### DEPARTMENT OF HEALTH AND HUMAN SERVICES

## Departmental Appeals Board

Civil Remedies Division

In the Case of:	)
Charles J. Burks, M.D.,	) ) DATE: <sup>NOV 16</sup> , 1989
Petitioner,	)
- v	) Docket No. C-111
The Inspector General.	) DECISION CR 54
	)

### DECISION AND ORDER

Petitioner requested a hearing to contest the Inspector General's (I.G.'s) determination to exclude him from participation in the Medicare and Medicaid programs for a period of ten years, pursuant to section 1128(b)(3) of the Social Security Act (Act), 42 U.S.C. 1320a-7(b)(3).<sup>1</sup> This Decision and Order resolves this case on the basis of written briefs and documentary evidence. I hereby grant the I.G.'s motion for summary disposition.

#### APPLICABLE STATUTES AND REGULATIONS

### I. The Federal Statute.

Section 1128 of the Social Security Act (Act) is codified at 42 U.S.C.A. 1320a-7 (West Supp. 1989). Section 1128(a)(1) of the Act provides for the exclusion from Medicare and Medicaid of those individuals or

<sup>&</sup>lt;sup>1</sup> Section 1128 of the Act provides for the exclusion of individuals and entities from the Medicare program and requires the I.G. to direct States to exclude those same individuals and entities from "any State health care program" as defined in section 1128(h) of the Act. The Medicaid program is one of three types of State health care programs defined in Section 1128(h) of the Act, and for the sake of brevity, I refer only to it in this Decision.

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).

While section 1128(a) of the Act provides for a minimum five-year mandatory exclusion for (1) convictions of program-related crimes and (2) convictions relating to patient abuse, section 1128(b) of the Act provides for the permissive exclusion of "individuals and entities" for twelve types of other convictions, infractions, or undesirable behavior, such as convictions relating to fraud, license revocation, or failure to supply payment information.

### II. The Federal Regulations.

The governing federal regulations (Regulations) are codified in 42 C.F.R., Parts 498, 1001, and 1002 (1988). 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 Medicare or Medicaid item or service; such exclusion must begin 15 days from the date on the notice.<sup>2</sup>

### BACKGROUND

By letter dated December 14, 1989 (Notice), the I.G. advised Petitioner of his ten-year exclusion from participation in the Medicare and Medicaid programs. The Notice stated that Petitioner's exclusion was based upon his conviction 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. The Notice further stated that the following factors were considered in determining Petitioner's period of exclusion: (1) the criminal acts which resulted in Petitioner's conviction were committed over a lengthy period of time, (2) the violations had a significant adverse physical, mental or financial impact on individuals, and (3) Petitioner had a prior criminal, civil or administrative record.

<sup>&</sup>lt;sup>2</sup> The I.G.'s notice letter allows an additional five days for receipt by mail.

By letter dated March 16, 1989, Petitioner timely requested a hearing to contest the I.G.'s determination, and this case was assigned to me for a hearing and decision. Thereafter, the I.G. filed a motion for summary disposition of this case.

Petitioner admits that he was "convicted" of a criminal offense within the meaning of section 1128(i) of the Act. However, Petitioner contends that his conviction was a result of his misconception that he operated under a valid DEA registration number which would have permitted him to lawfully dispense controlled substances. Petitioner also contends that the factors considered by the I.G. in determining the length of Petitioner's exclusion do not warrant a ten-year period of exclusion.

I conducted a prehearing telephone conference on June 1, 1989. During the prehearing conference: (1) Petitioner admitted that his conviction was for an 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, (2) the parties requested that the case be decided based upon the submission of briefs and documentary evidence, and (3) Petitioner waived his right to a formal evidentiary hearing.

I determined that Petitioner had raised legal issues in his Request which could be further developed by the parties through written briefing. I further determined that the material facts of this case were not in dispute. On June 1, 1989, I issued a Prehearing Order And Schedule For Filing Motions For Summary Disposition (Prehearing Order). Thereafter, the I.G. submitted a motion for summary disposition, a brief in support thereof, and six exhibits. Petitioner submitted a brief in support of his opposition to the I.G.'s motion and three exhibits. Both parties submitted certifications regarding the authenticity of their exhibits.

### ISSUES

The issues in this case are:

1. Whether 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.

2. Whether ten years is the appropriate length of exclusion to be imposed upon Petitioner.

# FINDINGS OF FACT AND CONCLUSIONS OF LAW 3 4

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 was licensed to practice medicine in the State of Pennsylvania until his license was suspended in May 1989. I.G. Ex. 6/335; P. Ex.A/5-7.

2. On June 26, 1978, Petitioner was convicted in the Allegheny County (Pennsylvania) Court of Common Pleas, Criminal Division, of seven felony counts of dispensing controlled substances that were not for a legitimate medical purpose, and of seven misdemeanor counts of prescribing controlled substances to drug dependent persons. I.G. Ex. 4; I.G. Br. 4; P. Br. 1; P. Ex. B.

3. As a result of Petitioner's 1978 conviction, on January 8, 1979, the Administrator of the Drug Enforcement Administration (DEA) issued an Order to Show Cause as to why Petitioner's two DEA Certificates of Registration should not be revoked. <u>Id</u>.

 $^3$  Citations to the record in this Decision and Order are as follows:

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

<sup>4</sup> Any part of this Decision and Order preceding the Findings of Fact and Conclusions of law which is obviously a finding of fact or conclusion of law is incorporated herein. 4. Also as a result of Petitioner's 1978 conviction, in March 1980 the Pennsylvania State Board of Medicine imposed a five year probationary period upon Petitioner and his medical license and placed a restriction upon his prescribing controlled substances. <u>Id</u>.

5. Petitioner requested a hearing before an Administrative Law Judge (ALJ) on the issue of whether his DEA Certificates of Registration should be revoked. A hearing was held on March 23, 1979. <u>Id</u>.

6. The ALJ conducting the March 23, 1979 hearing determined that Petitioner's two DEA Certificates of Registration should be revoked and that a private medical practice was no longer a viable option for Petitioner. P. Ex. B; P. Br. 1; I.G. Br. 5.

7. The Administrator of the DEA adopted the findings, conclusion, and recommended decision of the ALJ conducting the March 23, 1979 hearing. <u>Id</u>.

8. Between January 1, 1986 and March 9, 1987, Petitioner <u>prescribed</u> controlled substances under one of his revoked DEA registration numbers. I.G. Ex. 5; P. Br. 1.

9. As a result of Petitioner's prescription of controlled substances under his revoked DEA Certificates of Registration, Petitioner was charged with 303 counts of violating 21 U.S.C. 843(a)(2).<sup>5</sup> I.G. Ex. 2, 4; P. Br. 1.

10. On April 18, 1988, Petitioner was convicted by a jury of 303 counts of violating 21 U.S.C. 843(a)(2). <u>Id</u>.

<sup>5</sup> Petitioner was charged with 302 counts of violating 21 U.S.C. 843(a)(2) by:

knowingly, intentionally and unlawfully using in the course of dispensing oxycodone hydrochloride, a Schedule II narcotic drug controlled substance, a DEA Registration Number, which was revoked.

Petitioner was charged with one count of violating 21 U.S.C. 843(a)(2) by:

knowingly, intentionally and unlawfully using, in the course of dispensing diazepam, a Schedule IV narcotic drug controlled substance, a DEA Registration Number, which was revoked. 11. As a result of Petitioner's April 18, 1988 conviction, Petitioner was placed on probation for a period of five years and was ordered to pay a special assessment of \$15,150.00. <u>Id</u>.

12. Section 1128 of the Act permits the I.G. to exclude individuals convicted of criminal offenses "relating to the unlawful manufacture, distribution, prescription, or dispensing of a controlled substance" from participation in the Medicare and Medicaid programs.

13. Petitioner admits that his April 18, 1988 conviction was for criminal offenses "relating to the unlawful manufacture, distribution, prescription, or dispensing of a controlled substance" within the meaning of section 1128(b)(3) of the Act. P. Br. 1, 4-5, 7.

14. In addition to indicia of trustworthiness, the length of Petitioner's exclusion is to 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.

15. The fact that the criminal acts which formed the basis for Petitioner's conviction were committed over a period of time in excess of one year is an aggravating factor and is considered in determining an appropriate length of exclusion. FFCL 8, 10.

16. The fact that Petitioner was "convicted" of 303 counts of prescribing controlled substances under one of his two revoked DEA Certificates is an aggravating factor and is considered in determining an appropriate length of exclusion. FFCL 10.

17. The I.G. did not prove by a preponderance of the evidence, as an aggravating factor in determining an appropriate length of exclusion, that the special assessment of \$15,150.00, paid by Petitioner as a result of his April 18, 1988 conviction, represented actual damages to the Medicare or Medicaid programs. FFCL 11, 13.

18. The fact that Petitioner was placed on probation for five years, as a result of his April 18, 1988 conviction, is an aggravating factor and is considered in determining an appropriate length of exclusion. <u>Id</u>.

19. The fact that Petitioner was convicted in June 1978 of seven felony counts of dispensing controlled substances that were not for a legitimate medical purpose, and of seven misdemeanor counts of prescribing controlled substances to drug dependent persons is an aggravating factor and is considered in determining an appropriate length of exclusion. FFCL 2, 14.

20. The fact that Petitioner's two DEA Certificates were revoked, effective November 26, 1979, is an aggravating factor and is considered in determining an appropriate length of exclusion. FFCL 6, 7, 14.

21. The fact that, in March 1980, the Pennsylvania State Board of Medicine imposed a five year probationary period upon Petitioner and his medical license and placed a restriction upon his prescribing controlled substances is an aggravating factor and is considered in determining an appropriate length of exclusion. FFCL 4, 14.

22. The fact that in May 1989 Petitioner's license to practice medicine in the State of Pennsylvania was suspended for three years, one year of which is an active suspension, and two years of probationary suspension, and that Petitioner was ordered to pay a \$1,000.00 civil penalty by the Pennsylvania State Board of Medicine is an aggravating factor and is considered in determining an appropriate length of exclusion. P. Ex. A.

23. The I.G. has the burden of proving that Petitioner's criminal acts caused harm to individuals. The I.G. has not met this burden by a preponderance of the evidence.

24. In this case, a ten-year period of exclusion is reasonable.

### DISCUSSION

I. <u>Petitioner Was "Convicted" Of A Criminal Offense</u> <u>"Relating To The Unlawful Manufacture, Distribution,</u> <u>Prescription Or Dispensing Of Controlled Substances"</u> <u>Within The Meaning Of Section 1128(b)(3) of the Act</u>.

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 controlled substances". On April 18, 1988, Petitioner was convicted of 303 counts of unlawfully dispensing controlled substances. FFCL 10, 13. Petitioner admits that his conviction falls within the purview of criminal offenses enumerated in section 1128(b)(3) of the Act. FFCL 13.

## II. <u>Ten Years Is An Appropriate Length Of Exclusion In</u> <u>This Case</u>.

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 the appropriate length of exclusion to be imposed.

In making this determination, it is helpful to look at the purpose behind the enactment of 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. See, S. Rep. No. 109, 100th Conf., 1st Sess. 1; reprinted 1987 U.S. Code Cong. and Admin. News 682. 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 Through exclusion, individuals who have individuals. 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 provide to Medicare beneficiaries or Medicaid recipients. Thus, individuals are removed from a position which provides a potential avenue for causing harm to the programs. Exclusion also serves as a deterrent to other individuals against deviant behavior which may result in

harm to the Medicare and Medicaid programs or their beneficiaries and recipients.

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 the opportunity to demonstrate that he or she can and should be trusted to participate in the Medicare and Medicaid programs to provide items and services to program beneficiaries and recipients.

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 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).

As stated by Judge Kessel in the case of <u>Leonard N.</u> <u>Schwartz, R. Ph., Petitioner, v. The Inspector General</u>, Docket No. C-62 (1989), at p. 12:

The Regulations at section 1001.125(b) were adopted by the Secretary to implement the Act prior to the 1987 Amendment. The Regulations specifically apply only to exclusions for 'program-related' offenses. However, . . . to the extent that the Regulations have not been repealed or modified, they embody the Secretary's intent that they continue to apply, at least as broad guidelines, to those cases in which discretionary exclusions are imposed. A. The Fact That Petitioner Was Convicted Of 303 Offenses Relating To The Unlawful Distribution Of Controlled Substances Is An Aggravating Factor In Determining An Appropriate Length Of Exclusion.

Petitioner was convicted by a jury of a total of 303 criminal offenses of unlawfully distributing controlled substances. Petitioner's offenses were both numerous and of a serious nature. Certain substances are enumerated as "controlled" substances because of the potential for their abuse, and because of the potential harm which may be caused by their use. <u>See</u>, 21 U.S.C. 812(b)(2) and (4). Petitioner, through his position as a medical doctor, was allowed access to these controlled substances and was entrusted with the authority to administer and prescribe these controlled substances in an appropriate, legal and ethical manner. Petitioner's jury conviction is clear and convincing evidence of his blatant disregard for this duty.

# B. <u>The I.G. Has Not Proved By A Preponderance Of The</u> <u>Evidence That Respondents Criminal Acts Had An Adverse</u> <u>Impact On Program Beneficiaries</u>.

The I.G. argues that Congress' creation of a closed distribution system for controlled substances creates a legal presumption that harm to individuals results from dispensing those substances outside the legitimate chain of distribution. I disagree with the I.G.'s argument. The I.G. has the burden of proving that Respondent's actions resulted in harm to individuals. The I.G. has not met this burden. The I.G. has offered no evidence regarding whether the controlled substances, although unlawfully distributed, served a "legitimate medical purpose." The trial judge in Petitioner's 1987 criminal proceeding declined to presume that, because Petitioner failed to follow standard medical practices in prescribing controlled substances, he did not prescribe those controlled substances for a valid medical purpose. The I.G. is correct in his statement that the trial judge's reluctance to establish a presumption in a criminal trial is not binding on my decision in this proceeding. However, the I.G. must prove that Petitioner's criminal acts resulted in harm to individuals. Therefore, this factor will not be considered an aggravating factor in determining an appropriate period of exclusion.

# C. <u>The Fact That The Medicare Or Medicaid Program May</u> <u>Have Incurred Damages As A Result Of Petitioner's Acts Is</u> <u>An Aggravating Factor In Determining The Appropriate</u> Length Of Exclusion.

The I.G. has not presented sufficient evidence on the issue of whether the Medicare or Medicaid program incurred actual damages as a result of Petitioner's criminal acts. The I.G. presented evidence which proves that Petitioner was required to pay an assessment of \$15,150.00 as a result of his April 18, 1988 conviction. However, the purpose for the assessment is not stated. Thus, without further evidence regarding the purpose of the assessment, the fact that Petitioner was required to pay an assessment will not be considered an aggravating factor in determining an appropriate length of exclusion.

D. <u>Petitioner Has Not Proven The Existence Of Mitigating</u> <u>Circumstances Which Might Reduce The Period Imposed By</u> <u>The I.G.</u>

The Regulations allow for the consideration of mitigating circumstances in determining an appropriate length of exclusion. As I stated in <u>Mary Katherine Lyons</u>, <u>Petitioner v. The Inspector General</u>, Docket No. C-49 (1989), at p. 9: "it is reasonable to conclude that mitigating circumstances should constitute those circumstances which demonstrate trustworthiness." I conclude that Petitioner has offered no circumstances which are mitigating and which I might consider in determining an appropriate length of exclusion.

Petitioner argues that his alleged unawareness that his acts could be considered as criminal should be viewed as a mitigating circumstance. He cites the conclusion of the DEA Administrator permitting Petitioner to prescribe controlled substances in the course of his practice as an emergency room physician and the waiver by the Administrator of the prohibition against Petitioner's employment by a hospital as an emergency room physician. P. Ex. B. Petitioner's alleged misconception that he was permitted to prescribe controlled substances subsequent to the revocation of his DEA Certificates of Registration is not directly relevant to whether Petitioner should be excluded pursuant to section 1128(b)(3), but may be relevant to the issue of the length of the exclusion to be imposed. Petitioner was convicted by a jury of 303 counts of knowingly and illegally dispensing controlled The definition of Petitioner's criminal substances. offense shows that a jury determined that Petitioner did

in fact know that his acts were in violation of law. Thus, I do not consider this factor to be a mitigating circumstance.

# E. The Sentence Imposed By The Court Is An Aggravating Factor In Determining The Appropriate Length Of Exclusion.

Although Petitioner was not incarcerated as a result of his conviction, he was required to serve a five year term of probation. The fact that the court deemed it necessary to "monitor" Petitioner's actions for a period of five years is an important factor to be considered, and will be considered an aggravating factor in determining an appropriate length of exclusion.

# F. <u>Petitioner's Prior Offenses And Sanctions Are Factors</u> <u>Which Are Considered Aggravating Circumstances</u>.

Petitioner was previously sanctioned on two separate occasions for offenses relating to controlled substances. FFCL 2, 12. Petitioner does not deny the fact of these prior sanctions. However, Petitioner argues that all of the sanctions imposed against him, and his 1987 conviction itself, resulted from his 1978 conviction. It is not disputed that Petitioner received sanctions because of his 1978 conviction: (1) Petitioner was placed on probation by the State Board of Licensing and (2) his DEA Certificates were revoked. However, Petitioner's 1978 conviction, and the resulting sanctions, did not cause him to be convicted in 1987. Petitioner was convicted in 1987 because he knowingly disregarded the fact that his DEA Certificates were revoked and he elected to prescribe controlled substances without a required DEA certification number. Petitioner's convictions, and the sanctions which resulted from each, are independent of each other and will be viewed as such. Therefore, the fact that Petitioner has had criminal, civil, and administrative sanctions imposed against him is considered an aggravating factor.

### CONCLUSION

Based on the law and undisputed material facts in the record of this case, I grant the I.G.'s motion for

summary disposition and conclude that ten-years is an appropriate length of exclusion to be imposed against Petitioner.

/s/

Charles E. Stratton Administrative Law Judge