Department of Health and Human Services

DEPARTMENTAL APPEALS BOARD

Civil Remedies Division

In the Case of:	
Falah R. Garmo, R.Ph.,	DATE: Dec 20, 1990
Petitioner,	
- v. -	Docket No. C-222
The Inspector General.	Decision No. CR113

DECISION

Petitioner was notified by the Inspector General (I.G.) in a letter dated March 19, 1990 that he would be excluded from participation in the Medicare program and any federally-assisted State health care program (such as Medicaid), as defined in section 1128(h) of the Social Security Act (Act), for a period of five years.[1] The I.G. further advised Petitioner that his exclusion was due to his conviction in the United States District Court for the Eastern District of Michigan, Southern Division, of a criminal offense related to the unlawful manufacture, distribution, prescription, or dispensing of a controlled substance. Petitioner was informed that exclusions from Medicare and Medicaid programs after such a conviction are authorized by section 1128(b)(3) of the Act.

Petitioner timely requested a hearing before an Administrative Law Judge (ALJ) to contest the determination by the I.G. to exclude him from Medicare and Medicaid for five years. The parties agreed to have this case decided on the basis of submitted exhibits, in lieu of an in-person hearing. Based on the evidence in

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[1] "State health care program" is defined by section 1128(h) of the Social Security Act to cover three types of federally-assisted programs, including State plans approved under Title XIX (Medicaid) of the Act. I use the term "Medicaid" hereafter to represent all State health care programs from which Petitioner was excluded.

the record and the applicable law, I conclude that an exclusion of five years is reasonable and appropriate.

APPLICABLE STATUTES AND REGULATIONS

I. The Federal Statute.

Section 1128 of the Act is codified at 42 U.S.C. 1320a-7 (West U.S.C.A., 1989 Supp.). Section 1128(a) of the Act provides for the exclusion from Medicare and Medicaid of 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 for convictions, infractions, or undesirable behavior, such as convictions relating to fraud, license revocation, failure to supply payment information, or, as in this case, 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 (1989). Part 498 governs the procedural aspects of this exclusion case; parts 1001 and 1002 govern the substantive aspects.

ADMISSIONS

During the telephone prehearing conference on June 14, 1990, Petitioner admitted that he was convicted of an offense relating to a controlled substance.

ISSUES

The issues in the case are:

1. Whether Petitioner's exclusion is in violation of the ex post facto clause of the United States Constitution.

2. Whether the length of the exclusion is reasonable and appropriate.

FINDINGS OF FACT AND CONCLUSIONS OF LAW[2]

1. At all times relevant to this case, Petitioner was a registered pharmacist who operated a pharmacy in the State of Michigan. P. Br. 1.[3]

2. On January 30, 1989, in the United States District Court for the Eastern District of Michigan, Southern Division, Petitioner pled guilty to count six of a seven-count indictment. The remaining charges against Petitioner were dismissed. I.G. Ex. 1.

3. Count six charged that on April 22, 1986, while acting as a pharmacist, Petitioner did knowingly, intentionally, and unlawfully distribute 100 dosages of Phenaphen #2 with codeine and 100 dosages of Ascriptin #3 with codeine, without legitimate prescriptions or other legitimate authorizations. These drugs are both Schedule III controlled substances. I.G. Ex. 2/3.

4. On April 6, 1989, Petitioner was sentenced to a term of one year and one day imprisonment, followed by a two-year special parole; fined $30,000.00; and charged a special assessment fee of $50.00. I.G. Ex. 3.

5. On June 29, 1989, the Attorney General of the State of Michigan filed an eleven-count administrative complaint with the State Department of Licensing and Regulation Board of Pharmacy (Board), alleging that Petitioner was convicted of a criminal offense of knowingly, intentionally, and unlawfully distributing controlled substances, a violation of the Public Health Code. I.G. Ex. 4.

6. The administrative complaint stated that the Public Health Code provided that a license to manufacture,

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[2] 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.

[3]

Petitioner's Answer to I.G.'s Brief	P. An. (page)
Petitioner's Brief	P. Br. (page)
Petitioner's Exhibits	P. Ex. (letter)
I.G.'s Brief	I.G. Br. (page)
I.G.'s Exhibits	I.G. Ex. (number)/(page)
Findings of Fact and Conclusions of Law	FFCL (number)

distribute, prescribe, or dispense a controlled substance should be denied or revoked by the administrator if the licensee has been convicted of a felony under a state or federal law related to a controlled substance. I.G. Ex. 4/2.

7. The administrative complaint proposed that the Board revoke Petitioner's pharmacist and controlled substance licenses for a year for each of the eleven counts and fine him $5,000.00 on each of the first seven counts. I.G. Ex. 4/6-7.

8. On September 25, 1989, Petitioner acknowledged in a signed Stipulation (which is part of a document entitled "Consent Order and Stipulation") that the allegations contained in the administrative complaint were true and that he had been convicted of a violation of the Public Health Code. I.G. Ex. 5/4.

9. On October 18, 1989, the Board issued a Consent Order (which is part of a document entitled "Consent Order and Stipulation") and ordered (1) suspension of Petitioner's pharmacist's license for a minimum of three years, (2) revocation of Petitioner's controlled substance license, (3) a fine of $5,000.00, and (4) dismissal of seven counts in the administrative complaint, leaving four counts outstanding. I.G. Ex. 5.

10. On November 2, 1989, the I.G. advised Petitioner that he was considering being excluded from participating in the Medicare and Medicaid programs as a result of his conviction of a criminal offense, pursuant to section 1128(b)(3) of the Act. The I.G. informed Petitioner that he could provide mitigating factors before a final determination on the exclusion issue was made. I.G. Ex. 6.

11. On November 10, 1989, Petitioner wrote a letter to the I.G. alleging mitigating factors and claiming that ". . . the circumstances surrounding the allegations and the plea-based conviction occurred in a momentary place in time (April of 1986), and did not occur prior or subsequent thereto. [Petitioner] was a practicing pharmacist for eight years with no other hint of inappropriate, unethical or illegal conduct, before or after April, 1986. The isolated circumstances which led to the plea-based conviction reflect an aberration in [Petitioner's] character, not a permanent flaw." I.G. Ex. 7.

12. Petitioner was convicted of a criminal offense relating to the unlawful manufacture, distribution,

prescription, or dispensing of a controlled substance, within the meaning of section 1128(b)(3) of the Act. FFCL 2.

13. Pursuant to section 1128(b)(3) of the Act, the Secretary of the Department of Health and Human Services (Secretary) has authority to impose and direct an exclusion against Petitioner from participating in Medicare and Medicaid. Social Security Act, section 1128(b)(3).

14. The Secretary delegated to the I.G. the duty to impose and direct exclusions pursuant to section 1128 of the Act. 48 Fed. Reg. 21662 (May 13, 1983).

15. On March 19, 1990, the I.G. advised Petitioner that he was excluding him from participating in the Medicare and Medicaid programs for five years, pursuant to section 1128(b)(3) of the Act. I.G. Ex. 8.

16. A purpose of section 1128(b)(3) of the Act is to protect beneficiaries and program funds by excluding individuals or entities who by conduct have demonstrated a risk that they may engage in fraud, substandard services, abuse, or unsafe practices in connection with controlled substances until such time as those excluded can demonstrate that such risk no longer exists. S. Rep. No. 109, 100th Cong. 1st Sess. 2, reprinted in 1987 U.S. Code Cong. & Admin. News 682.

17. There is no length or period of exclusion mandated by statute for section 1128(b)(3) exclusions. The exclusion provisions of section 1128 of the Act do not establish a minimum nor maximum period of exclusion to be imposed and directed in cases where the I.G. has discretion to impose and direct exclusions. Social Security Act, section 1128(b)(1)-(14).

18. Petitioner was convicted of a serious criminal offense, resulting in his incarceration. FFCL 4.

19. The conduct engaged in by Petitioner endangered the health and safety of the individuals who obtained Phenaphen #2 with codeine and Ascriptin #3 with codeine. FFCL 3.

20. The I.G.'s determination that a relatively lengthy exclusion is justified in this case in order to deter other providers from engaging in unlawful conduct is reasonable. I.G. Br. 16; FFCL 15-16; see 42 C.F.R. 1001.125(b)(1)-(7).

21. Evidence offered by Petitioner's psychologist, indicating that at the time of the incident Petitioner had been suffering from situational depression and that Petitioner's conduct in April 1986 was entirely atypical, does not establish that the I.G.'s determination concerning the appropriate length of exclusion to impose on Petitioner is unreasonable. P. Ex. A.

22. The fact that the sentence resulting from the criminal conviction included incarceration is an aggravating factor considered in determining an appropriate length of exclusion. FFCL 4.

23. That Petitioner's pharmacist's license was suspended for three years, and his controlled substances license was revoked, are aggravating factors considered in determining an appropriate length of exclusion. FFCL 9.

24. Petitioner has not established that, in light of mitigating factors, the I.G.'s determination concerning the appropriate length of exclusion to impose on Petitioner is unreasonable. FFCL 11, 21-23.

25. The I.G.'s determination, that given Petitioner's conduct he cannot be trusted as a Medicare or Medicaid provider for five years, is reasonable. FFCL 18-19; FFCL See 42 C.F.R. 1001.125(b)(1)-(7).

ANALYSIS

I. Petitioner's exclusion does not violate the ex post facto clause of the United States Constitution.

The record demonstrates that the conduct for which Petitioner was "convicted" occurred in 1986, and that the final disposition of the proceedings resulting in the criminal conviction did not occur until April 1989. On August 18, 1987, during the pendency of Petitioner's criminal proceedings, Section 1128 of the Act was amended by the Medicare and Medicaid Patient and Program Protection Act of 1987, Public Law 100-93, 101 Stat. 680. The 1987 amendments extended the reach of the law to entities, added new categories of mandatory exclusions, specified a minimum five-year exclusion for cases in which mandatory exclusions were imposed, and enumerated circumstances in which the Secretary had discretion to impose exclusions. Social Security Act, sections 1128(a); 1128(b)(1)-(14).

Petitioner argues that the Act is unconstitutional as applied to him. Petitioner argues that application of the Act to this case amounts to an ex post facto violation of the Constitution, as the sanctions imposed are penal in nature and based on purported criminal conduct occurring before the date of the law's enactment. I.G. Ex. 7.

The I.G. argues that: (1) this tribunal is without jurisdiction to consider constitutional issues (I.G. Br. 8); (2) the constitutional prohibition against ex post facto laws applies only to criminal or penal laws which impose a penalty and that the exclusion law is remedial in nature and its purpose is to protect the Medicare and Medicaid program from financial loss (I.G. Br. 9); (3) if I determine that the statute constituted an ex post facto application of the law, I must then decide if the statute deprives Petitioner of his constitutional rights, since Petitioner's conviction took place after the enactment of the Act (I.G. Br. 12). The I.G. contends that Petitioner has stated that the acts for which he was convicted occurred prior to the enactment of the Act. The I.G. maintains that the statute places emphasis on the conviction for the acts rather than the acts themselves. I.G. Br. 12.

I have carefully considered the contentions of the parties and the relevant law. The scope of my review in these cases is stated in 42 C.F.R. 1001.128(a). This section limits an appeal in this type of case to the issues of (1) whether a petitioner was in fact convicted; (2) whether the conviction was related to his or her participation in the delivery of medical care or services under the Medicare, Medicaid, or social services program; and (3) whether the length of the suspension (exclusion) is reasonable. These issues relate to the propriety of the imposition of the exclusion in a particular case and although I do not have the authority to declare the 1987 amendments unconstitutional, I do have the authority to interpret and apply the federal statute and regulations. See Betsy Chua, M.D., DAB Civ. Rem. C-139 (1990), aff'd DAB App. 1204 (1990); Hai Nhu Bui, DAB Civ. Rem. C-103 (1990), (citing Jack W. Greene, DAB Civ. Rem. C-56, aff'd DAB App. 1078 (1989), aff'd Greene v. Sullivan, 731 F. Supp. 835 (E.D. Tenn. 1990)).

The prohibition against ex post facto laws applies to criminal or penal laws which impose punishment that is applied retroactively. The purpose of the exclusion law and the amendments thereto, however, is not to punish, but to protect program integrity by preventing untrustworthy providers from having ready access to the

Medicare and Medicaid programs. See Francis Shaenboen, R.Ph., DAB Civ. Rem. C-221 at p. 7 (1990); Chua, supra at 10, (citing Orlando Ariz and Ariz Pharmacy Inc., DAB Civ. Rem. C-115 (1990)). See also H.R. Rep. No. 158, 97th Cong., 1st Sess. Vol. III, 329, 344 (1981); S. Rep. No. 139, 97th Cong., 1st Sess. 461-462, reprinted in 1981 U.S. Code Cong. & Admin. News 727-738; Preamble to the Regulations at 48 Fed. Reg. 38827 to 38836 (August 26, 1983). Contrary to Petitioner's assertion, the exclusion in this instance is a civil remedy, not a penal remedy, and is not subject to ex post facto considerations. Even if the amendment were penal, however, Congress intended that the mandatory and permissive exclusion provisions apply prospectively from the date of the statute's enactment to all convictions occurring on or after the effective date of the 1987 amendment. See Shaenboen and Chua, supra. See also Donald O. Bernstein, D.C., DAB Civ. Rem. C-40 (1989), aff'd sub nom. Bernstein v. Sullivan, 914 F.2d 1395 (10th Cir. 1990).

It is unnecessary for me to decide whether the exclusion law may be applied retroactively in particular cases, because it is evident that it was not retroactively applied in this case. In this case, Petitioner pled guilty to, and was convicted of, a criminal offense related to the unlawful manufacture, distribution, prescription, or dispensing of a controlled substance under section 1128(b)(3). Petitioner's conviction occurred on April 6, 1989, nearly a year and a half after Congress amended section 1128. The I.G.'s authority to impose and direct exclusions against Petitioner arises from his conviction for a criminal offense. Therefore, the act which gave the I.G. grounds to exclude Petitioner occurred after the date that Congress enacted statutory revisions.

II. A five-year exclusion is appropriate and reasonable in this case.

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 is reasonable and appropriate. For the reasons set out below, I conclude that a five-year exclusion is reasonable.

As I stated in Victor M. Janze, M.D., DAB Civ. Rem. C-212 at p. 8 (1990), (citing Charles J. Burks, M.D., DAB Civ. Rem. C-111 (1989)), in making a determination regarding the length of the exclusion, it is helpful to look at the

purpose behind the exclusion law. 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 incompetent practitioners and inappropriate or inadequate care. S. Rep. No. 109, 100th Cong., 1st Sess. 1; reprinted in 1987 U.S. Code Cong. & Admin. News 682, 708. The key term to keep in mind 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 individuals and entities. Through the exclusion law, individuals or entities who have caused harm, or may cause harm, to the program or its beneficiaries or recipients are no longer permitted to receive reimbursement for items or services which they provided to Medicare beneficiaries or Medicaid recipients. Thus, individuals are removed from a position which provides a potential avenue for causing harm to the programs. An exclusion also serves as a deterrent to other individuals and entities against deviant behavior which may result in harm to the Medicare and Medicaid programs or their beneficiaries and recipients.

No statutory minimum mandatory exclusion period exists for section 1128(b)(3) exclusions. The I.G. asserts that the Secretary has published proposed regulations which would make five years a starting point for determining the exclusion period of permissive exclusions for convictions relating to fraud, obstruction of an investigation, and controlled substances. I.G. Br. 5-6. See also Fed. Reg. 12204, 12207, 12217, and 12208. Further, the I.G. claims that under these proposed regulations, the base period of exclusion might be increased or decreased in a specific case depending upon aggravating and/or mitigating factors. I.G. Br. 6. 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.

The determination of when an individual should be trusted and allowed to reapply for participation as a provider in the Medicare and Medicaid programs is a difficult issue and is one which is subject to much discretion; there is

no mechanical formula. The federal regulations provide some guidance which may be followed in making this determination. The regulations provide that the length of Petitioner's exclusion may be determined by reviewing (1) the number and nature of the offenses; (2) the nature and extent of any adverse impact the violations have had on beneficiaries; (3) the amount of the damages incurred by the Medicare, Medicaid, and social services programs; (4) the existence of mitigating circumstances; (5) the length of sentence imposed by the court; (6) any other facts bearing on the nature and seriousness of the violations; and (7) the previous sanction record of Petitioner. See 42 C.F.R. 1001.125(b). These regulations were adopted by the Secretary (and his delegate, the I.G.) to implement the Act prior to the 1987 Amendment. The regulations specifically apply only to exclusions for "program related" offenses. To the extent that they have not been repealed or modified, 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. See Janze, supra at 9; Leonard N. Schwartz, R.Ph., DAB Civ. Rem. C-62 at p. 12 (1989).

By not mandating that exclusions from participation in the Medicare and Medicaid program 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 Medicare and Medicaid programs as a provider of items and services to beneficiaries and recipients.

There are substantial reasons for a lengthy exclusion in this case, including aggravating factors. When Petitioner was authorized to prescribe controlled substances, he was put in a public position of great trust. Petitioner abused that trust when he prescribed 100 dosages of Phenaphen #2 with codeine and 100 dosages of Ascriptin #3 with codeine with potentially serious consequences for anyone who might have received those pills. I.G. Ex. 2. On that occasion, Petitioner received $250.00 cash after giving a customer, an undercover agent for the Federal Bureau of Investigation (FBI), a bag containing the above drugs. I.G. Ex. 9. The record contains written investigative reports of the agent and the nature of the drug transactions he made with Petitioner. I.G. 9.

Regulations do not define what circumstances may be considered as mitigating. See 42 C.F.R. 1001.114(b)(4).

However, given Congressional intent to exclude untrustworthy individuals from participation in Medicare and Medicaid programs, it is reasonable to conclude that mitigating circumstances should constitute those circumstances which demonstrate an individual or entity to be trustworthy.

Petitioner offers the following circumstances surrounding his conviction as mitigating factors: (1) " . . .the conduct which gave rise to his criminal charges constituted a single aberration from an otherwise unblemished record and life" (P. Br. 4); (2) in March 1986, he purchased a shipment of pharmaceuticals from a failed pharmacy; it was a bad investment and he suffered a financial loss when he discovered that the inventory was dated and contained primarily obscure products (P. Br. 1-2); (3) one of his regular customers,an undercover FBI agent) persisted in his attempt to purchase medication from Petitioner without a prescription and was eventually successful (P. Br. 1); and (4) his mental health during the period he committed these criminal offenses was fragile and his psychologist submitted findings from an examination suggesting that his behavior was " . . . a typical and situationally specific" (P. Ex. A)

The fact that Petitioner did not have a prior criminal record is essentially neutral, neither adding to nor detracting from the seriousness of his unlawful transactions in controlled substances. The fact that he succumbed to stress and unlawfully sold controlled substances is an aggravating, not a mitigating, factor. See Schwartz, supra.

None of the circumstances asserted to be mitigating by Petitioner derogate from the conclusion that, in light of the offenses he committed, he is an individual who should not be trusted to administer Medicare or Medicaid funds. The circumstances cited by Petitioner essentially address elements of his case which show that he is a relatively sympathetic individual. While these factors certainly should have some bearing on the extent to which Petitioner is punished for his crimes, they have little to do with the question of whether Petitioner can now or in the near future be trusted to dispense controlled substances to program beneficiaries.

Petitioner contends that, under the circumstances of his case, it is appropriate that no exclusion be imposed and, in the alternative, if an exclusion is imposed, it should be limited to two years. P. A. 1. He also argues that if

an exclusion is imposed it should begin to run from the date of the conviction. P. Br. 12.

In the instant case, a lengthy period of exclusion is necessary in order to protect the Medicare and Medicaid programs and to give Petitioner the time to show that he can again be trusted to provide items and services to program beneficiaries and recipients. The ALJ has no power to change the beginning date of the exclusion. See Samuel W. Chang, M.D., DAB App. 1198 at p. 9. Further, the District Court deemed Petitioner's conduct so grave that it fined him $30,000.00, incarcerated him for one year and a day, and then felt it had to monitor him through probation for another two years. FFCL 4. Further, Michigan suspended his controlled substance license for three years, revoked Petitioner's pharmacist license, and fined Petitioner $5,000.00. FFCL 9.

CONCLUSION

Based on the evidence in this case and the law, I conclude that the I.G.'s determination to exclude Petitioner from participation in the Medicare program, and to direct that Petitioner be excluded from participation in State health care programs, for five years, is reasonable and appropriate. Therefore, I am entering a decision in favor of the I.G. in this case.

/s/

Charles E. Stratton
Administrative Law Judge