# Department of Health and Human Services

# DEPARTMENTAL APPEALS BOARD

## Civil Remedies Division

In the Case of:

Thomas Andrew Hunter,

Petitioner,

- v. 
The Inspector General.

DATE: July 5, 1991

Docket No. C-337

Decision No. CR140

### **DECISION**

On December 21, 1990, the Inspector General (I.G.) notified Petitioner that he was being excluded from participation in the Medicare program and any State health care program for a period of five years. The I.G. told Petitioner that his exclusion was due to his conviction of a criminal offense within the meaning of section 1128(b)(3) of the Social Security Act (Act).

Petitioner timely requested a hearing, and the case was assigned to me for a hearing and decision. On April 2, 1991, I held a hearing in this case in Charlotte, North Carolina.

I have considered the evidence, the parties' arguments, and the applicable laws and regulations. I conclude that Petitioner has demonstrated by his conduct that he is not a trustworthy provider of health care and that an exclusion is merited in this case. I conclude further that, in light of the evidence, the five-year exclusion imposed and directed against Petitioner is reasonable. Therefore, I affirm the exclusion.

<sup>1 &</sup>quot;State health care program" is defined by section 1128(h) of the Social Security Act to cover three types of federally-financed health care programs, including Medicaid. I use the term "Medicaid" hereafter to represent all State health care programs from which Petitioner was excluded.

#### ISSUE

The issue in this case is whether the five-year exclusion which the I.G. imposed and directed against Petitioner is reasonable.

### FINDINGS OF FACT AND CONCLUSIONS OF LAW

- Petitioner is a pharmacist licensed to practice pharmacy in the State of North Carolina. ALJ Ex. 1; Tr. at 220.
- Beginning in 1986, Petitioner was one of the proprietors of the Monroe Family Pharmacy in Monroe, North Carolina. Tr. at 221-222.
- Petitioner was the head pharmacist and sole manager and supervisor at the Monroe Family Pharmacy. Tr. at 65, 221-222.
- 4. On October 2, 1989, an indictment was filed against Petitioner in the United States District Court for the Western District of North Carolina. ALJ Ex. 1; I.G. Ex. 1/1.
- Petitioner was charged in the indictment with five counts of knowingly, willfully, and unlawfully distributing controlled substances and three counts of knowingly, willfully, and unlawfully making and causing to be made false statements and representations of material facts in a claim made to the North Carolina Medicaid program. ALJ Ex. 1; I.G. Ex. 1/1-4.
- On February 27, 1990, the district court accepted Petitioner's quilty plea to count three of the indictment. I.G. Ex. 3/1.
- Petitioner pleaded guilty to knowingly, willfully, and unlawfully distributing 50 dosage units (2.5 milligrams each) of Diphenatol, a Schedule V narcotic

I.G. Exhibit I.G. Ex. (number)/(page)

Petitioner Exhibit P. Ex. (number)/(page)

ALJ Exhibit ALJ Ex. 1

Transcript Tr. at (page)

The exhibits and transcript of the hearing will be referred to as follows:

- controlled substance, in violation of 21 U.S.C. 841(a)(1). I.G. Ex. 3/1.
- 8. Petitioner was sentenced to one year of probation, payment of a fine of \$5,000.00, and payment of restitution to the State of North Carolina in the amount of \$1,066.00. I.G. Ex. 3/1.
- 9. Petitioner was additionally sentenced to surrender his pharmacy license to the North Carolina Pharmacy Board (Pharmacy Board) for one year and to not practice pharmacy for a period of one year, beginning with the date of his sentence. I.G. Ex. 3/1.
- 10. In October, 1990, the Pharmacy Board conducted a disciplinary hearing concerning Petitioner, based on Petitioner's plea of guilty to count three of the federal criminal indictment. Tr. at 145-148.
- 11. The Pharmacy Board concluded that Petitioner's conduct did not constitute a violation of North Carolina law, nor did it constitute a basis in fact for his guilty plea. P. Ex. 3/3.
- 12. A "controlled substance" is a "drug or other substance or immediate precursor, included in schedule I, II, IV, or V of [21 U.S.C. 812]." 21 U.S.C. 811(a)(1)(A), (C).
- 13. Drugs or other substances listed in Schedules I through V have a potential for abuse. See Tr. at 57.
- 14. The lower the number of the schedule in which a controlled substance is listed, the less the medical value of that substance, and the greater the potential for abuse. Tr. at 57.
- 15. The drug Diphenatol is also known by its brand name of Lomotil. I.G. Ex. 1.
- 16. On October 1, 1987, an individual requested Petitioner to refill a prescription for Lomotil 2.5 milligram tablets. I.G. Ex. 13/6.
- 17. Petitioner recognized the prescription as one which originally had been ordered by a physician, Dr. Eugene F. Hamer. I.G. Ex. 13/6.
- 18. Dr. Hamer died on July 26 1987, and Petitioner knew on October 1 1987, that Dr. Hamer was dead. I.G. Ex. 13/6.

- 19. Prior to his death, Dr. Hamer conversed with Petitioner and asked Petitioner to take care of his patients after he died. I.G. Ex. 13/7.
- 20. Petitioner knew that there were no refills authorized for the prescription for Lomotil which Dr. Hamer's former patient presented to him on October 1, 1987. I.G. Ex. 13/6.
- 21. Petitioner nonetheless sold Lomotil to the former patient. I.G. Ex. 13/6.
- 22. In order to document the sale of Lomotil as a legitimate prescription, Petitioner created a prescription, number 4006439, which he recorded as part of his computerized records. I.G. Ex. 13/6.
- 23. Petitioner filled other prescriptions after Dr. Hamer died, as having been ordered by Dr. Hamer. I.G. Ex. 13/7-8, 17/1-7, 21; Tr. at 257-258.
- 24. Among the other prescriptions which Petitioner filled after Dr. Hamer died as having been ordered by Dr. Hamer was a prescription for Valium. I.G. Ex. 13-7.
- 25. Valium is a Schedule IV controlled substance. I.G. Ex. 10/2, 4.
- 26. Petitioner's assertion that the prescriptions which he filled as having been ordered by Dr. Hamer had been specifically ordered by Dr. Hamer by telephone prior to his death is not credible. I.G. Ex. 13/1, 17/1-5; Tr. at 60-62, 96; See Tr. at 227-228, 251; See 21 C.F.R. 1304.04, 1306.05, 1306.21.
- 27. On March 21 1988, Petitioner caused to be presented a Medicaid reimbursement claim for the sale of Chronulac syrup to James Yarborough, a Medicaid recipient. I.G. Ex. 11/4.
- 28. Although Petitioner's records contain a record of a prescription for Chronulac syrup to James Yarborough dated November 13, 1987, Chronulac syrup was not prescribed to James Yarborough on that date or on other dates when James Yarborough visited a physician. I.G. Ex. 11/1; Tr. at 170-171.
- 29. The claim which Petitioner caused to be presented on March 21, 1988, for Medicaid reimbursement for the sale of Chronulac syrup to James Yarborough is false in that it purports to be for a prescription ordered by a physician. Findings 27 and 28.

- 30. Petitioner agreed, as a provider of Medicaid items or services, to be responsible for the accuracy and truthfulness of all claims for Medicaid reimbursement which he submitted or caused to be submitted. Tr. at 180, 182.
- 31. Petitioner is not absolved from his responsibility for the accuracy and truthfulness of claims for Medicaid reimbursement which he presented or caused to be presented by delegating the duty to prepare and present claims to an employee under his supervision. <u>See</u> Tr. at 180.
- 32. The I.G. did not prove that Petitioner knew that the Medicaid claim he caused to be presented on March 21, 1988, for the sale of Chronulac syrup to James Yarborough, was false. See Findings 27-31.
- 33. The I.G. proved that Petitioner was negligent in the presentation, on March 21, 1988, of the false claim for the sale of Chronulac syrup to James Yarborough. Findings 27-31.
- 34. On August 14 1986, Petitioner filled a prescription, #4001000, for 60 tablets of Tylenol #4 with codeine, for a customer named Betty Simpson. I.G. Ex. 18/6.
- 35. The prescription specified that there were to be no refills. I.G. Ex. 18/6.
- 36. Petitioner refilled prescription #4001000 on August 23, August 27, and September 3, 1986, despite the specification that no refills be made. I.G. Ex. 18/39.
- 37. Tylenol with codeine tablets are a Schedule III controlled substance. I.G. Ex. 10/47.
- 38. Codeine can produce drug dependence of the morphine type, and therefore has the potential for being abused. Psychic dependence, physical dependence, and tolerance may develop upon repeated administration of the drug, and it should be prescribed and administered with the same degree of caution appropriate to the use of other oral narcotic-containing medications. I.G. Ex. 10/47.
- 39. On June 24, 1987, Petitioner recorded prescription #4005032 for 60 tablets of Tylenol #4 with codeine, for Betty Simpson. I.G. Ex. 18/53.

- 40. Petitioner's records stated that prescription #4005032 was a "dummy," meaning that it was a void prescription that had not been filled and should not be refilled. I.G. Ex. 18/54; Tr. at 212-213, 215, 216-217.
- 41. Despite the fact that prescription #4005032 was a "dummy," Petitioner filled the prescription and refilled it on four subsequent occasions. I.G. Ex. 18/55-58; Tr. at 216-217.
- 42. Petitioner knew that Betty Simpson was addicted to codeine. Tr. at 245.
- 43. The I.G. proved that Petitioner sold Tylenol #4 with codeine, a Schedule III controlled substance which had not been prescribed by a physician, to Betty Simpson. Findings 34-42.
- 44. Petitioner either knew, had reason to know, or should have known that his refilling of prescription #4001000 and his filling and refilling of prescription #4005032 were not authorized by a physician. Findings 34-43.
- 45. A Schedule II controlled substance must normally be sold by a pharmacist only pursuant to a written prescription, filled out and signed by a physician in advance of the sale. 21 C.F.R. 1306.11(a).
- 46. A pharmacist may sell a Schedule II controlled substance based on the oral prescription of a physician only in an emergency. I.G. Ex. 23/1; Tr. at 68; 21 C.F.R. 1306.11(d).
- 47. A pharmacist may sell a Schedule II controlled substance based on the oral prescription of a physician only in a quantity limited to an amount adequate to deal with an emergency. 21 C.F.R. 1306.11(d)(1), (2).
- 48. A physician who orally prescribes a Schedule II controlled substance must, within 72 hours of prescribing it, send a written prescription to the pharmacist who fills the prescription. I.G. Ex. 23/1; Tr. at 68-69; 21 C.F.R. 1306.11(d)(4).
- 49. If the pharmacist who fills an oral prescription for a Schedule II controlled substance does not receive a written prescription from the prescribing physician within 72 hours from the time of the prescription, he or she must notify the Drug Enforcement Administration (DEA). I.G. Ex. 23/1; Tr. at 68-69; 21 C.F.R. 1306.11(d)(4).

- 50. Between 1986 and 1988, Monroe Family Pharmacy filled over 900 oral prescriptions for more than 23,000 dosage units of Schedule II controlled substances. I.G. Ex. 23/1-2; Tr. at 58, 69.
- 51. Of these prescriptions, 590 were filled by Petitioner. I.G. Ex. 23/1.
- 52. None of these prescriptions were designated as "emergency" prescriptions. I.G. Ex. 23/1; Tr. at 69.
- 53. Many of the oral prescriptions for Schedule II controlled substances which were filled at the Monroe Family Pharmacy were signed by the prescribing physician after they had been filled. I.G. Ex. 23/1-2; Tr. at 69, 247.
- 54. Some of the oral prescriptions for Schedule II controlled substances which were filled at the Monroe Family Pharmacy were signed by a physician other than the physician who ordered the prescriptions. I.G. Ex. 23/2, 23/12-19.
- 55. Nineteen prescriptions for Schedule II controlled substances which were filled by Petitioner were never signed by a physician. I.G. Ex. 23/2,4-11; Tr. at 70, 211-212, 261.
- 56. The I.G. proved that Petitioner knew or should have known that he authorized the filling of prescriptions for Schedule II controlled substances in violation of legal requirements. Findings 45-55.
- 57. Petitioner was convicted of a criminal offense relating to the unlawful distribution, prescription, or dispensing of a controlled substance, within the meaning of section 1128(b)(3) of the Act. Social Security Act, section 1128(b)(3).
- 58. The Secretary of Health and Human Services (Secretary) delegated to the I.G. the authority to determine, impose, and direct exclusions pursuant to section 1128 of the Act. 48 Fed. Reg. 21662 (May 13, 1983).
- 59. On December 21, 1990, the I.G. excluded Petitioner from participating in Medicare and directed that he be excluded from participating in Medicaid, pursuant to section 1128(b)(3) of the Act.
- 60. The exclusion imposed and directed against Petitioner is for five years.

- 61. The remedial purpose of section 1128 of the Act is to protect the integrity of federally-funded health care programs from individuals and entities who have been shown to be untrustworthy. Social Security Act, section 1128.
- 62. Petitioner engaged in a criminal act that jeopardized the health and safety of an individual. Findings 7, 12-23.
- 63. The I.G. proved that, between 1986 and 1988, Petitioner made unauthorized or unlawful sales of controlled substances which jeopardized the health and safety of individuals. Findings 24-26, 34-56; See 42 C.F.R. 1001.125(b)(2).
- 64. The I.G. proved that Petitioner made unauthorized or unlawful sales of controlled substances on numerous occasions over a nearly two-year period. Findings 7, 12-26, 34-56; See 42 C.F.R. 1001.125(b)(1).
- 65. The I.G. did not prove that Petitioner willfully made unauthorized or unlawful sales of controlled substances for personal gain.
- 66. The I.G. proved that Petitioner was either negligent or reckless with respect to the manner in which he made sales of controlled substances. Findings 44, 56.
- 67. Petitioner refuses to acknowledge the wrongfulness of his acts or the adverse impact that his acts may have had on individuals. <u>See</u> Tr. at 229, 238, 240-242, 245-246.
- 68. Petitioner, by his acts and his failure to comprehend the wrongfulness of his acts or the potential harm of his acts, has demonstrated that he cannot be trusted to deal with beneficiaries and recipients of federally-funded health care programs.
- 69. An exclusion is needed in this case to protect the beneficiaries and recipients of federally-funded health care programs from future harm by Petitioner.
- 70. The five-year exclusion imposed and directed against Petitioner by the I.G. is reasonable.

#### ANALYSIS

The parties do not dispute that Petitioner was convicted of a criminal offense within the meaning of section 1128(b)(3) of the Act. The I.G. therefore was authorized by section 1128(b)(3) to impose and direct an exclusion against Petitioner. The issue which I must decide is the reasonableness of the five-year exclusion which the I.G. imposed and directed against Petitioner.

Section 1128 is a civil remedies statute. The remedial purpose of section 1128 is to enable the Secretary to protect federally-funded health care programs and their beneficiaries and recipients from individuals and entities who have proven by their misconduct that they are untrustworthy. Exclusions are intended to protect against future misconduct by providers.

Federally-funded health care programs are no more obligated to deal with dishonest or untrustworthy providers than any purchaser of goods or services would be obligated to deal with a dishonest or untrustworthy supplier. The exclusion remedy allows the Secretary to suspend his contractual relationship with those providers of items or services who are dishonest or untrustworthy. The remedy enables the Secretary to assure that federally-funded health care programs will not continue to be harmed by dishonest or untrustworthy providers of items or services. The exclusion remedy is closely analogous to the civil remedy of termination or suspension of a contract to forestall future damages from a continuing breach of that contract.

Exclusion may have the ancillary benefit of deterring providers of items or services from engaging in the same or similar misconduct as that engaged in by excluded providers. However, the primary purpose of an exclusion is the remedial purpose of protecting the trust funds and beneficiaries and recipients of those funds. Deterrence cannot be a primary purpose for imposing an exclusion. Where deterrence becomes the primary purpose, section 1128 no longer accomplishes the civil remedies objectives intended by Congress. Punishment, rather than remedy, becomes the end.

[A] civil sanction that cannot fairly be said solely to serve a remedial purpose, but rather can be explained only as also serving either retributive or deterrent purposes, is punishment, as we have come to understand the term.

<u>United States v. Halper</u>, 490 U.S. 435, 448 (1989).

Therefore, in determining the reasonableness of an exclusion, the primary consideration must be the degree to which the exclusion serves the law's remedial objective of protecting program recipients and beneficiaries from untrustworthy providers. An exclusion is not excessive if it reasonably serves these objectives.

The hearing in an exclusion case is, by law, de novo. Social Security Act, section 205(b). Evidence which is relevant to the reasonableness of the length of an exclusion will be admitted in a hearing on an exclusion whether or not that evidence was available to the I.G. at the time the I.G. made his exclusion determination. Evidence which relates to a petitioner's trustworthiness or the remedial objectives of the exclusion law is admissible at an exclusion hearing even if that evidence is of conduct other than that which establishes statutory authority to exclude a petitioner. In this case, for example, Petitioner pleaded guilty to a single count of unlawful sale of a controlled substance. However, the I.G. offered evidence as to misconduct by Petitioner beyond the ambit of that offense, which I received. also permitted Petitioner to offer evidence as to his trustworthiness which did not strictly relate to his plea of guilty.

The purpose of the hearing is not to determine how accurately the I.G. applied the law to the facts before him, but whether, based on all relevant evidence, the exclusion comports with legislative intent. In this case, the I.G. offered the testimony of his agent, Marian Turner, to show what factors she considered in making her exclusion recommendation to the I.G. See Tr. 21-27. Petitioner extensively cross-examined Ms. Turner for the purpose of showing that, in making her recommendation, she omitted to consider factors which she should have See Tr. at 27-44. taken into consideration. Ms. Turner's testimony essentially to be irrelevant. Because of the <u>de</u> <u>novo</u> nature of the hearing, my duty is to objectively determine the reasonableness of the exclusion by considering what the I.G. determined to impose in light of the statutory purpose and the evidence which the parties offer and I admit. The I.G.'s thought processes in arriving at his exclusion determination are not relevant to my assessment of the reasonableness of the exclusion.

Furthermore, my purpose in hearing and deciding the issue of whether an exclusion is reasonable is not to second-guess the I.G.'s exclusion determination, but to decide whether the determination was extreme or excessive. 48

Fed. Reg. 3744 (Jan. 27, 1983). Should I determine that an exclusion is extreme or excessive, I have authority to modify the exclusion, based on the law and the evidence. Social Security Act, section 205(b).

The Secretary has adopted regulations to be applied in exclusion cases. The regulations specifically apply to exclusion cases for "program-related" offenses (convictions for criminal offenses relating to Medicare or Medicaid). The regulations express the Secretary's policy for evaluating cases where the I.G. has discretion in determining the length of an exclusion. The regulations require the I.G. to consider factors related to the seriousness and program impact of the offense and to balance those factors against any factors that may exist demonstrating trustworthiness. 42 C.F.R. 1001.125(b)(1) - (7).

Petitioner engaged in a pattern of misconduct which demonstrates that he is not a trustworthy provider of health care. The I.G. proved that, over an approximately two-year period, Petitioner persistently violated federal laws and regulations concerning the sale of controlled substances. What is more disturbing, however, is Petitioner's refusal to admit that he committed violations, even when confronted with overwhelming evidence to the contrary. Petitioner refuses to acknowledge even the possibility that his conduct could have adversely affected the health or safety of his In light of this refusal, I conclude that customers. Petitioner is untrustworthy and that a five-year exclusion is needed to provide reasonable protection to the well-being of program beneficiaries and recipients.

Petitioner was the owner and manager of a pharmacy. Beginning in April, 1988, Petitioner was investigated by agents of the DEA for purposes of determining whether Petitioner violated federal laws concerning his sale of controlled substances.

The DEA investigation established numerous and substantial improprieties by Petitioner in his sale of controlled substances. Petitioner admitted that he had sold controlled substances to former patients of Dr. Hamer, a physician who was deceased, based on a request by that physician, prior to his death, that Petitioner take care of his patients. Findings 16-26. Petitioner eventually pleaded guilty to a criminal charge emanating

<sup>&</sup>lt;sup>3</sup> Petitioner also negligently presented at least one false Medicaid claim. Findings 27-33.

from his unauthorized sale of a controlled substance to a patient of the dead physician. Findings 6-8. It was also established that Petitioner had sold substantial amounts of Tylenol with codeine, a potentially addictive Schedule III controlled substance, to a customer without having received proper authorization from a physician for such sales. Findings 34-44. Petitioner knew that this customer was addicted to codeine. Finding 42.

The DEA investigation also established massive irregularities in Petitioner's sale of Schedule II controlled substances. Federal regulations require that, except in emergencies, Schedule II controlled substances not be dispensed by a pharmacist without the pharmacist first having received a written prescription from a provider. These regulations reflect the potential for abuse of Schedule II controlled substances and the potential harm to the well-being of consumers that may result from misuse of such substances. Regulations additionally require that in an emergency where a Schedule II controlled substance is dispensed pursuant to an oral prescription, the prescribing provider must subsequently provide the dispensing pharmacist with a written prescription. If a written prescription is not made within 72 hours, the dispensing pharmacist is required to notify the DEA. 21 C.F.R. 1306.11(d); Findings 45-49.

Petitioner ignored these regulations. Over a two-year period, Petitioner filled over 900 prescriptions for Schedule II controlled substances based on "call-in" (oral) prescriptions. There is no evidence to establish that even a small percentage of these prescriptions was ordered and filled in emergencies. Although Petitioner did obtain after-the-fact written authorizations for most of these prescriptions, there were instances where no written provider authorization was obtained. Finding 55. Petitioner did not notify the DEA in any of these instances.<sup>4</sup>

<sup>4</sup> The I.G. also asserted, based on the DEA investigation of Petitioner, that there were numerous other irregularities in Petitioner's sale of controlled substances in addition to those which I find to have occurred. I have not made specific findings concerning each of these other alleged irregularities, because I conclude from my review of the evidence that they were not substantiated. For example, the I.G. alleged that Petitioner sold controlled substances to a customer, Esther Hathaway, allegedly based on call-in prescriptions from a physician, Dr. Harley. See I.G.'s Post-Hearing

Petitioner contends that the North Carolina Pharmacy Board found that he was not guilty of the criminal offense to which he pleaded. <u>See</u> Findings 9-11. Therefore, according to Petitioner, I should attach little weight to his guilty plea in determining his trustworthiness as a health care provider.

I have considered both the decision of the Pharmacy Board and the testimony of Mr. Work, the Pharmacy Board's Executive Director. I conclude that the Pharmacy Board's decision is of little weight in assessing Petitioner's trustworthiness as a health care provider. My obligation to hear and decide the issue of the reasonableness of the exclusion imposed and directed against Petitioner is independent of any obligations assumed and discharged by the Pharmacy Board. Section 205(b) of the Social Security Act vests in me the duty to independently assess the evidence on the issue of trustworthiness.<sup>5</sup>

The Pharmacy Board conducted a disciplinary hearing concerning Petitioner's pharmacy license in the aftermath of his pleading guilty to the unlawful sale of a controlled substance. The Pharmacy Board considered the narrow question of whether Petitioner's sale of drugs to

Brief at 20-21. According to the I.G., Dr. Harley was not licensed to practice in North Carolina and denied having called in prescriptions to the Monroe Family Pharmacy for Ms. Hathaway. Therefore, according to the I.G., Petitioner unlawfully sold controlled substances to Esther Hathaway. The evidence relied on by the I.G. to substantiate this assertion is a hearsay account of an interview of Dr. Harley by a DEA agent. No statement by Dr. Harley was offered by the I.G., either in the form of live testimony or a sworn affidavit. Absent some corroboration from Dr. Harley, I conclude that the account of the interview by the DEA agent is of insufficient probity to substantiate the I.G.'s allegation.

by contrast, the doctrine of collateral estoppel would apply to the decision of a state court or a state licensing agency in deciding whether the Secretary had derivative authority to impose an exclusion pursuant to one of the subsections of section 1128 of the Act. The Secretary derives his authority to impose and direct exclusions from actions by state courts and agencies, and not from the conduct which motivated these courts and agencies to take action. See Andy E. Bailey, C.T., DAB Civ. Rem. C-110 (1989), aff'd DAB App. 1131 (1990); John w. Foderick, M.D., DAB App. 1125 (1990).

former patients of Dr. Hamer was a crime. The Pharmacy Board did not make extensive findings of fact or conclusions of law. See P. Ex. 2, 3; I.G. Ex. 6. The Pharmacy Board evidently chose to discount both Petitioner's written statements to DEA agents and his plea of guilty to a criminal offense.

I disagree with the Pharmacy Board's conclusion. My conclusion is that not only did Petitioner admit his guilt, but that the I.G. offered evidence which proved that Petitioner knowingly sold controlled substances to former patients of Dr. Hamer without prescriptions required by law. Findings 16-26.

There is a pattern to the manner in which Petitioner sold controlled substances. The I.G. has not proven that Petitioner was motivated by venality to make unauthorized sales or sales which contravened federal regulations. The I.G. established that Petitioner was indifferent to his obligations to maintain strict controls over the manner in which he dispensed controlled substances. I have no doubt that Petitioner did not consider his acts to have been wrongful. I accept Petitioner's explanation that his acts were motivated by good intentions. However, his acts were illegal, and they were not excused by whatever benign intentions Petitioner may have had.

Initially, Petitioner told the DEA agents that his unauthorized sale of drugs after Dr. Hamer's death to Dr. Hamer's patients as a humanitarian gesture intended to assure that the patients continued to receive necessary medications. I accept Petitioner's initial explanation for his acts. However, Petitioner's explanation does not suggest that he can now be trusted to sell controlled substances in compliance with applicable laws and regulations. To the contrary, it suggests that Petitioner is capable of placing himself above the law, when he views the law's requirements as hindering the performance of what he views as his duties to his customers.

<sup>&</sup>lt;sup>6</sup> At the hearing, Petitioner offered a different explanation for the sale of drugs to Dr. Hamer's patients than that which he had given to the DEA agents. He contended that, in fact, Dr. Hamer had explicitly called in prescriptions for these drugs, shortly prior to his death. Therefore, according to Petitioner, he had done nothing illegal inasmuch as he had merely filled valid prescriptions. I find that this explanation is not credible. It directly contradicts statements which Petitioner signed at the time of the investigation. I.G.

Petitioner explained his unauthorized sale of Tylenol with codeine to a customer also as having been motivated by humanitarian considerations. Tr. at 245-246. Essentially, Petitioner asserted that he was trying to help this addicted person by monitoring and controlling her access to codeine. This explanation is uncontradicted and I accept it. However, it again demonstrates that Petitioner is indifferent to the requirements of law when those requirements conflict with his concept of his role as a pharmacist.

Finally, Petitioner explained his sale of Schedule II controlled substances based on call-in prescriptions as emanating from the close relationship he maintained with physicians whose offices were adjacent to his pharmacy. Tr. at 245-246. Petitioner did not deny that he knew that he was obligated under federal law to obtain advance written prescriptions for the sale of Schedule II controlled substances. From Petitioner's standpoint, the relationship of mutual trust evidently obviated the need to comply with federal regulations. Petitioner admitted that he changed the manner in which he sold Schedule II controlled substances only after he was directed to do so by DEA agents. As with Petitioner's other explanations for his conduct, this explanation demonstrates an indifference to the requirements of law. And although Petitioner's indifference may have been motivated by what he considered to be benign and practical considerations, it nonetheless establishes a propensity in Petitioner to ignore the requirements of law when he decides that they are inconvenient.

Federal laws and regulations concerning the sale of controlled substances reflect a legislative conclusion that these substances are potentially dangerous to the health and safety of consumers. Because of the potential for harm and abuse, Congress has decided that the sale of controlled substances must be strictly regulated. Undoubtedly the laws and regulations work at times to inconvenience providers, pharmacists, and consumers. But any inconvenience which results to these parties reflects the legislative determination that strict controls <u>must</u>

Ex. 13/6-7. It is not supported by any written evidence of call-in prescriptions from Dr. Hamer. Furthermore, I find not credible Petitioner's testimony that he did not understand the meaning of the written statements which he had given to I.G. agents. The statements were written in plain English. Petitioner is an educated person. There is nothing about those statements which suggests that Petitioner misunderstood what he signed.

be maintained for the public good. No individual has the right to exempt himself from inconvenient aspects of this system of controls, regardless of his motivation.

What most disturbs me about this case is that Petitioner demonstrates no understanding that his contravention of law and regulations potentially could cause great harm to those customers who relied on him. Petitioner has not satisfied me that he would not in the future violate laws and regulations concerning the sale of controlled substances in circumstances where he found compliance to be inconvenient. I draw the inference from Petitioner's testimony and his demeanor that to this day he does not accept his responsibility to comply with federal laws and regulations governing the sale of controlled substances where to do so might conflict with his perception of his duty to his customers. He did not acknowledge at any point in his testimony that he had done something wrong. Indeed, he rejected even the conclusion that he was actually quilty of the criminal offense to which he had entered a guilty plea. Furthermore, Petitioner sees himself as a victim of government harassment, rather than as one who repeatedly has failed to comply with his legal duties as a pharmacist. See Tr. at 254-255.7

In reaching this conclusion concerning Petitioner's propensity to disregard the requirements of law, I have considered the evidence which Petitioner offered concerning his trustworthiness and character. Petitioner offered the testimony of his minister, as well as the testimony of a former employee at Monroe Family Pharmacy, and that of a personal friend, to the effect that he was a highly moral, honest, and trustworthy individual. I find the testimony of these individuals credible insofar as it concerns Petitioner's personal honesty. However, none of this evidence derogates from my conclusion that Petitioner is an untrustworthy health care provider.

This case contrasts with the case of <u>Kenneth Behymer, M.D.</u>, DAB Civ. Rem. C-140 (1990). The petitioner in <u>Behymer</u> had unlawfully prescribed a controlled substance. As with the case of Petitioner's conduct herein, Dr. Behymer's act was motivated by what he considered at the time to be humanitarian considerations. However, unlike Petitioner, Dr. Behymer had engaged in an isolated episode of misconduct. Furthermore, I was persuaded by the evidence in that case that there was no likelihood that Dr. Behymer would in the future engage in unlawfully prescribing controlled substances. Therefore, I found the exclusion to be excessive and I modified it.

While it is evident that Petitioner is a highly moral person, it is equally evident that he manifests a certain contempt for law and regulations which he views as conflicting with his sense of duty. It is precisely because Petitioner is capable of contravening the law when he finds the law to be a hindrance, and because he does not accept the wrongfulness of such conduct, that I find Petitioner to be untrustworthy.

I conclude that the five-year exclusion imposed and directed against Petitioner by the I.G. is not extreme or excessive, in light of Petitioner's absence of trustworthiness. Petitioner manifests a propensity to engage in conduct which could jeopardize the health and safety of program beneficiaries and recipients. I have no assurance that Petitioner will not repeat this conduct if afforded the opportunity to do so.

#### CONCLUSION

Based on the law and the evidence, I conclude that the five-year exclusion from participating in Medicare and Medicaid imposed and directed against Petitioner was reasonable. Therefore, I sustain the exclusion.

/s/

Steven T. Kessel Administrative Law Judge