Department of Health and Human Services

DEPARTMENTAL APPEALS BOARD

Civil Remedies Division

In the Case of:	)	
	)	
Richard F. Jaskiewicz, R.N.,	)	DATE: May 9, 1994
	)	
Petitioner,	)	
	)	
- v. -	)	Docket No. C-93-073
	)	Decision No. CR315
The Inspector General.	)	
	)	

DECISION

By letter (Notice) dated March 23, 1993, the Inspector General (I.G.) notified Petitioner that he was being excluded from participation in the Medicare, Medicaid, Maternal and Child Health Services Block Grant and Block Grants to States for Social Services programs for five years.[1] The I.G. informed Petitioner that he was being excluded due to his conviction in the Superior Court of Arizona, Pima County, of a criminal offense related to the delivery of an item or service under the Medicaid program.[2] The I.G. further advised Petitioner that the exclusion of individuals convicted of such an offense is mandated by section 1128(a)(1) of the Social Security Act (Act), and that section 1128(c)(3)(B) of the Act provides that an exclusion effected pursuant to section 1128(a)(1) must be for a minimum five-year period.

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[1] The State health care programs from which Petitioner was excluded are defined in section 1128(h) of the Social Security Act and include the Medicaid program under Title XIX of the Act. Unless the context indicates otherwise, I use the term "Medicaid" here to refer to all State health care programs listed in section 1128(h).

[2] In her brief, the I.G. advised Petitioner that she was arguing also that his conviction related to the Medicare program.

As an additional basis for the exclusion, the I.G. notified Petitioner that he was being excluded also under section 1128(b)(1) of the Act. The I.G. told Petitioner that he was being excluded under section 1128(b)(1) of the Act because he was convicted of a criminal offense relating to fraud, theft, embezzlement, breach of fiduciary responsibility, or other financial misconduct. The regulations provide for a three-year exclusion when the exclusion is based on section 1128(b)(1). 42 C.F.R. § 1001.201. However, that period may be increased if aggravating circumstances exist. 42 C.F.R. § 1001.201(b)(2). The I.G. found such circumstances here, in that the acts which resulted in Petitioner's conviction had a significant adverse physical or mental impact on one or more program beneficiaries or other individuals; that Petitioner caused financial loss to the program in excess of $1500; and that the acts leading to Petitioner's conviction took place over a period longer than one year.[3] 42 C.F.R. §§ 1001.201(b)(2)(i) - (iii). The I.G. contends that these circumstances, as well as the mandatory five-year exclusion under section 1128(a)(1) of the Act, justify the five-year exclusion.

Petitioner, appearing pro se during this proceeding, requested a hearing on May 12, 1993, and the case was assigned to me for hearing and decision.[4] I have

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[3] In my Prehearing Order and Schedule for Filing Submissions for Summary Disposition (Prehearing Order) dated June 22, 1993, one of the issues posed was "[w]hether Petitioner was convicted of a criminal offense related to fraud, theft, embezzlement, breach of fiduciary responsibility, or other financial misconduct within the meaning of section 1128(b)(1) of the Act." I will not address the merits of a five-year exclusion under section 1128(b)(1) of the Act in this Decision, since I am sustaining the five-year exclusion under section 1128(a)(1) of the Act.

[4] This case was originally scheduled to be decided on the written submissions of the parties. Prehearing Order at 3. A schedule was set which allowed the I.G. to file a motion and brief for summary disposition, with supporting documents. Petitioner was given the opportunity to respond and the I.G. was permitted to file a reply brief. Both parties were given the opportunity to request oral argument. I convened a conference call on November 8, 1993, to determine whether a disputed issue of material fact existed which would require an in-person hearing. After listening to the

(continued...)

considered the parties' exhibits, their arguments, and the applicable law and regulations. I find that there are no disputed issues of fact and that summary disposition in favor of the I.G. is warranted. I conclude that, pursuant to section 1128(a)(1) of the Act, the I.G. has authority to exclude Petitioner from Medicare and to direct his exclusion from Medicaid. Further, I conclude that, pursuant to section 1128(c)(3)(B) of the Act, the five-year exclusion imposed by the I.G. is mandated by law.

ADMISSION

During the prehearing conference held on June 4, 1993, Petitioner admitted that he was convicted based on charges of fraudulent schemes and artifices and conflict of interest. Petitioner stated that his convictions are on appeal. Prehearing Order; see also Petitioner's response to the I.G.'s request for summary disposition (P. Br.) at 2.

ISSUES

1. Whether Petitioner was convicted of a criminal offense.

2. Whether Petitioner's conviction relates to the delivery of an item or service under the Medicare or Medicaid programs, within the meaning of section 1128(a)(1) of the Act.

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[4](...continued)
parties' arguments, I decided that an in-person hearing was not necessary. I afforded the parties the opportunity to supplement the record with additional evidence before I issued a Decision. As stated in my December 20, 1993 Order, I granted Petitioner's request for production of documents in part and denied it in part. The I.G. mailed documents required by my Order to Petitioner but they were returned from the post office marked "unclaimed." Upon receiving no further response from Petitioner, the parties were notified on March 7, 1994, that the record was closed.

FINDINGS OF FACT AND CONCLUSIONS OF LAW[5]

Background findings

1. At all times relevant to this case, Petitioner was a registered nurse, licensed to practice nursing by the Arizona State Board of Nursing, and an employee of Pima County, Arizona. I.G. Ex. 6 at 2.

2. In June 1987, Petitioner was employed as the administrator of Clinical Nursing and Medical Services for Pima County's Department of Aging and Medical Services (AMS). I.G. Ex. 7.

3. Petitioner's duties as administrator included: supervision of a professional nursing staff assigned to work in outside nursing homes under contract; provision of primary care as a member of a health care team; responsibility for on-going health maintenance and clinical management of stable, chronically ill patients; regulation or adjustment of medications and treatments as prescribed or authorized by a licensed physician; and ordering laboratory and x-ray procedures. I.G. Ex. 8.

4. At all times relevant to this case, Petitioner maintained a private business identified as Extended Care Limited (ECL). I.G. Ex. 9 at 4; I.G. Ex. 15 at 18 - 19.

The indictment

5. On December 19, 1990, an eight-count criminal indictment was filed against Petitioner and another individual in the Superior Court of the State of Arizona. I.G. Ex. 6.

6. Count two of the indictment charged that, between June 10, 1987 and June 16, 1989, Petitioner and another individual, pursuant to a scheme or artifice to defraud,

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[5] The I.G. submitted 28 exhibits. I admit all of the I.G.'s exhibits into evidence and refer to them as "I.G. Ex(s). (number) at (page)." I refer to the I.G.'s memorandum in support of the I.G.'s motion for summary disposition as "I.G. Br. at (page)." Petitioner submitted two exhibits and designated them as exhibits A and B. Since Petitioner's exhibits were not prepared in accordance with my Prehearing Order, I am redesignating Petitioner's exhibits. I admit Petitioner's exhibits into evidence and I refer to Petitioner's exhibit A as "P. Ex. 1 at (page)" and to Petitioner's exhibit B as "P. Ex. 2 at (page)."

knowingly obtained $65,140.73 from Marion Laboratories in connection with the clinical study of Agent M, by means of false or fraudulent pretenses, representations, promises, or material omissions. I.G. Ex. 6 at 10.

7. Count three of the indictment charged that, between August 15, 1988 and May 16, 1990, Petitioner and another individual, pursuant to a scheme or artifice to defraud, knowingly obtained $23,616.16 from Marion Laboratories in connection with a study of Ditropan, by means of false or fraudulent pretenses, representations, promises, or material omissions. I.G. Ex. 6 at 11.

8. Count five of the indictment charged that, between September 1987 and December 1989, Petitioner, a public employee of a public agency, maintained a substantial interest in a contract to such public agency and knowingly failed to make known that interest in the official records of such public agency, and failed to refrain from participating in any manner as an employee in such contract. Said conduct occurred in connection with Petitioner doing business as ECL and receiving $23,200 to conduct a test using an experimental drug, known as Agent M, on indigent and elderly county patients. Petitioner, a public employee of Pima County, was employed by the county to care for these patients. I.G. Ex. 6 at 13.

9. Count six of the indictment charged that, between January 13, 1989 and May 16, 1990, Petitioner, a public employee of a public agency, maintained a substantial interest in a contract to such public agency and knowingly failed to make known that interest in the official records of such public agency, and failed to refrain from participating in any manner as an employee in such contract. Said conduct occurred in connection with Petitioner doing business as ECL, receiving $12,650 to conduct a test using a drug known as Ditropan on indigent and elderly county patients. Petitioner, a public employee of Pima County, was employed by the county to care for these patients. I.G. Ex. 6 at 14.

Conviction and sentence

10. On June 23, 1992, a jury found Petitioner guilty of two counts of violating A.R.S. § 13-2310 (counts two and three of the indictment, pertaining to fraudulent schemes and artifices) and two counts of violating A.R.S. § 38-503 (counts five and six of the indictment, pertaining to conflicts of interest in public employment). I.G. Ex. 28.

11. On August 10, 1992, the State court, based on the jury verdict, rendered a judgment of conviction, imposing a fine and sentencing Petitioner to probation for two years. I.G. Ex. 2.

The Arizona Health Care Cost Containment System (AHCCCS)

12. On October 1, 1982, the State of Arizona established AHCCCS, a demonstration project receiving Title XIX (Medicaid) funding. AHCCCS consisted of contracts with providers of health care for the provision of hospitalization and medical care services to AHCCCS' members. I.G. Ex. 1 at 7 - 8; I.G. Ex. 5.

13. AHCCCS is a "prepaid capitated" system. "Prepaid capitated" is a mode of payment by which a health care provider directly delivers health care services for the duration of a contract to a maximum specified number of members based on a fixed rate per member. I.G. Ex. 1 at 3.

14. Services covered by AHCCCS include patient and outpatient hospital services, laboratory and x-ray services, and medications. I.G. Ex. 1 at 5 - 6.

15. Prior to January 1, 1989, AHCCCS capitation payments to the Pima County long-term care program were designated by identification number 010182. I.G. Ex. 17.

16. Effective January 1, 1989, AHCCCS expanded to cover long-term care services, with the implementation of the Arizona long-term care system (ALTCS). Under ALTCS, Title XIX (Medicaid) funds are available to pay for nursing home care for members, in addition to the medical care and other services they received prior to January 1, 1989. I.G. Ex. 5.

17. Under AHCCCS, capitation payments are made directly to providers to cover the costs of care rendered to the program's members. I.G. Ex. 1.

18. Long-term services covered by AHCCCS include nursing facility services and acute care health and medical services. I.G. Ex. 1 at 11.

The Agent M study

19. On September 1, 1987, Mario Valdez, M.D., a Pima County contract physician, entered into an agreement with Pima County to provide medical services to designated AMS long-term care patients. I.G. Ex. 10.

20. On September 21, 1987, Dr. Valdez and Dr. Martin Highbee, a nontenured clinical associate professor of pharmacy employed by the University of Arizona, executed a standardized "Statement of Investigator," a document required by the Food and Drug Administration (FDA) as a condition for conducting a study for Marion Laboratories, Inc., of an experimental drug, identified as "Agent M." I.G. Ex. 6 at 2; I.G. Ex. 11.

21. The Statement of Investigator includes a certification that the drug, Agent M, would be administered either under the personal supervision of Drs. Highbee or Valdez, or under the supervision of three investigators: Robert A. Mead, Pharm.D.; Dick Jaskiewicz, F.N.P.; or Barbara Jarrett, R.N. I.G. Ex. 11 at 2.

22. The purpose of the Agent M study was to "determine the dose which provides adequate benefit with acceptable safety following the application of Agent M versus placebo to pressure ulcers." I.G. Ex. 12 at 7.

23. On September 29, 1987, Petitioner participated in a meeting of the Pima County AMS Clinical Nursing and Medical Services, Research and Education Committee (committee). I.G. Ex. 13.

24. The minutes of the September 29th meeting indicated that the "committee discussion included concerns regarding patients being 'treated' with the placebo agent." This was not considered a problem because "due to the effect of the close monitoring of all patients involved in the study by the A.M.S. Clinical Nursing Division, it was agreed that patients presenting problems would be discontinued from the study." I.G. Ex. 13.

25. Neither the experimental nature of Agent M nor the plan to divert the compensation for the study to Petitioner's private company, ECL, was disclosed to the committee. I.G. Ex. 6 at 4; see also I.G. Ex. 12.

26. On February 3, 1988, Drs. Highbee and Valdez signed a letter of agreement with Marion Laboratories for the Agent M study. I.G. Ex. 6 at 4.

27. On March 24, 1988, Petitioner telephoned Marion Laboratories and told a representative there that Dr. Valdez was not authorized to sign any contractual agreement. Petitioner then requested that a copy of the budget and agreement letter for the Agent M study be sent to him. I.G. Ex. 6 at 4.

28. On March 30, 1988, Dr. Highbee telephoned Marion Laboratories and falsely informed it that AMS had changed its name and was now called ECL. I.G. Ex. 6 at 5.

29. The Agent M study began in or about April 1988. I.G. Ex. 14 at 7.

30. Petitioner's firm, ECL, received periodic payments for the study, either through the University of Arizona or directly from Marion Laboratories. I.G. Ex. 6 at 5 - 9; I.G. Ex. 15 at 16 - 18; I.G. Ex. 9 at 8.

31. ECL was paid $1000 per patient for the Agent M study. I.G. Ex. 9 at 8.

32. Before the study began, Petitioner recruited Pima County AMS nurse coordinators to take part in the Agent M study in exchange for a per-patient fee of approximately $250, which fee was paid by ECL. I.G. Ex. 14 at 3 - 8; see I.G. Ex. 15 at 4 - 5, 19 - 20.

33. AMS nurse coordinators were registered nurses who, as part of their regular duties as Pima County employees, oversaw the management of decubitus ulcers (e.g., bedsores) in facilities under contract with Pima County. I.G. Ex. 15 at 4 - 5.

34. AMS nurse coordinators used a protocol developed by AMS which listed the different types of decubitus ulcers and choices of treatments. I.G. Ex. 15 at 6.

35. The use of Agent M was not included in the AMS protocol. I.G. Ex. 15 at 7 - 8.

36. As part of their regular Pima County position, AMS nurse coordinators went to facilities under contract with Pima County once a week to see patients who had bedsores; the AMS nurse coordinators operated under a protocol with the medical staff to write orders for treatments for the decubitus ulcers and to take wound measurements. I.G. Ex. 15 at 5.

37. AMS nurse coordinators used the AMS protocol to be able to go out into the field to evaluate the ulcers and to write appropriate treatments for the Agent M study. I.G. Ex. 15 at 6.

38. Petitioner directed and encouraged the nurse coordinators under his supervision to participate in the Agent M study while working on Pima County time, and also Petitioner worked on the Agent M study on Pima County time. I.G. Ex. 15 at 25; see I.G. Ex. 9 at 19.

39. Petitioner was in charge of the Agent M study and directed and supervised the activities of the AMS nurse coordinators. I.G. Ex. 14 at 8; I.G. Ex. 15 at 9 - 15.

40. Pima County did not give Petitioner approval to participate in the Agent M study, and Petitioner concealed his receipt of payments for the study from the County. I.G. Ex. 6 at 3; see I.G. Ex. 9 at 19.

41. Neither Pima County nor AMS received any payment for the Agent M study. I.G. Ex. 6 at 3.

42. Pima County received acute care capitation payments from AHCCCS on behalf of the following patients for at least one month during the period in which these patients took part in the Agent M study: PCa, PCo, AM, LS, GS, and JT.[6] I.G. Exs. 16, 17. Petitioner's Pima County salary, and the salaries of the nurse coordinators working for him, were reimbursed, at least in part, by AHCCCS. I.G. Ex. 5.

43. Medicare claims were submitted and electrocardiograms (EKGs) were performed on the following patients in connection with their participation in the Agent M study: PCo, MC, MG, MH, GS, JT, RW, and EY. I.G. Ex. 18.

44. On August 25, 1988, Petitioner wrote a memorandum to the director of AMS requesting an increase in the staff of the Clinical Nursing and Medical Services Divisions, asserting that the current staff "is stretched beyond capacity and are stressed to their maximum capabilities." I.G. Ex. 19.

The Ditropan study

45. On August 30, 1988, Petitioner executed a letter of agreement on behalf of ECL, in which ECL would participate in a "Sustained Release Oxybutinin Study" (hereinafter referred to by the brand name "Ditropan"), in which ECL agreed, among other things, to receive $200 per patient for performing numerous functions, including the collection of clinical and laboratory data, patient monitoring, interviews, and visits. I.G. Ex. 20.

46. On January 13, 1989, Drs. Highbee and Valdez executed an FDA "Statement of Investigator" for "evaluation of the effect of Ditropan SR on the quality

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[6] Here, and elsewhere in this Decision, I use initials for the patients to protect their privacy.

of life and economic impact in elderly patients suffering with urinary incontinence." I.G. Exs. 21, 22.

47. Urinary incontinence is the failure of voluntary control of urination, which causes loss of urine through the urethra. I.G. Ex. 23 at 3.

48. Petitioner and members of his AMS nursing staff were listed as assistant investigators in the Ditropan study. I.G. Ex. 21; see I.G. Ex. 15 at 29 - 30; see also I.G. Ex. 14 at 20 - 21.

49. Each patient selected for the Ditropan study was to participate for a total of 13 weeks; the overall study duration was to be 10 months. I.G. Ex. 23 at 7 - 8, 32.

50. The primary providers in the Ditropan study were going to be the AMS nurse practitioners having responsibility for maintaining the books and doing the documentation for the study. I.G. Ex. 15 at 29 - 30.

51. Petitioner's firm, ECL, was to receive $2000 from Marion Laboratories for each patient in the Ditropan study. I.G. Ex. 20; I.G. Ex. 9 at 8.

52. The AMS nurses were paid approximately $250 to $350 per patient for the Ditropan study. I.G. Ex. 9 at 18.

53. Petitioner did not obtain approval from Pima County to participate in the Ditropan study, and he also concealed his receipt of payments for the study. I.G. Ex. 6 at 3; I.G. Ex. 9 at 20 - 21.

54. Pima County received AHCCCS acute care capitation payments for the following patients for at least one month during the period in which they took part in the Ditropan study: EB, HL, ES. I.G. Exs. 24, 25.

55. Long-term care for the following patients was paid for by ALTCS for at least one month during the period in which these patients took part in the Ditropan study: DC, BF, NM, MN. I.G. Exs. 26, 27.

56. Neither Pima County nor AMS received any compensation from Marion Laboratories for the Ditropan study. I.G. Ex. 9 at 20 - 21.

Other Findings of Fact and Conclusions of Law

57. On August 10, 1992, the State court issued a judgement of conviction, based on a jury verdict of June 23, 1992, finding Petitioner guilty of violating Arizona

criminal law. This action constitutes a "conviction" of Petitioner within the meaning of section 1128(i)(1) and(i)(2) of the Act. Findings 10 - 11.

58. Petitioner was convicted of a criminal offense related to the delivery of an item or service under Medicare and Medicaid, within the meaning of sections 1128(a)(1) and 1128(i) of the Act. Findings 1 - 57.

59. The Secretary of the Department of Health and Human Services has delegated to the I.G. the authority to determine, impose, and direct exclusions pursuant to section 1128 of the Act. 48 Fed. Reg. 21,662 (1983).

60. On March 23, 1993, the I.G. excluded Petitioner from participating in Medicare and directed that he be excluded from Medicaid, pursuant to section 1128(a)(1) of the Act.

61. The five-year exclusion imposed and directed against Petitioner by the I.G. is for the minimum period required by sections 1128(a)(1) and 1128(c)(3)(B) of the Act. Findings 57 - 58.

62. Neither the I.G. nor an administrative law judge has the authority to reduce the five-year minimum exclusion mandated by sections 1128(a)(1) and 1128(c)(3)(B) of the Act.

ANALYSIS

1. Petitioner was "convicted" within the meaning of sections 1128(a)(1) and 1128(i)(1) and (2) of the Act.

Section 1128(a)(1) of the Act requires that an individual be "convicted" of a criminal offense. The term "conviction" is defined in section 1128(i) of the Act. The applicable subsections of section 1128(i) are set forth below:

> (1) when a judgment of conviction has been entered against the individual or entity by a Federal, State, or local court, regardless of whether there is an appeal pending or whether the judgment of conviction or other record relating to criminal conduct has been expunged;
>
> (2) when there has been a finding of guilt against the individual or entity by a Federal, State, or local court.

Act, section 1128(i)(1) and (i)(2).

Petitioner admits that, on June 23, 1992, he was convicted based on charges of conflict of interest and fraudulent schemes and artifices. P. Br. at 2; Prehearing Order. Specifically, the record reflects that, on that date, a State court jury found petitioner guilty of two counts of violating A.R.S. § 13-2310 (counts two and three of the indictment, pertaining to fraudulent schemes and artifices) and two counts of violating A.R.S. § 38-503 (counts five and six of the indictment, pertaining to conflicts of interest in public employment). Finding 10. On August 10, 1992, the State court, based on that jury verdict against Petitioner, rendered a judgment imposing a fine and sentencing Petitioner to probation for two years. Finding 11. This judgment of the State court, based on the jury's finding of guilt, constitutes a "conviction" of Petitioner, within the meaning of section 1128(i)(1) and (2) of the Act. Finding 57.

Accordingly, I find that Petitioner was convicted, within the meaning of sections 1128(a)(1) and 1128(i) of the Act.

2. Petitioner was convicted of a criminal offense related to the delivery of an item or service under the Medicare and Medicaid programs.

Section 1128(a)(1) of the Act requires that Petitioner's criminal conviction be "program-related." Thus, the criminal offense for which Petitioner was convicted must be related to the delivery of an item or service under Medicare or Medicaid. The Act does not define the term "criminal offense related to the delivery of an item or service." However, a criminal offense has been held to meet the statutory test when there is a "common sense connection" between the criminal offense and the delivery of items or services under Medicare or Medicaid. Berton Siegel, D.O., DAB 1467, at 5 (1994); Thelma Walley, DAB CR207 (1992); Jack W. Greene, DAB 1078 (1989), aff'd sub nom. Greene v. Sullivan, 731 F. Supp. 835, 838 (E.D. Tenn. 1990); Larry W. Dabbs, R.Ph., et al., DAB CR151 (1991); Boris Lipovsky, M.D., DAB 1363 (1992).

A criminal offense has been held to meet the statutory test also where the unlawful conduct can be shown to affect an identifiable Medicare or Medicaid item or service or to affect reimbursement for such an item or service. Walley, DAB CR207 (1992); DeWayne Franzen, DAB 1165 (1990); Danny E. Harris, R.Ph., DAB CR166 (1991). A criminal offense has been held to meet the statutory test where either the Medicare or Medicaid program is the

victim of the crime. Napoleon S. Maminta, M.D., DAB 1135 (1990).

Petitioner's primary contention is that his offenses do not relate to the delivery of a health care item or service because the Arizona statutes under which he was convicted do not, on their face, state that his offenses are related to any State health care program. Petitioner's request for hearing, dated May 12, 1993. Petitioner contends further that the research for the Agent M study was conducted from September 1987 through December 1988, and, that, during this period, there was no Arizona long-term care program. He argues further that if there was a violation of AHCCCS' program, there should have been a policy outlining such procedure.

The I.G. contends that Petitioner was convicted of: (1) obtaining compensation from Marion Laboratories for the conduct of the Agent M and Ditropan drug studies by means of false or fraudulent pretenses, representations, promises, or material omissions; (2) failing to disclose to Pima County his private contract -- through ECL -- to conduct the drug studies; and (3) participating in the studies during his regular hours of employment with the County without official approval to do so. I agree with the I.G.'s contention that --

> [i]n establishing whether the relationship between an offense and the delivery of items or services under Medicare or Medicaid exists, . . . the I.G. is not bound by the four corners of the judgment but must look at the circumstances of the conviction and determine whether there is a "common sense connection" between the conduct for which Petitioner was convicted and the delivery of program-related items or services.

(citing Robert C. Greenwood, N.A., DAB 1423 (1993)). I.G. Br. at 17 - 18.

A. Medicare claims were paid for services required by the Agent M study protocol.

The I.G. argues that Petitioner's conviction is related to the delivery of an item or service under Medicare because Medicare patients participated in the experimental drug studies and that Medicare was billed for EKGs that were performed solely because of the patients' participation in the drug studies. Petitioner requested that the I.G. submit documentation "proving that I [Petitioner] subcontracted to do EKGs, that I took the EKGs, and that I billed Medicare for these EKGs, or

that I told anyone to bill Medicare." Petitioner's letter dated November 12, 1993. Such documentation of Petitioner's direct personal involvement in the program-related activities is unnecessary. I conclude that there is substantial evidence in the record to prove the relationship between Petitioner's conviction and the delivery of items or services. See Greene, DAB 1078 (1989) (a person may be guilty of a program-related offense even if he or she did not physically deliver items or services).

The protocol for the Agent M study required that each patient undergo clinical testing, which included an electrocardiogram or EKG. I.G. Ex. 12 at 10. The record indicates that Medicare was billed for EKGs performed solely for the purpose of complying with the Agent M study protocol. The record shows further that Medicare paid these claims on behalf of patients referred for EKGs performed in connection with their participation in the Agent M study. I.G. Ex. 18. There is no evidence that the EKGs were otherwise required for the diagnosis or treatment of these patients. The EKGs were performed only to be in compliance with the Agent M study protocol. Had Petitioner not participated in the actions for which he was convicted -- that is, illegally contracting for and conducting the Agent M study -- the EKGs would not have been done and Medicare would not have paid for them.

As the Departmental Appeals Board has explained, the task of the administrative law judge is to --

> examine all relevant conduct to determine if there is a relationship between the judgment of conviction and the Medicaid [or Medicare] program. Had Congress intended a different result, it would have used the phrase "conviction for" or conviction "restricted to" instead of "related to." An examination of whether a condition is "related to" Medicaid [or Medicare] necessarily involves an inquiry into Petitioner's conduct.

Franzen, DAB 1165, at 7 - 8, (quoting H. Gene Blankenship, DAB CR42, at 11 (1989)).

The Act does not require a conviction for Medicare or Medicaid program fraud to sustain a finding that the conviction is program-related. In this case, the criminal conduct for which Petitioner was convicted was directly related to the delivery of reimbursable but unnecessary Medicare services.

B. The drug studies were performed by on-duty nursing personnel whose salaries were paid, in part, by Medicaid.

Petitioner was the administrator of Clinical Nursing and Medical Services for Pima County's AMS. Finding 2. During this period, he also owned a private business -- ECL. Finding 4. In September 1987, Petitioner agreed to administer Agent M, an experimental drug, to designated AMS long-term care patients, beginning in April 1988. Findings 21, 23 - 29. His firm, ECL, received periodic payments for the study. Findings 30 - 31. Petitioner recruited Pima County AMS' nurse coordinators to take part in the Agent M study and they were paid by ECL. Finding 32. The AMS nurse coordinators were registered nurses who, as part of their regular duties as Pima County employees, oversaw the management of decubitus ulcers in facilities under contract with Pima County. Finding 33. The AMS nurse coordinators used a protocol developed by AMS which listed the different types of decubitus ulcers and choices of treatments -- Agent M was not included in the AMS protocol. Findings 34 - 35. The AMS nurse coordinators used the AMS protocol in the field to evaluate the ulcers and write appropriate treatments for the Agent M study. Finding 37. Petitioner directed and encouraged the nurse coordinators under his supervision to work on Pima County time while participating in the Agent M study, and he worked on Pima County time himself. Finding 38.

Petitioner agreed also, on behalf of ECL, to participate in a study for the drug Ditropan. Finding 45. Petitioner and members of his AMS nursing staff were listed as assistant investigators in the Ditropan study. Finding 48. The primary providers in the Ditropan study were the nurse practitioners, having responsibility for maintaining the books and doing the documentation for the study. Finding 50. Pima County did not give Petitioner approval to participate in the Agent M and Ditropan studies and Petitioner concealed his receipt of payments for the studies from the county. Findings 40, 53. Neither Pima county nor AMS received any payment for the Agent M or Ditropan studies. Findings 41, 56.

Effective October 1, 1982, the State of Arizona established a demonstration project under section 1115 of the Act. The project was designated AHCCCS. AHCCCS is funded by a combination of county, State, federal (which funding comes from the Title XIX (Medicaid) program), and private contributions. Finding 12; I.G. Br. at 4. Instead of the traditional Title XIX fee-for-service model, AHCCCS is a "prepaid capitated" system in which

contractors receive a designated sum each month for each person assigned to that contractor's program or plan. Finding 13; I.G. Br. at 4 - 5; see also Findings 14 - 18; I.G. Ex. 1 at 5 - 6, 11 - 12. AHCCCS expanded to cover long-term care services with the implementation of ALTCS, which program became effective on January 1, 1989. Finding 16; I.G. Ex. 5.

The I.G. asserts that Petitioner's conviction was related to the Medicaid program because the experimental drug studies which were found to have created a conflict of interest for Petitioner were performed by on-duty nursing personnel whose salaries were paid, in part, by Medicaid. I.G. Br. at 20 - 24. In support of this argument, the I.G. has offered a letter from the administrator of the Long Term Care Division of the Pima County Health System. I.G. Ex. 5. In that letter, the administrator asserts that Pima County received capitation payments from AHCCCS, a demonstration project which received Title XIX (Medicaid) funds, on behalf of nursing home residents who received medical services covered by AHCCCS. According to the administrator, these capitation payments, in part, covered the services of nurse service coordinators and nurse practitioners who were treating these patients.[7] I

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[7] Petitioner has contended that there were no Medicare or Medicaid programs in Arizona at the time he committed the offense for which he was convicted. Based on this assertion, he challenged the validity of the statements in I.G. Ex. 5 (a letter from the administrator of the Long Term Care Division of the Pima County Health System). Petitioner was advised in a conference call that his unsupported assertion about the funding for AHCCCS was insufficient to overcome the evidence submitted by the I.G. I gave Petitioner an opportunity to make a supplemental submission to support his claim. Petitioner submitted no evidence, but did argue that, by requiring him to supply such evidence, I had improperly placed the burden of proof on him. Moreover, Petitioner requested that the I.G. produce documents that would trace Medicaid funds to salary payments made to him and his nurses for work on the drug studies during the time he committed the offenses for which he was convicted. I ordered the I.G., pursuant to 42 C.F.R. § 1005.7, to turn over to Petitioner whatever documents in her possession were relevant to this issue. Order Re: Discovery, dated December 20, 1993. The I.G. replied on January 5, 1994, indicating that no documents existed other than I.G. Ex. 5. On January 24, 1994, Petitioner again contended that the I.G.'s exclusion action against him should be

(continued...)

conclude that Petitioner's illegal conflict of working on drug studies while he and those he supervised were being paid by Pima County is related to the Medicaid program because Petitioner's salary, and the salary of his subordinates, was paid for from AHCCCS capitation payments received by Pima County from Arizona's Medicaid program, AHCCCS, or, after January 1, 1989, from ALTCS. Specifically, the record shows that, for at least one month during the Agent M study, Pima County received acute care capitation payments from AHCCCS on behalf of six patients. Finding 42. Thus, Medicaid did, via AHCCCS, pay for services for participants in the Agent M study. These services should not have been reimbursed by Medicaid.

Petitioner queries also whether patients have a right to participate in drug studies without receiving permission from Medicare, Medicaid, or AHCCCS. Petitioner's question, however, has no bearing on the issue of whether his criminal offenses are program-related. Examination of Petitioner's conduct shows that what Petitioner did was to interfere with the treatment plan already implemented by these patients' treating physicians. These patients unknowingly became Petitioner's pawns. Not only were they denied prescribed treatment by their treating physician, but Agent M was substituted as the treatment of record. Moreover, some of the patients received placebos, which means that they were not receiving any medication at all for their bedsores. I find Petitioner's use of these patients for his own personal gain, and his interference with their treatment, to be reprehensible. Further, if such action on Petitioner's part was not enough, Medicaid payments (via AHCCCS) were made on behalf of these patients for at least one month while these patients received Agent M. Thus, there is a common sense connection between Petitioner's criminal offense and the delivery of items or services under Medicaid.

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[7](...continued)
dismissed, but he offered no additional evidence to support his prior assertions regarding Medicaid funding. An unsupported assertion is insufficient to place a fact in dispute. Requiring Petitioner to substantiate his assertion did not place the burden of proof on him. It remains on the I.G. Petitioner was given ample opportunity to support his contention with evidence. Discovery was afforded him. No evidence was ever submitted. Thus, the I.G.'s evidence relating to the existence of Medicaid funding remains unrefuted.

Finally, Petitioner attempts to rebut the program-relatedness of his conviction by arguing that Marion Laboratories never sought restitution from him for monies paid for his involvement in the drug studies because it was satisfied with his work. P. Br. at 2; P. Ex. 1. He argues also that Marion Laboratories is not related to Medicare or any State programs. P. Br. at 3. Petitioner's arguments completely miss the point. Marion Laboratories failure to seek restitution is irrelevant for purposes of determining whether Petitioner's criminal offenses are program-related. Similarly, there is no need to establish Marion Laboratories connection with program activities. Petitioner, not Marion Laboratories, is the subject of the I.G.'s five-year exclusion. The only nexus that is relevant to Petitioner's exclusion is his relationship to the Medicare or Medicaid program. Under the applicable case law, the required relationship has been established by this record.

3. The I.G. was required to exclude Petitioner for a minimum period of five years.

Petitioner was convicted of a criminal offense relating to the delivery of an item or service under the Medicare and Medicaid programs, within the meaning of section 1128(a)(1) of the Act. Thus, the I.G. has authority to impose and direct an exclusion against Petitioner pursuant to sections 1128(a)(1) and 1128(c)(3)(B) of the Act. Congress has mandated that the minimum period of exclusion be five years.

CONCLUSION

Based on the undisputed material facts, the evidence, and the law, I conclude that Petitioner was convicted of a criminal offense, within the meaning of section 1128(a)(1) of the Act. I conclude further that the I.G.'s determination to exclude Petitioner from participation in Medicare and to direct that Petitioner be excluded from Medicaid for five years is mandated by law. Therefore, I sustain Petitioner's five-year exclusion.

/s/

Edward D. Steinman
Administrative Law Judge