Department of Health and Human Services

DEPARTMENTAL APPEALS BOARD

Civil Remedies Division

In the Case of:	)	
	)	
Robert Matesic, R.Ph., d/b/a Northway Pharmacy,	)	DATE: October 18, 1991
	)	
Petitioner,	)	
	)	Docket No. C-270
- v. -	)	
	)	Decision No. CR158
The Inspector General.	)	
	)	

DECISION

In this case, governed by section 1128 of the Social Security Act (Act), the Inspector General (I.G.) of the United States Department of Health and Human Services notified Petitioner, Robert Matesic, R.Ph., d/b/a Northway Pharmacy (Pharmacy), by letter dated May 21, 1990, that both he and the Pharmacy would be excluded from participation in the Medicare and Medicaid programs for a period of five years.[1] The I.G. further advised Petitioner that his exclusion was due to his conviction in the Allegheny County Court of Common Pleas, Pittsburgh, Pennsylvania, of a criminal offense related to the unlawful manufacture, distribution, prescription, or dispensing of a controlled substance. Petitioner was informed that exclusions from the Medicare and Medicaid programs after such a conviction are authorized by section 1128(b)(3) of the Act.

Petitioner requested a hearing before an Administrative Law Judge (ALJ) to contest his exclusion. I held a prehearing conference in this case on October 17, 1990. During the conference, the parties requested that this

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[1] The Medicaid program is one of three types of federally-financed State health care programs from which Petitioner is excluded. I use the term "Medicaid" to represent all three of these programs, which are defined in section 1128(h) of the Act.

case be decided upon a written record. I established a schedule for filing motions, briefs, and documentary evidence (exhibits). Thereafter, the parties filed their motions, briefs, and exhibits. Subsequently, Petitioner requested an in-person evidentiary hearing. Prior to the hearing, Petitioner filed a motion in limine.[2] I held an in-person evidentiary hearing in this case on February 15, 1991 in Pittsburgh, Pennsylvania.

I have considered the evidence in the record, the parties' arguments, and the applicable laws and regulations. I conclude that the I.G.'s determination to exclude Petitioner from participation in the Medicare and Medicaid programs for five years is excessive. I conclude further that the remedial and deterrent purposes of section 1128 of the Act will be served in this case by a three-year exclusion, and I modify the exclusion accordingly.

APPLICABLE STATUTES AND REGULATIONS

I. The Federal Statute.

Section 1128 of the Social Security Act is codified at 42 U.S.C. 1320a-7 (1988). Section 1128(a) of the Act provides for the exclusion from Medicare and Medicaid of

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[2] In Petitioner's motion in limine, he argued that he had been excluded from the Medicare and Medicaid programs based solely on his conviction for failure to file records from December 1986 through May 1987. Petitioner contended that any evidence offered by the I.G. which was not based on his conviction should be excluded. Petitioner argued that he would be unfairly prejudiced if the I.G. were permitted to submit evidence that was irrelevant, immaterial, or its probative value was outweighed by its undue prejudicial effect. The I.G. submitted a reply brief in opposition to Petitioner's motion. The I.G. argued that in order to decide the issue of the reasonableness of the length of exclusion, Petitioner's trustworthiness as a pharmacist must be determined and that the factors set forth in the regulations at 42 C.F.R. 1001.125(b)(1)-(7) should be considered. I reserved ruling on Petitioner's motion until the hearing. During the hearing, I denied Petitioner's motion in limine. I held that evidence which was relevant to the reasonableness of an exclusion would be admitted at the hearing. I also held that evidence which related to Petitioner's trustworthiness would be admissible.

those individuals or entities "convicted" of a criminal offense "related to the delivery of an item or service" under the Medicare or Medicaid programs. Section 1128(c)(3)(B) provides for a five-year minimum period of exclusion for those excluded under section 1128(a)(1). Section 1128(b) of the Act provides for permissive exclusions after convictions relating to fraud, license revocations, failure to supply payment information, or, as in this case, conviction for a criminal offense related to the unlawful manufacture, distribution, prescription, or dispensing of a controlled substance under section 1128(b)(3).

II. The Federal Regulations.

The governing federal regulations are codified in 42 C.F.R. Parts 498, 1001, and 1002 (1990). Part 498 governs the procedural aspects of this exclusion case; Parts 1001 and 1002 govern the substantive aspects.

Section 1001.123 requires the I.G. to issue an exclusion notice to an individual whenever the I.G. has conclusive information that such individual has been "convicted" of a criminal offense "related to the delivery of an item or service" under the Medicare or Medicaid programs.

ADMISSIONS

During the hearing, and as documented by my October 25, 1990 Prehearing Order, Petitioner admitted that: (1) he was "convicted" of a criminal offense, within the meaning of section 1128(i) of the Act; and (2) the offense was "related to the unlawful manufacture, distribution, prescription, or dispensing of a controlled substance," within the meaning of section 1128(b)(3) of the Act. Tr. 14.[3]

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[3] Citations to the record and to Departmental Appeals Board cases in this decision are as follows:

Transcript	Tr. (page)
I.G.'s Exhibits	I.G. Ex. (number/page)
I.G.'s Brief	I.G. Br. (page)
I.G.'s Reply Brief	I.G. Rep. Br. (page)
I.G.'s Posthearing Brief	I.G. P. Br. (page)
Petitioner's Exhibits	P. Ex. (number/page)
Petitioner's Brief	P. Br. (page)
Petitioner's Reply Brief	P. Rep. Brief

ISSUE

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

FINDINGS OF FACT AND CONCLUSIONS OF LAW

Having considered the entire record, the arguments and submissions of the parties, and being fully advised herein, I make the following Findings of Fact and Conclusions of Law:

1. Petitioner, at all times relevant to this case, is a pharmacist licensed to practice pharmacy in Pennsylvania. Tr. 8.

2. Beginning in 1969, Petitioner was the sole owner of and sole pharmacist at Northway Pharmacy, located in Etna, Pennsylvania. Tr. 127.

3. During a routine inspection at Northway Pharmacy on December 11, 1985, an agent of the State Bureau of Narcotics Investigation (BNI) found numerous violations, which included Petitioner acquiring Schedule II drugs with an expired Drug Enforcement Administration (DEA) number and failing to submit monthly Bureau of Drug Control Form #6 (BDC-6 forms). I.G. Ex. 6.

4. A BDC-6 form is a monthly report that is required to be filed by every pharmacist, listing all prescriptions filled for Schedule II controlled substances. This form is filed with the Attorney General's Office. I.G. Ex. 15; Tr. 22.

Petitioner's Post-hearing Brief	P. P. Br. (page)
Findings of Fact and Conclusions of Law	FFCL (number)
Departmental Appeals Board ALJ decisions	DAB Civ. Rem. (docket no./ date)
Departmental Appeals Board appellate decisions	DAB App. (decision no./ date)

[4] Some of my statements in the sections preceding these formal findings and conclusions are also findings of fact and conclusions of law. To the extent that they are not repeated here, they were not in controversy.

5. The BDC-6 form provides BNI with the following information: identifies the Schedule II drugs being prescribed; identifies the doctors prescribing Schedule II drugs; and identifies the patients who are being prescribed Schedule II drugs. Tr. 23.

6. A criminal complaint was filed on July 14, 1987, after subsequent investigations at Petitioner's Pharmacy were conducted, revealing that Petitioner had failed to maintain a current DEA number and had failed to file BDC-6 forms during various periods of time. I.G. Ex. 14.

7. At a preliminary hearing held on July 23, 1987, Petitioner's counsel attempted to offer the six BDC-6 forms to the assistant district attorney and a DEA agent, both of whom refused to accept delivery or take possession of the forms. Tr. 45; I.G. Ex. 17/2-3.

8. On September 11, 1987, a seven-count information was filed against Petitioner in the Court of Common Pleas, Allegheny County, Pennsylvania. I.G. Ex. 15.

9. Petitioner was charged in the information with one felony count of knowingly and intentionally acquiring Schedule II drugs by misrepresentation by using an expired DEA number, in violation of 35 P.S. section 780-113(a)(12). I.G. Ex. 15.

10. Petitioner was also charged in the information with six misdemeanor counts of knowingly or intentionally refusing or failing to provide BNI with BDC-6 forms for the months of December 1986 through May 1987, in violation of 35 P.S. section 780-113(a)(21). I.G. Ex. 15.

11. On January 19, 1989, after a jury trial, Petitioner was convicted of six counts of failing to file BDC-6 forms for the months of December 1986 through May 1987. Petitioner was acquitted of the felony charge. I.G. Ex. 2, 16.

12. Petitioner was sentenced to one to six months' incarceration on count 2; sentenced to 30 months' probation on counts 3 through 7; fined $5,000; and ordered to pay court costs. Probation was conditioned on Petitioner filing the required BDC-6 forms. I.G. Ex. 2.

13. The trial judge sentenced Petitioner to jail because she concluded that incarceration was necessary since Petitioner was unwilling to conform to one of the main conditions of probation: that is, that Petitioner file the required forms. I.G. Ex. 16/58.

14. Petitioner filed the BDC-6 forms on March 12, 1990 and has been in compliance with the filing requirements since that date. Tr. 143.

15. By Consent Agreement dated September 17, 1990, the Pennsylvania State Board of Pharmacy suspended Petitioner's license to practice pharmacy and suspended his permit to operate a pharmacy for two years because he had no valid DEA registration in effect during the following time periods: November 1, 1972 to January 1, 1973; November 1, 1976 to November 9, 1977; November 1, 1978 to October 16, 1979; and November 1, 1984 to August 18, 1986. I.G. Ex. 17/2-3.

16. The State Board of Pharmacy found that Petitioner's failure to file the six BDC-6 forms was a record keeping violation. I.G. Ex. 17/3.

17. The State Board of Pharmacy stayed Petitioner's suspension in favor of two years' probation, subject to certain conditions of probation: (1) Petitioner was to adhere to the State's laws governing the practice of pharmacy or the distribution of drugs; (2) Petitioner was to obey the rules and regulations of the State Board of Pharmacy; and (3) Petitioner and the Pharmacy were to each pay a $500 civil penalty fee. I.G. Ex. 17.

18. Petitioner's failure to file the BDC-6 forms was motivated by his concern for the confidentiality of his patients' privacy and his belief that the Attorney General's office lacked authority to receive the BDC-6 forms. Tr. 132-134.

19. Petitioner did not profit from the conduct which resulted in his 1989 conviction, nor did his conduct cause direct injury to another person. P. P. Br. 10-11, 15-16.

20. Petitioner was convicted of a criminal offense relating to the unlawful manufacture, distribution, prescription, or dispensing of a controlled substance, within the meaning of sections 1128(i) and 1128(b)(3) of the Act. Act, section 1128(i) and 1128(b)(3).

21. Petitioner admits and I conclude that: (1) he was "convicted," within the meaning of section 1128(i) of the Act; and (2) the criminal offense was "related to the unlawful manufacture, distribution, prescription, or dispensing of a controlled substance," within the meaning of section 1128(b)(3) of the Act. Tr. 14; Prehearing Order.

22. 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).

23. On May 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. I.G. Ex. 1.

24. The exclusion imposed and directed against Petitioner is for five years.

25. The exclusion provisions of section 1128 of the Act establish neither minimum nor maximum exclusion terms in those circumstances where the I.G. has discretion to impose and direct exclusions. Act, section 1128(b)(1)-(14).

26. A remedial objective of section 1128 of the Act is to protect program beneficiaries and recipients by permitting the Secretary (or his delegate, the I.G.) to impose and direct exclusions from participation in Medicare and Medicaid of those individuals who demonstrate by their conduct that they cannot be trusted to provide items or services to program beneficiaries and recipients. Act, section 1128.

27. The I.G. has not shown that a five-year exclusion of Petitioner from participating in Medicare and Medicaid is reasonably necessary to satisfy the remedial purpose of section 1128 of the Act. See FFCL 1-19.

28. The remedial purpose of section 1128 of the Act will be satisfied in this case by modifying the exclusion imposed and directed against Petitioner to a term of three years.

29. Petitioner was convicted of a serious criminal offense. FFCL 8-13; see 42 C.F.R. 1001.125(b)(1).

30. Petitioner's unlawful conduct did not have a direct adverse impact on his patients or on program beneficiaries or recipients. FFCL 18-19; see 42 C.F.R. 1001.125(b)(2).

31. Petitioner's unlawful conduct was not intended to cause harm to patients or to the integrity of the Medicare and Medicaid programs. FFCL 18-19; see 42 C.F.R. 1001.125(b)(4).

32. The remedial considerations of section 1128 of the Act will be served in this case by a three-year exclusion.

DISCUSSION

I. The I.G. is authorized to exclude Petitioner by section 1128(b)(3) of the Act.

Section 1128(b)(3) of the Act authorizes the I.G. to exclude from participation in the Medicare and Medicaid programs individuals who have been "convicted" of criminal offenses "relating to the unlawful manufacture, distribution, prescription, or dispensing of a controlled substance." On January 19, 1989, Petitioner was convicted of six counts of failing to file BDC-6 forms. Petitioner admits, and I find and conclude, that he was "convicted" within the meaning of section 1128(i) of the Act and that his conviction falls within the purview of criminal offenses enumerated in section 1128(b)(3) of the Act.

Since Petitioner has admitted, and I have concluded, that Petitioner was convicted of a criminal offense for which the I.G. may impose an exclusion, pursuant to section 1128(b)(3) of the Act, the remaining issue is whether the five-year exclusion imposed on Petitioner by the I.G. is reasonable and appropriate under the circumstances of this case.

II. A three-year exclusion is reasonable.

A. The remedial purpose of section 1128 of the Act is to protect federally-funded health care programs and their beneficiaries and recipients from untrustworthy providers.

Congress enacted section 1128 of the Act to protect the Medicare and Medicaid programs from fraud and abuse and to protect the beneficiaries and recipients of those programs from impaired and incompetent practitioners and inappropriate or inadequate care. S. Rep. No. 109, 100th Cong., 1st Sess. 27, reprinted in U.S. Code Cong. & Admin. News 682, 708; Greene v. Sullivan, 731 F. Supp. 835, 838 (E.D. Tenn. 1990).

The key term is "protection," the prevention of harm. See Webster's II New Riverside University Dictionary 946 (1984). As a means of protecting the Medicare and Medicaid programs and their beneficiaries and recipients,

Congress chose to mandate, and in other instances to permit, the exclusion of untrustworthy providers. Through the exclusion law, individuals and entities who have caused harm, or demonstrated that they may cause harm, to the federally-funded programs or their beneficiaries or recipients are no longer permitted to receive reimbursement for items or services which they provide to Medicare beneficiaries or Medicaid recipients. Thus, untrustworthy providers are removed from a position which provides a potential avenue for causing harm to the programs or to its beneficiaries or recipients. See Vladimir Coric, M.D., DAB Civ. Rem. C-244 (1991).

By not mandating that exclusions from participation in federally-funded health care programs be permanent, Congress has allowed the I.G. the opportunity to give individuals a "second chance." The placement of a limit on the period of exclusion allows an excluded individual or entity the opportunity to demonstrate that he or she can and should be trusted to participate in the federally-funded health care programs as a provider of items and services to beneficiaries and recipients. See Thomas J. DePietro, R.Ph., DAB Civ. Rem. C-282 at 8 (1991).

The ultimate issue to be determined at a hearing pertaining to an exclusion imposed pursuant to section 1128 of the Act is whether the exclusion is reasonable. 42 C.F.R. 1001.128(a)(3). In adopting this regulation, the Secretary stated that:

> The word 'reasonable' conveys the meaning that . . . [the I.G.] is required at the hearing only to show that the length of the [exclusion] determined . . . was not extreme or excessive.

48 Fed. Reg. 3744 (January 27, 1983).

An exclusion determination will be held to be reasonable where, given the evidence of the case, it is consistent with the legislative purpose of protecting federally-funded health care programs and their beneficiaries and recipients and it is not extreme or excessive as a length of time necessary to establish that the excluded provider no longer poses a risk to covered programs and their beneficiaries and recipients. See Basem F. Kandah, R. Ph., DAB Civ. Rem. C-155 at 5 (1990).

In order to be adjudged reasonable under section 1128, an exclusion must satisfy the remedial objective of protecting federally-funded health care programs and

their beneficiaries and recipients from untrustworthy providers of items or services. An exclusion which satisfies this purpose may also have the ancillary benefit of deterring wrongdoing. However, an exclusion fashioned solely to achieve the objective of deterrence is punitive if it does not reasonably serve the Act's remedial objective. See Elias Goldstein, DAB Civ. Rem. C-104 (1989).

B. The fact finder must evaluate the totality of the circumstances of each case in light of the remedial purpose of the exclusion law in order to determine the appropriate length of an exclusion.

Guidance in determining the appropriate length of an exclusion is found in regulations contained in 42 C.F.R. 1001.125(b). These regulations were adopted by the Secretary prior to the enactment of the 1987 Amendments to the Act. The regulations specifically apply only to exclusions for "program-related" offenses. To the extent that they have not been repealed, however, they embody the Secretary's intent that they continue to apply, at least as broad guidelines, to the cases in which discretionary exclusions are imposed. 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 demonstrate trustworthiness. Leonard N. Schwartz, R.Ph., DAB Civ. Rem. C-62 (1989).

There are proposed regulations which, if adopted by the Secretary, would supersede the regulations which presently govern exclusions.[5] See 55 Fed. Reg. 12205 (April 2, 1990). The I.G.'s program analyst Joseph V. Patti testified that the I.G. uses the proposed regulations as guidelines to establish the length of an exclusion. Tr. 94-95. For convictions resulting in exclusions under section 1128(b)(3), Mr. Patti stated that the I.G. starts with a base period of exclusion of five years and increases or decreases the exclusion depending on whether aggravating or mitigating

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[5] These proposed regulations, however, have not been finally adopted. It would not be appropriate for me to assume that they will be adopted in their proposed form. Moreover, it is not clear that, if and when these proposed regulations are adopted, they would apply retroactively to exclusions imposed prior to the date of their adoption. I must make an independent assessment of the reasonableness of the exclusion, taking into consideration all of the factors discussed above.

circumstances are present. Tr. 94-95. Mr. Patti testified that he did not consider aggravating factors in determining the length of the exclusion in this case because it did not appear to him that Petitioner was involved in the direct illegal distribution of drugs. Tr. 95-96, 100.

Since the exclusion remedy is not intended to be a punishment for wrongdoing, the regulations should not be applied as sentencing guidelines to the facts of a case to determine the degree of a provider's culpability with a view to determining the punishment he "deserves." Instead, the regulations provide guidance as to the factors that should be considered in order to make inferences about a provider's trustworthiness and the length of time a provider should be excluded to provide the Secretary adequate opportunity to determine that a provider no longer poses a risk to the covered programs and to their beneficiaries and recipients.

A determination of the length of time necessary to establish that a provider is no longer a threat to the covered programs and to their beneficiaries and recipients necessitates an evaluation of the myriad facts of each case, including the nature of the offenses committed by the provider, the circumstances surrounding the offense, whether and when the provider sought help to correct the behavior which led to the offense, how far the provider has come toward rehabilitation, and any other factors relating to the provider's character and trustworthiness. See DePietro, supra; Joyce Faye Hughey, DAB App. 1121 (1991).

The I.G. argued that under the facts of this case a five-year exclusion is reasonable since Petitioner was sentenced to incarceration and probation; was ordered to pay fines and court costs; operated the Pharmacy without proper DEA registration; continued his conduct over a lengthy period of time; and was sanctioned by the State Pharmacy Board. I.G. Br. 12-17.

Petitioner argued that a five-year exclusion is unreasonable and that he is now trustworthy to provide goods and services to the Medicare and Medicaid programs. Petitioner asserted that his length of exclusion should be reduced to a term of less than one year or dismissed

in its entirety with retroactive reinstatement to the date the exclusion was imposed.[6,7] P. Rep. Br. 12.

Based on the evidence in the record, I find that an exclusion of five years is unreasonable. I conclude that the I.G. has failed to show a meaningful remedial basis for the five-year exclusion which he requested that I impose. I conclude that a five-year exclusion would be excessive given the evidence of record. I do not believe that Petitioner presents a high risk to offend again. Imposition of a three-year exclusion will give Petitioner enough time to demonstrate that he is fully trustworthy. A three-year exclusion will provide an ancillary benefit. It will put providers to the Medicare and Medicaid programs on notice that they may not with impunity disregard their record keeping responsibility over long periods of time and expect to escape exclusion solely by expressing remorse and declaring themselves no longer a threat to the integrity of the Medicare and Medicaid programs.

III. The nature and gravity of Petitioner's offenses were serious.

The record reveals that, as the sole owner and sole pharmacist of Northway Pharmacy since 1969, Petitioner fills approximately 15,000 to 20,000 prescriptions per year for the residents of Etna, Pennsylvania, a community of about 4,000. Tr. 127-129. The average age of Petitioner's patients is 65 and these patients typically suffer from chronic illnesses necessitating daily medication or maintenance-type medicines. Tr. 128. The next nearest pharmacy is approximately one and one-half

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[6] In Samuel W. Chang, M.D., DAB App. 1198 at 9 (1990), an appellate panel of the Departmental Appeals Board found that an ALJ cannot decide when the exclusion is to begin. Thus, I am without authority to adjust the effective date of the exclusion.

[7] Congress has not mandated that exclusions from participation in the federally-funded health care programs be permanent. Instead, section 1128(g) of the Act provides that an excluded provider may apply for reinstatement into the program at the end of the exclusion period. The Secretary may then reinstate the provider if there is no basis to deny reinstatement and there are reasonable assurances that the types of actions which formed the basis for the exclusion have not recurred and will not recur.

miles from Petitioner's Pharmacy. Tr. 127-129. Although some of his patients have automobiles, many of Petitioner's patients are served by his direct delivery service. Tr. 127-129.

Petitioner was convicted of failing to submit monthly reports to the Attorney General's Office on Schedule II controlled substances on six occasions from December 1986 through May 1987. Petitioner testified that he failed to file the BDC-6 forms because the forms required him to list the name of the physician prescribing Schedule II drugs, as well as the name of the patient being prescribed Schedule II drugs. Tr. 131-132. Petitioner alleged that neither the patient nor the prescribing physician was aware of this reporting requirement. Petitioner said he believed that disclosure of this information to a third party without the consent or knowledge of the patient or physician would be an invasion of their privacy and a breach of confidentiality. Tr. 132.

Petitioner testified also that before he released this information to the Attorney General's Office, he requested that they furnish him with the statutory authority requiring him to furnish such confidential information. Tr. 131-133. He stated also that when he received a copy of the statute authorizing the release of this information, it directed him to send the forms to the Secretary of Health. Tr. 133. Petitioner averred that this confused him because previously he had been directed to send the forms to the Attorney General's Office. Petitioner contended that, because of this conflicting information, he was fearful of doing anything until he clearly understood which agency should receive the forms. Tr. 137. At his sentencing hearing, testifying about providing this information to the Attorney General, Petitioner stated "[i]t occurred to me, at that time, that providing this information to a police agency would, in effect, transform me into a willing or unwilling police informant. I made every effort that I could to determine that." I.G. Ex. 16/48-49. Petitioner maintained that his failure to file these forms was not done out of defiance of the law. Tr. 138.

I believe that Petitioner acted out of a motivation to protect his customers and the prescribing physicians from a perceived invasion of privacy and breach of confidentiality. Petitioner did not want to be an "informant" on his patients who were legitimately being prescribed certain types of drugs for their ongoing ailments. His behavior seems typical of the way a small town pharmacist would react to a request to divulge

information pertaining to his customers and their physicians, especially, as in this case, where the Attorney General is to receive the information. I believe also that it is possible that Petitioner received conflicting information regarding which agency was to receive the forms. However, I do not condone the manner in which Petitioner resolved the conflict. As a pharmacist, Petitioner is obliged to abide by the laws regulating the practice of pharmacy and the distribution of drugs.

Since December 1985, Petitioner has had notice and the opportunity to file the BDC-6 forms. Petitioner's attorney did attempt to give the completed BDC-6 forms for the months covered in the indictment to the prosecutor and a narcotics agent during a preliminary hearing held on July 23, 1987. Tr. 141-143; P. Ex. 2. At the hearing, narcotics agent Anthony Iorio confirmed that Petitioner's attorney attempted to deliver the forms. Tr. 44-45. However, agent Iorio testified that he did not accept the forms because Petitioner offered the forms in exchange for having the charges in the criminal complaint dropped. Agent Iorio stated that since Petitioner had not complied with the law for years, there was no way to guarantee future compliance by him, and, therefore, no one accepted the forms. Tr. 45-46.

Petitioner's misconduct was considered to be so serious that the trial judge sentenced Petitioner to jail because she concluded that incarceration was necessary since Petitioner was unwilling to conform to one of the main conditions of probation, filing the required forms.[8] The State Board of Pharmacy found Petitioner's failure to file the forms to be a record keeping violation. However, because Petitioner had operated his Pharmacy with an unexpired DEA registration during various periods of time, the State Board of Pharmacy suspended his license and then stayed the suspension in favor of two years' probation. I conclude that Petitioner's conviction for the unlawful manufacture, distribution, prescription, or dispensing of a controlled substance, together with his other misconduct, gave the I.G. the reasons to conclude that a substantial exclusion was needed to protect the welfare of beneficiaries and

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[8] In an article dated October 2, 1989, a newspaper, the Pittsburgh Post-Gazette, reported that Petitioner was incarcerated for one day for failing to turn over the BDC-6 forms in a timely manner. I.G. Ex. 18.

recipients and the integrity of the Medicare and Medicaid programs. See 42 C.F.R. 1001.125(b)(6).

The I.G. argued that if I apply the reasoning used to sustain the exclusion imposed in the case of Schwartz, supra, to the present case, then I must sustain the exclusion imposed here. I disagree. The petitioner in Schwartz was a pharmacist convicted of failing to maintain records pertaining to the sale, during a 16-month period, of more than 34,000 tablets of Preludin, a Schedule II controlled substance. He admitted that he had sold many Preludin tablets without receiving prescriptions for them. As a consequence of his conviction, he was sentenced to a period of incarceration plus five years' probation. The ALJ sustained an eight-year exclusion in that case, based in part on the seriousness of the petitioner's criminal misconduct, but also based on his conclusions that the petitioner's conduct had been motivated by personal gain and that the petitioner had not proven that he could be trusted to deal with program recipients and beneficiaries.

Schwartz is distinguishable from the present case on several grounds. In Schwartz, the criminal misconduct upon which the exclusion was premised was motivated by considerations of personal gain. In the present case, Petitioner's unlawful conduct stemmed from his concern for protecting the privacy and confidentiality of his customers and their physicians. However, the most important distinction between this case and Schwartz is that, in this case, Petitioner offered convincing evidence as to his willingness to comply with the filing requirements as indicia of his trustworthiness to provide services to program beneficiaries and recipients. I am not minimizing the seriousness of Petitioner's problems. Petitioner was convicted of a serious criminal offense. See 42 C.F.R. 1001.125(b)(1). Petitioner's past misconduct of not filing the monthly BDC-6 forms demonstrated that he has displayed exceedingly poor judgment.

Petitioner contends that two previous decisions support his position that the length of his exclusion is unreasonable: Kenneth Behymer, M.D., DAB Civ. Rem. C-140 (1990) and James E. Keil, M.D., DAB Civ. Rem. C-154 (1990). In Keil, the petitioner's exclusion was reduced from five years to one. The petitioner had been convicted of one count of unlawfully dispensing a controlled substance. The petitioner in Keil was himself addicted and the drug he prescribed was for himself. The petitioner in Keil also sought help before his indictment and demonstrated to the ALJ that he had faithfully

adhered to his treatment regimen and was drug free. The instant case is very different. Although Petitioner was not involved in the unlawful sale of drugs, he was convicted of six counts of failing to file monthly forms. Although the record reflects that Petitioner attempted to submit the forms in July 1987, the record does not reveal any further attempts by Petitioner to comply with the law until March 1990 when he filed the forms and was finally in compliance with the law. The record does not reflect an immediate concept of self-help on Petitioner's part as was shown by Dr. Keil.

This case contrasts with the case of Behymer. The petitioner in Behymer had unlawfully prescribed a controlled substance. Dr. Behymer's act was motivated by what he considered at the time to be humanitarian considerations. In the instant case, Petitioner was motivated by protecting his customers and their doctors from an invasion of privacy or breach of confidentiality by divulging information about their prescriptions. However, unlike Petitioner, Dr. Behymer had engaged in an isolated episode of misconduct. Dr. Behymer persuaded the ALJ by the evidence presented in that case that there was no likelihood that he would in the future engage in unlawfully prescribing controlled substances. Thus, the ALJ found the exclusion to be excessive and modified it accordingly. In this case, Petitioner did not engage in an isolated episode of misconduct: that is, for a substantial period of time between December 1985 and March 1987, he was reluctant to turn over the forms. His behavior was so egregious that the trial court was compelled to impose incarceration, probation conditioned on Petitioner turning in the forms, and a $5,000 fine. The record reflects that Petitioner did not feel compelled to obey the law.

In short, the misconduct engaged in by Petitioner posed a much more serious threat to program integrity and to the welfare of beneficiaries and recipients than that engaged in by the petitioners in Keil and Behymer. The threat posed to programs and to beneficiaries and recipients by a repetition of unlawful conduct therefore is greater in this case than was the case in Keil and Behymer. Petitioner, in what appears to be a self-serving course of action, decided to abide by his own set of rules as opposed to the existing rules and regulations regarding the filing requirements for Schedule II drugs as promulgated by the Commonwealth of Pennsylvania.

Moreover, I am somewhat perplexed at Petitioner's attitude toward the DEA agents who were involved in the investigation of his Pharmacy. The record reveals that during a routine inspection of Petitioner's Pharmacy, he physically assaulted a DEA agent, and this eventually led to Petitioner's arrest and arraignment. I.G. Br. 3-4. See I.G. Ex. 6-13. Although the charges were dismissed, the judge lectured Petitioner about his behavior toward these agents. I.G. Ex. 9. Agent Iorio also testified that Petitioner was not very cooperative during an inspection of his Pharmacy in 1987. Tr. 25-28. I do not condone Petitioner's behavior toward DEA agents, who are representatives of the government, attempting to get Petitioner to conform to the law. Providers of health care should show considerable respect toward these agents and physical or verbal abuse in dealing with these agents is not to be treated lightly. However, I do believe that Petitioner's obstinacy in filing these forms is tied into the relationship that was initially established with these agents. Thus, I believe Petitioner learned a very hard lesson and he appears to be on the right track toward complying with the law.

IV. The evidence shows that Petitioner has made some progress toward being trustworthy.

Petitioner's conduct poses a threat to the integrity of the programs served by Medicare and Medicaid and to the welfare of program recipients and beneficiaries. See 42 C.F.R. 1001.125(b)(2), (b)(6). The I.G. had reason, as well as authority, to exclude Petitioner. However, the five-year exclusion imposed and directed in this case is excessive, because it bars Petitioner from participation for a longer period of time than is reasonably required for Petitioner to demonstrate that he is trustworthy since he has successfully continued to file the monthly BDC-6 forms since March 1990.

The picture of Petitioner that emerges from the record is that of a pharmacist in a small town who appears to be overly protective of the elderly patients whom he serves. Because of his roots in that community since 1969, Petitioner has put himself in a position of being a watchdog of these patients, many of whom he has probably known since he opened his Pharmacy. In testifying regarding why he did not file the BDC-6 forms, petitioner stated: "In my work, I have to be competent, compassionate, and trustworthy, and without that valid authority, I would have considered that a violation of my trustworthiness in my patients that I was serving." Tr. 151. This seems to be in line with how a pharmacist in a small town

would conduct his business. Thus, Petitioner put himself in a position of not adhering to the law in order to protect the privacy rights of his customers.

Even though the record reveals that, since March 1990, Petitioner has faithfully filed the forms, I feel that Petitioner still needs time to prove that he is trustworthy. I am persuaded that, in this case, a three-year exclusion is reasonable. The State Board of Pharmacy will scrutinize his conduct and noncompliance with any rules pertaining to the practice of pharmacy would be a violation of his probation, resulting in a suspension of his license. However, I believe that Petitioner's conduct needs to be monitored for a period of time after the State Board of Pharmacy's probationary period terminates. Assuming that Petitioner continues to adhere to the proper filing requirements for BDC-6 forms, when he is eligible to apply for reinstatement he will have complied more than three years. That is long enough, given Petitioner's determination to fully comply with the law, to establish that he no longer constitutes a threat to the integrity of the Medicare or Medicaid programs, or to the welfare of program beneficiaries and recipients. See 42 C.F.R. 1001.125(b)(4), (b)(6).

CONCLUSION

Based on the evidence in this case and the law, I conclude that the five-year exclusion imposed against Petitioner from participating in the Medicare and Medicaid programs is excessive and unreasonable. I modify the exclusion to a three-year exclusion from participating in the Medicare and Medicaid programs.

/s/

Charles E. Stratton
Administrative Law Judge