgery, even if that patient's ultimate decision is to decline the surgery.

In this case, if it was Petitioner's decision to rule out surgery, his failure to order the Doppler ultrasound meant that he made that decision without an important piece of diagnostic information. Petitioner argues that he should not be faulted for choosing what the I.G. acknowledges was the appropriate medical treatment for the patient. Petitioner's Brief at 39. Petitioner misses the point. While Dr. Sperling did testify that Petitioner's treatment was the correct therapy for someone who was a non-surgical candidate, he repeatedly emphasized that a decision on the appropriateness of surgical intervention could not be properly made without initiating diagnostic tests evaluating the degree of stenosis. Tr. at 113, 120 - 124, 135 - 136. Without having the patient undergo the non-invasive Doppler study and an angiography, depending on the Doppler results, there is insufficient diagnostic information to conclude

---

[25] At the IPRO hearing on November 10, 1992, Petitioner testified that, based on an adverse result from an endarterectomy of a brother of a patient of his, and based on his research into the literature on this surgery, he decided not to consider patient 060460 as a surgical candidate. I.G. Ex. 6 at 148 - 149.

that oral medication therapy was the appropriate medical treatment for this patient.

Moreover, I reject Petitioner's attempt to shield his conduct by focusing almost exclusively on the risks of surgical intervention as justification for his failure to do the necessary diagnostic tests. The I.G.'s cited violation does not address the issue of whether this patient was an appropriate surgical candidate. Consequently, I make no findings on the merits of having this patient undergo a carotid endarterectomy. Neither the I.G. nor IPRO ever specifically addressed this issue since their concern was that Petitioner failed to do the diagnostic tests that were necessary to make an informed, knowledgeable decision on whether to undergo such surgery. The evidence supports that such diagnostic studies were a necessary element of this patient's treatment and that Petitioner improperly failed to do such studies. Therefore, I conclude that Petitioner failed to meet professionally recognized standards of health care because he embarked on that course of treatment without obtaining the potentially significant diagnostic information that the Doppler ultrasound could have provided.

On the other hand, if it was the patient who was adamant in his refusal of surgery, it still was incumbent upon Petitioner to obtain the Doppler ultrasound, because more specific information about the risks and benefits of surgery might have led the patient to change his mind. Moreover, nowhere in the medical record did Petitioner document that he discussed the option of surgery with the patient or that the patient refused surgical treatment. Tr. at 616. This, in itself, would constitute a violation of professionally recognized standards, if such a conversation took place and it was not documented in the record.

For these reasons, I conclude that Petitioner's failure to order a Doppler ultrasound study of this patient's carotid arteries before initiating treatment for his TIAs was a substantial violation of his obligation to provide care of a quality which meets professionally recognized standards of health care.

Patient 060717

> PRO Findings: Potential adverse patient effect when patient discharged with instructions to take a higher dosage of medication.

[I.G.] Analysis: Dosage of cardiac medication was changed in progress notes, but not on order sheet. Discharge instructions reflect the higher dosage of medication. The medical record shows discharge summary with five mg Capoten BID, but do not show any such medication being given during hospital admission. The record does show Vasotec, 10 mg BID, prior to discharge. Practitioner advised why he lowered the dosage, which is not disputed by the PRO.

[I.G.] Decision: The medical record supports the PRO findings. This case will be retained as a documentation failure.

My Analysis: This patient, a 69-year old male, was admitted to Little Falls Hospital on December 2, 1991. At the time of his admission, the patient's chief complaint was acute dyspnea. He was diagnosed at that time as having arteriosclerotic heart disease with acute severe pulmonary edema, severe chronic obstructive pulmonary disease, and mild renal insufficiency. I.G. Ex. 23 at 11.

At the time of his admission, the patient had been taking Capoten. I.G. Ex. 23 at 41. During his admission, on December 3, 1991, the patient started to take Vasotec instead of Capoten. I.G. Ex. 23 at 19; Tr. at 243 - 244. Vasotec and Capoten are both ACE (angiotensin converting enzyme) inhibitors which are used in the treatment of hypertension and congestive heart failure. Tr. at 245.

The patient's initial dose of Vasotec was five milligrams. Petitioner prescribed five milligrams of Vasotec twice a day on December 3, 1991. He increased the dosage later that day to five milligrams in the morning and ten milligrams at night. I.G. Ex. 23 at 19; Tr. at 244. On December 4, 1991, Petitioner increased the dosage again, to ten milligrams twice daily, and this was continued until the date of discharge. I.G. Ex. 23 at 20; Tr. at 244.

The patient was discharged on December 9, 1991. I.G. Ex. 23 at 21. Petitioner's progress notes of this date state that the patient was to go home with a prescription for five milligrams of Vasotec to be taken twice a day. I.G. Ex. 23 at 25; Tr. at 244 - 245. However, the discharge summary which was dictated by Petitioner on December 30, 1991, 21 days after the patient was discharged, contained different information. It states that the patient was discharged from the hospital on five milligrams of Capoten to be taken twice a day. I.G. Ex. 23 at 14.

The Notice states that IPRO found that there were potential adverse effects when this patient was "discharged with instructions to take a higher dosage of medication." In accepting the PRO findings set forth in the Notice, it appears that the I.G. is alleging that, although Petitioner intended the patient to take the lower dosage of five milligrams of Vasotec twice a day after he returned home, he was in fact discharged with instructions to take the higher dosage of ten milligrams of Vasotec twice a day, which had been given to him in the hospital prior to his discharge. I find that the evidence does not prove this allegation.

The supporting analysis contained in the Notice states that "[d]ischarge instructions reflect the higher dosage of medication." However, the patient's medical chart does not include a discharge instruction sheet that contains written instructions that had been given to this patient prior to his discharge from the hospital. Tr. at 248, 251. The record is devoid of written discharge instructions which support the I.G.'s allegation that the patient was instructed to take the higher dosage of ten milligrams of Vasotec twice a day at the time he was discharged.

In addition, the record fails to establish that the patient was orally instructed to take the higher dosage of 10 milligrams of Vasotec twice a day at the time he was discharged. To the contrary, the evidence establishes that the patient was discharged with instructions to take the lower dosage of five milligrams of Vasotec twice a day.

Petitioner testified that he relies primarily on direct contact with his patients with respect to discharge instructions. Tr. at 514 - 515. Petitioner testified that it was his practice prior to discharge to discuss discharge instructions with the patient directly. He testified that his patients receive prescriptions for the medications they are to take at home directly from him, in their rooms prior to discharge. Tr. at 504.

With regard to this patient, Petitioner testified that he discussed his discharge instructions in the patient's hospital room prior to his discharge. He stated that, since the patient's wife maintained records of her husband's medication orders, he discussed the discharge instructions with both the patient and his wife. Petitioner testified that the discharge instructions he discussed with the patient and his wife were consistent with the instructions documented on his December 9, 1991 progress note. He stated that he instructed the patient

to take five milligrams of Vasotec twice a day, and that he wrote the prescription for this medication while he was in the patient's room. Tr. at 503 - 504, 506.

I find credible Petitioner's testimony that he discharged the patient with oral instructions to take five milligrams of Vasotec twice a day. This testimony is corroborated by Petitioner's contemporaneous progress note documenting that the patient was to be discharged with instructions to take five milligrams of Vasotec twice a day. In the absence of evidence showing that the patient received written instructions to take 10 milligrams of Vasotec twice a day, I find that the evidence fails to establish that the patient was discharged with instructions to take the higher dosage of medication.

While the evidence fails to establish that the patient was instructed to take the higher dosage of medication, the discharge summary dictated by Petitioner on December 30, 1991, is not consistent with the final progress note. It states that the patient was discharged with a prescription to take five milligrams of Capoten twice a day. No mention of Vasotec is made in the discharge summary.

The PRO findings contained in the Notice do not explicitly refer to this inconsistency, but the supporting Analysis notes that the discharge summary indicated that the patient was discharged on Capoten rather than Vasotec. Reading the PRO findings together with the supporting Analysis contained in the Notice, I find that Petitioner was placed on sufficient notice that the I.G. was alleging that Petitioner inaccurately documented his treatment of the patient on the discharge summary and that this documentation error was a basis for the I.G.'s determination to exclude Petitioner.

Petitioner testified that the statement in the discharge summary that the patient was discharged on Capoten was an error, and he acknowledged that the discrepancy between his progress notes and the discharge summary might be confusing to a physician attempting to treat the patient if he was readmitted to the hospital. Tr. at 506 - 507, 509 - 510. Based on this testimony, I find that the evidence establishes that Petitioner's documentation of his discharge instructions is deficient insofar as the discharge summary inaccurately documented the medication the patient was given at the time he was discharged.

While Petitioner concedes that he made a documentation error, he argues that it was a minor error. Petitioner

testified that there is no pill form of five milligrams for Capoten. Tr. at 511. In view of this, Petitioner argues that another physician reading the discharge summary would be on notice that this notation on the discharge summary was an error. In addition, Petitioner argues that, since the discharge summary was dictated several weeks after the patient was discharged from the hospital, it did not influence what the patient was actually instructed at the time that he was discharged.

I do not agree that the documentation error is insubstantial. Even if another physician reading the discharge summary realizes that there is no pill form of five milligrams for Capoten, the physician would still have some doubt as to the exact medication and dose that the patient was directed to take at the time of his discharge. Due to the confusing inconsistency between the progress note and the discharge summary, another physician would be required to expend his or her time to resolve an issue that easily could and should have been avoided if Petitioner had been more careful in his documentation of treatment for this patient.

In isolation, such error by Petitioner is arguably not significant. However, it takes on significance when viewed in light of his record of failing to adequately document patient records, despite his promise to do so in his CAP in response to a prior PRO sanction action. If anything, Petitioner should have been on notice to be extra careful in his documentation.

The Analysis contained in the Notice states that the "[d]osage of medication was changed in progress notes, but not on the order sheet." This statement implies that Petitioner's documentation of the dosage of medication the patient was to take at home is deficient because it does not appear on "the order sheet" as well as on the progress notes.

The record contains a document captioned "Physician's Orders." The entry for December 9, 1991 on that document states only that the patient was to be discharged on that date. No mention is made of medications the patient was to take after he was discharged. I.G. Ex. 23 at 21. I find that, while the evidence establishes that Petitioner did not document his discharge instructions both in his progress notes and on his physician order sheet, it fails to establish that this constitutes a documentation deficiency.

Dr. Nicholas testified that it was common procedure in 1991 that a patient released from a hospital would be

provided with written discharge instructions prepared by the nursing staff. Tr. at 620 - 621. He stated also that a nurse preparing a discharge instruction sheet would expect to find a written description of the physician's discharge instructions in the chart. Tr. at 624. However, he stated that whether this description is written in the progress notes or on the physician order sheet may vary depending on the local procedures in place at a given hospital. Tr. at 623 - 624. The I.G. did not offer any evidence to rebut this testimony.

The medical expert testimony does not support a finding that a recognized standard of care requires Petitioner to write the discharge instructions in the progress notes and on the physician's order sheet. Furthermore, the record is devoid of evidence showing that the patient received written discharge instructions which were incorrectly prepared by the nurses. To the contrary, the evidence establishes that the patient received correct oral discharge instructions in accordance with Petitioner's progress notes. In view of the foregoing, I find that Petitioner's failure to write discharge instructions on his order sheet and in his progress notes does not constitute a deficiency in his documentation of his treatment of this patient.

Dr. Kops testified that most hospitals require that a patient be given written discharge instructions when the patient is released from the hospital. Tr. at 248. The medical record in this case does not include a copy of written discharge instructions that were given to this patient. The I.G. argues in her brief that the absence of written discharge instructions prepared for the patient constitutes another documentation deficiency in this case.

It is undisputed that the patient's chart in evidence does not include a written discharge instruction sheet prepared for him at the time of this discharge. During the posthearing phase of these proceedings, the I.G. contended for the first time that the fact that the patient's chart does not include a discharge instruction sheet is a basis for exclusion in this case. However, this criticism is not included in the Notice. In fact, the Notice alleges that the "[d]ischarge instructions reflect the higher dosage of medication." This suggests that, at some point during the course of the proceedings before IPRO, the record contained a discharge instruction sheet that was reviewed by IPRO. Assuming that the chart once included a discharge instruction sheet, Petitioner cannot be faulted because this discharge instruction is no longer in the record made available for this

proceeding by the I.G. That is not Petitioner's responsibility and cannot be construed as reflecting any adverse impact on his meeting professional standards of care. Even assuming such conduct was contrary to professional standards of care, I find that the I.G. did not adequately notify Petitioner of such allegation. For the above reasons, Petitioner cannot be held accountable for this allegation.

The I.G. argues also that Petitioner's documentation of his treatment of this patient is deficient because "the chart is devoid of any explanation for Dr. Burke's frequent changes in the patient's cardiac medication." I.G.'s Response at 22. During the hearing, the I.G. attempted to pursue a line of questioning related to this allegation. However, I pointed out that this allegation was not encompassed by the allegations in the Notice. Tr. at 246 - 247, 249. In view of the fact that Petitioner did not receive adequate notice of this allegation, he cannot be held accountable for it.

Patient 030053

> PRO Findings: Failure to properly manage and treat a diabetic patient.
>
> [I.G.] Analysis: Patient had persistent hypoglycemia which was not addressed. The medical records show that the intravenous solution of 10% dextrose in water was ordered "at rate to obtain blood sugar above 80 then slow IV down to KVO for the nite" (telephone order). The PRO noted that a rate should be given; medical records show no rate ordered. Orders should include checking blood glucose level frequently, which were not ordered.
>
> [I.G.] Decision: The medical records support the PRO findings, and the findings are upheld. (Quality of care violation)

My Analysis: This patient was a 76-year old male who suffered from diabetes mellitus. He was brought by ambulance to the emergency room at Little Falls Hospital on December 27, 1991, after an episode of coma induced by his overdosing himself with 70 units of insulin that morning. I.G. Ex. 24 at 12 - 13. The emergency medical technicians reported that the patient's blood sugar was 33 mg/dL; the normal range for blood sugar is 80 - 120 mg/dL. I.G. Ex. 24 at 10; Tr. at 140. The emergency medical technicians administered 50 percent glucose to the patient, and by the time he reached the emergency room, his blood sugar was 180 mg/dL and he was alert and

oriented. I.G. Ex. 24 at 10. He suffered another episode of hypoglycemia in the emergency room and he was admitted to the hospital for observation. Id. at 12.

In the hospital, the patient's blood sugar was recorded at 4:30 p.m. as 77 mg/dL. Id. at 32 - 33. The next blood sugar level, which was 26 mg/dL, was recorded at 9:30 p.m. Id. After that significantly low result was obtained, the nursing staff administered orange juice and Karo syrup. Id. at 33. At 9:45 p.m. the patient's blood sugar was 57 mg/dL. Id. at 32 - 33. The nursing staff again administered orange juice and Karo syrup. Id. at 33. At 10:15 p.m., the nursing staff telephoned Petitioner to inform him of the patient's blood sugar levels. Id. The nursing staff noted a telephone order from Petitioner to "change IV solution to Dextrose 10% -- run at rate to obtain blood sugar above 80 then slow IV down to KVO for the n[ight]." Id. at 14. The patient's blood sugar was recorded as 108 mg/dL at 10:30 p.m. There is no record that the nursing staff checked the patient's blood sugar level again until 6:30 a.m. on December 28, 1991, when the patient's blood sugar level was 134. Id. at 32 - 33, 35.

The I.G. argues that Petitioner's treatment of this patient failed to meet professionally recognized standards of health care in two respects. First, the I.G. contends that Petitioner's order to administer 10 percent dextrose to the patient was deficient in failing to specify the rate at which the IV was to run. Second, the I.G. alleges that Petitioner failed to order frequent monitoring of the patient's blood sugar values. I conclude that the I.G. proved that Petitioner failed to meet professionally recognized standards of health care in these two respects.

Dr. Sperling testified that the professionally recognized standard of care for a diabetic patient with hypoglycemia that was not stabilized requires the attending physician to specify the rate at which IV dextrose is to be administered. Tr. at 137, 139. In essence, Petitioner's telephone order left to the nursing staff the determination of what rate of flow would bring the patient's blood sugar above 80. Dr. Nicholas testified that, in the setting of a teaching hospital, it would be acceptable for an attending physician to delegate to house staff (i.e. medical residents) the decision as to the rate for the IV. Tr. at 531 - 532. He opined that, in a community hospital, such as the one at which Petitioner practices, the nursing staff may take on responsibilities performed by residents at larger hospitals. Tr. at 532. Dr. Nicholas' testimony does not

provide evidence of significantly different professionally recognized standards than those presented by the I.G. expert. The testimony of Dr. Nicholas supports the view that the determination of a flow rate for IV dextrose is properly the province of a physician, whether it be the attending physician or the medical resident.[26]

I conclude that the I.G. proved that professionally recognized standards of health care require that the physician be responsible for ordering a flow rate for administering IV dextrose to a diabetic patient with hypoglycemia. This Petitioner did not do. His specification of a rate of KVO for the night once blood sugar was above 80 was insufficient, as the crucial decision required of Petitioner was the rate to be administered to achieve a blood sugar of 80 mg/dL or greater. Accordingly, Petitioner violated his duty to provide care that met professionally recognized standards in ordering the IV for this patient.

Petitioner failed also to order that the patient's blood sugar be monitored at regular intervals. This, too, was a violation of his duty to provide care that met professionally recognized standards. The I.G.'s expert testified that professionally recognized standards of health care require a physician to order frequent monitoring of a patient's blood sugar. Tr. at 138. He testified further that it was not accepted practice to monitor a hypoglycemic patient's blood sugar at five- or six-hour intervals. Id. Petitioner himself stated at the September 28, 1993 IPRO hearing that it would be appropriate to check blood sugar levels every hour or two hours. I.G. Ex. 3 at 119 - 120. Nevertheless, there is no indication in the medical record that Petitioner ever gave orders specifying the frequency at which the nursing staff should monitor the patient's blood sugar. In fact, the patient's medical record reflects that, on the day of admission, the patient's blood sugar dropped from 77 at 4:30 p.m. to 26 at 9:30 p.m., with no blood sugar levels recorded during the five-hour interval. Presumably, had more frequent monitoring been ordered, the patient's falling blood sugar could have been counteracted before it fell to such a low level. Again, after the patient's

---

[26] Dr. Nicholas' testimony is not that the nursing staff would have the responsibility to determine the initial flow rate for the IV. Instead, the thrust of Dr. Nicholas' testimony is that, in a community hospital, it would be appropriate for the nursing staff to adjust the flow rate, depending upon the patient's reaction.

blood sugar had recovered to a level of 108 at 10:30 p.m., his blood sugar was not monitored again until 6:30 a.m. the following morning, eight hours later.

Petitioner argues that the patient recovered and suffered no permanent ill effects from his hypoglycemia. Additionally, Dr. Nicholas testified that, even though the patient's blood sugar level was not monitored, the patient was sufficiently monitored by having the nursing staff observe that he was alert and oriented at several points during the night. Tr. at 537. However, the nursing notes indicate that the patient was alert and conversing well at the time the patient's blood sugar level had fallen to 26 mg/dL. I.G. Ex. 24 at 33. For this reason, it does not appear that the mere fact that the patient was alert and oriented would rule out the possibility of significant hypoglycemia. Moreover, the fact that the patient recovered does not negate the possibility that Petitioner failed to order the appropriate treatment.[27] Therefore, I conclude that Petitioner has not refuted the I.G.'s proof that professionally recognized standards of care required him to order monitoring of the patient's blood sugar at regular intervals.

Thus, I conclude that Petitioner's failure to order a rate for administering the IV dextrose and his failure to order regular monitoring of the patient's blood sugar were substantial violations of his obligation to provide care of a quality which meets professionally recognized standards of health care.

Patient 030344

> PRO Finding: Failure to document discharge plans for patient.
>
> [I.G.] Analysis: The patient had a cardiac history and was admitted in atrial fibrillation. Patient was not discharged on coumadin or aspirin.

---

[27] On cross-examination, Dr. Sperling agreed that the patient was monitored and treated and that his hypoglycemia was reduced. Tr. at 145. The medical record demonstrates that the patient was monitored and received treatment and that his blood sugar returned to normal. This in no way contradicts Dr. Sperling's direct testimony that the patient's blood sugar was not monitored at frequent, regular intervals during the day and night of December 27 - 28, 1991.

> Physician states coumadin was started on an outpatient basis.
>
> [I.G.] Decision: The medical records support the PRO findings. This case is being retained as a documentation failure.

My Analysis: This patient, a 76-year-old male, was admitted to Little Falls Hospital on August 15, 1991, with complaints of dyspnea, weakness and chest discomfort. Petitioner diagnosed auricular fibrillation. I.G. Ex. 25 at 7, 13, 15.[28] On August 20, 1991, the patient was started on Heparin, an intravenous anticoagulant medication. I.G. Ex. 25 at 11, 19; Tr. at 277. Petitioner consulted another doctor from Little Falls Hospital, Dr. Apone. In his consultation report, Dr. Apone advised Petitioner to "stop the IV Heparin and see if the patient can be maintained chest pain free just on Aspirin and antiplatelet therapy and possibly with addition of Persantine." I.G. Ex. 25 at 27.

Petitioner discharged the patient 10 days after admission with instructions to follow a low sodium diet and to take Vasotec, Lasix, and Isosorbide. Petitioner instructed him also to return to Petitioner's office for a follow-up visit. I.G. Ex. 25 at 11, 25, 76. There is no indication on the medical chart that Petitioner instructed the patient to take Coumadin at the time that he was discharged. Petitioner states, however, that Coumadin was started on an outpatient basis. I.G. Ex. 25 at 4; I.G. Ex. 3 at 42; I.G. Ex. 6 at 206.

Petitioner wrote discharge instructions in his handwritten notes of August 25, 1991. I.G. Ex. 25 at 25. He wrote also the discharge instructions in his typewritten notes of September 18, 1991. I.G. Ex. 25 at 11. A nurse filled out the discharge instructions which were given to the patient, and, in accordance with customary practice, based the instructions on

---

[28] Petitioner's progress notes indicate that the patient was admitted with auricular fibrillation, and Dr. Kops testified that the patient was admitted with atrial fibrillation. Apparently, the two terms are used synonymously. Dr. Kops defined atrial fibrillation as: "an uncoordinated activity of the atrium. The heart loses its efficiency to pump. Because of atrial fibrillation, there's stagnation of blood flow in the heart." Tr. at 276. Since Petitioner did not contest this definition, I accept it as true.

Petitioner's progress notes. Tr. at 286; I.G. Ex. 25 at 76.

The nurse's discharge instructions mirror Petitioner's progress notes, with the exception of an additional instruction for the patient to take Digoxin. I.G. Ex. 25 at 76. Dr. Kops indicated that the nurse's variance from Petitioner's progress notes was probably due to the fact that the patient had been given Digoxin up until the time of discharge and that this prescription would be noted in the medication record. Tr. at 287. The patient visited Petitioner a week to 10 days after discharge. Petitioner noted in his typewritten progress notes that the patient "still had auricular fibrillation, which increased abnormally with effort." I.G. Ex. 25 at 11.

The I.G. contends that Petitioner substantially violated professionally recognized standards of care by his failure to document the prescription of Coumadin in the discharge plans for the patient. I.G.'s Brief at 56 - 57. Dr. Kops testified that the standard of care for anti-coagulating a patient is to start the patient on Heparin while in the hospital. He stated that Coumadin should then be started while the patient is on Heparin and while the patient is still in the hospital and adequately anti-coagulated. He explained that Heparin is only discontinued once the Coumadin has achieved its desired effect, and that it takes several days for the Coumadin to do so. He stated that a prothrombin test is used to measure whether the Coumadin is within a satisfactory range. Tr. at 277 - 278.

In response to questions regarding Petitioner's failure to document the prescription of Coumadin in the discharge plans for the patient, Dr. Kops explained how the discharge instructions are given. Dr. Kops indicated that customary practice is for the attending physician to write his discharge instructions in the medical chart. He explained that the nurse who discharges the patient will include the doctor's instructions in the discharge instruction sheet which is given to the patient. Tr. at 285 - 287. In this case, in addition to the medications prescribed by Petitioner in his progress notes, the nurse included an additional medication which was not listed in Petitioner's notes. I.G. Ex. 25 at 25, 76. As I stated earlier, Dr. Kops explained that the nurse could have included this medication in the discharge summary on the basis of the medication history and the fact that the patient was on this medication up until discharge. Tr. at 287.

Petitioner did not refute the I.G.'s definition of the recognized standards of care. Moreover, Petitioner conceded the documentation error, and asserted that he "is currently documenting discharge medications in the medical chart. Petitioner's Brief at 56 - 57. Petitioner contends, however, that the allegation that he never prescribed Coumadin for this patient went beyond the scope of the PRO finding that he had failed to document any prescription for Coumadin. Petitioner asserts that he prescribed Coumadin for the patient on an outpatient basis, and he told IPRO this at the 1992 and 1993 IPRO hearings and in his Physician Response to the IPRO reviews. I.G. Ex. 25 at 4, I.G. Ex. 3 at 42, I.G. Ex. 6 at 206.

The issue of whether Petitioner prescribed Coumadin to this patient after he was discharged goes beyond the scope of this case. IPRO found that Petitioner had failed to document the prescription of Coumadin in his discharge notes. IPRO did not make any findings with regard to whether Petitioner failed to prescribe Coumadin.

With regard to the allegation that Petitioner did not adequately document his discharge plans, the record shows that recognized standards of care required him to document his discharge instructions in the medical chart. Neither Petitioner's handwritten or typewritten progress notes include an instruction that Coumadin be prescribed to the patient upon discharge. I.G. Ex. 25 at 11, 25. As a result of Petitioner's failure to document a Coumadin prescription, the discharging nurse was unaware that the patient should be anti-coagulated with Coumadin. The nurse's discharge instructions to the patient do not include a prescription for Coumadin. I.G. Ex. 25 at 76. Petitioner admits that he made a documentation error and he claims that he is now documenting instructions for all discharge medications. Based on the foregoing, I find that Petitioner's failure to document his intent to prescribe Coumadin to this patient on discharge is a substantial violation of his obligation to provide necessary documentation of his care of the patient.

Patient 039069

> PRO Findings: Failure to document omission of a diagnostic test.
>
> [I.G.] Analysis: Patient admitted with vertigo and a history of atrial fibrillation (for which he was receiving anticoagulation), a recent 25-pound weight loss and fatigue. A complete blood count was not

done on admission. The test was performed prior to admission and was reportedly within normal limits. However, the omission of the test at admission, and the reason for omission are not clear. The failure to provide documents showing prior recent complete blood counts is applicable.

[I.G.] Decision: The medical records support the PRO findings. This case is being retained as a documentation failure.

My Analysis: This patient was a 76-year-old male who was admitted to Little Falls Hospital with complaints of vertigo and nausea. I.G. Ex. 26 at 9 - 10. Upon initial examination, Petitioner found that the patient had generalized arteriosclerosis with acute episodes of vertigo; mild organic brain syndrome; and arteriosclerotic heart disease with ongoing auricular fibrillation and cardiac prominence. I.G. Ex. 26 at 9. Petitioner noted in his progress notes that the patient had been under the care of several physicians in the area for cardiac and orthopedic care, but there is no mention of any contact with these physicians during his admission. Id. There is no documentation in the patient's admission record of a CBC. There is also no explanation in the admission record as to why a CBC was not done on admission, nor are the results of a prior CBC documented. I.G. Ex. 26.

The I.G. did not offer any direct testimony at the hearing in support of the PRO findings. Instead, the I.G. contends that the record substantiates the PRO findings set forth in the Notice. Petitioner did not present any testimony either.

The I.G. argues that Petitioner's failure to document in this case is an example of the deficiencies that Petitioner's CAP was intended to correct. I.G.'s Brief at 60 - 61. The I.G. contends that this failure to document is one of a number of events, which together demonstrate a pattern of practice by Petitioner, which fails to conform to professionally recognized standards. Id.

Petitioner admitted that his failure to do a CBC on admission was an oversight. I.G. Ex. 26 at 4, I.G. Ex. 6 at 182. He stated that he now performs a CBC as part of the routine admission blood tests he orders to be performed on all of his patients. I.G. Ex 6 at 183; Petitioner's Brief at 89. Petitioner asserted also that the patient had a CBC done approximately seven days before admission. I.G. Ex. 3 at 23. However, Petitioner

did not offer any explanation for his failure to document the omission of a CBC on admission, or for his failure to document an explanation for the omission. Moreover, Petitioner did not explain why he failed to include in the medical record the results of the previous CBC.

Although Petitioner concedes that his failure to obtain the CBC on admission was an oversight, he attempts to reduce the significance of the violation by relying on: 1) a comment made by an I.G. medical advisor that the inclusion of this patient's case as a documentation rather than a quality of care failure seemed inappropriate; and 2) the fact that IPRO's physician reviewer reduced his rating of the violation from Level II to Level I. Petitioner's Brief at 89 - 90. An I.G. medical advisor stated that documentation of a CBC in this case would be necessary only if the CBC itself was necessary. I.G. Ex. 29 at 7. Petitioner argued also that he did not get fair notice and the opportunity to be heard on the I.G.'s contention in her brief that this deficiency was one of several deficiencies that the CAP was intended to address. Petitioner's Response at 23 - 24.

Petitioner's reliance on one statement by the I.G.'s medical advisor is without merit. The medical advisor's concern was IPRO's selection of the nature of the violation. He suggested that the omission of the test was a quality of care violation rather than a documentation failure. He opined that, if IPRO did not find it to be a quality of care violation, then arguably failure to document the test was not a documentation violation. However, he acknowledged that, despite his concerns, the I.G. could agree with IPRO because of the wide latitude of the PRO documentation standards. I.G. Ex. 29 at 7. A second analysis performed for the I.G. concluded also that the CBC was necessary at admission. I.G. Ex. 30 at 11. So, at best, Petitioner is quibbling with the I.G.'s choice as to the type of violation. The record supports that the CBC was necessary at admission. Thus, Petitioner is advantaged by the I.G. choosing the lesser violation of documentation failure.

Petitioner's argument that he was not given proper notice or an opportunity to be heard is also without merit. The Notice makes specific reference to the CAP. The Notice alleges that the cited cases, including those reflecting documentation problems, establish that Petitioner's pattern of practice with regard to treatment of patients has not improved in spite of the CAP. Notice at 10.

Upon review of the record, I find that Petitioner's failure to document that he did not perform a CBC on this patient at the time he was admitted, his failure to explain why he did not perform a CBC on admission, and his failure to document the results of the CBC performed prior to admission, is a substantial violation of Petitioner's obligation to provide necessary documentation of care.

Patient 037680

> PRO Findings: Failure to perform a procedure with consent. Failure to document in the medical record the diagnosis, procedure and the lack of fluid analysis.
>
> [I.G.] Analysis: Patient admitted for organic brain syndrome with hallucinations. Arthrocentesis of the right knee was performed. Medical records provided do not contain a consent for this procedure, neither do they contain a general hospital consent form or procedure note.
>
> [I.G.] Decision: The medical records support the PRO findings, and the findings are upheld. (Quality of care violation)

My Analysis: Patient 037680, an 85-year-old female, was admitted to Little Falls Hospital on August 21, 1991. The patient's chief complaint at the time of admission was that she was having hallucinations. In the hospital admission report, Petitioner stated that the patient had some insight into her problem, but that the hallucinations had a considerable reality to her and were quite disturbing. The patient had a brother who lived nearby. I.G. Ex. 27 at 5 - 6.

At the time of the patient's admission to the hospital, Petitioner diagnosed organic brain syndrome with hallucinatory and delusional state. In addition, Petitioner reported that his physical examination of the patient revealed evidence of bilateral arthritis of both knees, and he noted that the right knee was acutely inflamed. I.G. Ex. 27 at 5 - 6.

During her hospitalization, the patient was disoriented at times. The nursing notes describing her condition from August 21 through August 23, 1991 reveal that she alternated between being confused and being lucid. At times, she did not realize that she was in the hospital and at other times she was oriented and gave appropriate verbal responses. I.G. Ex. 27 at 56, 59 - 61.

On August 23, 1991, Petitioner performed an arthrocentesis of the patient's right knee. This is an invasive procedure, which involves inserting a needle into a patient's knee and withdrawing fluid. I.G. Ex. 27 at 61; Tr. at 149 - 151, 223. Petitioner's progress notes describe the procedure and its results as follows: "Tapped Rt[right] Knee - Old Blood - Hemarthrosis." I.G. Ex. 27 at 19. There is no consent form for the procedure in the patient's medical chart.

Within 45 minutes after this procedure was performed, the patient began to cry and stated that she saw snakes coming out of the box containing needles. The patient stated that, although she knew the snakes were not real, she nevertheless could still see them. I.G. Ex. 27 at 61. The patient reported seeing snakes the next day. I.G. Ex. 27 at 65.

During the course of her hospital stay, the patient was treated with insulin, and her hallucinations improved. On September 10, 1991, the patient was discharged from the hospital to the County Home for ongoing care. At the time of discharge, the patient had achieved mental equilibrium. I.G. Ex. 27 at 25, 26.

IPRO made several findings with respect to this patient, and I will discuss each in turn.

Failure to perform procedure with consent

The record establishes that professionally recognized standards of health care require that a physician obtain informed consent prior to performing an invasive procedure on a patient. Arthrocentesis is an invasive procedure which requires informed consent. Tr. at 149 - 150.

The professionally recognized standards regarding the process for obtaining informed consent require the physician to explain the purpose of the procedure, how it will be performed, the possible benefits of the procedure, and the possible complications of the procedure. In addition, the patient should be given the opportunity to ask questions of the physician. Tr. at 300.

If the patient is incapable of understanding information pertaining to the procedure, the procedure should be explained to an adult who is the closest relative to the patient. Consent to perform the procedure should be obtained from that individual. Tr. at 151.

In this case, Petitioner does not dispute that he was required to obtain informed consent prior to performing arthrocentesis. In addition, Petitioner does not dispute that he failed to obtain written informed consent for this procedure. While Petitioner admits that he erred in not adequately documenting the fact that he obtained informed consent, he contends that he obtained the requisite informed consent orally from this patient.

I find that the weight of the evidence establishes that Petitioner did not obtain informed consent from this patient.

The undisputed evidence establishes that the patient's chief complaint at the time she was admitted to Little Falls Hospital was that she was experiencing hallucinations. During the two day period from the time she was admitted until the time the arthrocentesis was performed, she alternated between being disoriented and lucid. In addition, she was delusional within one hour of the arthrocentesis.

Dr. Nicholas testified that the fact that the patient was experiencing hallucinations alone does not necessarily mean that she was not capable of giving informed consent for the arthrocentesis. He expressed the view that it is possible to experience hallucinations about certain limited aspects about what is going on, but still be capable of understanding the benefits and risks associated with a medical procedure. Tr. at 561.

I accept Dr. Nicholas' testimony that the fact that the patient was delusional does not automatically mean that she was incapable of providing informed consent. I recognize that the evidence does not definitively establish that the patient was not competent to provide informed consent. Indeed, the evidence shows that she had some insight into her problem and realized that the hallucinations were not real. Nevertheless, I am troubled by the evidence regarding the patient's mental condition. At the least, the evidence regarding the patient's changing mental status creates some doubt about her ability to understand the procedure and to give informed consent.

At the hearing before me, Petitioner testified that the patient's hallucinations "didn't leave her psychotic" and that on the day the procedure was performed, the patient was "quite lucid." Tr. at 231. He testified that the patient's knee was swollen and hot. According to Petitioner, the patient "was advised that she would probably improve symptomatically if she had the fluid

removed from her right knee. She said, all right." Tr. at 223. Petitioner stated that he did not make any attempt to contact the patient's brother in order to obtain consent. Tr. at 231.

In addition, Petitioner testified that the practice at Little Falls Hospital in 1991 was that the physician had the responsibility to make sure that the patient was agreeable to having a procedure performed. He stated that consent forms were not always signed in 1991, and if they were, the nurses typically took care of it. Tr. at 225, 230.

I am not persuaded by Petitioner's testimony that the patient gave informed consent in this case. While Petitioner claims that he discussed the procedure with the patient and that she agreed to it, there is nothing in the record to substantiate that the patient was fully informed of her condition, of the need for the procedure, and of the risks attendant to it. The record is devoid of evidence corroborating Petitioner's assertion that the patient knowingly approved of the procedure. There is no signed consent form, nor is there any contemporaneous notation either in Petitioner's progress notes or the nursing notes indicating that the procedure was even discussed with the patient. Also absent from the record is testimony from a nurse who may have witnessed the patient consenting to the procedure. I am not convinced by Petitioner's self-serving, unsubstantiated assertion that he obtained informed consent, particularly in light of the undisputed evidence showing that the patient had periods of confusion and hallucinations on the day the procedure was performed.

Moreover, statements made by Petitioner in the September 28, 1993 hearing before IPRO suggest that the patient was not fully informed about the procedure. Petitioner stated in that hearing that, while he told the patient what he was going to do, he did not explain the procedure in detail. He stated that the patient was "a very compliant individual" and that he did not "think she would have understood a full explanation." I.G. Ex. 3 at 52. These statements undermine Petitioner's assertion that the patient gave "proper consent." Id.

Based on the totality of the circumstances of this case, I conclude that Petitioner did not obtain informed consent from this patient. This is a substantial violation of Petitioner's obligation to provide care of a quality that meets professionally recognized standards of care.

Petitioner's violation of this obligation is a serious offense. Dr. Nicholas acknowledged in his testimony that the right of a patient to be fully informed about the treatment being recommended and to refuse that treatment is a "basic" right of patients. Tr. at 563. In addition, this right is codified in the Patients' Bill of Rights given to patients admitted to hospitals in New York State. I.G. Ex. 27 at 111. Petitioner's failure to obtain informed consent from one of his patients shows a disturbing indifference to the fundamental rights of patients.

Even if I were to construe the facts in favor of Petitioner and find that he obtained informed consent from this patient orally, which I do not, I would still find that Petitioner committed a substantial violation of his obligation to document the quality of his care based on his failure to describe such consent in the written record of the patient's treatment.

Petitioner argues that obtaining written consent is not required under the laws of the State of New York in order for oral consent to be valid. Petitioner's Response at 11. Since I find that Petitioner did not obtain consent orally, I do not need to address the issue of whether written consent is necessary for oral consent to be valid. Moreover, even assuming that written consent is not necessary for oral consent to be valid, I still find that failure to document that valid oral consent was obtained is a violation of professionally recognized standards of care.

Even Petitioner admits that documenting the patient's oral consent would have been "the better practice." Petitioner's Response at 11. In addition, during the first IPRO hearing on November 10, 1992, Petitioner admitted that he was "absolutely wrong" in not making sure that the patient signed a written consent form before Petitioner performed the arthrocentesis. I.G. Ex. 6 at 99.

Dr. Nicholas testified that the professionally recognized standard of care is to obtain written consent to document that the physician has discussed the procedure with the patient and that the patient has given oral informed consent. Tr. at 563 - 565. Dr. Nicholas further testified that while oral consent is obtained before written consent, he teaches his students to obtain written consent. Tr. at 564 - 565. Both Drs. Kops and Sperling testified that oral consent should not be obtained from a patient with changes in mental status. Tr. at 151, 301. Dr. Sperling testified that, under such

circumstances, he would obtain consent from a relative and that, if only oral consent could be obtained from the relative, he would document such consent in the patient's record. Tr. at 151 - 152.

Petitioner's failure to document the record is especially egregious in this case because of the patient's changing mental state. Based on her compromised mental state, this patient was totally dependent on Petitioner to determine whether she was sufficiently lucid to give informed consent. In the event that the patient was too confused to give informed consent, Petitioner was obligated to obtain consent from a relative.

Petitioner chose not to discuss the patient's treatment with her brother, and, as a result, the patient's brother could not exercise any judgment for her. Under circumstances such as these, when a patient's capacity to give informed consent is open to question, it is particularly important for the attending physician to document that the physician had a full discussion of the treatment alternatives with the patient and that based on this discussion, the patient knowingly gave consent to the procedure. As previously stated, no such documentation exists in this case.

Failure to document the diagnosis

This patient was treated during her hospital stay for more than one condition. The PRO finding that Petitioner failed to document the diagnosis refers to the patient's right knee condition for which the arthrocentesis was performed.

Petitioner testified that the fluid removed from the patient's right knee "turned out to be old degenerated blood." Tr. at 223. He stated that the fluid was "just dead blood which was a complication of her arthritis. It's not too unusual." Tr. at 224. Petitioner contends that he documented his diagnosis of the patient's right knee condition in his August 23, 1991 progress note which reads, "Tapped Rt[right] Knee - Old Blood - Hemarthrosis." I.G. Ex. 27 at 19. He contends that hemarthrosis is his documented diagnosis. Petitioner's Brief at 70.

Dr. Nicholas' testimony supports Petitioner's contention. He stated that "hemarthrosis is a diagnostic term indicating that blood was found in the knee joint. You can't make that diagnosis without having obtained blood in the -- old blood was what was obtained." Tr. at 557. The testimony of the I.G.'s expert witness, Dr. Sperling,

is consistent with this. He testified that hemarthrosis is a diagnosis meaning blood in the joint. Tr. at 160.

I conclude that the expert medical testimony establishes that Petitioner diagnosed the patient's medical condition based on his observations of the fluid withdrawn from her knee and that he documented this diagnosis in the patient's chart.

While it is clear that Petitioner documented his diagnostic impression after he performed the arthrocentesis, there is a remaining question as to whether he should have taken additional steps in order to make a more complete and informed diagnosis. Dr. Sperling testified that obtaining a laboratory analysis of the fluid was necessary to "find out what you are dealing with; what's the diagnosis." Tr. at 163. Thus, Dr. Sperling's testimony suggests that hemarthrosis was a properly documented diagnosis based on the available information immediately following the arthrocentesis, but that it is not necessarily a final or complete diagnosis based on all the tests that should have been performed. Since the issue of whether Petitioner documented a final and complete diagnosis is interrelated with the issue of whether he should have performed a fluid analysis, I will address it in the context of my discussion of the lack of fluid analysis.

Failure to document the procedure

IPRO found also that Petitioner failed to document the procedure that was performed. The Analysis supporting this allegation states that the medical record does not contain a procedure note.

Petitioner contends that his August 23, 1991 progress note which reads, "Tapped Rt[right] Knee - Old Blood - Hemarthrosis" documents the procedure which was performed on this patient. Petitioner's Brief at 70. The I.G. contends that this is not a sufficient description of the procedure performed on the patient to meet accepted professional standards. I.G.'s Brief at 37 - 38.

Dr. Kops testified that, if an invasive procedure is performed at bedside, then the attending physician should write a procedure note for the chart. Tr. at 301. Dr. Kops stated that a procedure note should contain the following:

> . . . the indication for the procedure, the procedure then should be specified. Whatever preparation made of the skin. If a local anesthetic

> is used, that should be documented. And the procedure itself should be documented, the technique used, and the physician should comment on how the patient tolerated the procedure after it's completed.

Tr. at 301 - 302.

Dr. Sperling's testimony was consistent with Dr. Kops' testimony. Dr. Sperling stated that a procedure note should describe how the procedure was performed. He stated that, if the procedure is arthrocentesis, the procedure note should describe the fluid that was obtained. Dr. Sperling opined that while the words "tapped right knee" is indicative of the fact that arthrocentesis was performed, it does not describe how the procedure was performed in sufficient detail to comport with recognized professional standards. He stated that the words "old blood" do not meet the standard of practice in describing the fluid that was drained from the knee because it does not indicate characteristics such as the fluid's viscosity, turbidity, whether it clots, whether there is evidence of pus, how thick it was, how much was obtained, and whether there was an odor. Tr. at 160 - 161.

I find the testimony of these expert witnesses to be persuasive. This testimony establishes that professionally recognized standards of care require that a physician write a procedure note for invasive procedures, such as arthrocentesis, performed at bedside. This requirement is not fulfilled by simply writing in the chart that a procedure was done. Instead, the procedure note should contain a comprehensive description of the indication for the procedure, the procedure itself, and the results.

Petitioner's August 23, 1991 entry in the chart does not meet this standard. While this entry documents that arthrocentesis was performed and that old blood was obtained, it does not describe the procedure and the results in sufficient detail to meet the professionally recognized standard of care as set forth by Dr. Kops and Dr. Sperling.

Petitioner has not brought forward convincing evidence to rebut the testimony of the I.G.'s expert witnesses. His responses to IPRO charges are inconsistent and unpersuasive.

Petitioner initially responded to the IPRO charge that he did not describe the procedure adequately by stating that

a "procedure note is not required for a procedure of a limited extent accomplished in the patient's room. In the Emergency Room or Surgery, then a note is required." I.G. Ex. 27 at 4. By defending himself against IPRO's charge in this manner, he implicitly admitted that the entries he made in the chart do not constitute a detailed procedure note. Instead, he argues that he was not required to write a detailed procedure note since the procedure was performed at bedside in a non-emergency situation.

However, in the November 10, 1992 hearing with IPRO, Petitioner stated that there were "not enough words" in his August 23, 1991 entry. I.G. Ex. 6 at 100. In making this statement, Petitioner appears to be saying that he recognizes that he was required to document the procedure in greater detail, but that he failed in his obligation to do so.

Petitioner's position changed again in the proceedings before me. Dr. Nicholas, his expert witness, characterized the August 23, 1991 entry as a procedure note which documented the procedure and what was found. Tr. at 559 - 560. Petitioner's argument in his posthearing briefs was consistent with Dr. Nicholas' testimony. He abandoned his argument that a procedure note is not required for a procedure performed at bedside. In addition, he no longer contended that there were "not enough words" in the August 23, 1991 entry. Instead, he took the position that the August 23, 1991 entry adequately documented the procedure.

In view of the inconsistencies in Petitioner's statements, I find that Petitioner has not overcome the evidence adduced by the I.G. Even Dr. Nicholas' testimony does not directly rebut the testimony of the I.G.'s expert witnesses. While Dr. Nicholas stated that the August 23, 1991 entry was a "very concise description of what happened," he does not explicitly disagree with Dr. Kops' and Dr. Sperling's testimony regarding the requirements for a full and complete procedure note. Tr. at 557. I do not agree with Dr. Nicholas that Petitioner's cryptic procedural note meets the professionally recognized standards of care. A simple comparison of what Petitioner wrote in his note and of the required description of the procedure reflected in the I.G.'s experts' testimony demonstrates the inadequacy of Petitioner's documentation of the procedure.

In view of the foregoing, I find that the preponderance of the evidence rests with the testimony of Dr. Kops and Dr. Sperling. This evidence establishes that

Petitioner's failure to document adequately the procedure performed on this patient was a substantial violation of professionally recognized standards of health care.

Lack of Fluid Analysis

IPRO found also that "the lack of fluid analysis" violated Petitioner's obligation to provide care that meets professionally recognized standards of care.

In support of this PRO finding, the I.G. offered the testimony of Dr. Sperling. Dr. Sperling testified that professionally recognized standards of care and State law require that every time fluid is withdrawn from a knee joint in the course of an arthrocentesis, samples of that fluid should be sent to a pathology laboratory for analysis. Tr. at 161 - 163. According to Dr. Sperling, the laboratory:

> can spin out the blood, see whether or not they get cells any number of ways, what their culture and sensitivities are, what the gram stains [are] . . .

Tr. at 162. Dr. Sperling stated that the purpose of obtaining a laboratory analysis of the fluid is to "find out what you are dealing with; what's the diagnosis" and he indicated that the results of the laboratory analysis are typically documented in the record. Tr. at 162 - 163. Dr. Sperling stated that there are no exceptions to this requirement. In particular, he testified that this requirement is not obviated by the fact that the withdrawn fluid is described by the attending physician as being "old blood." He asserted that the fact that Petitioner indicated that the withdrawn fluid was old blood "doesn't mean anything" because "[y]ou can still have an infection with old blood." Tr. at 157.

Dr. Sperling's testimony is supported by the Merck Manual. The Merck Manual includes a Table setting forth an outline for performing arthrocentesis. That table sets forth detailed instructions for handling the withdrawn fluid in preparation for laboratory tests. The Merck Manual indicates that the proper aspiration of fluid and its preservation for laboratory analysis is a critical step in the diagnostic process. While the Merck Manual states that "[n]ot all tests need to be done on each fluid," it does not state anywhere that laboratory tests need not be performed on "old blood." Merck Manual (4th ed. 1982) at 1174. Indeed, the Merck Manual expressly notes that the specimen may be hemorrhagic, and that this suggests fracture or malignancy. In addition, the Merck Manual states that intensely inflammatory

effusions suggest pyogenic infection. The Table containing the outline for performing arthrocentesis specifically states that, if infection is considered a possibility, the fluid should be placed immediately in a sterile tube for routine cultures. Merck Manual (14th ed. 1982) at 1174 - 1176; (15th ed. 1987) at 1231.

Petitioner does not dispute that, as a general rule, a physician should send blood withdrawn from a knee joint to a laboratory for analysis. However, he asserts that, under the circumstances of this case, he was justified in discarding the fluid without sending it to a laboratory for analysis.

Petitioner testified that the substance he removed from this patient was old, degenerated blood. He stated that he did not send it for laboratory analysis because lab values such as cell counts and proteins are not interpretable on old blood. Tr. at 223 - 224. Petitioner's testimony is deficient because he does not adequately explain the basis for his conclusion that this fluid had degenerated to the point that sending it for analysis would yield meaningless results. Petitioner does not describe a recognized objective standard that is used to determine whether a withdrawn fluid has the characteristics which would justify throwing it away without analysis. In addition, Petitioner does not describe the fluid he actually withdrew with sufficient specificity to ascertain whether it possesses those characteristics. It is noteworthy that the Merck Manual classifies fluids based on viscosity, color, and clarity. While Petitioner's progress note states that he withdrew "old blood," it does not describe the viscosity, color, and clarity of the withdrawn fluid.

Moreover, even Petitioner equivocated on the issue of whether the fluid he withdrew from this patient would have produced results which were not interpretable. In the September 28, 1993 hearing before IPRO, Petitioner stated that even though the withdrawn fluid was old blood, a "culture could have been done." I.G. Ex. 3 at 51 - 52. This statement is inconsistent with his subsequent statement that he was justified in his decision not to obtain any laboratory tests on this fluid, and it undermines his credibility. Tr. at 223 - 224.

Dr. Nicholas did not dispute that, as a general rule, a physician would send fluid withdrawn from a knee to a laboratory for analysis. However, he asserts that an exception to this general rule should be made under the circumstances of this case.

Dr. Nicholas opined that "once you've decided this is a hemarthrosis with old blood in it, any of the numbers you get back, either high or low, would be not interpretable." Tr. at 558. He acknowledged that ordinarily measuring protein is an important thing to do in a joint fluid. However, he stated that old blood has "disintegrated lysate cells in it which would contribute to the fluid in general and elevate the protein some, and make the protein analysis not really helpful." Id. In addition, he stated that "blood simply being in the joint can incite a white cell response." Id.

Dr. Nicholas reasoned that "one shouldn't send a lab test if the results are not going to be interpretable. And that rule certainly overrides the general rule, the general rules about what you should with any -- you know -- with either the fluid or the specimen or with what you would ordinarily do." Tr. at 558 - 559. Dr. Nicholas asserted that obtaining tests that have no potential to give interpretable results is wasteful and potentially misleading. Tr. at 559.

I am not persuaded by Dr. Nicholas' testimony. While Dr. Nicholas asserts the cellular components of blood can disintegrate to the point that a laboratory analysis of the blood would be meaningless, he does not offer an objective standard to determine when the blood has disintegrated to that point. Instead, he relies merely on Petitioner's conclusory statement that the withdrawn blood was "old."

Moreover, the record is devoid of evidence showing that either Dr. Nicholas or Petitioner possess the expertise to offer an opinion on the issue of whether the withdrawn fluid has disintegrated to the point that laboratory test results would be meaningless. It is noteworthy that Dr. Kops declined to offer an opinion on this issue on the grounds that he is "not a rheumatologist." Tr. at 308.

Based on the foregoing, I conclude that the weight of the evidence establishes that professionally recognized standards require that fluid withdrawn from a knee in the course of arthrocentesis should be sent for laboratory analysis. I find also that the evidence adduced by Petitioner fails to establish that an exception to this general rule was justified under the circumstances of this case. In view of the fact that Petitioner failed to obtain the requisite laboratory tests on the withdrawn fluid, I find that he did not take all the necessary steps to make a final and complete diagnosis. In the absence of the fluid analysis, Petitioner did not establish that his preliminary diagnosis was accurate.

Petitioner's failure to take the necessary steps to make a final diagnosis is a substantial violation of his obligation to provide care in accordance with professionally recognized standards of care.

Patient 034026

PRO Findings: Failure to evaluate or follow-up an abnormal lab value or document etiology of elevated glucose.

[I.G.] Analysis: Patient was admitted for renal colic. A blood sugar of 232 was found on admission. The Medical records show the elevated blood sugar determination (232 mg/dL) on 7/24/91 at 1:09. No further blood sugar determinations are listed in the laboratory section of the chart. Hospital stay was from 7/24-26/91. There is no discussion of this in discharge summary, as there is no discharge summary in the medical records submitted. Repeat studies (SMA 18) ordered on 7/26/91; no results in chart. Practitioner claims subsequent outpatient blood sugar determinations were normal.

[I.G.] Decision: The medical records support the PRO findings, and the findings are upheld. (Quality of care violation)

My Analysis: This patient was a 75-year old female, who was admitted to Little Falls Hospital on July 24, 1991 with a diagnosis of renal colic. I.G. Ex. 28 at 8 - 11. A laboratory test conducted on July 24, 1991 indicated that the patient had a blood glucose level of 232 mg/dL, an abnormally high result. I.G. Ex. 28 at 12. The patient was discharged from the hospital on July 26, 1991. I.G. Ex. 28 at 8. While another blood test was apparently ordered, the patient's medical record does not reveal the results of that test. I.G. Ex. 28.

The I.G. did not present any expert testimony as to what professionally recognized standards of health care would require in this case. On the other hand, Petitioner admitted that the result of the follow-up blood test should have been in the chart. I.G. Ex. 28 at 4; Petitioner's Brief at 91. Because evidence regarding the professionally recognized standards of health care is absent in this case, I have no basis to conclude that Petitioner's actions in this case represent a quality of care violation. However, because Petitioner admitted that the results of the follow-up blood test should have

been in the medical record, I conclude that this case does represent a documentation violation.

This concludes my analysis of the evidence pertaining to the 13 cases at issue. The totality of the evidence persuades me that Petitioner engaged in a pattern of acts or omissions which contravened his obligations under section 1156(a) of the Act. I find that the cumulative evidence proves that Petitioner failed in a substantial number of cases substantially to comply with his obligations under section 1156(a).

Petitioner argues that there is no basis for an exclusion in this case because the I.G. has failed to prove that his treatment of patients has caused harm to them. However, under section 1156 of the Act, it is not necessary for the I.G. to prove that Petitioner harmed his patients. Instead, section 1156 is intended to protect program beneficiaries and recipients from the risk of harm by identifying practitioners whose care fails to meet the standards of practice of their professions.

The I.G. met her burden of proof by showing that Petitioner engaged in a pattern of care that is inappropriate, unnecessary, does not meet professionally recognized standards of care, or is not supported by the necessary documentation of care as required by a PRO. 42 C.F.R. § 1004.1(b). Thus, even if I accept as true Petitioner's assertion that his treatment of patients has not caused harm, the lack of harm to patients does not prove that Petitioner has complied with his obligations under section 1156(a) of the Act.

Petitioner argues that an exclusion is not justified because he committed "only documentation errors." Petitioner's Brief at 95. Petitioner admits that his documentation of the treatment of patients needs improvement. Tr. 516. Indeed, Little Falls Hospital physicians who submitted an affidavit in lieu of testimony on Petitioner's behalf acknowledge that IPRO had legitimate concerns about Petitioner's documentation practices. P. Ex. 47 at 3. Thus, while Petitioner admits that the record shows deficiencies in his documentation of patient charts, he takes the position that these documentation deficiencies do not justify an exclusion.

The excluded practitioner in Corkill v. Shalala, No. Civ-S-94-669, slip op. at 5 (E.D. Cal. April 14, 1995) made the same argument. The court rejected the argument, stating:

> . . . even assuming that plaintiff is correct that in all four cases the Secretary has proved only a 'documentation' violation, converting the medical necessity violations into documentation violations does not provide plaintiff a basis for overturning the suspension.

I agree with the court in Corkill. Petitioner is obligated under section 1156(a) of the Act to document the quality of his care in a form that is reasonably required by a reviewing PRO. A showing that Petitioner engaged in a pattern of acts or omissions which contravened this obligation proves that he substantially violated his obligations under section 1156(a) in a substantial number of cases. Petitioner's attempt to characterize his violations as mere documentation deficiencies rather than quality of care violations does not call into question the ultimate determination that he failed in a substantial number of cases substantially to comply with his statutory obligations.

Moreover, I do not agree with Petitioner that the I.G. proved only documentation deficiencies. While the record shows that Petitioner violated his obligation to provide adequate documentation in some instances, it shows that, in other instances, Petitioner violated his obligation to provide care of a quality which meets professionally recognized standards of health care.

I find also that these violations constitute a pattern of inappropriate treatment. The evidence establishes that there is some form of violation in 11 of the 13 cases at issue and that there are multiple violations in many of those cases. In addition, the violations of statutory obligations have common features. The evidence establishes that Petitioner has repeatedly failed to provide adequate documentation, to order necessary tests, and to keep pace with accepted treatment modalities.

Petitioner points out that Dr. Sperling testified that IPRO and its predecessor ESMSEF have been reviewing his charts since 1988, and he argues that the 13 cases at issue represent only a small fraction of his total workload during the period from 1988 through 1991. I find that Petitioner's assertion that the cases at issue comprise only a small part of his total practice does not rebut the evidence of a pattern of substantial violations which emerges from the 13 cases before me.

c. Petitioner has demonstrated an unwillingness and lack of ability substantially to comply with the

obligations imposed on him by section 1156(a) of the Act.

The I.G. determined that Petitioner has demonstrated an unwillingness and inability substantially to comply with the obligations imposed on him by section 1156(a) of the Act. The I.G. made this determination in accordance with the Act, which, as a prerequisite to the imposition of an exclusion against a provider, requires that the Secretary determine whether that provider has demonstrated an unwillingness or lack of ability substantially to comply with his obligation to provide health care as specified by the Act. Act, section 1156(b)(1).

The Act does not require the I.G. to determine that a provider is both unwilling and unable substantially to comply with his obligations under the Act as a prerequisite to excluding the provider. The Act's criteria for exclusion are met if the I.G. determines either that a provider is unable to comply with his statutory obligations or that a provider is unwilling to comply with such obligations. In this case, the I.G. determined that Petitioner has demonstrated both an unwillingness and an inability substantially to comply with his obligations. I find that the I.G.'s determination is supported by the evidence.

The I.G.'s determination is supported by Petitioner's pattern of inappropriate treatment. Petitioner's unwillingness and inability to comply with his statutory obligations is established by his consistent failure to comply with accepted medical standards in his treatment of the patients in the cases at issue in this proceeding. The multiple episodes of Petitioner's failure to obtain necessary diagnostic tests and his failure to adequately document his treatment demonstrate his unwillingness and inability to comply with his statutory obligations.

Moreover, this proceeding did not arise in a vacuum. The record shows that the violations which are the basis for this proceeding occurred after Petitioner entered into a CAP with IPRO's predecessor, ESMSEF, in 1989. Petitioner's unwillingness and inability to comply with his statutory obligations is established by his pattern of substantial violations, coupled with his failure to rectify his deficiencies, despite having been counseled to do so by the PRO.

In June of 1989, ESMSEF advised Petitioner that it had made an initial determination that he had failed to comply substantially with his obligations under the Act

in 14 cases. Petitioner met with ESMSEF in August 1989 to discuss this determination. I.G. Ex. 7, 8.

During that meeting, ESMSEF representatives expounded at length on the treatment deficiencies they observed. They criticized Petitioner's documentation of his treatment of patients. In addition, they criticized Petitioner for failing to obtain necessary medical tests and consultations. I.G. Ex. 8. At that time, Petitioner represented that his documentation practices were improving. He indicated also that he had begun to obtain more tests and consultations. I.G. Ex. 8 at 136 - 137. However, even as he was promising that his medical practices were changing, he made comments to suggest that he was making these changes under duress.

With regard to ESMSEF's criticism of his documentation practices, Petitioner stated that the "more words that are written, sometimes the more confusion you throw. You don't know what is going on." I.G. Ex. 8 at 136. With regard to ESMSEF's criticism of his failure to obtain medical tests, he stated:

> I may have not done all the tests that are proper, you know. So I am getting defensive now. I get somebody who comes in with a hopeless stroke, I will get a CAT scan out of him. I am ashamed of myself, but I do it. Radiologist thinks I am crazy but I will do it. See? That is how I am trying to keep you off my back.

I.G. Ex. 8 at 136 - 137. With regard to obtaining consultations, Petitioner stated "[s]ometimes they are valuable, sometimes they are not." I.G. Ex. 8 at 137.

These remarks suggest that although Petitioner promised to change his medical practices in response to criticisms of ESMSEF, he did not do so willingly. Instead, any changes he made were made under protest, in order to prevent ESMSEF from imposing additional sanctions. In addition, these remarks show that Petitioner was not persuaded by the reviewing authorities that there were true deficiencies in the way he practiced medicine. Petitioner's refusal to acknowledge any deficiencies in his practice suggests that he may have lacked the ability to discern what constitutes appropriate care.

In an attempt to rectify the substandard care it discerned in Petitioner's practices, ESMSEF proposed a CAP which had three elements: (1) ESMSEF would review all of Petitioner's hospital admissions for the previous three month period; (2) Petitioner would take CME courses

approved by ESMSEF; and (3) Petitioner would improve the quality of his documentation. Petitioner agreed to this CAP. I.G. Ex. 8, 9.

In December 1989, IPRO was awarded the New York State PRO contract. IPRO assumed the responsibility for monitoring the implementation of the CAP. Tr. at 25 - 26; I.G. Ex. 10. By letter dated March 29, 1990, IPRO informed Petitioner that it would review all of Petitioner's Medicare medical records for a period of three months. P. Ex. 15. Petitioner agreed also to enter into an educational intervention program. I.G. Ex. 14 at 3. At IPRO's request, Petitioner submitted regular reports on the CME tapes he watched and the CME lectures and conferences he attended. I.G. Ex. 31.

The reviews and interventions undertaken by the PROs did not remedy the deficiencies discerned by the PROs. It is significant that the pattern of quality of care and documentation violations which I have found in this proceeding occurred in 1991, after Petitioner entered into a CAP in 1989. The type of violations which I have found in this proceeding are similar to the deficiencies identified by ESMSEF in 1989. Given the resurgence of similar deficiencies over the years, there is no valid basis for concluding that Petitioner is willing and able to comply substantially with his obligations under the Act.

In this proceeding, Petitioner has again represented that he is changing his treatment practices in response to the deficiencies identified by IPRO. However, I am skeptical of Petitioner's assertions that he is willing and able to change his treatment practices in view of his continued refusal to accept wholeheartedly that there are substantial deficiencies in the way in which he practices medicine. It is apparent to me, both from Petitioner's testimony and his demeanor as a witness, that Petitioner has not fully acknowledged his shortcomings.

During the hearing, Petitioner testified that he practices "a very good brand of medicine." Tr. at 517. While he has acknowledged that the documentation in his charts may have some deficiencies, his testimony suggests that he believed these deficiencies to be technical violations which are minor in nature. Petitioner stated that the reviewing authorities have been "chasing me with enthusiasm for -- oh, it must be 10 or 12 years." Id. He expressed the view that the treatment deficiencies identified by the reviewing authorities are minor and that they would be found in the charts of any physician who is exposed to the same level of scrutiny. While

Petitioner represented that he is improving his documentation practices and obtaining more tests and consultations, he stated that he was doing this because "I try to protect myself from those people." Tr. at 520.

This testimony shows that Petitioner refuses to fully accept that his care does not comply with professionally recognized standards of care. Petitioner's refusal to accept the deficiencies in his treatment of patients demonstrates that he is unwilling and unable to comply with his statutory obligations.

Petitioner argues that he did not receive proper notice and opportunity to be heard on the issue of whether he complied with the CAP. This argument is unavailing.

The Act requires that, in deciding whether to exclude a party, the Secretary (or her delegate, the I.G.) shall consider a party's willingness or lack of ability to enter into and successfully complete a CAP. This provision states:

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

Act, section 1156(b)(1). Thus, statutory language explicitly provides that a provider's willingness and ability to comply with a CAP is relevant to the I.G.'s determination of the provider's willingness and ability to comply with his statutory obligations.

In this case, the I.G. fulfilled this statutory obligation. In the Notice, the I.G. notified Petitioner that, in making the determination that Petitioner is unwilling and unable to comply with his obligations, the I.G. considered Petitioner's failure to improve his practice pattern even after he entered into the CAP in 1989. Notice at 7. Petitioner was notified that this was an issue in this proceeding and he had an opportunity to be heard on it in this forum. Moreover, IPRO informed Petitioner in its sanction notices and other correspondence that Petitioner had not rectified his treatment deficiencies in spite of the 1989 CAP. I.G. Ex. 14 at 1, 4, I.G. Ex. 15 at 13, I.G. Ex. 1. Based on the foregoing, I find that Petitioner has not shown that

his notice and hearing rights were abridged at any stage of the sanction process.

Petitioner argues also that he complied with the 1989 CAP. He asserts that he met the requisite CME requirements and that he improved his medical treatment practices. Petitioner's Response at 20.

CAPs are proposed by a PRO when the PRO discerns a pattern of substandard care. The purpose of a CAP is to rectify a provider's deficiencies so that he can render care that meets professional standards. In this case, Petitioner was to take CME courses as part of the CAP. The record shows that he cooperated in meeting the CME requirements imposed by the PRO. However, the fact that Petitioner took the requisite CME courses did not prevent him from continuing to render substandard care. In addition, Petitioner's assertion that he improved his treatment practices is not persuasive in light of Petitioner's pattern of violations of his obligations after he entered into the 1989 CAP. Petitioner's failure to rectify his deficiencies after he agreed to a CAP is convincing evidence that he is unwilling and unable to comply with his statutory obligations.

I conclude that the I.G. proved by a preponderance of the evidence that authority exists to exclude Petitioner. I find that the evidence in this case strongly supports IPRO's recommendations, as adopted by the I.G., that Petitioner engaged in a pattern of substantially inappropriate treatment of his patients, in violation of his obligations under section 1156(a) of the Act. In addition, the evidence supports the I.G.'s conclusion that Petitioner has demonstrated an unwillingness and lack of ability to substantially comply with his obligations.

II. Petitioner's five-year exclusion is reasonable, comports with the remedial purposes of the Act and is supported by the evidence.

Petitioner argues in his briefs that the I.G. has failed to meet her burden of proof and, consequently, the statutory bases for the exclusion have not been met. I have already addressed those arguments in this decision and have found them without merit. Therefore, having concluded that the I.G. has met the statutory requirements for an exclusion of Petitioner, the remaining issue before me is whether the proposed exclusion is reasonable and comports with the remedial purposes of the Act. For the reasons cited below, I

conclude that the record before me amply supports the proposed five-year exclusion.

Particularly troubling to me is the fact that the conduct which formed the basis of IPRO's recommendation to the I.G. arose after Petitioner had agreed to a CAP imposed by ESMSEF in 1989 in response to earlier alleged substantial violations of Petitioner's obligations under section 1156 of the Act. The conduct challenged in this case arose from a focused review of Petitioner's hospital admissions over the course of several months in 1991. Moreover, Petitioner, as part of the CAP, agreed to enroll in a CME program designed to remedy the conduct previously found not to meet professionally recognized standards of care. In addition, Petitioner agreed to improve the quality of his documentation of the treatment provided to hospitalized patients, including the basis for a patient's admission to a hospital and a description of Petitioner's treatment of such patient. The practices Petitioner engaged in which IPRO and the I.G. challenged in this case are, for the most part, very similar to the practices Petitioner engaged in which led to the CAP; e.g, failure to order appropriate tests and to adequately document in hospital records his treatment of patients. Therefore, serious questions exist as to whether Petitioner can ever conform his conduct to that mandated by professionally recognized standards of care.

Equally disturbing is Petitioner's explanation that he disliked engaging in "defensive medicine" which may cause some discomfort to his patients. Tr. at 348 - 349. As shown by this record, Petitioner's refusal to have a number of his patients undergo appropriate diagnostic tests placed these patients at risk of exposure to undiagnosed diseases with attendant possible serious consequences. See, for example, discussions related to patients 031409, 031943, and 060460. The mandatory CME courses Petitioner was required to take had little effect on his practice of medicine. Moreover, such practice of medicine occurred after his prior treatment of patients was subject to close scrutiny by IPRO, with an understanding that continuation of the challenged conduct would result in a recommendation by IPRO that he be

excluded.[29] Despite the threat of an exclusion, Petitioner did not alter his conduct.

At the hearing, Petitioner attempted to counter the findings of IPRO with the testimony of his expert, Dr. Nicholas. While in some cases Dr. Nicholas did raise some legitimate issues, at other times he offered damaging testimony that Petitioner's treatment failed to meet the professionally recognized standards of care.

In addition, in some instances, Dr. Nicholas raised medical issues that Petitioner did not consider at the time of treatment. See, for example, the discussions relating to patients 031409 and 060460. Such obvious post hoc rationalizations fail to offset the credible evidence offered by the I.G. that Petitioner failed to meet professionally recognized standards of care in the treatment of such patients.

Petitioner has asserted inadequate documentation as a response on more than one occasion when IPRO has criticized the quality of his care. See, for example, the discussions relating to patients 031943, 030053, and 037680. Considering Petitioner's pattern of failure to have his patients undergo requisite diagnostic testing and the absence in the record of written or telephonic orders for nursing staff that is consistent with Petitioner's version of his treatment of such patients, I find Petitioner's reliance on documentation lapses to explain his conduct to be unpersuasive and lacking in credibility. There is no basis for me to believe that Petitioner provided more appropriate care than that which he documented in his patients' records.

Petitioner still fails to fully understand the significance of his conduct. Even if I accept that Petitioner will be more careful in documenting his treatment of patients in the future, I am not convinced that such documentation will alter his treatment decisions. In short, his treatment of patients will arguably continue to be below professionally recognized standards of care with regard to diagnostic decisions concerning choices of treatment, even if such decisions

---

[29] While there is no specific admission by Petitioner to this effect in the record, I conclude from the vigor with which he defended his conduct throughout the lengthy sanction process by the various New York State PRO's that he was aware of the possibility that an exclusion could be recommended as a result of the PROs' investigations.

are better documented. This would result in his future treatment of program beneficiaries and recipients being at an unacceptable level.

I am mindful that Petitioner has practiced general medicine in Little Falls, New York, for approximately fifty years. This is a laudable accomplishment considering the general lack of medical providers in non-metropolitan areas. I am cognizant that the Little Falls Hospital, where Petitioner admitted the patients at issue, is a relatively small hospital which does not have access to the latest equipment or to the level of expertise that might be found at a teaching hospital in a major metropolitan area. But as Dr. Nicholas testified, even with the understanding that the practice of medicine may be different at a teaching hospital, certain of Petitioner's practices are still below professionally recognized standards of care. See, for example, the discussion related to patient 037680. Unfortunately, Petitioner's failures to have his patients undergo appropriate diagnostic tests, and the resulting choice of treatment, may have prevented his patients from going to other hospitals where they could have received care that met professionally recognized standards. Petitioner exposed such patients to the possible unnecessary risk of illnesses for which they were not properly diagnosed or treated. Similarly, Petitioner's documentation failures could lead to confusion in the future treatment of his patients when the current treatment is not clearly set forth in the patient records. Although the record contains no evidence of any direct connection between Petitioners's conduct and the onset of an undiagnosed or untreated illness or problems with subsequent treatment of his patients, the possibility that such occurrences could result is sufficient to warrant an exclusion in his case.

The I.G. proposes a five-year exclusion. There is nothing in this record to support a finding that the five-year exclusion is either extreme or excessive. I base this on the extensive history that Petitioner has had with the State of New York PROs, including the intensive review of his hospital treatment records over a period of several months in 1991, the unwillingness and inability of Petitioner to understand the gravity and significance of his conduct, and his reliance on post hoc rationalizations to justify or excuse his conduct. I am hopeful that the imposition of the exclusion will cause Petitioner to more seriously examine his treatment procedures and practices, so that at the end of the five-year exclusion he will qualify to be reinstated as a program provider. The record reflects that Petitioner is

motivated by the belief that he is acting in the best interests of his patients. I am hopeful that, once Petitioner accepts that such conduct is not in their best interest, he will be similarly motivated to conform his practices with professionally recognized standards of care, and thereby provide a basis for his participation as a program provider.

III. Petitioner poses a serious risk to patients.

A provider who is the subject of an exclusion determination made pursuant to section 1156 is entitled to a de novo hearing before an administrative law judge on the issues of whether the exclusion is authorized under law and whether the length of the exclusion is reasonable. Ordinarily, the I.G. may effectuate an exclusion determination made pursuant to section 1156 prior to any administrative hearing. Thus, while the hearing is de novo, the exclusion ordinarily is in effect prior to the hearing on the merits of the case.

The exception to this procedure is in the case of a provider whose practice is located in a rural health professional shortage area or in a county with a population of less than 70,000. The Act provides that, in such a case, before any exclusion may be imposed, the excluded provider is entitled to a hearing and a ruling as to whether he or she poses a serious risk to patients.

In this case, by letter dated May 3, 1994, the I.G. notified Petitioner that he was excluded pursuant to the authority under section 1156 of the Act. Petitioner requested a hearing. By letter dated August 31, 1994, the I.G. informed Petitioner that she had determined that the population of the county in which Petitioner practices medicine is less than 70,000. The I.G. informed Petitioner that, before an exclusion could be effected, Petitioner was entitled to a hearing on the issue of whether he posed a serious risk to patients. Based on this, the I.G. informed Petitioner that the I.G. was reinstating Petitioner's eligibility to be reimbursed for items and services provided to program patients.

In order to avoid the duplication and delays which would result from two hearings, the parties requested that I consolidate the hearing on the issue of serious risk and the hearing on the authority to exclude and the reasonableness of the length of the exclusion. They also requested that posthearing briefs consolidate arguments on all of these issues. I granted the parties' request, and this decision consolidates the issues of serious

risk, the authority to exclude, and the reasonableness of the length of the exclusion.

Although there may be some question as to the necessity of the serious risk finding at this stage of the proceeding, the issue is not completely clear as to whether the exclusion will take effect should Petitioner appeal my decision to uphold the five-year exclusion. It is my understanding that the intent of the statute is that the exclusion should take effect after a decision on the merits that is adverse to a provider. However, as there have been no rulings on this issue, I have decided to address the serious risk issue here.

The Act does not define the term "serious risk." However, it 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 Serious Risk, at 5 (April 20, 1992). To prove serious risk, it is not necessary that the I.G. prove repeated episodes of patient endangerment. Exposure of a patient to a grave hazard in any one case, or to less grave but serious errors occurring with enough frequency to place patients in danger of serious harm, is sufficient.

I find that the evidence offered by the I.G. supports the conclusion that Petitioner poses a serious risk to patients. This finding is based on the pattern of care which I have found in Petitioner's treatment of his patients. Petitioner's treatment of patients demonstrates both a lack of judgment and of knowledge of appropriate basic medical responses in the evaluation and care of patients.

My conclusion that Petitioner is a serious risk is not based on findings that Petitioner actually harmed his patients. This conclusion is based on my finding that Petitioner's treatment practices exhibit serious deficiencies. I am concerned about the overall substandard quality of care shown by Petitioner.

The evidence adduced by the I.G. establishes that Petitioner failed repeatedly to obtain basic diagnostic information. Petitioner's care of several patients displayed significant gaps in his understanding of the tests which were needed to adequately evaluate a medical condition. Petitioner's failure to obtain necessary diagnostic information exposed his patients to unacceptable risk of harm in several cases.

For example, in the case of patient 031943, Petitioner's failure to obtain an endoscopy or an upper GI series before selecting treatment for a patient with an upper GI bleed exposed the patient to the serious risk of having the cause of her bleed go undetected and untreated. This exposed the patient to the risk of a recurrence of the bleeding. In addition, the severity of the error was amplified by the fact that this patient had a family history of stomach cancer.

Another example of an unacceptable risk caused by Petitioner's treatment is found in his care of patient 039837. The testimony related to this patient established that an x-ray should have been taken immediately after a thoracentesis was performed, in order to determine whether the procedure was done properly and that it did not damage the patient's lung. Petitioner's failure to take an x-ray immediately after this procedure exposed the patient to the risk of serious complications affecting her ability to breathe.

The evidence establishes a pattern of Petitioner's failure to follow appropriate medical practices to evaluate patients. It establishes also a pattern of inadequate documentation of medical care. I infer from the pattern of practice which the I.G. proved that the acts and omissions engaged in by Petitioner are representative of Petitioner's ongoing practice and are not isolated instances.

I recognize that Petitioner has asserted that he does not pose a serious risk to patients because he now practices medicine in a way that responds to the concerns identified by the I.G.'s experts. It is possible that Petitioner may have made some changes to his medical practice. However, it is apparent to me that Petitioner still does not appreciate the seriousness of his deficiencies in the way he practices medicine. For that reason, Petitioner's self-serving averments that he has conformed his medical practice to meet the I.G.'s concerns are not persuasive.

CONCLUSION

I conclude that the I.G. has the authority to impose and direct an exclusion against Petitioner pursuant to section 1156(b)(1) of the Act. In addition, the five-year exclusion which the I.G. imposed and directed is reasonable. I conclude also that Petitioner is a serious risk to patients within the meaning of section 1156 of

the Act. Accordingly, this exclusion is to go into effect 20 days after the date of this decision.

/s/

Edward D. Steinman
Administrative Law Judge