Department of Health and Human Services

DEPARTMENTAL APPEALS BOARD

Civil Remedies Division

In the Case of:	DATE: May 9, 1994
Mildred J. Stevens, M.D.,	Docket No. C-93-057
Petitioner,	Decision No. CR314
- v. -	
The Inspector General.	

DECISION

By notice letter dated February 11, 1993, the Inspector General (I.G.) informed Petitioner of her determination that, in a single instance involving a newborn patient named Amanda, Petitioner had grossly and flagrantly violated her professional obligations under section 1156(a)(2) of the Social Security Act (Act).[1] Using the problems identified in Petitioner's care of Amanda and 13 other patients, the I.G. determined also that Petitioner had demonstrated an unwillingness or inability to substantially comply with the obligations imposed on her by section 1156(a)(2) of the Act. The I.G. notified Petitioner that she was to be excluded from participation in the Medicare, and any State health care program as

[1] "Gross and flagrant" is defined at 42 C.F.R. § 1004.1 as a violation which represents "an imminent danger to the health, safety or well-being of a Medicare beneficiary or places the beneficiary unnecessarily in high-risk situations." Section 1156(a)(2) of the Act specifies that the health care provided to Medicare beneficiaries must be "of a quality which meets professionally recognized standards of health care."

defined in section 1128(h) of the Act, for a period of three years.[2]

On February 13, 1993, the I.G. sent Petitioner another letter to inform her of her option to have the effective date of the exclusion stayed pending an evidentiary hearing on the issue of whether she poses a serious risk to patients. Section 1156(b)(5) of the Act specifies such an option for program providers whose practices are located in a rural health manpower shortage area or in a county with a population of less than 70,000. Petitioner requested a hearing on the serious risk issue and also on the issue of whether there was a gross and flagrant violation of her professional obligations. The case was assigned to me for a hearing and a decision.

In my prehearing order dated April 6, 1993, I noted additional relevant procedural history on the serious risk issue.[3] I denied the I.G.'s motion that I hold a separate hearing on that issue. However, in ruling that the hearing on all issues should be consolidated, I granted the I.G.'s motion that I issue an expedited ruling on the serious risk issue.

I held an in-person hearing in this case on September 13 and September 14, 1993 in Kansas City, Missouri. At the close of the hearing, I established a schedule for the parties to brief the issues before me. On December 16, 1993, I issued a ruling in which I found that Petitioner posed a serious risk to patients and directed that the

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[2] Unless the context indicates otherwise, hereinafter I refer to all programs from which Petitioner has been excluded, other than Medicare, as "Medicaid."

[3] My prehearing order reflects the I.G.'s prior representations that, on behalf of the Secretary of the Department of Health and Human Services, the Peer Review Organization (PRO) had been continuously conducting a 100 percent intensified prepayment review of the care provided by Petitioner to her Medicare and Medicaid patients. See, e.g., I.G. letter to me dated April 15, 1993. At hearing, counsel for the I.G. informed me that the foregoing description was not totally accurate. Transcript (Tr.) at 30. The PRO's medical director testified that, except for a brief period during 1987, the PRO conducted its intensified reviews only after Petitioner had discharged her Medicare patients from the hospital; in some instances, the reviews were conducted after Petitioner had received reimbursement from the Medicare program. Tr. at 30.

exclusion be implemented immediately pending a final decision in this case. My December 16th ruling did not address the issues of whether the I.G. had authority to exclude Petitioner or whether the exclusion imposed against Petitioner by the I.G. is reasonable. In my ruling on serious risk, I extended the parties' deadline for filing briefs on the remaining issues.

By ruling dated December 16, 1993, I denied Petitioner's motion to supplement the record with a memorandum prepared by Dr. David Johnsen for Petitioner's defense of a medical malpractice lawsuit. Thereafter, on December 22, 1993 (by correspondence pro se) and on January 14, 1994 (by correspondence through counsel), Petitioner attempted to file the same memorandum by Dr. Johnsen once again, along with a copy of a document that was already admitted into the record at hearing as Petitioner's Exhibit 19. Petitioner has not explained why her Exhibit 19 should be admitted a second time, and her reasons for resubmitting the same memorandum from Dr. Johnsen do not establish any good reason for me to modify my earlier denial of her first motion. Therefore, I am denying her motions of December 22, 1993 and January 14, 1994 to supplement the record with the same memorandum.

Having considered the applicable legal principles, the evidence I received at hearing, and the arguments raised by the parties in their posthearing briefs and other submissions,[4] I conclude that the I.G. proved that she had the authority under section 1156 of the Act to impose and direct Petitioner's exclusion from participating in Medicare and Medicaid. I find also that the three-year exclusion is reasonable.

ISSUES

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[4] The parties filed posthearing briefs, together with proposed findings of fact and conclusions of law, and reply briefs. Petitioner then withdrew her posthearing brief and requested that her "First Amended Dr. Stevens' Post Hearing Memorandum of Law" be substituted. The I.G. did not object, and I permitted the substitution. I refer to the documents submitted by the parties as follows: I.G.'s exhibits as I.G. Ex(s). (number) at (page). Petitioner's exhibits as P. Ex(s). (number) at (page). I.G.'s posthearing brief as I.G. Br. at (page). Petitioner's posthearing brief as P. Br. at (page).

The issues in this case are:

1. Whether Petitioner has grossly and flagrantly violated her obligations under section 1156(a)(2) of the Act;

2. Whether Petitioner has demonstrated a lack of ability or unwillingness to comply with her obligation under section 1156(a)(2) of the Act; and

3. Whether the three-year exclusion imposed and directed by the I.G. is reasonable.

FINDINGS OF FACT AND CONCLUSIONS OF LAW

Statutory and regulatory framework

1. The Kansas Foundation for Medical Care, Inc. (KFMC) is a peer review organization (PRO), within the meaning of section 1154 of the Act.

2. The PRO's duties include reviewing the professional activities of physicians in Kansas for the purpose of determining whether the quality of services that physicians provide to Medicare beneficiaries and Medicaid recipients meets professionally recognized standards of health care. Social Security Act, section 1154(a)(1)(B); 42 C.F.R. § 1004.10(b).

3. Professionally recognized standards of care are "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.

4. A PRO has the discretion to establish specific criteria and standards to be applied to certain locations and facilities in the PRO area if the PRO determines that both the following conditions have been satisfied:

(a) the patterns of practice in those locations and facilities are substantially different from patterns in the remainder of the PRO area; and

(b) there is a reasonable basis for the difference which makes the variation appropriate.

5. 42 C.F.R. § 466.100(d).

6. Where the PRO has determined that a physician has violated the obligation to provide services of a quality that meets professionally recognized standards, the PRO is required to give the physician reasonable notice and an opportunity for discussion, and, if appropriate, a suggested method for correcting the situation during a designated period of time under a corrective action plan. 42 C.F.R. §§ 1004.30(c), 1004.40(c)(4).

7. If a physician has grossly and flagrantly violated the aforesaid obligation in one or more instances, the PRO must also submit a report of the violation to the I.G. 42 C.F.R. § 1004.30(c).

8. A "gross and flagrant violation" is the violation of an obligation to provide care in one or more instances which presents an imminent danger to the health, safety, or well-being of a Medicare beneficiary or places the beneficiary unnecessarily in a high-risk situation. 42 C.F.R. § 1004.1(b).

9. The Secretary of the Department of Health and Human Services, or by delegation, the I.G., may impose and direct the exclusion of a health care practitioner from participating in Medicare and Medicaid where the Secretary determines, based on a recommendation by a PRO, that the practitioner has: (1) in one or more instances, grossly and flagrantly violated the obligation to provide health care of a quality which meets professionally recognized standards of care; and (2) demonstrated an inability or unwillingness to substantially comply with the obligation to provide such care. Social Security Act, section 1156(b)(1).

10. In determining the appropriateness of a sanction after the practitioner has been found to have grossly and flagrantly violated the aforesaid obligation, the I.G. must consider factors that include the PRO's recommendations, the type of offense at issue, the severity of the offense, the availability of alternate sources of service in the community, and whether the practitioner has entered into corrective actions plans (CAPs) prior to the PRO's recommendation and, if so, whether she has successfully completed such plans. 42 C.F.R. § 1004.90(d).

11. A party subject to an exclusion determination under section 1156(b)(1) of the Act has a right to a de novo administrative hearing on all relevant issues. Section

205(b) of the Act (as incorporated by section 1156(b)(4) of the Act).

Background facts

12. In the notice letter, the I.G. imposed and directed an exclusion on the basis of the PRO's finding that Petitioner, in treating a newborn patient named Amanda, had grossly and flagrantly violated her obligation to provide services of a quality that meets professionally recognized standards of health care. I.G. Ex. 25.

13. Petitioner delivered Amanda on May 19, 1991 at Anderson County Hospital. I.G. Ex. 1.

14. After the delivery, Petitioner also cared for Amanda at Anderson County Hospital, until the afternoon of May 20, 1991. Id.

15. Anderson County Hospital is a small hospital located in Garnett, Kansas. Tr. at 553; I.G. Ex. 1.

16. Garnett, a rural community of approximately 3200 people, is the county seat of Anderson County, Kansas, which has a population of 7000. Tr. at 413.

17. Petitioner has practiced general medicine in Garnett, Kansas, since 1948. Tr. at 468 - 69.

18. Of the approximately 4000 babies Petitioner has delivered over the past 45 years, only a few were delivered by Petitioner during the years immediately preceding Amanda's birth. I.G. Ex. 14 at 47, 66; Tr. at 554 - 56.

19. Few babies with health conditions like Amanda's have been born at Anderson County Hospital. Tr. at 450, 504 - 05.

20. Petitioner has 4000 active patient charts, of which 50 percent are for Medicare beneficiaries and Medicaid recipients. Tr. at 580.

21. During the period in issue, there were five doctors practicing medicine in Garnett: Petitioner, who practiced full time; two other doctors, who practiced full time; a doctor who practiced part time; and another doctor who occasionally treated patients. I.G. Ex. 17 at 2.

22. Petitioner's husband, who also was on the medical staff of Anderson County Hospital, was included among the physicians practicing in Garnett. Tr. at 409 - 10.

23. All five doctors on the medical staff of Anderson County Hospital were eligible to vote on applications (including their own) for privileges to practice particular types of medicine at that hospital. Tr. at 407 - 10.

24. In 1991, Petitioner and Dr. David Henderson were the only physicians practicing obstetrical medicine in Garnett and at Anderson County Hospital. Tr. at 397.

25. At the time Petitioner delivered and cared for Amanda, Petitioner was the chief of the obstetrical department at Anderson County Hospital. Tr. at 371.

26. At the time of Amanda's birth, Dr. Henderson was the chief of the pulmonary medicine department and the emergency department, as well as the chief of staff at Anderson County Hospital. Tr. at 362, 460 - 61.

27. The foregoing titles do not signify medical expertise in the respective fields because, due to the small size of the medical staff, the department chief positions are given to whichever doctors are willing to assume them. Tr. at 461.

28. Dr. Henderson saw Amanda on the night of her birth in his capacity as the chief of staff for Anderson County Hospital. Tr. at 366, 430 - 34.

29. Both Petitioner and Dr. Henderson have been sued in a malpractice action involving the care given to Amanda. Tr. at 446 - 47.

30. During the time that Petitioner delivered and cared for Amanda at Anderson County Hospital, some health care employees of the hospital disagreed with Petitioner's actions and decisions with respect to Amanda's treatment. See, e.g., Tr. at 430, 487 - 88; I.G. Ex. 1 at 17.

31. After Amanda's birth, Anderson County Hospital suspended Petitioner's privileges to practice obstetrical medicine there. Tr. at 407 - 10.

The applicable "professionally recognized standards of health care"

32. Neither the I.G. nor the PRO had attempted to develop or apply any professionally recognized standards

of health care that are unique to Anderson County Hospital or Garnett, Kansas. Tr. at 45 - 46; P. Br. at 7.

33. The PRO applied a statewide standard in evaluating the quality of care at issue. Tr. at 46 - 47.

34. The focus of the inquiries by the I.G. and the PRO was whether Petitioner had certain minimum medical knowledge of a sufficiently current nature that would enable her to provide reasonably up-to-date care that meets currently recognized standards of health care. Tr. at 39, 42, 285; I.G. Ex. 21 at 2.

35. No matter where a physician practices, there are minimum professional standards that each physician must satisfy under the Act. Tr. at 285; see section 1158(a)(2) of the Act.

36. Petitioner recognizes that a physician must have the requisite knowledge base in order to make use of available resources, tests, or procedures in the physician's treatment of patients. I.G. Ex. 14 at 7.

37. Anderson County Hospital had the basic resources and equipment -- e.g., oxygen, a delee catheter, a fetalscope or fetal monitor, a telephone -- that would have enabled a physician to assess and treat Amanda in the manner described by the I.G.'s experts. Tr. at 203 - 04, 406, 437, 452; I.G. Ex. 1 at 17 - 20, 45 - 49.

38. There has been no effort by the PRO or the I.G. to hold Petitioner to a standard of care applicable to medical specialists or to physicians practicing in large urban health care facilities with state-of-the art equipment. Tr. at 285, 350 - 51.

39. Petitioner does not contend that she would have given different treatment to Amanda had Petitioner been practicing in a different hospital with different resources or more advanced technologies. See Tr. at 501 - 09.

40. The issues in this case do not involve a physician's need to accommodate geographical differences or limitations in available health care resources in order to avoid placing her patients unnecessarily in high-risk situations.

41. Given the unique issues and factual background of this case, the PRO and the I.G. were not required to develop any relevant professionally recognized standards

of health care that are unique to Anderson County Hospital or Garnett, Kansas. See Findings 31 - 39.

42. In alleging local standards as an affirmative defense, Petitioner has not proven that there exists local factors or standards of practice in Garnett or Anderson County Hospital that would eliminate a physician's need to have at least a minimal level of reasonably up-to-date knowledge concerning those commonly known medical facts and procedures which will enable the physician to meet patients' needs by making appropriate use of available medical resources.

43. The evidence does not credibly establish the existence of any relevant pattern of practice in Garnett or Anderson County Hospital that is substantially different from the patterns of practice in the rest of Kansas, which has many other small rural communities as well. See 42 C.F.R. § 466.100(d); Findings 31 - 40; P. Ex. 10.

44. The evidence also does not establish the existence of a reasonable basis for any variation between whatever pattern of practice may exist in Petitioner's locality or at Anderson County Hospital and the pattern of practice in the rest of Kansas. See 42 C.F.R. § 466.100(d); Findings 31 - 37.

45. The evidence does not establish that Petitioner's treatment of Amanda conformed to any professionally recognized standards of health care. See P. Exs. 1 - 4, 8, 9; Tr. at 439.

46. Petitioner's actions at issue cannot constitute a professionally recognized standard within the meaning of the Act, even though she has no doubt contributed significantly to shaping the quality level of the treatment available to patients in Garnett and at Anderson County Hospital due to the length of her professional career, the small size of the medical staff, her high number of patients, and her having been only one of two doctors practicing obstetrics in the area until her hospital privileges were revoked. Section 1156(a)(2) of the Act; Findings 31 - 44.

47. The PRO and the I.G. correctly applied an appropriate standard in this case. Findings 31 - 45.

Petitioner's delivery and treatment of Amanda

48. When Petitioner went to the hospital on May 19, 1991 to deliver Amanda, Petitioner was aware that the nursing

staff had independently requested the assistance of a respiratory therapist (RT), that an RT was not called for normal deliveries, and that there was an unspecified "disagreement" or an "electric charged situation" between herself and the nurses that began prior to delivery. Tr. at 475 - 76, 478, 495.

49. Petitioner did not ask why an RT had been called or why the nursing staff seemed concerned about potential complications in the delivery. Id.

50. Petitioner stated that giving birth is a normal physiological process and, if given enough time and emotional support, most women will deliver a baby that is alive. I.G. Ex. 22 at 2.

51. Petitioner stated also that "to cut a baby out" ruins a mother forever and reflects little skill or patience on the part of a physician. Id.

52. Petitioner failed or refused to recognize the significance of heavy meconium staining in the amniotic fluid when Petitioner ruptured the fetal membrane at 5:06 p.m. on May 19, 1991. Tr. at 131, 134 - 35, 284 - 85, 485; I.G. Ex. 1 at 45.

53. In accordance with professionally recognized standards of health care, Petitioner should have recognized meconium aspiration as a sign of fetal distress and related to the birth of infants suffering from severe respiratory depression. Tr. at 133 - 35; P. Exs. 1 - 4.

54. Twenty-four minutes after the heavy meconium staining appeared, Petitioner was informed that the fetal heart rate had dropped from 136 to 64. I.G. Ex. 1 at 17, 45.

55. Petitioner ordered the staff to cease monitoring the fetal heart rate after it decreased to 64. Id.

56. Petitioner failed or refused to recognize the significance of the drastic reduction in Amanda's fetal heart tone. Findings 51 - 54; Tr. at 131, 201 - 02.

57. In accordance with professionally recognized standards of health care, Petitioner should have known that a fetal heart rate of 64 was an additional sign of fetal distress, and she should have ordered continuous monitoring of the fetal heart rate. Tr. at 131 - 32, 281; P. Ex. 3.

58. Petitioner did not order the RT to enter the delivery room even when the fetal heart rate had dropped to 64. Id.; Tr. at 476.

59. In accordance with professionally recognized standards of health care, Petitioner should have given the RT instructions in preparation for the baby's potential problems during and after delivery. Tr. at 131 - 32, 287 - 88.

60. In accordance with professionally recognized standards of health care, Petitioner should have known to order oxygen therapy promptly by the two signs of fetal distress: the heavy meconium staining that was present at 38 minutes before Amanda's birth, and the significantly decreased fetal heart rate that occurred at 14 minutes before Amanda's birth. Tr. at 201.

61. Petitioner did not order the RT to begin oxygen therapy until two minutes before Amanda was born. Tr. at 201 - 02; I.G. Ex. 1 at 17, 45; I.G. Ex. 21 at 3.

62. With the initiation of oxygen therapy at two minutes before Amanda's birth, the fetal heart rate increased to 96. I.G. Ex. 1 at 45.

63. Petitioner incurred an unnecessary delay of up to 36 minutes in ordering oxygen therapy because she failed or refused to recognize the signs of fetal distress. Findings 52 - 61; Tr. at 201 - 02.

64. Amanda's life and health were placed unnecessarily at high risk by Petitioner's failure or refusal to recognize the signs of fetal distress, to begin appropriate treatments, and to make preparations for possible complications in the delivery of an infant in distress. Findings 51 - 62; Tr. at 134 - 35, 284 - 85.

65. In accordance with professionally recognized standards, Petitioner should have used the procedure called "suctioning the baby on the perineum" in delivering Amanda. P. Exs. 1 - 4; Tr. at 132 - 33, 275 - 78, 437, 439.

66. Suctioning the baby on the perineum involves the physicians' stopping the descent of the baby's head at the mother's perineum (or bottom) for no more than 10 seconds during delivery in order to suction out the meconium from the baby's upper respiratory tract at the earliest time possible while the baby is still attached to the mother by the umbilical cord and has no need to attempt breathing. Tr. at 132 - 33, 275 - 76, 282 - 83.

67. Petitioner did not suction Amanda on the mother's perineum during delivery. Tr. at 277.

68. Because the delivery took six minutes, there was ample time for Petitioner to suction the baby on the perineum. Tr. at 486, 498; Finding 66.

69. In explaining her standard of care for delivering babies like Amanda, Petitioner objected to suctioning them on the perineum because, in her view, the procedure is the equivalent of hanging the babies by the neck, may cause "neck syndrome," may cause brain damage, and is related to red patches she has seen on newborns. Tr. at 482 - 84.

70. Suctioning the baby on the perineum presents no risk to mother or child. Tr. at 275 - 76, 283.

71. Suctioning the baby on the perineum was not a procedure that was commonly performed at Anderson County Hospital around the time of Amanda's birth because few respiratorily depressed babies have been born at that hospital and Petitioner was one of only two doctors then delivering babies at that hospital under her own standard of care. Tr. at 437 - 39, 450 - 01, 504 - 05; Finding 68.

72. Petitioner's failure to suction the baby on the perineum unnecessarily increased the risk of Amanda's inhaling meconium and developing additional complications as a result. Findings 64 - 70.

73. When Amanda was born at 5:44 p.m. on May 19, 1991, she was flaccid, silent, and without spontaneous respiration. I.G. Ex. 1 at 4, 31, 45.

74. Following Amanda's birth, Petitioner placed Amanda unnecessarily at high risk for additional respiratory complications, damage to her central nervous system and other organs, hypothermia, or life-threatening cold stress, by failing to recognize that Amanda's airways needed immediate and extensive ventilation, by laying Amanda on her mother's abdomen, and by merely rubbing Amanda's back. I.G. Ex. 1 at 17, 45; Tr. at 136 - 37, 182, 185 - 87, 292 - 95, 477 - 78, 487 - 88.

75. On her own initiative, the RT entered the delivery room, removed Amanda from Petitioner's hands and the mother's abdomen, and placed Amanda on an appropriate surface in a warm environment, where the RT began suctioning out thick green secretions and later administered oxygen therapy to the baby by mechanically

controlling the airways. I.G. Ex. 1 at 17 - 18, 45; Tr. at 182, 185 - 87, 292 - 93, 295, 477 - 78, 487 - 88.

76. Petitioner's placement of Amanda on the mother's abdomen and rubbing Amanda's back immediately after delivery was contrary to professionally recognized standards of health care for a newborn in Amanda's condition. Id.

77. The RT's independent actions (Finding 74) were proper and appropriate. Id.

78. Out of a possible total of "10," Amanda's Apgar score remained a "2" at 1 minute, 5 minutes, and 10 minutes after birth. Tr. at 129 - 30, 290 - 91.

79. Apgar scores measure various functions of the baby -- such as heart rate, breathing, and reflexes -- in five categories. Tr. at 290 - 01.

80. A healthy baby's Apgar score at one minute after birth is typically "8;" at 5 minutes after birth the typical score for a healthy baby is "9;" and Apgar scores are not taken at 10 minutes after birth for healthy babies. Tr. at 291.

81. Amanda's Apgar score of "2" at even 10 minutes after birth indicated that her coloring remained poor, her respiratory effort remained absent, her neurotone remained absent, and she remained unresponsive to stimulation; she received points only for her heart rate. Tr. at 130.

82. There is no credible evidence supporting Petitioner's contention that someone told her Amanda's Apgar score had increased to "4" at 5 minutes after birth. See Tr. at 341 - 42, 496 - 97.

83. There is no credible evidence supporting Petitioner's additional contention that Amanda's Apgar score at 10 minutes was "more like 10 instead of 2." See I.G. Ex. 4 at 1.

84. During the evening of Amanda's birth, Petitioner did not request or accept consultation by another physician, and she repeatedly rejected the suggestion of the nurses and the RT to transfer Amanda to a tertiary care hospital. I.G. Ex. 1 at 3; Tr. at 368, 430 - 34, 517, 525 - 26.

85. Contrary to professionally recognized standards of health care, Petitioner viewed Amanda as a healthy infant

in need of only mouth to mouth resuscitation, or having air forced into her lungs, in order to get well. I.G. Ex. 22 at 1; Tr. at 517 - 18; Findings 77 - 83.

86. In accordance with professionally recognized standards of health care, Petitioner should have transferred Amanda to a tertiary care facility as soon as possible, because Amanda was experiencing severe respiratory problems and had an Apgar score of "2" at 10 minutes after birth. Tr. at 142, 192, 297.

87. Dr. Henderson believed also that Petitioner should have transferred Amanda shortly after Amanda's birth, and most doctors practicing at Anderson County Hospital would have agreed with that opinion. Tr. at 419.

88. In accordance with professionally recognized standards of health care, a physician in Petitioner's situation should have called at least for a pediatric consultation when a newborn's Apgar score remained at "2" at 10 minutes after birth. Tr. at 142.

89. Petitioner's refusal to accept consultation or transfer Amanda to a tertiary care unit, along with her failure to recognize the seriousness of Amanda's condition, continued to place Amanda unnecessarily in a high-risk situation. Findings 77 - 78.

90. After 63 minutes of aggressive treatment, Amanda's coloring turned from blue to "pink with acrocyanosis," and Amanda began to have some spontaneous movement. P. Ex. 8 at 1 - 2.

91. Even though Amanda was breathing by 7:05 p.m. on May 19, 1991, she was doing so with tremors, crackles, grunting, cat-like crying, and coarse sounds. I.G. Ex. 1 at 48 - 49.

92. Petitioner did not order a chest x-ray for Amanda until the following day, despite Amanda's obvious breathing difficulties. I.G. Ex. 14 at 46.

93. Petitioner did not order any diagnostic tests for Amanda. Tr. at 142 - 50.

94. Petitioner considers all babies healthy and, for that reason, did not view Amanda as being in need of diagnostic tests or extraordinary intervention. Tr. at 503 - 06.

95. In accordance with professionally recognized standards of health care, Petitioner should have ordered

ABG (arterial blood gas) tests; ABGs are necessary because a physical examination cannot reveal the acidosis or carbon dioxide level in a baby's blood. Tr. at 142 - 44, 299 - 300.

96. In accordance with professionally recognized standards of health care, Petitioner should have ordered blood sugar level studies for Amanda because, with stress, an infant can become hypoglycemic -- i.e., suffer symptoms similar to a cardiac arrest -- and there is no clinical sign that a physician can use in place of a blood test. Tr. at 144 - 46, 355 - 56.

97. In accordance with professionally recognized standards of health care, Petitioner should have ordered culture studies in anticipation of possible infections and to help determine possible causes for Amanda's respiratory condition. Tr. at 150, 302, 356.

98. In accordance with professionally recognized standards of health care, Petitioner should have started Amanda on risk-free prophylactic antibiotics as a matter of course, because time is critical in the care of newborns and the results of the cultures for infection may not be known for up to 72 hours. Tr. at 150 - 51, 303.

99. Petitioner's failure to order ABGs, blood sugar evaluations, culture studies, or prophylactic antibiotics for Amanda has nothing to do with the unavailability of diagnostic testing capability in the delivery room of Anderson County Hospital or the hospital's inability to provide results to a physician in less than 20 minutes. Finding 93; Tr. at 513.

100. At approximately 7:00 p.m. on May 19, 1991, the oxygen saturation level of Amanda's blood dropped to 85 percent and continued to decrease because, on Petitioner's order, the RT removed the endotracheal tube from Amanda. Tr. at 146.

101. In accordance with professionally recognized standards of health care, Petitioner should have initiated intensive treatment and closely monitored the oxygen flow in order to bring the baby's oxygen saturation up to the clinically acceptable range of 92 to 95 percent. Tr. at 147 - 49, 298 - 99.

102. With Amanda's low oxygen saturation level of about 80 percent, Petitioner placed Amanda unnecessarily at high risk for brain damage and related complications by carrying Amanda to the nursery without oxygen, by

ordering routine care for Amanda on a form sheet, and by allowing Amanda to be taken without oxygen to the mother's room. Tr. at 151 - 52, 298 - 99, 304; I.G. Ex. 1 at 5.

103. Petitioner ordered oxygen "prn" (oxygen as needed) for Amanda. Tr. at 300; I.G. Ex. 1 at 6.

104. Only 40 percent oxygen was started for Amanda in the warmer after she was taken to the nursery with a low oxygen saturation level of 82 percent, and Amanda's breathing was labored, with crackling sounds throughout. P. Ex. 8 at 2; I.G. Ex. 1 at 48 - 49.

105. Amanda's oxygen saturation level was at 80 percent and 85 percent a few minutes before she was taken, without oxygen, to the mother's room. I.G. Ex. 1 at 49.

106. Amanda's oxygen saturation level was at 85 percent when she was returned to the nursery without oxygen. Id.

107. Amanda continued to have labored breathing and was given oxygen intermittently for 20 hours at Anderson County Hospital. I.G. Ex. 2 at 6.

108. In accordance with professionally recognized standards of health care, Petitioner should not have delegated to the nurses or RT the decisions of how much or how frequently oxygen should have been given to a newborn with respiratory problems like Amanda's. Tr. at 200, 300; I.G. Ex. 1 at 6.

109. In accordance with professionally recognized standards of health care, Petitioner should not have ordered routine feeding for Amanda in the nursery. Tr. at 301; I.G. Ex. 1 at 5.

110. Petitioner's ordering that Amanda be fed as a normal baby placed Amanda unnecessarily at high risk for infarction of the intestines (rupture of the gut) after Amanda had undergone great and prolonged stress during and after delivery. Tr. at 301.

111. When Petitioner authorized Amanda's transfer to another hospital more than 20 hours after her birth, Petitioner did not do so voluntarily or for reasons she considered medically sound. I.G. Ex. 1 at 4; Tr. at 443 - 45, 531.

112. Professionally recognized standards of health care require proper and complete documentation by the physician, including a history and physical evaluation of

the patient, progress notes, and a delivery note in an obstetrics case. Tr. at 201, 204.

113. The purpose of good documentation is to establish sound communication between various health practitioners caring for the same patient and to help the physician recall details about the patient's condition. Tr. at 204.

114. Petitioner concedes that her records relating to Amanda are inadequate. See P. Proposed Findings of Fact at 11.

115. Petitioner's inadequate documentation in Amanda's case is an additional example of how she placed Amanda's health unnecessarily at risk; Petitioner's insufficient documentation is consistent with the conclusion that Petitioner's treatment of Amanda failed to satisfy the professionally recognized standards of health care. Findings 110 - 12.

116. Even though it is possible that Amanda may have suffered from genetic defects, prenatal injuries, or epilepsy of unknown origin at birth, Petitioner did not suspect such possibilities on May 19 to 20, 1991, when she cared for Amanda by viewing her as a healthy newborn. P. Exs. 8, 10, 17 - 19; Tr. at 471 - 72, 501 - 09.

117. There is no evidence that a newborn with genetic impairments, prenatal injuries, or epilepsy of unknown origin would have been impervious to the health risks created by Petitioner in her care of Amanda.

118. There is no evidence that Petitioner's treatment of Amanda satisfied professionally recognized standards of health care for a newborn with genetic impairments, prenatal injuries, or epilepsy of unknown origin.

119. Given that the definition of "gross and flagrant" violation does not require proof of actual damage to the patient, the I.G. has satisfied her burden of showing that Petitioner grossly and flagrantly violated her obligations under the Act in her treatment of Amanda. Findings 47 - 116.

Petitioner's inability or unwillingness to comply substantially with her professional obligations

120. Petitioner's treatment of Amanda demonstrates her inability to comply substantially with her obligation to provide health care of a quality that meets professionally recognized standards. Findings 1 - 118.

121. Petitioner's recent justification of her omissions in her care of Amanda demonstrate a continuing unwillingness to comply substantially with her professional obligations. E.g., Tr. at 501 - 07; Findings 68, 73, 93.

122. Petitioner's placement of fault on the RT, Amanda's possible genetic defect, Amanda's mother's allegedly deficient prenatal care, and the alleged limitations at Anderson County Hospital also demonstrate Petitioner's inability or unwillingness to comply substantially with her professional obligations. P. Br. at 5 - 20.

123. For several years before Petitioner treated Amanda, the PRO had attempted to correct quality of care problems in at least 13 other patients' cases that reflected Petitioner's non-current medical knowledge base, non-standard or unusual practices, and lack of familiarity with commonly used diagnostic techniques and procedures. I.G. Exs. 16, 29 - 41.

124. Since 1987, the PRO has done intensified reviews of the care Petitioner rendered to Medicare patients due to patterns of quality problems. I.G. Ex. 16 at 3; I.G. Ex. 38 at 6; I.G. Ex. 41; Tr. at 30.

125. Petitioner has completed at least two CAPs (corrective action plans) to date. Tr. at 34 - 36, 93 - 96.

126. At the time she cared for Amanda, Petitioner was nearing the end of a six-month long CAP (either her second or third one). Id.

127. At the time Petitioner cared for Amanda, Dr. Henderson was proctoring the treatment she provided to her Medicare patients under the CAP then in effect. Tr. at 80 - 81.

128. Dr. Henderson was not proctoring Petitioner's treatment of Amanda, because Amanda was a Medicaid recipient and, therefore, not within the purview of the CAP. Tr. at 80 - 81.

129. Petitioner denies that she needs additional training in any area of her current practice because she has not been notified of any deficiency in her care during the past two and one half years. Tr. at 585.

130. Petitioner has provided no credible evidence in support of her allegation that she has been complying with her obligations under section 1156(a)(2) of the Act

during the past two and one half years. See Tr. at 585; e.g., Findings 118 - 26.

131. During the past two and one half years, the PRO (and later the I.G.) was moving toward having Petitioner remedy her practices or be excluded from the Medicare and Medicaid programs. E.g., I.G. Exs. 3 - 27.

132. At hearing, Petitioner expressed her satisfaction with the care she provided to Amanda and the other 13 patients by describing it as "good care" with "good results." Tr. at 562.

133. Petitioner's defense of the care she provided to the 13 patients does not differ significantly from her explanations to the PRO several years before. Tr. at 558 - 76; I.G. Exs. 16, 29 - 41.

134. Petitioner's unwillingness or inability to comply substantially with her professional obligations is demonstrated further by: problems in her care of the other 13 patients; the continuing quality problems she has exhibited despite the PRO's efforts to have her remedy them; her current inability to recognize deficiencies in her care of those 13 patients; her unwillingness to take responsibility for the problems in her care of the 13 patients; and her continuous insistence that she provided good care to those patients. E.g., Findings 129 - 131.

135. Petitioner defines a "gross and flagrant" violation of her obligation under section 1156(a)(2) of the Act as "you don't give a darn." Tr. at 576 - 77.

136. Petitioner believes that no finding of "gross and flagrant" violation can be made in this case because she did "give a darn" about Amanda. Tr. at 576 - 77.

137. Petitioner's interpretation of her professional obligation does not assure that she will not be placing patients' lives and health unnecessarily at high risk. Findings 133, 134.

138. Approximately six months prior to Amanda's birth, Petitioner had attended a continuing medical education course in emergency cardiopulmonary resuscitation involving neonates. Tr. at 469 - 70.

139. During 1993, Petitioner completed the 50 hours of continuing medical education required for licensure in the State of Kansas. Tr. at 583 - 84.

140. Petitioner believes she has taken twice as many hours of continuing medical education classes as required by the State. Tr. at 469.

141. Petitioner was unable to cogently describe the details of any continuing medical education classes she has taken. Tr. at 583 - 84; see also Tr. at 469 - 70.

142. Petitioner's unwillingness or inability at present to comply substantially with professionally recognized standards of health care is demonstrated also by Petitioner's inability to describe any continuing medical education class she has taken and her denial that she needs additional training in any area of her current practice. Findings 128, 137 - 40.

143. After noting the quality of care problem in Amanda's case, the PRO proposed two alternative CAPs: that Petitioner enter a mini-residency program of at least six months in duration, or that she enter a program in Colorado for the period necessary to evaluate and remedy her educational needs. Tr. at 40, 552; I.G. Ex. 16.

144. The purpose of these two proposed CAPs was to help improve Petitioner's knowledge base so that she might provide care of a quality consistent with the requirements of the Act. Id.

145. Petitioner rejected both proposed CAPs because she wanted to maintain her practice in Garnett and believed that either proposed option would "eliminate" her practice or put her "out of business." See Tr. at 547 - 52.

146. Petitioner offered to take more continuing medical education classes or to have Dr. Henderson proctor her hospital admissions once again. Tr. at 581.

147. Given the number of continuing medical education classes Petitioner had taken when the patient care problems arose, her inability to cogently describe any of those classes, and her denial that she needs training in any area of her practice, Petitioner's taking more classes will not substantially improve the quality of her practice. Findings 128 - 41.

148. There is inadequate support for Petitioner's contention that no significant violations of Petitioner's professional obligations will recur if she is proctored by another physician. See, e.g., Findings 124 - 26.

149. Petitioner's rejection of the proposed CAPs in order to maintain her medical practice and the futility of her alternative proposals demonstrate her unwillingness to comply substantially with her professional obligations. Findings 142 - 47.

150. The preponderance of the evidence supports the I.G.'s determination that Petitioner was unwilling or unable to comply substantially with her obligation to provide care of a quality consistent with professionally recognized standards. Findings 119 - 48.

The reasonableness of the exclusion period

151. Petitioner has not voluntarily given up any area of her medical practice. Tr. at 584 - 85.

152. The PRO recommended an exclusion of 10 years. I.G. Ex. 16 at 9.

153. The I.G. imposed and directed an exclusion of only three years. I.G. Ex. 25 at 3.

154. An exclusion imposed under section 1156 of the Act is intended to protect the welfare of program beneficiaries and recipients from parties who are untrustworthy to provide heath care of the requisite quality.

155. Petitioner's untrustworthiness has been shown by evidence that establishes her unwillingness or inability to comply with her professional obligations under the Act. Findings 47 - 148.

156. The totality of evidence, including Petitioner's intransigence, inability to recognize problems in her treatment of patients, and unreasonable defense of her personal pattern of practice, demonstrate a strong likelihood that Petitioner will again place Medicare beneficiaries and Medicaid recipients unnecessarily at high risk. Findings 68, 94, 119 - 49.

157. The three-year exclusion is reasonable given the extent and duration of the quality of care problems in the present record, Petitioner's persistent unwillingness or inability to comply substantially with professionally recognized standards, Petitioner's reasons for rejecting the CAPs proposed by the PRO, together with the other factors considered by the I.G. I.G. Ex. 25 at 4.

158. The three-year exclusion is reasonable also in light of Petitioner's effectiveness in providing

understanding and compassion to patients; her willingness to see patients at locations convenient to them; her concern for the nonmedical needs of her elderly patients; her commitment to the people of her community for more than four decades; her good intentions; and the limited number of physicians currently practicing in Garnett. See, e.g., I.G. Ex. 17; P. letter dated January 3, 1994; Tr. 448 - 49.

159. Even if it were true that Petitioner provides treatment to Medicare and Medicaid patients at lower cost than other local physicians, I cannot allow her to remain in the programs to provide health care which is unlikely to be of the quality specified by law. P. letter dated January 3, 1994; section 1156(b)(1) of the Act.

160. The possibility that Amanda may have genetic defects or suffered from prenatal injuries carries no weight for countering the reasonableness of an exclusion imposed for the purpose of protecting program beneficiaries and recipients from being placed unnecessarily at high risk by the acts or omissions of their physician. I.G. Ex. 25 at 4.

161. Because half of Petitioner's active charts are of Medicare and Medicaid patients, it is likely that the exclusion will cause Petitioner to cut back her practice by 50 percent. See Tr. at 580.

162. The three-year exclusion will provide Petitioner with the time and opportunity to undertake the types of improvements she needs. Finding 160.

163. The I.G. has proven by a preponderance of the evidence that an exclusion of three years is reasonable. Findings 1 - 161.

ANALYSIS

Section 1156(a) of the Act imposes three professional obligations on individuals who provide items or services to program beneficiaries and recipients. One such requirement is that the health care provided to program beneficiaries and recipients

> will be of a quality which meets professionally recognized standards of health care[.]

A PRO may recommend to the I.G. that an individual be excluded if it determines that the individual has either failed in a substantial number of cases to comply

substantially with a professional obligation, or if the individual has grossly and flagrantly violated any obligation in one or more instances. Section 1156(b)(1) of the Act.

The Act also specifies the responsibilities to be undertaken by the I.G. (as the Secretary's delegate) in the sanction process. The factors the I.G. must consider are identified by regulation. 42 C.F.R. § 1004.90(d).

Section 1156(b)(4) of the Act entitles an excluded health care practitioner to a hearing as provided by section 205(b) of the Act. My obligation in conducting a hearing under sections 205(b) and 1156(b)(1) of the Act is to decide Petitioner's case de novo.

I. The I.G. applied the appropriate standard of professionally recognized health care in the present case.

The exclusion in issue resulted from the I.G.'s agreeing with the PRO that, when Petitioner treated an infant Medicaid recipient named Amanda, Petitioner grossly and flagrantly violated her obligation to provide services of a quality which meets professionally recognized standards of health care. Petitioner had delivered Amanda and cared for her at Anderson County Hospital in Garnett, Kansas, from Amanda's birth at 5:44 p.m. on May 19, 1991 until 7:00 p.m. on May 20, 1991, when Amanda was taken by a mobile transport unit to the University of Kansas Hospital in Kansas City. I.G. Exs. 1 at 2; 2 at 4.

Garnett is a rural community of about 3200 people, and it is located in a county having a population of approximately 7000 people. Tr. at 413 - 14. Petitioner has had a general medical and surgical practice in Garnett for approximately 45 years. Tr. at 469. Even though Petitioner had delivered nearly 4000 babies to date, she had not delivered many babies in the years preceding Amanda's birth, due to the older age of her patients. I.G. Ex. 14 at 47, 66; Tr. 554.

In 1991, when Amanda was born, there were only two physicians, Dr. David Henderson and Petitioner, who were practicing obstetrical medicine in Garnett and Anderson County Hospital. Tr. at 397. Dr. Henderson's involvement with Amanda's delivery was as the hospital's chief of staff. See Tr. at 446 - 47. Petitioner was the chief of the obstetrical department at the hospital at the time she delivered Amanda. Tr. at 371. A

malpractice suit filed on behalf of Amanda is pending against both of them. Tr. at 446 - 47.

In opposing the I.G.'s basis for excluding her from participation in the Medicare and Medicaid programs, Petitioner argued as a threshold matter that the I.G. applied the incorrect standard in deciding that she grossly and flagrantly violated standards of professional care in treating Amanda. P. Br. at 5. Petitioner reasoned that the standards of care in Petitioner's local community should have been considered in determining whether Petitioner's treatment of Amanda constituted a "gross and flagrant" violation of the local "professionally recognized standards of health care" contemplated by section 1156(a) of the Act. P. Br. at 5, 8 - 9. Petitioner raised this contention as an affirmative defense to the serious risk issue as well as to the ultimate issue of whether she should be excluded at all under section 1156 of the Act.

There is no dispute that neither the PRO nor the I.G. had ever inspected Garnett or Anderson County Hospital, and neither had attempted to develop or apply any professional criteria unique to that town or that hospital. E.g., Tr. at 45 - 46, 161; P. Br. at 7. The I.G. contends that the PRO acted consistently with the regulation at 42 C.F.R. § 466.100(d) and that, under the facts of this case, there is no basis for establishing criteria unique to Anderson County Hospital or Garnett, Kansas. I.G. Br. at 4 - 8.

Previously, I considered the parties' arguments on the applicable standards of professionally recognized care in the context of the "serious risk" issue. Under my authority to conduct a de novo hearing on all relevant matters, I found that the professional standards applied by the I.G. and the PRO were appropriate even though the PRO had not specifically assessed the conditions in Garnett or Anderson County Hospital. My full analysis of the standard of care issue is contained in my "Ruling Finding Serious Risk," at 4 - 11.

Since receiving my "Ruling Finding Serious Risk," Petitioner has not urged me to reconsider my conclusions on the applicable standard of care. However, Petitioner has not withdrawn the legal arguments she made in her briefs addressing issues other than "serious risk." It is therefore necessary for me to make formal findings on the appropriate standard of care in deciding whether gross and flagrant violations have occurred.

In assessing whether Petitioner grossly and flagrantly violated her obligations under section 1156(b)(2) of the Act, I find that Petitioner has not proven that the PRO abused its discretion under 42 C.F.R. § 466.100(d), and, moreover, the general statewide standards used by the PRO and the I.G. are consistent with the regulations. See 42 C.F.R. §§ 1001.2, 466.100(d); 50 Fed. Reg. 15,337 (1985)[5]; see also Tr. at 46 - 47. I make these findings for many of those reasons already set forth in my "Ruling Finding Serious Risk." The "serious risk" question is logically related to the I.G.'s basis for imposing the exclusion at issue, and the relevant regulations are the same for both issues.

I continue to construe the term "standards" in section 1156(a)(2) of the Act as necessarily denoting a level of knowledge and ensuing quality of patient care below which no physician may fall. I found especially persuasive the testimony of Dr. Hal Copple, an expert witness called by the I.G.[6], who noted that every physician must meet certain minimum standards in order to do the best they can with what they have available in order to meet the needs of patients. Tr. at 285. As further indicated by the testimony of Dr. James Allen, the PRO's medical director when it reviewed Amanda's case, the "standard" applied by the PRO requires a physician to possess common

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[5] This portion of the preamble to the regulations states in relevant part:

> In rendering medical judgments, the [PRO] must apply as principal points of evaluation and review, professionally developed norms of care, diagnosis, and treatment based on typical patterns or practice within the geographic area served by the organization.

[6] At hearing, I heard testimony from three witnesses called by the I.G.: Dr. James E. Allen, Dr. Joseph Schwarting, and Dr. Hal Copple. All these witnesses were highly qualified practitioners with credentials not disputed by Petitioner. Dr. Allen is the principal clinical coordinator for the PRO, the Kansas Foundation for Medical Care (KFMC). He was also the medical director of KFMC at the time it recommended to the I.G. that Petitioner be excluded from the Medicare and Medicaid programs. Dr. Schwarting is a board-certified family practitioner. Tr. at 124. Dr. Copple practices office-based pediatrics with full hospital privileges for providing intensive care to children and infants. Tr. at 265.

medical knowledge of a sufficiently current nature that will enable the doctor to treat patients safely. See Tr. at 39, 42.[7]

There is no dispute among the experts that hospitals may have different equipment and different levels of technological capabilities. Testifying for Petitioner, Dr. David Henderson observed that different hospital settings may affect a physician's ability to do "things" for her patients. See Tr. at 390 - 91. However, as even Petitioner acknowledged:

> I wasn't trained in the day when you automatically think of doing a bunch of -- I mean in order to make a diagnosis, you got to think of it. In order to order a test, you got to think of it.

I.G. Ex. 14 at 47.

I find inapposite Petitioner's contention that "[a] standard of care practiced in one geographical area may place a beneficiary at risk, but that same care may not elsewhere." P. Br. at 5. The factual context of the present case does not give rise to any legitimate issue of a physician's need to make reasonable adjustments in her manner of practice due to geographical constraints or the limitations of a hospital's resources in order to safeguard her patients' health or safety from undue risks. I have found no effort by the PRO or the I.G. to hold Petitioner to a standard of expertise applicable to medical specialists or to physicians practicing in large urban hospitals with state of the art equipment. See, e.g., Tr. at 350 - 51. Nor has Petitioner shown that she would have cared for Amanda in a different manner if Amanda had been born in a different hospital outside of Garnett. See, e.g., Tr. at 501 - 09.

The PRO applied statewide standards of care. Tr. at 46 - 47.

Given that Kansas has many small rural towns, I inferred that the PRO's statewide standards encompass the reasonable features of medical practices in small rural

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[7] Dr. Allen expressed his opinion as follows:

> Dr. Stevens' medical knowledge is not of sufficiently current character that she can provide reasonably up-to-date care that meets currently recognized standards. Tr. at 39.

communities. Dr. Schwarting, for example, who reviews patient charts for the PRO and who testified for the I.G. at hearing, noted that he practices in a rural Kansas town of 7500 people and at a rural hospital with a census of only six to eight patients per day. Tr. at 125, 175.

There has been no effort by the PRO or the I.G. to equate the resources of Anderson County Hospital with those of a tertiary care center. The I.G.'s complaint seems to be Petitioner's underutilization of common and available medical resources. The I.G.'s position on this point is reflected in the opinions of Drs. Richard Granville and Stephen Mawn of the Armed Forces Institute of Pathology, Department of the Army, who wrote the I.G. as follows concerning their assessment of the treatment provided by Petitioner to Amanda:

> [W]e are particularly struck by the paucity of even the most basic medical technology for the benefit of this sick infant. In this era of overly aggressive treatment and excessive use of testing, it is interesting to note that there may be something worse.

I.G. Ex. 21 at 2.

Here, the evidence does not permit me to find that a local standard of care exists because Petitioner lacked the external resources necessary for assessing and treating Amanda in the manner deemed proper by the PRO. The very opposite has been shown by the evidence. See Tr. at 203 - 04. For example, the I.G. established the availability of a fetalscope or a Doppler that could have been used by Petitioner to listen to the fetal heartbeat after there were signs of fetal distress, and even though a fetal monitor was not a necessity in the protocol described by the PRO, Dr. Henderson's testimony established its presence in the delivery room at Anderson County Hospital. Id.; Tr. at 406, 452. A delee catheter was also available at Anderson County Hospital for Petitioner to use in performing the simple suctioning procedure described by the I.G.'s witnesses. Tr. at 437. Oxygen and a trained respiratory therapist were available throughout the period that the baby exhibited signs of distress in utero and was later born respiratorily depressed. Tr. at 203; I.G. Ex. 1 at 17 - 20, 45 - 49. A telephone was available for Petitioner to use to seek consultations from specialists or other physicians for Amanda's care. When it became appropriate to transfer Amanda out of Anderson County Hospital, a telephone was available for Petitioner to use in arranging for the

transfer to a nearby tertiary care facility such as the University Of Kansas Medical Center. Tr. at 203 - 04.

The physician's obligation to deliver a quality of care commensurate with a "professionally recognized standard of care" exists for the benefit of patients. If local doctors and hospital staff lack the knowledge to treat newborns like Amanda competently and safely, then their lack of knowledge and ensuing actions cannot be used to set any professional standard cognizable under section 1156(a)(2) of the Act. A physician also should have the judgment and knowledge to refrain from retaining patients whose conditions become more complicated than he or she is capable of treating competently and safely. See Tr. at 357. A physician can refer patients to specialists practicing elsewhere or have patients transferred to other hospitals. Therefore, whatever the limitations of Anderson County Hospital or other practitioners in Garnett, Petitioner cannot now allege their inadequacies as a defense after having decided to keep Amanda there for nearly 26 hours. See, e.g., Tr. at 289 - 90; I.G. Exs. 1 at 3; 2 at 4. Petitioner is responsible for the state of her own knowledge and the judgment calls she makes in the course of treating her patients.

The regulation permits the PRO to deviate from statewide standards. 42 C.F.R. §§ 1001.2, 466.100(c), and 466.100(d) ("A PRO may establish specific criteria and standards to be applied to certain locations and facilities . . . .") The PRO may exercise such discretion only if there exists a substantial difference in the local pattern of practice from the remainder of the PRO area, and there is "a reasonable basis for the difference which makes the variation appropriate." 42 C.F.R. § 466.100(d). Petitioner has not shown that the PRO abused its discretion because she has failed to prove that either requirement has been satisfied in this case.

Petitioner has shown no relevant pattern of practice in Garnett or Anderson County Hospital that is substantially different from what exists in the rest of Kansas. In fact, it is doubtful that there exists a discernible pattern of practice in Petitioner's local area. I infer from Petitioner's testimony and certain findings proposed by Petitioner that she believes she has developed her own professional standards of practice over the years, and, therefore, she could not have violated section 1156(a)(2) of the Act when her actions or omissions conformed to her usual quality of care. See, e.g., P. Proposed Findings of Fact at 7 (¶ 42: "Petitioner does not, as a professional standard of care, routinely perform diagnostic testing."); see also Tr. at 484. Petitioner

testified that the manner in which she delivered Amanda reflected her "standard of care." Tr. at 484. Using Petitioner's own disputed practices as the local standard is patently unreasonable and would render section 1156 of the Act a nullity.

Nor was I persuaded to embrace Petitioner's view of a local practice standard because she was chief of the obstetrical department at Anderson County Hospital. See Tr. at 371. Dr. Henderson testified that department chairmanships do not connote superior accomplishments, training, or expertise. See Tr. at 461. The positions are given to whichever doctor on the medical staff will take them. Id.

In addition, Anderson County Hospital itself has imposed higher standards of professional care on its physicians on staff than that which Petitioner has sought to attribute to the hospital. See P. Br. at 28. The evidence shows the hospital's disagreement with Petitioner's contention that her delivery of Amanda was consistent with the professional standards of care in existence at that hospital. After Amanda's birth, Petitioner's obstetrical privileges at Anderson County Hospital were suspended by the hospital. Tr. at 407 - 10. Petitioner's privileges were restored by vote of the five-member medical staff that included Petitioner, Petitioner's husband, and Dr. Henderson -- all three of whom were allowed to vote on Petitioner's application for reinstatement of her privileges, despite their obvious personal bias or involvement with Amanda's case. Id. However, following this vote, the hospital board suspended Petitioner's obstetrical privileges once again. Id.

The evidence shows also that some of Anderson County Hospital's professional employees were dissatisfied with the quality of treatment provided by Petitioner to Amanda.[8] For example, a respiratory therapist physically removed Amanda from Petitioner in order to administer the

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[8] Petitioner raised the issue of the hospital employees' bias in the context of their potential liability in a malpractice lawsuit filed on Amanda's behalf. P. Br. at 14 - 15. The possibility of bias due to a lawsuit is overly speculative where, as here, Petitioner and Dr. Henderson confirmed during hearing that the employees raised their concerns, made recommendations, or took independent actions contemporaneous to the time Petitioner was in charge of Amanda's care.

needed oxygen therapy and to avoid the onset of other life-threatening complications for Amanda. See Tr. at 487 - 88; P. Proposed Findings of Fact at 4 - 5. After witnessing Amanda's delivery and care by Petitioner, both a nurse and the respiratory therapist spoke to Dr. Henderson in his capacity as chief of staff, to raise with him their quality of care concerns. Tr. at 430, 433 - 34. The respiratory therapist, a nurse, and administrators of the hospital all urged Petitioner to transfer Amanda to a tertiary care hospital, a recommendation which Petitioner resisted until she had no option left. Tr. at 443, 517, 533; I.G. Ex. 1 at 46. Those health care professionals who were employed by Anderson County Hospital and who also cared for Amanda viewed Amanda's condition with great concern, whereas Petitioner repeatedly denigrated them for having allegedly "panicked." E.g., Tr. at 517 - 18, 531. I therefore find that the standards of care perceived by the health care employees of Anderson County Hospital are different from that which Petitioner attempts to attribute to them.

Even Dr. Henderson, who had an incentive to give testimony fully favorable to Petitioner, did not view Petitioner as having acted in accord with the medical standards as he knew them at all times in her treatment of Amanda. E.g., Tr. at 438, 439. Because he is defending against in the same malpractice lawsuit as Petitioner concerning his involvement in Amanda's case, I do not give great weight to his opinion that she rendered a proper standard of care "to the extent [he] was involved." Tr. at 450. However, he testified also that, unlike Petitioner, he would have transferred Amanda after delivery. Tr. at 419. He noted also that, if the local medical staff were to vote on the matter in a peer review setting, most would have voted to transfer Amanda to another facility after delivery instead of keeping her at Anderson County Hospital as Petitioner had done. Tr. at 419. Such opinions are in accord with the conclusions the I.G. formed on the basis of a statewide standard of care. Dr. Henderson's testimony does not persuade me that there existed local standards as Petitioner attempted to depict in her defense.

The opinions submitted by Petitioner's non-testifying experts on the standard of care issue were ambiguous at best. For example, Dr. Earl B. Gehrt's opinion was that Amanda's care "may be" typical of what is given in hospitals the size of Anderson County Hospital to babies in similar condition. P. Ex. 10 at 2. Moreover, Dr. Gehrt's opinion remains unsound for implying that, as long as physicians on staff at a small hospital practice

in the same deficient manner, they would have created a professional standard they also meet. Applying Dr. Gehrt's rationale to the facts of the present case would mean, for example, that Dr. Henderson and Petitioner could never have deviated from the local professional standards for obstetrical care in Garnett and Anderson County Hospital during 1991 because they were setting the local standards at that time as the only two doctors practicing obstetrics in Garnett and Anderson County Hospital. Such an outcome would be illogical and contrary to the purpose of section 1156 of the Act.

Another of Petitioner's non-testifying experts, Dr. Michael Radetsky, formed an opinion on the basis of certain documents sent to him by Petitioner's malpractice defense attorney. P. Ex. 8 at 1; P. Ex. 9. Even though he was of the opinion that Petitioner met the standard of care recommended in medical literature and as ordinarily used by physicians, Dr. Radetsky was not subject to cross-examination, the documents he received from Petitioner's malpractice attorney were not identified for the record, and one of the I.G.'s witnesses was of the opinion that Dr. Radetsky had not attended a delivery in many years. Tr. at 346. Therefore, I do not find his conclusions persuasive.

I found the expert witnesses presented by the I.G. very well qualified and more credible in their opinions. Each of the I.G.'s witnesses explained his opinions cogently, with references to specific evidence of record, and each articulated his opinions consistently, even during rigorous cross-examination. I found very persuasive Dr. Copple's explanation of how he approached the issue of whether Petitioner had breached the professionally recognized standards of health care in her treatment of Amanda:

> Things change. Times change. So when I am asked to evaluate by [the PRO] . . . I review it, and I say to myself, Is that acceptable?
>
> Could I see a doctor doing that? That is not necessarily the way I would have done it, but can I see another doctor in another place provide this kind of care? Because, you see, I am not one of those doctors that says it has to be done my way, or any other way is not right . . . I don't feel that way. So I get a spectrum in my mind of very appropriate care, a little marginal, but still acceptable standard of care, barely outside, not quite meeting some minimal standards that I have.

> And then there are cases like this [Amanda's case] that are so far out there, I just am astounded.

Tr. at 350 - 51. I conclude that the other experts called by the I.G. used similar methods of evaluation because they reached conclusions very similar to Dr. Copple's. The I.G. committed no error in having relied on the application of such a standard.

II. The I.G. has established by a preponderance of the evidence that Petitioner grossly and flagrantly violated her obligation to provide treatment to Amanda that was of a quality that met professionally recognized standards of health care.

I have allowed the parties the opportunity to offer evidence concerning the sufficiency of the facts on which the PRO's recommendation and the I.G.'s ultimate determination are based. As already noted, the I.G.'s authority to exclude under section 1156(b)(1) is derived from the PRO's reviews and recommendations. Therefore, in deciding the issue of whether the I.G. had a statutory basis for the exclusion determination, I did not give weight to any evidence presented by the I.G. that concerned materials, conduct, or facts not reviewed by the PRO in formulating its recommendation to the I.G. on the same issue.[9] Also, I considered the evidence offered by Petitioner to rebut the factual basis for the PRO's determination and recommendation to the I.G.

A gross and flagrant violation of the obligation to provide health care which meets professionally recognized standards must include an element of either actual or potential harm to a patient. 42 C.F.R. § 1004.1(b). Here, the PRO's recommendation to exclude Petitioner was based on a single instance of a "gross and flagrant"

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[9] I do not imply that the I.G. has attempted to support her authority to impose and direct an exclusion with evidence beyond that reviewed by the PRO in this case. The I.G.'s experts confined their analysis of Petitioner's conduct to the records that were reviewed by the PRO. In those instances where physicians have reviewed the patient records in issue as experts for the parties and not as the PRO's agents, I have been mindful of the physicians' roles in deciding whether or to what extent I should give weight to their independent expert explanations, comments, or clarifications of the patient records also reviewed by the PRO.

violation. I.G. Ex. 25 at 1. The I.G. agreed with the PRO that the care Petitioner provided to Amanda deviated from the professionally recognized standards of care in a number of ways which were identified in the notice letter.

The evidence before me fully supports the I.G.'s conclusion that Petitioner placed Amanda unnecessarily in a high-risk situation. Amanda's care was very badly managed by Petitioner from beginning to end. Out of deficient knowledge or stubbornness, Petitioner provided grossly inappropriate and substandard medical care to an almost moribund infant. Such a substandard quality of care placed that infant's fragile life and health in even greater peril.

A. Petitioner placed Amanda's life and health in a high-risk situation by failing or refusing to recognize the significance of a significantly decreased fetal heart rate and heavy meconium staining in the amniotic fluid, both of which are signs of fetal distress.

Petitioner has persisted in her opinion that Amanda's mother had a normal delivery and that Amanda was born a healthy infant. I.G. Ex. 1; Tr. at 133, 503 - 04. I find that, except for Amanda's having been born full-term, there was nothing normal or healthy about Amanda's condition. The delivery occurred with significant indications of fetal distress that were not recognized or addressed by Petitioner, and Amanda was born barely alive. See Tr. at 273.

When Petitioner was called to Anderson County Hospital for the delivery on May 19, 1991, she had not delivered many babies in the years immediately preceding, because most of her patients were of advanced age. I.G. Ex. 14 at 47, 66. In addition, Petitioner chose not to ask the nursing staff why they were so concerned about the delivery that they had called independently for a respiratory therapist. Tr. at 474 - 76, 478. Petitioner was aware that the RT does not come for routine deliveries, and Petitioner was aware also that there was an unspecified "disagreement" between the nurse and herself, which created an "electric charged situation" that began prior to delivery. Tr. at 478, 495. Yet, as the physician in charge, she never asked the nursing staff the reasons for their concerns nor decided for herself whether an RT was needed.

At 5:06 p.m. on May 19, 1991, complications began to occur. After Petitioner ruptured the fetal membrane, the amniotic fluid that leaked was stained with heavy

meconium. Tr. at 131, 485; I.G. Ex. 1 at 45. Petitioner later testified that meconium staining indicated that the baby had moved her bowels. Tr. at 485. Petitioner did not appear to have understood the significance of the heavy meconium staining. She did not write down a diagnosis of meconium aspiration. Tr. at 134 - 35. Both Dr. Schwarting and Dr. Copple opined that Petitioner's failure to properly diagnose meconium aspiration syndrome placed the baby unnecessarily at risk. Tr. at 134 - 35, 284 - 85. I agree.

Meconium staining of the amniotic fluid is a sign of probable fetal distress. Tr. at 131 - 32. Meconium aspiration requires very aggressive treatment as early as possible because, when a physician does not see it as a problem, the physician can delay providing the types of treatment that can prevent the baby from getting into distress or help the baby breathe normally and get off to a normal start. Tr. at 135. The medical writings submitted by Petitioner also establish the significance of meconium staining. See, e.g., P. Exs. 1 - 4. The studies submitted by Petitioner include information that as many as 62 percent of neonates born through meconium stained amniotic fluid subsequently suffered respiratory distress, and up to 46 percent of neonates with meconium aspiration syndrome reportedly died from the disorder. P. Ex. 2 at 1. Therefore, Petitioner should have been alerted to make provisions for something other than an uncomplicated delivery of a normal baby. See Tr. at 133.

In addition, 24 minutes later (at 5:30 p.m., or 14 minutes before birth), the fetal heart rate decreased from 136 to 64. Tr. at 131, 201; I.G. Ex. 1 at 17, 45. Mild fetal brachycardia (slowness of heartbeat) is indicated by a heart rate of 100 to 90; severe fetal brachycardia is indicated by a heart rate of less than 90. Tr. at 202. Amanda's fetal heart rate of 64 was indicative of very severe problems. Petitioner ignored the significance of these signs. The expert opinions from both parties show that the fetal heartbeat should have been monitored for continued or additional signs of distress. E.g., Tr. at 281; P. Ex. 3. Petitioner, however, ordered the staff to stop monitoring the fetal heart rate even though a fetal heart monitor was in the delivery room.[10] I.G. Ex. 1 at 17.

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[10] Dr. Henderson testified that a fetal heart monitor was located in the delivery room of Anderson County Hospital, but he was the only area doctor who had used it during deliveries. Tr. at 406, 452.

According to the RT, a nurse told Petitioner at the time Petitioner gave her order to cease checking the fetal heart rate that such an order was contrary to law. I.G. Ex. 1 at 17. During this period of time, the RT remained outside the delivery room. Id. Because Petitioner did not order any oxygen for Amanda's mother for 12 additional minutes, the fetal heart rate remained at 64 for that period of time. Id.

Petitioner's failure to attribute significance to either the meconium staining or the decreased fetal heart rate resulted in her failure to initiate oxygen therapy promptly for the mother and fetus. Dr. Schwarting noted that oxygen was unreasonably and improperly withheld from the mother and fetus until just two minutes before birth. Tr. at 201; I.G. Ex. 21 at 3. According to Dr. Schwarting, two parameters should have indicated to Petitioner that the fetus was in distress and needed oxygen: the thick meconium staining and the decrease in fetal heart rate to 64. Tr. at 201. There was an unnecessarily long delay in initiating oxygen therapy. Petitioner could have and should have had oxygen flowing to the mother and fetus at as early as 38 minutes before the birth. Tr. at 201 - 02. When oxygen was finally given at two minutes before birth, the fetal heart rate increased from 64 to 96. I.G. Ex. 1 at 17.

Petitioner's inattention to potential problems is further evidenced by her failure to ensure that the RT was inside the delivery room and ready to render assistance. Dr. Schwarting and Dr. Copple both described the responsibilities they would have given an RT in anticipation of an infant experiencing respiratory problems. Tr. at 131 - 32, 274, 287 - 88. By contrast, Petitioner did not give the RT even any orders on being inside or outside the delivery room for the birth. Tr. at 476.

Petitioner later attempted to persuade me that she was aware of the risks and had considered the option of transferring Amanda's mother to a tertiary care unit after the fetal heart rate dropped. She contends that she did not attempt the transfer because she felt "the baby would be out of the woods" by the time the transport team arrived. Tr. at 508 - 09.

I find these post hoc assertions to be lacking in support and irrelevant as a defense to Petitioner's failure to make provisions at Anderson County Hospital for her delivery of a respiratorily depressed baby. The absence of a diagnosis for meconium staining syndrome, the order to discontinue monitoring the fetal heart tone, and the

undue delay in ordering oxygen therapy demonstrate Petitioner's lack of awareness of any potential medical problems. There is no persuasive evidence that Petitioner considered the option of transferring Amanda's mother prior to delivery or that Petitioner was justified in her belief that she could bring the baby "out of the woods" after delivery. Given some of the opinions she has expressed to the PRO, I find that on May 19, 1991, Petitioner was giving effect to her strong preference for allowing all babies (no matter in what state of health) to enter the world naturally and in their own good time. I.G. Ex. 22 at 2.

Even more importantly, if Petitioner decided to keep Amanda's mother at Anderson County Hospital and perform the delivery there, then Petitioner should have made provisions for delivering an unhealthy, very respiratorily depressed baby. Petitioner's decision not to transfer Amanda's mother did not relieve her of her obligations to treat Amanda competently and in accordance with professionally recognized standards of health care.

B. Petitioner placed Amanda at high risk for inhaling meconium and incurring related complications by failing to suction Amanda's airways in a manner required by professionally recognized standards of care.

Petitioner should have been aware from the medical literature she submitted that the most important preventative measure a physician can provide to a neonate with meconium aspiration syndrome is careful, thorough catheter suctioning of secretions from the oropharynx before the baby takes her first breath. P. Ex. 1 at 1 - 2; P. Ex. 2 at 5. According to the I.G.'s experts and the medical literature introduced by Petitioner, the procedure called "suctioning the baby on the perineum" has been widely used by physicians for many years in deliveries like Amanda's. E.g., P. Exs. 1 - 4; Tr. at 133, 275 - 82. The procedure involves the physician's stopping the descent of the baby's head at the mother's perineum (or bottom) during delivery in order to suction out the meconium from the baby's upper respiratory tract while the baby is still attached to the mother by the umbilical cord and before the baby takes her first breath. Tr. at 132 - 33. The procedure takes no more than 10 seconds to complete, and only in very rare instances is the procedure precluded by the speed of the delivery. Tr. at 280. Physicians use the procedure because it is safe for mother and baby, it is done at the earliest presentation of the baby's head, and there is no need for the baby to breathe while she is still attached by the umbilical cord. Tr. at 132, 275 - 76, 283.

Physicians suction the baby on the perineum to conserve critical time and to reduce the risk of the baby's inhaling the meconium in her airways.

Petitioner acknowledges that the delivery of Amanda took six minutes. P. Proposed Findings of Fact at 3 (citing Tr. at 486, 498). She had earlier attempted to convey the misimpression to the PRO that there was inadequate time to suction Amanda on the perineum because the delivery took place "rather quickly." I.G. Ex. 4 at 1. In fact, there was ample time for Petitioner to have suctioned the baby on the perineum for the 10 seconds or less the procedure usually takes. See Tr. at 280.

Suctioning the baby on the perineum was a procedure that a rural practitioner should be familiar with and capable of performing. Tr. at 133. There is no specialized equipment required. Tr. at 132 - 33. Dr. Henderson's testimony establishes that a delee catheter, a simple suctioning instrument, was available at Anderson County Hospital. Tr. at 437, 132 - 33. Dr. Henderson also agreed that a prevailing standard was to suction a baby with heavy meconium staining on the perineum. Tr. at 437. He does not know why Petitioner did not suction the baby on the perineum. Tr. at 438 - 39.

Even after hearing the testimony from the I.G.'s experts concerning the benefits of the procedure, Petitioner argued that suctioning the baby on the perineum was not appropriate because she viewed the procedure as the equivalent of hanging the baby by the neck and with the potential for causing a "neck syndrome." Tr. at 484. Petitioner doubted also the wisdom of slowing down the descent of the baby's shoulders from the birth canal in order to suction the baby while the baby is attached by the umbilical cord; Petitioner asserted that "there would be more damage to the brain than you would save in [the] lung." Tr. at 482. Petitioner based the latter opinion on the small red marks (petechia) she has seen on some infants' heads after delivery. Id.

I find Petitioner's concerns peculiar and unsubstantiated by the medical evidence of record. Her objections to suctioning the baby on the perineum supports Dr. Allen's conclusion on behalf of the PRO and the I.G. that Petitioner's medical knowledge "is not of sufficiently current character that she can provide reasonably up-to-date care that meets currently recognized standards." Tr. at 39.

Having considered the totality of Dr. Henderson's testimony, I reject Petitioner's contention that Dr.

Henderson did not discern any deviation from the applicable standards of care. See P. Br. at 28. Dr. Henderson did not state that as of 1991 he had never suctioned a baby on the perineum. When asked about his experiences with the procedure, Dr. Henderson testified that it was not done very much at Anderson County Hospital and that the procedure is not usually done in the deliveries he has witnessed with other practitioners. Tr. at 451. This testimony must be viewed in the context of Dr. Henderson's additional information that few respiratorily depressed babies have been born at Anderson County Hospital. Tr. at 450, 504 - 05. Therefore, Dr. Henderson's not having seen many babies suctioned on the perineum is attributable to the uncomplicated births of respiratorily healthy babies that usually occur at Anderson County Hospital.

I find that Petitioner's delay of the suctioning until the baby was fully delivered placed the baby unnecessarily in a high-risk situation for inhaling meconium. Petitioner contends that the difference between her actions and the procedure described by the experts amounts to only split seconds. Tr. at 481. This contention appears to be an exaggeration and does not eliminate the issue of unnecessary risk to Amanda. Moreover, it does not take more than a split second for a baby to begin inhaling. The evidence persuades me that Petitioner suctioned Amanda after delivery because Petitioner had not understood the signs of fetal distress, was not familiar with suctioning the baby on the perineum, had illogical fears of the procedure, and did not realize the dangers she created for Amanda by delaying the suctioning.

I agree with Dr. Schwarting's opinion that, even by themselves, Petitioner's failure to recognize and prepare for addressing probable complications prior to delivery and Petitioner's failure to suction Amanda on the perineum demonstrated a gross and flagrant violation of her obligation to provide Amanda with health care of a quality that met professionally recognized standards. See Tr. at 135 - 36.

C. Petitioner placed Amanda in a high-risk situation by failing or refusing to recognize that Amanda was critically ill at birth, by not properly managing the resuscitation efforts for Amanda shortly after delivery, and by exposing Amanda to further life-threatening complications, such as hypothermia.

Petitioner's mismanagement of Amanda's care did not end after delivery. When Amanda was born at 5:44 p.m., she

was flaccid, and she did not cry. I.G. Ex. 1 at 45. Amanda's Apgar score[11] remained a "2" at one minute, five minutes, and ten minutes after birth. Tr. at 129 - 30. The typical score for a healthy baby at one minute after birth is "8," and the typical score for a healthy baby at five minutes after birth is "9;" Apgar scores are not normally taken at 10 minutes after birth for healthy babies. Tr. at 293. Amanda's score of "2" meant that "the only thing that the baby could get points for was the heart rate." Tr. at 130. Despite Amanda's consistently poor Apgar score, Petitioner testified at hearing that she considers all babies healthy and, for that reason, she did not consider Amanda to have been in need of diagnostic testing or extraordinary intervention. E.g., Tr. at 503 - 06.

I am appalled by the sworn statements of Petitioner that she viewed all babies, including Amanda, as being healthy. Tr. at 503 - 06. For more than one hour after her birth, Amanda remained flaccid, cyanotic, blue in color, and unable to breathe on her own. P. Ex. 8 at 1 - 2. During the time Petitioner viewed Amanda as healthy, Amanda was nearly dead. Petitioner was unable to treat Amanda properly because Petitioner was unable or unwilling to recognize Amanda's abnormalities and poor health.

Petitioner created unnecessary risks for Amanda immediately after delivery by having placed Amanda on the mother's abdomen to rub the baby's back. Tr. at 293 - 95. Petitioner gave no instructions to the RT immediately following delivery. Instead, Petitioner laid the baby on the mother's abdomen and rubbed the baby's back. Tr. at 477 - 78, 487 - 88. The RT rushed into the delivery room on her own initiative, physically removed the baby from Petitioner, placed the baby on a warming tray, and began pumping oxygen into the baby. Tr. at 487 - 89.

What the RT accomplished without Petitioner's orders was appropriate because Amanda needed to be ventilated by mechanically controlling her airways, Amanda needed to be placed on a secure and well lit surface for the resuscitation treatments, and Amanda needed to be in a warm environment to avoid the onset of further life-

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[11] The Apgar score reflects the total score given for the newborn's functions, such as heart rate, breathing, and reflexes; the newborn is given a rating in five specified categories with each category having a potential of two points. Tr. at 290 - 91.

threatening complications such as cold-stress. E.g., Tr. at 182, 185 - 87, 292 - 93, 295. Consistent with Petitioner's contention that she believed Amanda was a healthy baby, Petitioner's placing Amanda on her mother's abdomen reflected Petitioner's failure to recognize that Amanda's airways needed immediate and extensive ventilation, which could only be done on an appropriate surface. Petitioner's approach immediately after delivery wasted critical moments in Amanda's health and development, risked doing damage to Amanda's central nervous system and other organs, and exposed Amanda to the risk of hypothermia. Tr. at 136 - 37, 140.

Even Dr. Gehrt, who did not take the stand, gave his written opinion that Amanda was "critically ill" at the moment of delivery, and "[m]aximum effort was needed to help the baby breathe and to clear the lungs." P. Ex. 10 at 1. Dr. Gehrt observed that there was no suctioning of the vocal cords noted, and he believed this should have been done. Id. Even though he suggested that a vigorous term baby can usually clear his own lungs (Amanda was a critically ill term baby), Dr. Gehrt was of the opinion that Amanda probably suffered an episode of injury after birth due to the meconium and other amniotic fluid that had been in her lungs when she tried to breath.[12]

D. Petitioner kept Amanda at Anderson County Hospital and did not call for consultation by other physicians because, against signs to the contrary, Petitioner thought Amanda was a normal, healthy newborn.

Petitioner never sought the help of other physicians after delivering Amanda, and she consistently rejected others' suggestions that she take a more prudent course of action. Petitioner should have been aware of the benefits of seeking help from other physicians since, at the time she delivered Amanda, she was still under a six-month long CAP (her second or third one) required by the PRO. Tr. at 34 - 36, 93 - 94, 96. Under this CAP, Dr. Henderson was proctoring Petitioner's treatment of all her Medicare patients. Tr. at 80 - 81; I.G. Ex. 41 at 25 - 26. Dr. Henderson was not required to oversee

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[12] "After birth the changeover from fetal circulation to pulmonary oxygenation may have been hampered by the meconium and other amniotic fluid that apparently was in the lungs initially. This however probably would not have been a problem had the baby been vigorous baby at birth. In other words, a term baby, born vertex with meconium staining, very seldom has trouble clearing his lungs." P. Ex. 10 at 2.

Petitioner's delivery of Amanda under the CAP, only because Amanda and her mother were Medicaid recipients. Id.

I agree with the opinion of the I.G.'s witnesses that, when Amanda's Apgar score remained at "2" even 10 minutes after birth,[13] Petitioner should have taken additional action, such as calling for pediatric consultations or ordering that Amanda be transferred to another hospital with physicians and personnel more capable of treating respiratorily depressed newborns. Tr. at 142. Dr. Copple noted the appropriateness of the latter option as soon as the resuscitation efforts had been accomplished and it was apparent that Amanda was barely alive. Tr. at 297 - 98. Transferring Amanda would have been appropriate since Anderson County Hospital has had little experience with such babies. Tr. at 450, 504 - 05. Petitioner herself noted at hearing that the RT was not a registered respiratory therapist. Tr. at 516. In spite of having delivered 4000 babies since she began practicing, Petitioner had not delivered many babies in the years preceding Amanda's birth. I.G. Ex. 14 at 47, 66; Tr. at 554.

Ten minutes after Amanda was born, the RT and a nurse requested that Amanda be transported to another hospital. I.G. Ex. 1 at 3; Tr. at 517. Petitioner rejected that request. Id. Even at hearing, Petitioner described the RT as having "panicked," like "somebody yelling fire," while she saw herself as having maintained "sense" by refusing to transfer Amanda out of Anderson County Hospital, a facility she later associated with those local circumstances that allegedly impacted on her professionally recognized standards of care. Tr. at 517 - 18; I.G. Ex. 22 at 1; P. Br. at 9 - 14. Petitioner thought that all Amanda needed to get well was mouth to mouth resuscitation or to have air forced into her lungs. I.G. Ex. 14 at 35; I.G. Ex. 22 at 1. I find Petitioner's refusal to transfer Amanda or to seek consultation to be a further reflection of her inability, failure, or

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[13] I did not find credible Petitioner's contention that someone told her Amanda's Apgar score had increased to "4" at five minutes after birth. Tr. at 341 - 42, 496 - 97. Petitioner could not state the source of this information, and there is no documentation of this score. Id. Moreover, Petitioner had alleged at another time that Amanda's Apgar score was close to "10" at 10 minutes after birth. I.G. Ex. 4 at 1. Petitioner has used these same types of self-serving excuses before to justify other deficiencies in her care of patients.

refusal to recognize the seriousness of Amanda's condition, which continued to place Amanda unnecessarily in a high-risk situation.

Approximately 45 minutes after the delivery, Dr. Henderson was called to the hospital in his capacity as the chief of staff -- but not at Petitioner's request and not with her consent. Tr. at 366, 430 - 34, 525.[14] Dr. Henderson looked at Amanda in the delivery room for two minutes from a distance of two feet and heard her make a "weak, squeaky, crying noise." Tr. at 367. Petitioner declined his offer to stay and assist her. Tr. at 526. When he inquired if she had considered transferring the baby to another facility, she told him a transfer was not necessary. Tr. at 368. According to Petitioner's later testimony, she did not see the need for a transfer because she did not perceive the baby to be in ill health. Tr. at 504. Dr. Henderson testified at hearing that he believed Petitioner should have transferred the baby that evening. Tr. at 419. He thought she had done what she could have at Anderson County Hospital by the time he departed from the hospital. Id.

Petitioner asked that I find fault with the RT's having absented herself from the delivery room without Petitioner's permission during a period when Petitioner allegedly needed her. P. Proposed Findings of Fact at 5 - 6. According to Petitioner, shortly after Amanda's birth, the RT left the delivery room for approximately 15 minutes without having first told Petitioner where she was going or for how long. Tr. at 519 - 22. Petitioner stated that, during this period, the RT was calling Dr. Henderson to ask that he countermand Petitioner's decision to retain Amanda at Anderson County Hospital. Tr. at 363 - 65, 520 - 21. Petitioner said she needed the RT's assistance during the 15 minutes and, also, that she personally removed the endotracheal tube from Amanda while the RT was gone because Amanda was breathing well. Tr. at 521 - 22.

According to the RT, she left the delivery room to obtain a pediatric probe because the oxygen saturation in

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[14] Petitioner stated that the RT called Dr. Henderson to countermand her refusal to transfer Amanda. Tr. at 520, 521. Dr. Henderson testified that a nurse called him under established procedures because the nurse thought there was a quality of care problem in Petitioner's treatment of Amanda; later, the phone was handed to the RT to speak with Dr. Henderson. Tr. at 363, 431 - 34.

Amanda's blood had been at only 83 percent and her heart rate was at 118. I.G. Ex. 1 at 19. The RT noted in the records that she left directions for the nurse to continue oxygen therapy in her absence, and while she was out of the delivery room, she did ask that Dr. Henderson be called. Id. When the RT returned with the pediatric probe, Amanda's oxygen saturation was 87 percent and her heart rate was 128. Id. Amanda was still flaccid, unresponsive to stimuli or to suctioning of her mouth and nose. Id. Green secretions were still being aspirated. Id. There is no notation of the RT's awareness that Petitioner had removed the infant's endotracheal tube during the RT's absence from the delivery room or that the infant had been breathing well spontaneously during those 15 minutes as alleged by Petitioner. See Tr. at 521 - 22.

Even if Petitioner did not know why the RT had left the delivery room, I agree with Dr. Schwarting's view that the physician in charge cannot delegate the resuscitation of a newborn in severe distress to a nurse or an RT. Tr. at 200 (testifying in response to Petitioner's remarks that she assumed the RT was capable of resuscitating the baby and had left the matter in the RT's hands). Petitioner was supposed to have been in charge of Amanda's care and in command of the support team.

Petitioner allowed the RT to do as she saw fit. Petitioner did not order the RT to attend the delivery; she gave no order for the RT to be either inside or outside the delivery room during delivery; and, without orders from Petitioner, the RT rushed into the delivery room to remove the baby from Petitioner in order to begin resuscitation efforts on a warming tray. The RT's absence does not excuse Petitioner's failure to manage Amanda's care appropriately in her capacity as the attending physician. If Petitioner did not want the RT to come and go from the delivery room as the RT had been doing, then Petitioner should have ordered the RT to stay. Petitioner could have given the RT specific orders on the resuscitation therapy. Since Petitioner had been permitting the RT to take independent actions without orders, the RT cannot be faulted for leaving the delivery room at her own discretion for purposes she believed appropriate.

E. Petitioner placed Amanda in a high-risk situation by having failed to order appropriate tests or prophylactic antibiotics.

The evidence persuades me that Petitioner continued to perceive and treat Amanda as if she had been born a normal, healthy infant when, in fact, Amanda's moribund state had been reversed only through vigorous artificial management of her airways for more than one hour. Even Petitioner's own expert stated that it was after 63 minutes of aggressive treatment that Amanda's coloring turned from blue to "pink with acrocyanosis" and Amanda began to have spontaneous movement after having been born flaccid. P. Ex. 8 at 1 - 2. After Amanda began to breath on her own with an endotracheal tube down her throat and her color improved, Petitioner "just did not think of" any diagnostic tests to order. Tr. at 514.

The nurse's notes are replete with observations that, even though the baby was breathing by 7:05 p.m. on May 19, 1991, she was doing so with "tremors," "crackles," "grunting," "cat-like crying," and with "coarse breath sounds" throughout. I.G. Ex. 1 at 48 - 49. Yet Petitioner did not order a chest x-ray for Amanda until the following day. I.G. Ex. 1 at 13. When asked by the PRO why she did not order a chest x-ray until the next day in the face of these obvious signs of respiratory difficulties, Petitioner's only answer was "I guess I just didn't order it at that point." I.G. Ex. 14 at 46.

I find that Petitioner placed Amanda unnecessarily at risk by having failed to order arterial blood gas (ABG) tests, culture studies, blood sugar tests, or prophylactic antibiotics. ABG tests are appropriate for infants born in Amanda's condition with an Apgar score of "2" at 10 minutes because, even if her coloring had improved later, a physical examination would not have revealed significant acidosis or the carbon dioxide level in her blood. Tr. at 143 - 44, 299. The blood sugar level test was appropriate for Amanda also because, with stress, infants can frequently become hypoglycemic,[15] and there is no clinical sign a physician can use as substitute for a blood test. Tr. at 144 - 46, 355 - 56.

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[15] Hypoglycemia pertains to a deficiency of glucose concentration in the blood, which may lead to nervousness, hypothermia, headache, confusion, and sometimes convulsions and coma. Dorland's Pocket Medical Dictionary (22d ed.). Dr. Copple likened the dangers of hypoglycemia to cardiac arrest. Tr. at 356.

Without the blood glucose results, a physician cannot know whether treatment is needed. Tr. at 355.

With Amanda's having had the meconium in her airways and having undergone the aggressive suctioning and related resuscitation efforts during the first hour of her life, Petitioner should have ordered culture studies in anticipation of possible infections. Tr. at 149 - 50, 302, 356. Culture studies could have helped to eliminate or confirm a possible cause of Amanda's respiratory condition. See Tr. at 302. Petitioner should have started Amanda on prophylactic antibiotics as a matter of course because time is critical in the care of newborns, and the results of the cultures for infection may not be known for up to 72 hours. Tr. at 150 - 51, 303. Prophylactic antibiotics offer no risk and could have been given easily. Tr. at 151. Petitioner has offered no valid evidence to contradict the need for the tests identified by the I.G.'s experts.

Earlier, at a hearing before the PRO, Petitioner was unable to respond to the PRO's repeated requests to identify those clinical indicators that she looks for in deciding whether to order septic workup, blood sugar tests, or other procedures for infants. I.G. Ex. 14 at 69 - 71. Her answers were either evasive or inapposite, and she could not identify the indicators even after a conference with her attorney. Id. Her answer was merely that, if she thought the child was in trouble and needed tests, she would transfer the child elsewhere. Id. However, even after a conference with her attorney, she could recall only one instance three years ago when she transferred a child for suspected meningitis. Id. at 73. She provided some examples of the indicators for sepsis only after a PRO doctor gave away the answers in his question. Id. at 71 - 72.[16]

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[16] Petitioner cited "temperature" as an indicator of suspected sepsis. I.G. Ex. 14 at 70 - 71. However, she did not associate Amanda's increasing temperature with possible infection. See Tr. at 502. She told the PRO that no test was done for infection because she thought Amanda had been in a sterile environment that included sterile meconium, and, therefore, Petitioner had no reason to think Amanda had an infection. I.G. Ex. 14 at 49; I.G. Ex. 4 at 2. There is no proof that infants cannot become infected because they have been in a sterile environment. At the very least, Petitioner should have been aware that, after birth, Amanda was no longer in a sterile environment.

With regard to the blood tests, Petitioner had told the PRO that she could have run blood gas and blood sugar tests, but, in her opinion, they would not have made any difference in her treatment of Amanda. I.G. Ex. 14 at 65. At hearing, upon being asked why she had not obtained blood sugar readings for Amanda, Petitioner said it was because she "[j]ust didn't think of it[,]" and "nobody suggested it" to her. Tr. at 500. She noted also that if the RT had thought any diagnostic testing should have been done, the RT should have let Petitioner know, as Petitioner was relying on the RT's assistance. Tr. at 513. I find the RT's thoughts to be irrelevant to the standard of care to which Petitioner is held as the physician in charge.

Petitioner has asked me to find that diagnostic testing could not have been performed in the delivery room of Anderson County Hospital, that testing would have taken more than 20 minutes to perform, and that the RT was not surprised that Petitioner had not ordered tests on the day of delivery. P. Proposed Findings of Fact at 7. I conclude that these proposed findings, even if proven, are irrelevant and unavailable as a defense to Petitioner. The experts never contended that the tests needed to have been done in the delivery room or in less than 20 minutes after Amanda's birth. Moreover, Petitioner's reasons for failing to order the appropriate tests had nothing to do with where or after what period of time the tests could be performed. As for the RT's not being surprised by the absence of any order for tests, I think it sufficient to remind Petitioner that she is a physician, not an RT.

As a physician, Petitioner could articulate no medical reason for her omissions other than her opinion that Amanda was a healthy, normal newborn. E.g., Tr. at 504, 506. Petitioner repeatedly testified at hearing that she believed Amanda was healthy and needed no tests or antibiotics. Id. Such a clearly erroneous opinion evidences the inadequate state of Petitioner's medical knowledge that resulted in the gross and flagrant violation of the professionally recognized standards of her care on May 19 and 20, 1991.

F. Petitioner placed Amanda in a high-risk situation by sending her to the nursery with routine orders and failing to address Amanda's hypoxia.

By about 7:00 p.m. on the evening of Amanda's birth, Amanda was breathing only because she had been given more than one hour of extraordinary intervention that included having had large amounts of meconium suctioned out of

her, having had air forced manually into her lungs, and having had an endotracheal tube inserted in her to ensure the continued flow of oxygen. E.g., Tr. at 514 - 15. Approximately one hour and 15 minutes after Amanda's birth, Petitioner ordered the RT to extubate the baby. Tr. at 146. The RT was apparently so surprised by the order that she asked Petitioner to repeat it.[17] Id.

Five minutes after the RT removed the tube from the baby on Petitioner's order, the oximetry[18] reading showed that Amanda's oxygen saturation level was at only 85 percent. Id. Fifteen minutes after the baby was extubated, the oximetry reading had dropped to 82 percent, which was considered very low and should have caused Petitioner to order that intubation be resumed or that other procedures be used to bring the baby's oxygen saturation up to the clinically acceptable range of 92 to 95 percent. Tr. at 147 - 48, 299. Instead of heeding the oximetry readings, treating Amanda intensively, and closely monitoring Amanda's oxygen input and output, Petitioner took Amanda to the nursery in her arms without oxygen and wrote routine orders on a form sheet as if Amanda were a normal newborn. Tr. at 148 - 49, 273, 299.

Petitioner then allowed the baby to be taken out of the nursery to the mother's room when the baby was already at risk due to a oxygen saturation of 80 some percent and the need for continuous oxygen. Tr. at 151 - 52. Dr. Schwarting noted that the mother could have come to the nursery to view the baby, which would have eliminated the added risk of hypothermia for an already unhealthy baby while allowing the nursery staff to continue the monitoring for apnea in a baby who was not yet breathing well. Tr. at 152. Dr. Copple noted, too, that when Amanda's blood oxygen was low, there was less oxygen going to her brain; therefore, it was inappropriate for Petitioner to permit the baby to be taken out of the nursery. Tr. at 304.

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[17] Dr. Copple was of the opinion that at this juncture, after having saved the baby's life, a rural practitioner would have anticipated a number of problems and decided to transfer the baby to another facility better suited to care for those potential problems. Tr. at 297 - 98.

[18] An oximeter is a photoelectric device for determining oxygen saturation of the blood. Dorland's Pocket Medical Dictionary (22d ed.).

Petitioner's response to the above criticism was and continues to be that she did not know the oxygen saturation was as low as 80 percent on room air when she authorized the baby to go to the mother's room. See Tr. at 152, 505. Her inadequate documentation pertained to Amanda's first 55 minutes of life, during which time Petitioner believes she had "pretty much" continuously given Amanda oxygen. Tr. at 499 - 500. One of Petitioner's experts found that only 40 percent oxygen was started in the warmer after Amanda was taken to the nursery at the 81st minute of her life, and Amanda's breathing was labored with crackles throughout. P. Ex. 8 at 2. After the first 113 minutes of life, supplemental oxygen was given to Amanda only intermittently. Id. Petitioner's lack of concern for Amanda's condition after the removal of the endotracheal tube supports the conclusion that Petitioner grossly and flagrantly violated her professional obligations to Amanda.

I accept Dr. Copple's opinion that Petitioner's ordering "[o]xygen, go to PRN" (oxygen as necessary) for Amanda also was inappropriate. Tr. at 300; I.G. Ex. 1 at 6. It is the responsibility of the physician to determine when and how much oxygen is required by a patient. Id. That responsibility cannot be and should not be delegated to a nurse, especially where a newborn has been suffering severe respiratory problems. Id.; see also Tr. at 200. I note that Petitioner has asked for a finding that she "did not undermine the resuscitation of Amanda" (P. Proposed Findings of Fact at 4), which is clearly inapposite to the professionally recognized standards applicable to physicians.

Petitioner created grave health risks for Amanda when she sent the baby to the nursery with routine orders that she be fed as a normal baby. See I.G. Ex. 1 at 5. According to Dr. Copple, no other doctor would have risked having the Amanda fed after she had been exposed to stress during delivery and for at least one hour after delivery. Tr. at 301. Infarction of the intestines, or rupture of the gut, could have occurred within hours of ingesting food or water due to the blood flow to the intestines and the way the newborn's body handles blood pressure after such stress. Id.

Petitioner did not refute Dr. Copple's opinion concerning possible infarction of the intestines. Nor did she indicate any awareness of that possibility when explaining her concern for Amanda's not having tolerated the glucose water she had ordered on the second day. Tr. at 531 - 32. (Earlier, Amanda had ingested glucose water two or three times. I.G. Ex. 1 at 3.) Petitioner

authorized Amanda's transfer to another hospital only after Amanda failed to drink fluids on the afternoon following her birth. Tr. at 531 - 32.

Even at hearing, Petitioner continued to imply that there was no medical need for the transfer. She had described a report of Amanda's deteriorating condition at Anderson County Hospital as a "panic call" to her. Tr. at 531. Petitioner noted that she had examined the baby and determined from an x-ray only that the lungs had not fully expanded after delivery. Tr. at 530 - 31. She wrote that Amanda's lungs were clearing but the nursing staff insisted on a transfer. I.G. Ex. 1 at 4.

I find that, even in ultimately transferring Amanda, Petitioner did not exhibit any knowledge or judgment commensurate with professionally recognized standards. She signed the transfer papers only because she knew that the hospital administrator was prepared to effectuate a transfer without her consent. Tr. at 533. Dr. Henderson confirmed that, earlier in the afternoon of May 20, 1991, the head of the hospital had already met with Dr. Henderson in his capacity as the chief of staff; in this very unusual meeting, it was decided that Amanda would be transferred. Tr. at 443 - 45. (But this conflicts with Petitioner's testimony that the decision to transfer was her decision. Tr. at 533.)

Of the helicopter (Life Star) or ground (Jay Stork) neonatal transportation units available for the transfer, Petitioner chose the latter, which took one hour and a half to arrive from Kansas University Medical Center, one or two hours to take custody of Amanda, and another one and one half hours for the return trip. Tr. at 532 - 35. The RT had been urging Petitioner to call for the helicopter transport unit, Life Star, since 10 minutes after Amanda's birth. Tr. at 517; I.G. Ex. 1 at 3. The helicopter transport unit would have arrived at Anderson County Hospital in no more than 30 to 40 minutes, less if the helicopter was already airborne at the time of the call. Tr. at 441.

Petitioner asked for findings by me that Anderson County Hospital did not have supplemental fluids required by newborns, and Amanda needed supplemental fluids when she was transferred to the tertiary care unit. P. Proposed Findings of Fact at 10 (citing Tr. at 494, 497, 532). These facts may be true, but Petitioner's decision to order the transfer appear to have been motivated more by the nonmedical factors already discussed. Moreover, Petitioner's decision to order ground transportation for the transfer, instead of the speedier helicopter

transport service that was also available, appears to be further manifestation of Petitioner's failure or refusal to acknowledge the medical needs of Amanda.

G. Petitioner's inadequate documentation in Amanda's case is further evidence that she created unnecessary risks for Amanda on May 20, 1992.

An attending physician, acting in accordance with professionally recognized standards of health care, needs to provide documentation of her assessments of the patient, the tests that were ordered, and sufficient progress notes for other health care providers to ascertain the patient's condition, history of treatment, and progress. Louis W. DeInnocentes, Jr., M.D., DAB CR247, at 45 - 46 (1992). Dr. Schwarting explained that complete documentation -- including history and physical examination results, admission notes, progress notes, and discharge summary -- not only establishes good communication between health care providers, it also helps the physician to recall particular information concerning the patient. Tr. at 204.

Here, the deficiencies in Petitioner's documentation were significant, in that Amanda was being transferred to another facility to be treated by doctors and nurses who had not personally observed details of her poor health at birth and needed a good understanding of what had been done on Petitioner's orders and why. Good communication between Petitioner and the health care professionals at Kansas University Medical Center was important in this situation. I therefore agree with the I.G. that Petitioner deviated from professionally recognized standards with her inadequate documentation.

Petitioner asks that I find "[t]he medical records of Amanda['s] delivery are not documented correctly and are incomplete." P. Proposed Findings of Fact at 11. Petitioner contends also that incomplete records "in and of itself" are not an indication of a deficiency in standard of care. P. Proposed Findings of Fact at 11. I agree with Petitioner and the I.G. that the records in Amanda's case are inadequate. However, I find that Petitioner is responsible for the inadequacy because she failed to gather the information that would have made the medical records more complete. Petitioner's inadequate documentation is consistent with and an accurate reflection of Petitioner's substandard medical knowledge and the ensuing inferior quality of patient care.

Petitioner has asserted inadequate documentation as a response on more than one occasion when the PRO has

criticized the quality of her care to patients. The totality of the evidence persuades me that Petitioner uses inadequate documentation to signify her disdain for some of the PRO's criticisms. For example, when she alleged inadequate documentation in the case of a patient named OB, Petitioner testified repeatedly about having failed to enter certain information required by the PRO in the charts, and such testimony implied that she had actually ordered the tests thought appropriate by the PRO but failed to record them. See, e.g., Tr. at 561 - 62. Later, when asked directly if she had ordered such tests, she answered she had not. Tr. at 562 - 63. Similarly, Petitioner acknowledged that, even if she had ordered blood gas and blood sugar tests for Amanda, Petitioner "would have basically done the same thing" for Amanda. I.G. Ex. 14 at 65. I therefore conclude that, in Petitioner's mind, the tests or procedures found appropriate by the PRO amounted to nothing more than documentation requirements, i.e., something that was of no practical use to her, but which she would need to do pro forma so she could make the entries on the charts to satisfy the PRO's review of her records. There is no basis for me to believe that Petitioner provided better or more appropriate patient care than what she thought to write down in Amanda's records.

III. Petitioner's definition of "gross and flagrant" violation is incorrect.

Petitioner denies that she could have "grossly and flagrantly" violated her professional obligations to Amanda. Tr. at 576. She contends that the PRO has attributed an incorrect definition to that term. Tr. at 577. To Petitioner, a "gross and flagrant" violation means that the physician did not "give a darn." Tr. at 576 - 77. She believes she "gave a darn" and therefore committed no gross and flagrant violation of her professional obligation to Amanda under section 1156 of the Act.

I think it sufficient to note that physicians who wish to provide services to Medicare patients and Medicaid recipients must know more and do more than "give a darn" about their patients.

IV. The possibility that Amanda may have genetic defects or may have suffered injuries or brain damage before Petitioner delivered her does not suffice as an affirmative defense to the I.G.'s basis for excluding her.

Petitioner placed evidence before me concerning the possibility that Amanda may have genetic defects or may have suffered prenatal injuries or brain damage before birth that were not caused by Petitioner. E.g., P. Exs. 8, 10, 17,[19] 18, 19; Tr. at 341, 387 - 88. I admitted such documents because Petitioner contended that Amanda's condition before birth is relevant to her defense. Tr. at 20. At the time of their admission, Petitioner and other witnesses had not yet testified concerning the standard of care that was appropriate to Amanda's situation. Before hearing the witnesses' testimony, I considered it possible that there might exist standards of care that are uniquely applicable to the delivery and aftercare of genetically or prenatally impaired newborns. Therefore, I did not wish to foreclose a possible avenue of defense for Petitioner.

At hearing, Petitioner did not attempt to prove as an affirmative defense that her actions and omissions with respect to Amanda had been influenced in any way by her suspicion or knowledge that Amanda may have been genetically or prenatally impaired. In fact, Petitioner repeatedly explained her actions in controversy by asserting that she believed at the time of Amanda's birth that Amanda was a healthy and normal baby. Even in her earlier correspondence with the PRO, she expressed her suspicion that another baby had been "substituted" for the healthy one she delivered on May 19, 1991. I.G. Ex. 17 at 2. It was not until a malpractice lawsuit had been filed against her that she began to hear reports that Amanda's mother might have been drinking, smoking, using drugs, staying out late, and eating poorly during pregnancy. Tr. at 471 - 73. Thereafter, Petitioner formed a belief that the conduct of Amanda's mother prior to delivery contributed to Amanda's cerebral palsy (Tr. at 473), and her malpractice defense attorney has sought expert opinions on the possibility of prenatal injuries or genetic imperfections (see, e.g., P. Exs. 8, 10).

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[19] At one point during the hearing, I misidentified as Petitioner's exhibit 17 a document that was withdrawn by Petitioner. Tr. at 19. Petitioner withdrew proposed exhibit 16 after an extended discussion of the I.G.'s objection to it. Tr. at 17 - 19. I admitted Petitioner's proposed exhibit 17. Tr. at 21.

Since the conclusion of the evidentiary hearing and the closure of the evidentiary record, Petitioner has made repeated motions to supplement the record with an additional report to Petitioner's malpractice defense attorney concerning the possibility that Amanda's present health problems may have prenatal origins. I have denied such requests, for the reasons stated in my ruling dated December 16, 1993.

While I am aware that there exists a possibility that Amanda suffers from cerebral palsy and other afflictions due to prenatal injuries or genetic abnormalities, I do not find that the care Petitioner delivered to Amanda was consistent with professionally recognized standards. Petitioner's efforts to exculpate herself by finding fault in others is relevant to the issues of Petitioner's trustworthiness and whether the length of exclusion is reasonable.

Amanda's prenatal condition is an inapposite defense to the I.G.'s authority to direct and impose an exclusion. The I.G. has not contended that Petitioner caused actual damage to Amanda. A "gross and flagrant violation" under section 1156(a)(2) of the Act can be proven by evidence that Petitioner's actions or omissions presented an imminent danger to the health, safety, or well-being of her patient, or that Petitioner placed her patient unnecessarily in a high-risk situation. 42 C.F.R. § 1004.1(b).

Comparative fault and contributory negligence are not issues before me. Petitioner has inappropriately asked me to make formal findings that Amanda's mother had not followed Petitioner's prenatal care instructions, and, therefore, the mother's conduct prior to delivering Amanda contributed to Amanda's having cerebral palsy. P. Proposed Findings of Fact at 2 - 3. Petitioner asks for these findings in reliance on information she claims to have received from Amanda's mother's foster mother. Tr. at 471 - 72. If such information had been known to Petitioner prior to her delivery of Amanda, Petitioner should have anticipated complications and poor health in the baby, and I would find Petitioner's conduct even more egregious than I have. However, Petitioner does not claim to have had such information prior to Amanda's birth (Tr. at 472), and I find this multiple, uncorroborated hearsay to be inherently unreliable as alleged by Petitioner in her efforts to shift attention away from the quality of the treatment she provided to Amanda.

More importantly, it is not possible to reconcile Petitioner's professional conduct at issue with Amanda's prenatal problems (assuming Amanda had any problems independent of those that might have been caused by Petitioner's failure to initiate oxygen therapy promptly when Petitioner should have equated heavy meconium staining and severe fetal brachycardia with fetal distress). Whether or not Amanda had genetic defects or prenatal injuries, professionally recognized health care standards did not permit Petitioner to treat Amanda as a normal, healthy newborn who did not need any of the procedures, interventions, or tests identified by the I.G.'s expert witnesses. Except for stubbornly maintaining that she saw all infants as healthy, Petitioner has offered no contrary medical conclusion. Nor has Petitioner attempted to prove that genetically defective newborns or newborns who suffer prenatal injuries would be impervious to the risks created by Petitioner, such as oxygen deprivation, the possibility of inhaling meconium, suffering cold-stress and hypoxia, becoming hypoglycemic, becoming infected, or having their intestines rupture.

I find wholly credible and reasonable Dr. Schwarting's opinion that, however a baby's cerebral palsy is caused, a physician has a duty to resuscitate all newborns the same way, to aggressively intubate those newborns, to get their oxygen level up, and to avoid their "downhill" slide. Tr. at 199. Dr. Allen gave similar testimony to the effect that, had appropriate tests been timely ordered by Petitioner, earlier testing could have revealed problems that warranted treatment even though the same tests given 24 hours later yielded negative results. Tr. at 119. In addition, there is no evidence that Petitioner adjusted the care she gave Amanda due to the possible existence of prenatal abnormalities. I simply cannot excuse Petitioner's having created unnecessary health risks for Amanda because, after Petitioner failed in her professional obligations to Amanda, Petitioner found reasons to suspect that Amanda may have genetic or other prenatal problems as well.

Nothing before me remotely suggests that a respiratorily depressed newborn in Amanda's condition deserved a lesser quality of medical care and attention than that described by the I.G.'s witnesses. The dangers created by Petitioner could have caused life-threatening complications or additional injuries even to a newborn with possible genetic defects or prenatal injuries. I sincerely hope that Petitioner is not suggesting with her affirmative defense that, because Amanda may have been genetically imperfect or unhealthy in utero, Amanda

therefore deserved to be exposed to the risks of harm created by Petitioner.

V. The I.G. has established by the preponderance of the evidence that Petitioner is unwilling or unable to meet her obligations under section 1156(a) of the Act.

Both Petitioner and the I.G. agree that Petitioner's treatment of Amanda is unique to her obstetrics practice. I.G. Br. at 21; P. Br. at 21. Before forwarding Amanda's case to the I.G. for review with a recommendation for a 10-year exclusion, the PRO had assigned Amanda's case a Level III quality of care problem, meaning that, in the PRO's opinion, there was a "[c]onfirmed quality problem with significant adverse effects on the patient." I.G. Ex. 5.[20] The PRO had also endeavored to negotiate a CAP with Petitioner to correct the type of deficiencies found in Amanda's care. I.G. Ex. 8. The I.G. considered Petitioner's failure to enter into a CAP proposed by the PRO, the facts in Amanda's case and the facts in the 13 other patient cases also reviewed by the PRO. I.G. Ex. 25 at 3 - 5. The I.G. found Petitioner unable to meet her obligations under section 1156(a) of the Act due to her "lack of current medical practices" and the problems identified by the PRO in the 13 other cases. Id. at 3.

At hearing, the I.G. presented testimony from Dr. Schwarting, a reviewing physician for the PRO in some of the 13 cases, to summarize and explain the problems the PRO or he had identified in each of those cases. See, e.g., Tr. at 205, 210, 218; I.G. Ex. 28 to 40. Even though Dr. Schwarting did not evaluate all of the 13 cases for the PRO, his testimony helped summarize and clarify what was stated by the PRO in its notices to Petitioner. There was no indication that he had reached any opinion on the basis of documents not in the PRO's possession. Where he expressed his own opinions on the cases he had not reviewed for the PRO, his opinions did not vary significantly from the written conclusions of the PRO. Petitioner had the opportunity at hearing to dispute the accuracy of Dr. Schwarting's summaries and opinions on all 13 cases. She did not dispute the

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[20] The I.G.'s determination was that, in Amanda's case, Petitioner's treatment presented "an imminent danger to the health, safety, or well-being" of Amanda, or had placed Amanda "unnecessarily in a high-risk situation." I.G. Ex. 25 at 4. In these proceedings, the I.G. has not asked for any finding of actual harm done by Petitioner.

accuracy of his summaries, but she did explain her present perspectives on the problems identified by the PRO.

I find that the preponderance of the evidence supports the I.G.'s conclusion that Petitioner is unwilling or unable to comply with her obligations to conform her practice to professionally recognized standards of health care. Petitioner's treatment of Amanda, along with Petitioner's recent justifications for her actions and omissions, has demonstrated an intransigence on Petitioner's part that reflects her unwillingness and inability to substantially modify her health care practices. Moreover, Petitioner's treatment of Amanda and the 13 other patients identified by the I.G. demonstrate deficiencies in Petitioner's medical knowledge that render her unable to meet her obligations under section 1156(a) of the Act. There is insufficient support for Petitioner's contention that her practices have changed dramatically over the past six years. Tr. at 558.

In my earlier ruling on the serious risk issue, I have detailed the treatment problems in the cases of the 13 patients identified by the I.G., together with Petitioner's defenses.[21] However, I will summarize the history of Petitioner's dealings with the PRO and her explanations of the 13 cases because such evidence persuaded me that Amanda's was not an isolated case, that Petitioner has maintained her unique standards of care despite the PRO's efforts to remedy them, and that Petitioner's base of medical knowledge remains significantly below current professional standards. Having examined the 13 cases together with what occurred in Amanda's case, I find fully credible the opinions of Dr. Allen that Petitioner has given "multiple demonstrations in the past of [her] lack of current common knowledge regarding [in]numerable medical facts that would make the treatment of those patients . . . dangerous" and her "medical knowledge is not of sufficiently current character that she can provide reasonably up-to-date care that meets currently recognized standards." Tr. at 39, 42.

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[21] I incorporate by reference my discussions at pages 23 to 35 of my Ruling Finding Serious Risk.

A. The Quality of Care Problems Identified by the PRO in 1987

On March 17, 1987, the PRO initiated an intensified review[22] of the care rendered by Petitioner because it noted a pattern of quality of care problems. I.G. Ex. 16 at 3. The PRO continued its intensified review of Petitioner's Medicare admissions to hospitals after October 1987, when the PRO ended some aspects of its intervention. Id.

In May 1987, the PRO notified Petitioner that it had assigned to her treatment of HH a "Class II" designation, which meant "nonstandard or unusual treatment/practice that clearly endangers the patient, resulting in short-term detrimental effect." I.G. Ex. 28 at 2, 11.[23] This patient, then 67, had been admitted to Anderson County Hospital with ashen coloring, difficulties in breathing, clammy skin, increased perspiration, and wet riles in both lungs. I.G. Ex. 28; Tr. at 205, 559. Among the problems noted by the PRO was Petitioner's failure to order an EKG (electrocardiogram) when the patient was admitted. Id.; I.G. Ex. 16 at 4.

Even though the medical records show that HH was alive for more than one hour after his admission (see Tr. at 208), Petitioner contended to the PRO that she had no time to order an EKG because HH died 20 minutes after admission. I.G. Ex. 28 at 9. At hearing, Petitioner indicated that an EKG was unnecessary because she knew HH

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[22] Usually, the PRO evaluates a physician's work by sampling 20 to 25 percent of cases. Tr. at 29. Intensified reviews occur after the PRO identifies a specific number or type of problem in the sampled cases. Id. For an intensified review, the PRO normally reviews 100 percent of a physician's cases during a given period. Id. Since 1987, such reviews have been done posttreatment, that is, retrospectively by the PRO after the patients have been discharged from hospitals. Tr. at 30. However, for a brief period during 1987, there were some reviews that were done by nonphysician employees of the PRO who called a hospital during a patient's stay to inquire about the patient's status. Id.

[23] At hearing and in her brief, Petitioner has erroneously referred to a "Level IV" rating in reliance upon earlier dated documents from the PRO. P. Br. at 18; Tr. at 49 - 53. The PRO revised the rating to a "Class II" after having considered Petitioner's explanations. I.G. Ex. 28 at 11.

was about to die, and did die, in any event. Tr. at 559.

I find Petitioner's reasoning in HH's case to be representative of the excuses she had offered in the other patients' cases as well as in Amanda's case. Petitioner usually blames her patients' poor health (e.g., HH's having been on the threshold of death and Amanda's possible genetic defects) when the adequacy or appropriateness of her treatment efforts is questioned. I find Petitioner's approach to be inappropriate to the patient care issues under consideration. Under professionally recognized standards of care, a doctor has a duty to do what is appropriate for the patient's condition. After the doctor has failed in such a duty to the patient, it does not follow that the doctor should then conjecture about the inevitability of death or poor health problems to excuse the failure.

On May 7, 1987, the PRO notified Petitioner that it had assigned to her treatment of RL a "Class II" quality problem designation, the same as in HH's case. I.G. Ex. 29 at 39. This 93-year-old female patient had been found by her neighbors and was admitted to the hospital due to exposure. I.G. Ex. 16 at 5. She was cold, blue, and had been neglecting herself for days. Id. The PRO criticized Petitioner's failure to order the continuation of the patient's antibiotics on her discharge, failure to order a diabetic diet for the patient who was hyperglycemic, and failure to investigate the cause of the patient's elevated enzymes. Tr. at 210 - 12; see also I.G. Exs. 29; 16 at 5.

At hearing, Petitioner refuted these criticisms by claiming that the result she achieved for RL without the tests was good because RL survived. Tr. at 560. As in Amanda's case, Petitioner attempted also to refute or minimize the merits of the PRO's criticism by asserting that "the chart is terrible." Id.

On October 12, 1987, the PRO notified Petitioner that it was continuing to identify patterns of care that required her attention, such as lack of generally accepted followup to clinical findings and appropriate testing and monitoring of cardiac and respiratory functions for those patients in her care. I.G. Ex. 41 at 10.

In December 1987, the PRO notified Petitioner that it had assigned to her treatment of OB a "Level I" designation, which means "nonstandard or unusual treatment/practice that potentially endangers the patient, but no detrimental effect is realized." I.G. Ex. 30 at 4, 6. OB was diagnosed to have various respiratory problems.

Tr. at 212. The PRO criticized Petitioner for her failure to order ABGs (arterial blood gas tests) for this patient, even though he was found to have oxygen saturation of 79 percent on room air. Tr. at 212 - 13; I.G. Exs. 30; 16 at 4.

Petitioner told the PRO that ABGs could do nothing except make the patient more anemic. Tr. at 213; I.G. Ex. 30 at 2.[24] At hearing, Petitioner testified that OB's case involved only inadequate documentation that occurred many years ago. Tr. at 561. However, her testimony with respect to Amanda's care made clear also that she still sought to rely on inadequate documentation as an excuse for substandard care. Moreover, Petitioner failed to obtain ABG tests for Amanda, whom she treated several years after the PRO criticized her for failing to obtain ABG tests for OB, also a patient with respiratory problems and low oxygen saturation in the blood on room air.

Petitioner's testimony concerning OB's case and other cases persuades me that she does not understand the usefulness of diagnostic tests. To Petitioner, the tests thought appropriate by the PRO amount to nothing more than documentation requirements, i.e., something that is of no practical use to her, but which she would need to order so she could make the entries on the charts to satisfy the PRO's review of her records. See discussion supra.

In June 1987, the PRO notified Petitioner that it had assigned to her treatment of BH a "Level I" quality problem designation, the same as for OB's case. I.G. Ex. 31 at 46. On admission to the hospital, this 86-year-old patient had shortness of breath, congestive heart failure, and possibly pneumonia. Tr. at 215; see also I.G. Ex. 31. However, Petitioner did not order ABGs or respiratory therapy for assessments, and, according to the records provided to the PRO, the patient appeared very ill with an increased respiratory rate even at the time of her discharge. I.G. Exs. 31 at 46; 16 at 5.

Petitioner explained to the PRO that she did not order ABG tests because BH was cyanotic, and ABG tests would have accomplished nothing except to deprive the patient of needed blood. I.G. Ex. 31 at 44; see also Tr. at 217. She also cited nonmedical reasons, such as the patient's

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[24] There is no scientific basis for Petitioner's opinion. The miniscule amount of blood needed for ABGs cannot possibly cause anemia. Tr. at 213.

limited budget, to explain her other omissions in treatment and for having ordered discharge when the patient was still not well. Id.[25] She further told the PRO to "get off my case" as she had a good success rate and:

> [f]urther be it known that I went to school when you did have to know a little something and you did not have to do a lot of unnecessary tests. I have not become extravagant in ordering tests. I will try to do better in the future.

I.G. Ex. 31 at 44.

In testimony before me, Petitioner alleged only that her management of patients has changed considerably during the six years since she treated BH. Tr. at 564. However, Petitioner repeated her sentiments concerning the uselessness of diagnostic tests when she answered my question on what, if any, benefit she had derived from one of her CAPs:

> Well, companionship and learning more the modern ways of doing things. See, I came from when you had to know something. I mean, it is the art of medicine.
>
> Nowadays, it is science. I mean, if you have an MI, you have got it -- you don't just know it. You have got to prove it with a bunch of tests and your enzyme tests and your EKG's and your Doppler studies and all that type of thing.

Tr. at 582. I infer from this answer and other relevant evidence that Petitioner continues to believe that tests are superfluous for doctors of her training and skill who can make diagnoses and decide treatment courses without them.

Dr. Henderson testified that Petitioner had started practice in the days when "medicine was maybe 20 percent science and 80 percent where she learned how to put a

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[25] Petitioner's letter fails to explain why she felt the Medicare program would not have paid for this beneficiary's continued hospitalization due to illness. BH had been hospitalized for only three days when she was sent home in a condition that even Petitioner described as "definitely ill." I.G. Ex. 31 at 44.

stethoscope on a human and check them." Tr. at 447. He pointed out also:

> Much that she does for the patient doesn't come out of a bottle or the series of tests that she does for the patients because she takes care of a group of patients that need, probably, as much as anything, kind, compassionate understanding care.

Tr. at 448.

Nevertheless, as the cases discussed herein demonstrate, there may be significant underlying problems that cannot be discerned on examination alone. Not all patients need only Petitioner's kindness, compassion, and understanding. There have been many advances in medical technology and treatment techniques since the days when 80 percent of what a physician did was with a stethoscope. Today, a physician needs to have the knowledge and willingness to make use of the commonly known medical advances in order to treat patients in a manner commensurate with currently recognized standards of professional care. Professionally recognized standards of care for the present day and age no longer permit a physician to practice in the same manner as Petitioner did more than four decades ago. I agree with Dr. Allen that Petitioner has given multiple demonstrations of her lack of current common medical knowledge regarding many medical facts that have rendered her treatment of patients dangerous by today's standards. Tr. at 42. The I.G. correctly concluded that Petitioner's inability to substantially comply with her obligations under section 1156(a)(2) of the Act is demonstrated by her "lack of current medical practices." I.G. Ex. 25 at 3.

B. Evidence on the Quality of Care Problems Identified by the PRO in 1988

On March 21, 1988, the PRO notified Petitioner that it had assigned to her treatment of LT a "Level I" quality problem. I.G. Ex. 32 at 35. Petitioner had ordered the admission of this 84-year-old patient for a severe cough, for a cut elbow that had required suturing, and for having hit her head while falling down. Tr. at 218; I.G. Exs. 32; 16 at 5. A treatment problem in this case was that Petitioner did not order monitoring of the patient's possible head injury. Tr. at 218; I.G. Exs. 16 at 5; 32 at 33; 34. Petitioner did not explain her care to the PRO.

Petitioner testified that LT had fallen and gotten a small cut on her arm, but Petitioner did not believe the patient had anything more serious than "minimal concussion." Tr. at 565. Petitioner alleged that she ordered a hospital admission that was not medically necessary because LT "was elderly and didn't have anybody to look after her at her home." Id. Petitioner therefore reasoned that the care she rendered was adequate and appropriate. Id.

Petitioner's excuse begs the question of whether she violated another subsection of the Act, which places an obligation on all Medicare and Medicaid providers to assure, to the extent of their authority, that the services they render under the programs will be "only when, and to the extent, medically necessary." Section 1156(a)(1) of the Act. Petitioner's unnecessary admission of a Medicare beneficiary to a hospital, if true as alleged, wasted program funds on unnecessary hospital stays and possibly diverted available hospital resources from those patients who were truly in need of the acute level services available only at hospitals.

C. Evidence on the Quality of Care Problems Identified by the PRO in 1989

On September 25, 1989, the PRO notified Petitioner that it had assigned to her treatment of HA during one hospitalization a "Level III" designation (i.e., "Medical mismanagement with significant adverse effects on the patient"). I.G. Ex. 41 at 11. The PRO identified concerns with inadequate preoperative cardiorespiratory evaluation, inadequate preoperative blood workup, inadequate assessment of operative risk, and inappropriate treatment of congestive heart failure. Id.; I.G. Ex. 16 at 5. The intervention the PRO chose to do as a consequence included a focused review of Petitioner's cardiorespiratory Medicare discharges for 15 cases, or for the period of 90 days starting from April 1, 1989. I.G. Ex. 41 at 12.

On October 19, 1989, Petitioner entered into a CAP. I.G. Ex. 16 at 3. Under this plan, the PRO conducted a focused review of all the Medicare patients with cardiopulmonary problems that Petitioner had discharged from hospitals, as well as a 100 percent prospective review of all of Petitioner's Medicare discharges; the CAP required her also to obtain continuing medical education (CME) directed at the diagnosing and treating of myocardial infarctions, congestive heart failure, and pre- and post- operative care. Id. Petitioner met the CME requirements of the CAP. Id.

On October 25, 1989, the PRO notified Petitioner that it had assigned to her treatment of HA during two earlier hospitalizations a "Level II" designation (i.e., "Medical mismanagement with the potential for significant adverse effects on the patient"). I.G. Ex. 33 at 2, 5 - 7.

According to the PRO, during HA's first admission to the hospital by Petitioner (assigned a Level II designation), the quality of care problems included inadequate laboratory evaluations of a possible acute myocardial infarction, no serum potassium evaluation despite intravenous Lasix being given, failure to repeat liver enzyme studies despite the patient's anorexia and vomiting, and no ABG tests, despite dyspnea. I.G. Ex. 16 at 6. The second Level II designation applies to HA's admission to the hospital's skilled nursing facility on Petitioner's orders. Id. The treatment provided by Petitioner for the second admission included an inappropriate selection of antibiotics for his urinary tract infection, the use of Quinidine on a PRN (as needed) basis for his cardiac arrhythmias, and the absence of followup on liver-function tests. Id. So that surgery could be performed, HA was subsequently readmitted to the acute care unit of the hospital from the skilled nursing facility. Id. This third admission by Petitioner (assigned a Level III designation) was problematic because the PRO questioned the stability of the patient for surgery at the time of transfer. Id. The PRO's other concerns for HA's final hospital admission (HA died in the hospital) included inadequate preoperative cardiorespiratory evaluation, inadequate preoperative blood work-up, inadequate assessment of operative risk, and inappropriate treatment of congestive heart failure. Id.

Petitioner had admitted HA to the hospital on more than one occasion for chest pain, poor color, and a possible myocardial infarction. I.G. Ex. 33; Tr. at 220. At hearing, Dr. Schwarting explained the several different types of problems noted by the PRO in Petitioner's treatment of the patient, such as Petitioner's not having ordered laboratory tests that were sufficient for determining whether a heart attack had occurred, not having documented a "do not resuscitate" request alleged by Petitioner, not having taken actions that conformed to this alleged "do not resuscitate" request from the patient, and not having been in good control of the treatment as the patient's attending physician. Tr. 220 - 25; see also I.G. Ex. 33 at 8.

Petitioner explained at hearing that HA was a 93-year-old gentleman and had been her patient for more than 40 years

when he passed away. Tr. at 566. Petitioner reiterated that there was a "do not resuscitate" request by the patient. Tr. at 566. She then alluded to an "untimely and ill advised" surgery that she did not attempt and from which the patient died. Tr. at 567. I infer that Petitioner was addressing the Level III designation the PRO had assigned to the care she provided HA during his final hospital stay.

Petitioner testified that she realized that HA needed an evaluation by a cardiologist, and she did not attempt to do the evaluation. Tr. at 566. However, she could have transferred the patient but did not. Tr. at 566 -67. She said she advised another doctor of the poor risk factors for surgery, but the other doctor proceeded with surgery. Tr. at 567. She stated then that the patient's death was not the other doctor's fault ("[i]t was just galloping old age"), and she claimed also that she did not harm the patient or place him at risk. Id. I was not able to discern from her explanations the extent of responsibility, if she felt she had any, for preventing HA's death. Instead, her opinion about the doctors' not being at fault is consistent with her tendency to blame the patient's condition when a patient failed to improve under her care.

On October 10, 1989, the PRO notified Petitioner that it had assigned a "Level II" quality problem designation to her treatment of GH. I.G. Ex. 34 at 5. GH had a history of recently diagnosed cancer of the prostate; he asked Petitioner to perform an orchiectomy (excision of one or both testes) as treatment for that disease. I.G. Ex. 34; Tr. at 226. The PRO accepted Petitioner's explanation that the patient had been instructed on self-catheterization after surgery, even though there was no documentation of that fact. I.G. Ex. 34 at 2 - 4. However, the PRO found other aspects of Petitioner's treatment problematic.

First, the treatment was problematic in that Petitioner provided no written explanation for the drainage on the dressing from the surgery site on the morning that the patient was discharged, and Petitioner claimed to have been surprised and chagrined by the PRO's finding of a drainage problem. I.G. Ex. 34 at 3, 4; Tr. at 226 - 28. Petitioner explained at the hearing that GH was a 70-year-old patient. Tr. at 567 - 68. She described the surgery she performed as "a beautiful job," and she said she had sent him home the following day. Tr. at 568.

Dr. Schwarting testified that Petitioner's alleged unawareness of the drainage problem did not make sense to

him since the drainage was documented in the nurses' notes. Tr. at 226 - 28. In Dr. Schwarting's opinion, Petitioner should not have been surprised that the PRO would discern the drainage problem that was apparent from the nurses' notes. Tr. at 227.

The records concerning GH also lacked any patient history and progress notes, and contained only a bit of information concerning the patient's "physical." Tr. at 226.[26] I find the documentation problems to be related to Petitioner's having excised GH's body parts based on the patient's own verbal report of his pathology. I.G. Ex. 16 at 6. Petitioner did not await any official notification of carcinoma of the prostate from the University of Kansas Medical Center, where GH had been referred; nor had she received any official written recommendation from that institute concerning an orchiectomy when she performed the procedure. Id. The PRO believed that Petitioner proceeded prematurely before receiving such information. Id.

These findings by the PRO are consistent with Petitioner's testimony at hearing that the patient told her of a recommendation to have an orchiectomy and that she performed the bilateral procedure at the patient's request. Tr. at 567 - 68. Petitioner did not indicate that she saw anything wrong with relying on a patient's information in this manner. Her testimony did not intimate that there might have been a need to secure confirmation of the patient's pathology or the patient's belief that orchiectomy had been recommended as appropriate treatment. I find Petitioner's actions in the GH's case to have been premature, unsafe for GH, and lacking in sound professional judgment.

D. Evidence on the Quality of Care Problems Identified by the PRO in 1990

On March 2, 1990, the PRO notified Petitioner that it had assigned to the treatment of FP a "Level II" designation (i.e., "Medical mismanagement with the potential for significant adverse effects on the patient"). I.G. Ex. 35 at 10. The PRO's concerns included Petitioner's failure to identify the etiology of FP's melena (the passage of dark stools stained with altered blood) as recommended by a gastroenterology consultant,

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[26] The information lacking from the patient's records is consistent with Petitioner's contention that she performed the orchiectomy upon being asked to do so by the patient. Tr. at 568.

Petitioner's failure to consider the possibility of obstructive uropathy as a cause for FP's renal failure, Petitioner's failure to address the etiology of FP's severe hyponatremia (salt depletion), and the administration of excessive doses of IV Digoxin (medication used in the treatment of heart failure) without adequate documentation in the chart to warrant its use in the first place. I.G. Ex. 16 at 7. According to the PRO, Petitioner should have treated this 86-year-old patient more aggressively after having admitted her to the hospital for 12 days. I.G. Ex. 35 at 10; Tr. at 229 - 30.

At hearing, Petitioner said of this patient, "[t]his was an elderly, nursing home patient with renal failure, and she should never have even been admitted to the hospital because her body was too diseased to try to bring back anything." Tr. at 569. Such testimony implied that someone other than Petitioner had admitted this patient. However, upon being asked who had admitted this patient, Petitioner acknowledged that she ordered the admission but explained that the patient's son insisted on the hospitalization and "I should have been more persuasive and said, it isn't appropriate to put her in the hospital." Id. I find these excuses as problematic as in the 1988 case involving LT. Moreover, Petitioner's opinion concerning FP's inevitable death is inherently suspect since Petitioner failed to adequately assess the sources of FP's various problems.

On March 26, 1990, the PRO notified Petitioner that it had assigned to her treatment of EN a "Level II" quality problem designation as well. I.G. Ex. 36 at 4 - 6. This 78-year-old nursing home patient was admitted to the hospital with symptoms that included congestive heart failure and bronchial pneumonia. E.g., I.G. Exs. 36 at 9; 16 at 7. According to the nurse's notes, the patient had swelling in her ankles, was diaphoretic (perspiring profusely), and had labored respirations of 36 times per minute because she was in respiratory distress. Tr. at 231.

The PRO found Petitioner's treatment of EN problematic due to a significant lack of documentation; that is, no admission notes, no "history & physical, etc." were put on the patient's chart at the time of admission or after she passed away. I.G. Ex. 36 at 5. Moreover, Petitioner first saw this patient two and one-half hours after she was admitted in an obviously critical condition. Id.; Tr. at 231. The PRO noted the discrepancy between Petitioner's treatment orders and her assertion to the PRO that, at admission, EN's "end was inevitable" even

though EN continued to survive. I.G. Exs. 36 at 3; 5. The PRO did not accept Petitioner's contention that EN had been "dying in the nursing home for several days and was admitted to die [in the hospital]." I.G. Ex. 16 at 7 - 8. The chest x-rays, an EKG, a liquid diet, and other treatment Petitioner ordered for this patient were all contrary to Petitioner's later declarations that the patient was dying and needed only to be made comfortable in the hospital. Tr. at 233 - 34; I.G. Ex. 36 at 5. The PRO assigned the Level II designation also because Petitioner never explained in the charts or after the fact why more therapeutic measures were not undertaken, and there was no documentation in the patient's records of a "do not resuscitate" order. Tr. at 232 - 34.

In response to criticisms of the care she rendered to EN, Petitioner testified at hearing that her decision to admit this dying patient to the hospital was ill advised. Tr. at 570. Petitioner claims to have "made some effort to try to reverse the dying findings." Id. I find her testimony concerning EN very similar to the excuses she offered for having failed to order appropriate treatment for LT and FP, the other two patients she said she admitted to the hospital without medical necessity. For reasons already stated, I do not find this excuse credible.

On March 2, 1990, the PRO notified Petitioner that it had assigned to her treatment of GP a "Level I" designation (i.e., "Medical mismanagement without the potential for significant adverse effects on the patient"). I.G. Ex. 35 at 5. This 91 year old patient was admitted to the hospital with an acute abdominal obstruction. I.G. Exs. 16, 35, 37. The problem the PRO initially found in this case was Petitioner's failure to adequately address GP's elevated liver enzymes that were revealed by the routine admitting laboratory tests. I.G. Ex. 16 at 7; Tr. at 236 - 37; I.G. Ex. 35 at 4. Later, the PRO accepted Petitioner's proof that follow-up tests were done on an out-patient basis. I.G. Ex. 16 at 7. The PRO remained concerned that the foregoing information was not documented in the charts. Id.

During April 1990, the PRO notified Petitioner that it had assigned to her treatment of IM a "Level II" quality problem designation as well. I.G. Ex. 38 at 4 - 6. IM, a 73-year-old patient, was hospitalized on complaints of chest pain underneath the left clavicle and epigastric distress. I.G. Ex. 38 at 8. Petitioner's final diagnosis included acute cholecystitis (inflammation of the gallbladder). Id.; I.G. Ex. 16 at 8. The PRO found that Petitioner had diagnosed chronic hepatitis without

any evidence in the chart to support such a diagnosis. I.G. Ex. 16 at 8. The PRO found also that Petitioner's choice of antibiotic, penicillin, was inappropriate for treating the patient's acute cholecystitis. I.G. Ex. 38 at 4, 5; Tr. at 238. At hearing, Dr. Schwarting explained that penicillin does not cover the multitude of bacteria associated with acute cholecystis, and Petitioner put the patient at risk for progressive infection, abscess, or other complications with her choice of antibiotics. Tr. at 238 - 39.

Petitioner acknowledged at hearing that the PRO had found penicillin inappropriate, but she argued --

> I gave her penicillin, and she got well. So I mean, who can argue with success?

Tr. at 571. I inferred from this testimony that Petitioner still does not understand the risks identified by the PRO and does not acknowledge the availability of safer antibiotics. I find that patients should not be exposed to unnecessary risks of complications when there exists safer antibiotics. The rationale adopted by Petitioner to explain her use of penicillin for IM reflects her continued disregard for current professional standards of care. Moreover, as discussed below in the case of another patient (RE), Petitioner prescribed other inappropriate antibiotics in December 1990 after having been alerted to the problem by the PRO in April.

On April 20, 1990, the PRO notified Petitioner that, of the total of 19 cases of hers it reviewed, there were four additional Level II quality problems and an additional Level I problem. I.G. Ex. 41 at 15. The PRO notified Petitioner also that she was to remain on 100 percent retrospective intensified review of all her Medicare discharges for 90 days beginning on April 1, 1990. Tr. at 76; I.G. Ex. 38 at 6. The PRO invited Petitioner to help formulate an additional Corrective Action Plan. Id. Petitioner proposed various terms, such as having Petitioner's husband proctor her work. E.g., I.G. Ex. 41 at 21, 23.

On August 13, 1990, in rejecting one of Petitioner's proposals for a CAP, the PRO notified Petitioner that it was initiating sanctions against her under section 1156 of the Act because she had substantially violated her obligations in a substantial number of cases. I.G. Ex. 41 at 18 - 22. The PRO identified 14 cases and summarized the problems in each case. Id.

On December 18, 1990, the PRO confirmed the formulation of a CAP that required Dr. David Henderson to proctor Petitioner on an ongoing and concurrent basis to confirm her diagnosis and approve her treatment plan for Medicare patients within 24 hours of their admission, to review prospectively major therapeutic intervention (e.g., surgery, transfer in and out of acute care units and discharges), to review progress on an average of every 48 hours to determine whether her patient's condition has changed or was failing to respond to therapy. I.G. Ex. 41 at 25 - 26. The proctoring was to last up to one year, beginning on January 1, 1991, with the option for the PRO to discontinue or modify it after six months. Id.

E. Evidence on the Quality of Care Problems Identified by the PRO in 1991

On January 7, 1991, the PRO notified Petitioner that it had assigned to her treatment of ND a "Level III" designation (i.e., "Confirmed quality problem with significant adverse effects on the patient").[27] This 90-year-old patient was admitted to the hospital with symptoms of acute abdominal pain and a diagnosis of perforated ulcer. I.G. Ex. 39.[28] The PRO was concerned by Petitioner's failure to recognize the perforation and to obtain timely consultation. I.G. Ex. 16 at 8. Dr. Schwarting described ND's perforated ulcer as "a very risky, life-threatening situation," which is in accord with the PRO's assessment. Tr. at 239; I.G. Ex. 39 at 8. The patient arrived at the emergency room at 10:00 p.m., but she was not operated on until the afternoon of the following day, which was an unnecessary delay in surgical care. Tr. at 240; I.G. Ex. 39 at 8.

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[27] "Significant adverse effect" means either "unnecessary prolonged treatment, complications, or readmission," or "patient management which results in anatomical or physiological impairment, disability, or death." I.G. Ex. 39 at 9.

[28] The PRO issued its notice during the period Petitioner was under proctoring by Dr. Henderson and was not creating any quality of care problems. I.G. Ex. 41 at 27. However, for this and the following case, the patients were discharged from the hospital prior to January 1, 1991 when the proctoring began; therefore, these were not among the patients whose care was overseen by Dr. Henderson under the CAP.

In her response to the PRO, Petitioner explained that the delay in surgery was not unreasonable given the distance which the surgeon was travelling. I.G. Ex. 39 at 6; Tr. at 240. Dr. Schwarting explained, however, that when there is an acutely ill patient, the patient must be treated timely. Id. Thus, according to Dr. Schwarting, Petitioner should have called another surgeon, or transferred the patient to Kansas University Medical Center, which was about an hour away. Id. Dr. Schwarting explained also that the PRO's finding that Petitioner's use of Lithium for this patient was inconsistent with professionally recognized standards of health care was due to the drug's potential for causing life-threatening complications. Tr. at 243; I.G. Ex. 39 at 8.

At hearing, Petitioner alleged that she had endeavored to do everything timely for ND. Tr. at 572 - 74. She said she told ND to go to the hospital immediately, but ND did not go there for six hours; she called a board certified surgeon living in another town at about 1:00 a.m. (three hours after the patient's arrival) to come and operate on the perforated ulcer, but the surgeon said he would be there later that morning. Tr. at 571 - 72. Petitioner did not specify whether the surgeon had committed to an arrival time to do the operation or whether Petitioner had asked him for his arrival time. The surgeon did not arrive until 8:00 a.m. and then wanted another chest x-ray to confirm the diagnosis. Tr. at 572. Petitioner testified that, even today, she would make the same decision to keep the patient instead of transferring her because a board certified surgeon was coming to do the surgery. Tr. at 573.

I find that Petitioner contributed significantly to the unreasonable delay of more than 12 hours by not immediately recognizing ND's life-threatening condition, by not seeking a surgical consultation for three hours, by not ordering ND transferred to another hospital forthwith, and by acquiescing to the surgeon's delayed arrival. The manner in which Petitioner distanced herself from the surgeon's actions in ND's case is akin to her explanations of HA's death from the surgery performed on Petitioner's referral. The impression she conveyed is that she had no responsibility to either patient, even though she had been the attending physician to both and had referred both of them for surgery.

There is no support for Petitioner's allegation that surgery could not have been done on ND without a delay of at least 10 hours. There is also no support for Petitioner's proposition that more than 12 hours of delay

did not significantly increase the risk of death for ND. While Petitioner's preference for a board certified surgeon was laudable, it is not credible that only by keeping ND at Anderson County Hospital could ND have had access to a board certified surgeon. There is also no evidence to support Petitioner's contention that transferring the patient to another hospital, such as the Kansas University Medical Center suggested by Dr. Schwarting, would have resulted in the same delay of more than 12 hours. Therefore, Petitioner's testimony that she would make the same decisions again for this patient evidences her continuing unwillingness and inability to conform her practices to professionally recognized standards of health care.

The PRO's notice to Petitioner concerning the unreasonable delay in ND's treatment predated Amanda's birth by several months. The PRO's notice concerning ND's case should have alerted Petitioner to evaluate the wisdom of transferring a patient when specialists are not readily available at Anderson County Hospital and the patient is critically ill. Yet, several months later, Petitioner again incurred many, many hours of unreasonable delays before she signed the order to transfer Amanda to another hospital.

On June 11, 1991, the PRO notified Petitioner that it had assigned to her treatment of RE a "Level II" designation (i.e., "Confirmed quality problem with the potential for significant adverse effects on the patient"). I.G. Ex. 40 at 4. This 68-year-old patient had a history of diabetes and came to the hospital with a high fever. I.G. Ex. 40 at 8. After x-rays showed pneumonia, he was admitted for IV antibiotics. Id. The PRO was concerned with Petitioner's failure to monitor RE's renal function studies or to obtain blood level readings of the antibiotics used. I.G. Ex. 16 at 8. The PRO noted as an additional problem the antibiotic Petitioner used for this patient with diabetes and pneumonia. I.G. Ex. 40 at 1. Dr. Schwarting explained that Petitioner's choice of antibiotic, Garamycin, had placed RE at risk during the 12-day hospital course because Garamycin has a very high potential for causing nephrotoxicity or problems with the kidneys. Tr. at 245.

Petitioner asserted, that seven years ago, the hospital lacked the capacity to provide prompt test results that would have assisted her in selecting the correct antibiotics for this patient. Tr. at 575. In her view, by the time any test results could have arrived, the patient would have been well or nearly so. Id.

I reject Petitioner's suggestion that she could not have known the potential dangers of Garamycin without receiving test results. I note, too, that the care in question took place in December 1990, not seven years ago when the conditions may have been as Petitioner described. Moreover, regardless of when the results could have arrived, as in her treatment of HH and other patients, it does not appear that Petitioner ever ordered the tests. In April 1990, eight months before she treated RE, Petitioner had been alerted to her improper use of antibiotics in her treatment of IM. Even if I accepted Petitioner's contentions, the risks created by Petitioner's selection of a potentially dangerous antibiotic in the first instance cannot be mitigated by the unavailability of test results to monitor their actual effects on RE.

VI. Petitioner has not proven that she is willing or able to meet her obligations under section 1156(a)(2) of the Act.

Petitioner contends that every previous CAP she entered into was voluntarily ended by the PRO without any problems. P. Proposed Findings of Fact at 15 (citing Tr. at 76 - 82, 97). She claims that her practices have changed significantly in the past six years. Tr. at 558. Petitioner opposes the exclusion at issue on the belief that her medical practice would be ruined if she agreed to either one of the two CAPs that have been proposed by the PRO pursuant to its review of Amanda's case. P. Proposed Findings of Fact at 16; Tr. at 547 - 52. Petitioner contends that the PRO unjustifiably refused to allow the formulation of a new CAP, which would once again allow Dr. Henderson to proctor Petitioner's care of patients. See Tr. at 40. She expressed a willingness to take more continuing medical education classes. Tr. at 581. She believes that the PRO is seeking to punish her with the alternative CAPs it proposes. Tr. at 547.

I do not find Petitioner's contentions meritorious. For example, the CAP Petitioner entered into on January 1, 1991 ended in July 1991 only because the plan was limited to Medicare patients. Dr. Henderson proctored her treatment of Medicare patients, and no quality of care problems were identified by the PRO for the Medicare patients she admitted during the period with Dr. Henderson's oversight. I.G. Ex. 41 at 27. However, the PRO continued its intensified review of those Medicaid patients Petitioner discharged after July 1991, that is, after the CAP ended. Id. Petitioner has been under 100 percent intensified review by the PRO since at least

1989, and under some type of review since at least 1987. Tr. at 29 - 30; I.G. Ex. 16 at 3. Petitioner continues to have 100 percent of her Medicare and Medicaid cases reviewed retrospectively by the PRO. Tr. at 31. To date, she has taken part in at least two CAPs. Tr. at 34 - 36, 93 - 94, 96; I.G. Ex. 16 at 3. The reviews, interventions, and CAPs have not remedied the underlying problems.

Very significantly, the quality problems in Amanda's case arose on May 19 and 20, 1991, while Petitioner was under the CAP for Medicare patients. The proctoring by Dr. Henderson did not occur for Amanda because Amanda was a Medicaid recipient. Given the resurgence of similar quality problems over the years despite Petitioner's technical compliance with previously negotiated CAPs of limited scope, there is no valid basis for concluding that Petitioner is willing and able to comply substantially with her obligations under the Act.

The CAPs are proposed by the PRO for the benefit of Medicare beneficiaries and Medicaid recipients when the PRO discerns a pattern of substandard care. Tr. at 32. CAPs are not intended to safeguard the fiscal viability of any physician's medical practice. Nor are CAPs intended to remedy a physician's knowledge base only to the extent convenient to that physician. After noting the problems in Amanda's case, the PRO proposed that Petitioner enter a mini-residency program of six months, or that she enter a program in Colorado for the duration necessary to evaluate and remedy her educational needs. Tr. at 40; I.G. Ex. 16. In rejecting these proposed CAPs, Petitioner was motivated by her desire to maintain her current medical practice. Tr. at 546 - 52. She offered to take continuing medical education (CME) classes because she can do so without disrupting her existing practice, even though she had been taking CME classes during the years that she treated Amanda and the other 13 patients. See Tr. at 469 - 70, 581.

The CAP initiated in October 1989 required her to complete CME in designated areas. I.G. Ex. 16 at 3. Yet, quality of care problems continued to arise. In addition, Petitioner claimed that she had completed more than twice the courses required for maintaining licensure by the State of Kansas and that she had completed the required 50 hours for 1993. Tr. at 469, 582 - 84. However, Petitioner was not able to describe cogently even one continuing medical education course she had attended or what such education entailed for her. Tr. at 469 - 70, 583 - 84.

Even at hearing, Petitioner persisted in describing the care she gave to Amanda and the other 13 patients as "good care" with "wonderful results." Tr. at 562. Earlier, she alleged to the PRO that the healthy, normal baby she delivered on May 19, 1991 had been substituted with another baby in order to maintain a malpractice suit against her. I.G. Ex. 7 at 2. She contended that she had fallen victim to a conspiracy to "character assassinate" her and to "discredit" her care by making it appear inadequate or casual. I.G. Ex. 4. She believed the hospital staff had been lying in wait for her to make a "tragic mistake" in order to thereby prove her incompetency. I.G. Ex. 4 at 1. At hearing, she denied specifically that she needs training in any aspect of her current practice. Tr. at 585.

Having acknowledged no deficiency and no problem, Petitioner has indicated also no commitment to making changes of any specific nature or to achieving any specific goals. She has therefore given no evidence of her trustworthiness for being willing or able to remedy her deficiencies under section 1156(a) of the Act. All evidence points to the futility of allowing her to choose the additional classes she wishes to attend as a remedy.

I agree with the I.G. that having another physician proctor Petitioner again is not an appropriate solution. See Tr. at 41. First, no doctor has come forth to volunteer as Petitioner's proctor. I.G. Ex. 16 at 2. Proctoring is cumbersome and not likely to correct the educational deficiencies in Petitioner's medical knowledge base. Tr. at 41. There is also no guarantee that, if Dr. Henderson (Petitioner's nominee for her proctor) were out of town, there would be another physician to proctor Petitioner. Tr. at 40 - 41. Proctoring might have to be continued indefinitely, given the deficiencies in Petitioner's knowledge base, and having two doctors examining all Medicare and Medicaid patients is an expensive and inefficient process to have in place indefinitely. Id.; I.G. Ex. 16 at 2. Moreover, contemporaneous proctoring by Dr. Henderson for all of Petitioner's Medicare patients in May 1991 did not eliminate the quality of care problems for Amanda, a Medicaid recipient. There is no persuasive proof that another period of proctoring will have lasting benefits for anyone.

VII. The I.G. has proven by a preponderance of the evidence that the three-year exclusion is reasonable.

Under section 1156(a) of the Act, evidence of Petitioner's violations of her professional obligations is highly probative on the issue of whether a given length of the exclusion is proper. Evidence of past wrongdoing by a party tends to be an important predictor of that party's propensity for engaging in similar conduct in the future. The Act is not punitive in nature. It is intended only to provide a remedy against possible wrongful conduct by a party in the future.

I have already discussed Petitioner's intransigence, misunderstanding of her professional obligations, and unreasonable defense of her own practices. All such evidence indicates a strong likelihood that Petitioner will continue to place Medicare beneficiaries and Medicaid recipients unnecessarily in high-risk situations. Petitioner has not voluntarily cut back or given up any area of her practice. Tr. at 585. She rejected the CAPs proposed by the PRO because she wished to maintain her current volume of practice and could not afford the time to be away. Tr. at 547. Some period of exclusion is necessary because Medicare beneficiaries and Medicaid recipients need to be protected from the risk of harm Petitioner is likely to create for them.

The PRO recommended that Petitioner be excluded from the Medicare and Medicaid programs for a period of 10 years. I.G. Ex. 16 at 9. The I.G. directed and imposed an exclusion of only three years. I.G. Ex. 25 at 3. In arriving at the period of exclusion, the I.G. had considered factors that included the severity of the offense, the availability of other physicians in the area, and any problems the Medicare carrier or intermediary may have had with Petitioner. Id. at 4. The I.G.'s findings under those factors are in accord with the facts of record.

I have considered also Petitioner's arguments concerning her honesty and good intentions, her willingness to charge less than other area physicians, her long history of practice in the community, her view that she is irreplaceable, her having approximately 4000 active patient charts in her practice (50 percent of which are for Medicare and Medicaid patients), her having never been sued for malpractice until she delivered Amanda, the limited number of other physicians in the area, and her desire to help lower health care costs for the American people. See, e.g., Tr. at 580; I.G. Ex. 17; P. letter

dated January 3, 1994.[29] I have noted Dr. Henderson's testimony concerning the compassion, care, and understanding Petitioner has shown to her elderly patients. Tr. at 448 - 49. He expressed the opinion that her patients need kindness, compassion, and understanding from her; that the human understanding element she provides may be as critical to the caring of some elderly patients as lab tests; that she is willing to make a house call in the middle of the night and in situations where the patient would receive no care at all were she not there. Id. I have no reason to doubt the sincerity of Petitioner's beliefs in arguing for mitigation. Nor do I have reason to doubt the general accuracy of Dr. Henderson's observations.

I find that these factors contribute to the reasonableness of a three year exclusion for Petitioner. Absent the foregoing considerations, the 10-year exclusion recommended by the PRO would appear to be more appropriate for remedying the types of problems encountered in Amanda's case and in the other 13 patients' cases. In limiting the exclusion to three years, I am recognizing those points in Petitioner's favor -- her being a long-time practitioner, the nonmedical needs of some patients, the unique accommodations she makes for patients who cannot visit her office, and the good Petitioner has done for her patients over the past four decades. However, it would be unreasonable to further reduce the three-year exclusion by attributing additional weight to the factors identified by Petitioner.

Containing or lowering health care costs for the benefit of society, for example, is a worthy goal expressed by Petitioner. It does not, however, suffice for remedying Petitioner's inability or unwillingness to meet professionally recognized current standards of care. Section 1156 of the Act is not cast in terms of having physicians cut costs for the Medicare and Medicaid programs by eliminating medically necessary and appropriate procedures for patients, or by adopting the view that the quality of treatment makes no difference to those patients who are of advanced age or seriously ill. While program providers should deliver services economically, they must still deliver services when and

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[29] Because this letter was received in our office and served on counsel for the I.G. during the period I set aside for the filing of posthearing briefs, I have considered the letter as the equivalent of a posthearing brief from Petitioner.

to the extent medically necessary, and of a quality which meets professionally recognized standards of health care. Section 1156(a)(1), (2) of the Act.

Similarly, Petitioner's compassion, understanding, and willingness to care for her patients on house-calls cannot completely offset the serious health risks created by Petitioner's deficient medical knowledge base. I am without the authority to limit Petitioner to treating only those patients who need nothing beyond her expressions of compassion, kindness, and understanding. Without authorizing an exclusion of reasonable duration, I cannot provide adequate protection to those Medicare beneficiaries and Medicaid recipients whose lives may depend on their receiving appropriate diagnostic tests or up-to-date therapeutic interventions.

As for Petitioner's argument that the population of Garnett needs more (not fewer) doctors, I conclude from Petitioner's proposal to have another doctor proctor her practice that at least one other area doctor has the time to take on additional patients. The three-year exclusion will not prevent Petitioner from treating patients who are not in either the Medicare or the Medicaid programs. No area doctor has testified that he will be unwilling to treat more Medicaid or Medicare patients if Petitioner is excluded. In addition, the evidence in this case shows that Anderson County Hospital has an emergency room. I have been given no reason to doubt that the hospital's emergency room has the capability for, or has made suitable provisions for, treating those acutely ill patients who go there, without regard for whether such patients have their own private physicians as well.

I have considered the issue of whether Petitioner also has caused actual injury to Amanda in deciding that a three-year exclusion is appropriate. The possibility that Amanda suffers from problems not of Petitioner's creation does not warrant further reducing the exclusion. In discussing the period of exclusion, there was no finding by the I.G. or the PRO that damage was actually done by Petitioner. The I.G.'s notice, for example, stated only:

> In the one instance cited, your treatment presented an imminent danger to the health, safety, or well-being of the [Medicaid] recipient involved or placed the recipient unnecessarily in a high-risk situation.

I.G. Ex. 25 at 4 (emphasis added). The significance of this conclusion, which is supported by a preponderance of

the evidence of record, is neither nullified nor outweighed by the possibility that genetic defects or prenatal injuries may have caused additional problems for Amanda.

In addition to protecting the programs and their beneficiaries and recipients in the interim, an exclusion of three years will afford Petitioner a meaningful opportunity to improve her medical knowledge base and conform her treatment to the quality level specified by section 1156(a) of the Act. Because Petitioner said 50 percent of her practice was taken up by Medicare and Medicaid patients (Tr. at 580), Petitioner is likely to have more free time during the three-year exclusion. If she wishes, she may use her free time over the three-year period to accomplish at her own pace what she was unwilling to undertake in the six months of intensive retraining suggested by the PRO's CAPs. An exclusion of less than three years is unlikely to provide Petitioner with adequate time for maintaining her non-Medicare and non-Medicaid practice while she attempts (if she wishes) those changes that may result in the I.G.'s granting her reinstatement into the programs after the exclusion expires.

For all the foregoing reasons, I find a three-year exclusion to be reasonable.

/s/

Mimi Hwang Leahy
Administrative Law Judge