DEPARTMENT OF HEALTH AND HUMAN SERVICES

Departmental Appeals Board

Civil Remedies Division

In the Case of:	)	
	)	
Bernard Lerner, M.D.,	)	DATE: December 22, 1989
	)	
Petitioner,	)	
	)	
- v. -	)	Docket No. C-48
	)	
The Inspector General.	)	DECISION CR 60
	)	

DECISION OF ADMINISTRATIVE LAW JUDGE

On July 1, 1988, the Inspector General (the I.G.) notified Petitioner that he was being excluded from participation in Medicare and State health care programs for 15 years.[1] The I.G. told Petitioner that he was being excluded as a result of his conviction in federal court of a criminal offense related to the unlawful manufacture, distribution, prescription, or dispensing of a controlled substance. Petitioner was advised that exclusion from participation in Medicare and Medicaid of individuals or entities convicted of such an offense is permitted by section 1128(b)(3) of the Social Security Act. The I.G. stated that the 15-year exclusion imposed and directed against Petitioner was based on factors which included the fact that the sentence resulting from Petitioner's criminal conviction included incarceration.

Petitioner requested a hearing, and the case was assigned to me for a hearing and a decision. I held a hearing in Chicago, Illinois on August 1, 1989. Based on the evidence introduced at the hearing, and on applicable

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[1] "State health care program" is defined by section 1128(h) of the Social Security Act to include any State Plan approved under Title XIX of the Act (such as Medicaid). I use the term "Medicaid" hereafter to represent all State health care programs from which Petitioner was excluded.

law, I conclude that the exclusion imposed and directed against Petitioner is reasonable. Therefore, I am entering a decision in this case sustaining the exclusion imposed and directed against Petitioner.

ISSUE

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

FINDINGS OF FACT AND CONCLUSIONS OF LAW

1. Petitioner is a physician who has specialized in neurosurgery. Tr. at 157; I.G. Ex. 15/ 2, 5.[2]

2. On April 10, 1987, Petitioner was charged in a 167 count indictment with knowingly, willfully and unlawfully obtaining, possessing controlled substances, in violation of 21 U.S.C. 841(a)(1) and 843(a)(3), and 21 C.F.R. 1306.04(a). I.G. Ex. 6.

3. Following a jury trial, on November 25, 1987, Petitioner was convicted of 163 counts of the indictment. I.G. Ex. 1.

4. Petitioner was convicted of possessing and distributing Dilaudid in violation of 21 U.S.C. 841(a)(1) and 843(a)(3), and 21 C.F.R.1306.04(a). I.G. Ex. 1; 6/3-1, 32-34, 36-40, 41-54, 56-93.

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[2] The parties' stipulations, exhibits, transcript of the hearing, and the parties' briefs will be cited as follows:

Stipulation	Stip. (number)
I.G.'s Exhibit I.G.	Ex. (number)/(page)
Petitioner's Exhibit P.	Ex. (number)/(page)
Transcript	Tr. at (page)
I.G.'s Posthearing Brief	I.G.'s Brief at (page)
Petitioner's Posthearing Brief	P.'s Brief at (page)

5. Dilaudid is a Schedule II controlled substance. 21 C.F.R. 1308.12(c).

6. A Schedule II controlled substance is a drug that meets the following criteria: (1) it has a high potential for abuse; (2) it has a currently accepted medical use in the United States or a currently accepted medical use with severe restrictions; and (3) abuse of the drug may lead to severe psychological or physical dependence. 21 U.S.C. 812(b)(2).

7. Administration of Dilaudid may cause side effects, including drowsiness and impaired judgment. I.G. Ex. 19/9; 32; Tr. at 287, 289.

8. Dilaudid has a very high potential for abuse. I.G. Ex. 19/9.

9. Petitioner was convicted of possessing and distributing biphetamine in violation of 21 U.S.C. 841(a)(1) and 21 C.F.R. 1306.04(a). I.G. Ex. 1; 6/94-95; 132-133.

10. Biphetamine is a Schedule III controlled substance. I.G. Ex. 19/13; 21 C.F.R. 1308.13(b).

11. A Schedule III controlled substance is a drug which meets the following criteria: (1) it has a potential for abuse; (2) it has a currently accepted medical use in the United States or a currently accepted medical use with severe restrictions; and (3) abuse of the drug may lead to limited physical or high psychological dependence. 21 U.S.C. 812(b)(3).

12. Petitioner was convicted of possessing and distributing Quaaludes in violation of 21 U.S.C. 841(a)(1) and 21 C.F.R. 1306.04(a). I.G. Ex. 1; 6/146-147.

13. At the time Petitioner unlawfully possessed and distributed Quaaludes, it was a Schedule II controlled substance. I.G. Ex. 19/14.

14. Petitioner was convicted of possessing and distributing Dolophine in violation of 21 U.S.C. 841(a)(1), and 21 C.F.R. 1306.04(a). I.G. Ex. 1; 6/146-169.

15. Dolophine is a Schedule II controlled substance. 21 C.F.R. 1308.12(c); I.G. Ex. 33/1191.

16. On January 14, 1988, Petitioner was sentenced to three and one-half years incarceration and five years probation to run consecutively to the prison sentence, and to a special parole term of ten years. Stip. 3.

17. Between 1981 and 1986, Petitioner engaged in criminal activity whereby he wrote prescriptions for controlled substances to some patients who gave some of these drugs back to him for his use. I.G. Ex. 6/1-2; Tr. at 36, 172.

18. Between 1980 and 1987 Petitioner unlawfully used Dilaudid, Dolophine, biphetamines and cocaine. Tr. at 247.

19. Between 1980 and 1987 Petitioner was addicted to Dilaudid. Tr. at 172.

20. Petitioner continued to treat patients and perform neurological surgeries while he suffered from the physical and mental problems associated with his addiction to drugs and his withdrawal from drug addiction. Stip. 8; Tr. at 247-248.

21. Several of the individuals to whom Petitioner prescribed controlled substances had received treatment for drug addiction. I.G. 16/90; Tr. at 236, 263.

22. The individuals who had received treatment for drug addiction and to whom Petitioner prescribed controlled substances included a 15-year old female employed by Petitioner as a receptionist. Tr. at 263.

23. Petitioner persisted in his unlawful conduct despite warnings from investigative and regulatory agencies. Tr. at 35, 50, 108, 303.

24. Petitioner did not seek treatment for his addiction until after he had been indicted for criminal violations. Tr. at 182.

25. Petitioner did not complete the drug rehabilitation programs in which he enrolled. I.G. Ex. 35/25, 60-65, 74; Tr. at 184-185.

26. Petitioner was convicted of criminal offenses relating to the unlawful manufacture, distribution, prescription, or dispensing of controlled substances. Findings 3-16.

27. The criminal offenses of which Petitioner was convicted are criminal offenses as described in section 1128(b)(3) of the Social Security Act. Social Security Act, section 1128(b)(3).

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

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

30. On July 1, 1988, the I.G. notified Petitioner that he was being excluded from participation in the Medicare and Medicaid programs as a result of his conviction of a criminal offense related to the unlawful manufacture, distribution, prescription, or dispensing of a controlled substance. I.G. Ex. 4; Stip. 6.

31. Petitioner was notified that he was being excluded pursuant to section 1128(b)(3) of the Social Security Act. I.G. ex. 4.

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

33. A remedial objective of section 1128 of the Social Security 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 treat beneficiaries and recipients. Social Security Act, section 1128.

34. An additional remedial objective of section 1128 of the Social Security Act is to deter individuals from engaging in conduct which jeopardizes the integrity of federally-funded health care programs. Social Security Act, section 1128.

35. Petitioner was convicted of many criminal violations. Findings 3-16; see 42 C.F.R. 1001.125(b)(1).

36. Petitioner's actions endangered the health and safety of individuals, including Petitioner's patients, who obtained prescriptions for controlled substances from Petitioner. Findings 3-16, 20-22; see 42 C.F.R. 1001.125(b)(2).

37. Petitioner's criminal activities were perpetrated over a six-year period, a lengthy period of time. Findings 3-19; see 42 C.F.R. 1001.125(b)(6).

38. As a result of his convictions, Petitioner was sentenced to a lengthy period of incarceration, three and one-half years. Finding 16; see 42 C.F.R. 1001.125(b)(5).

39. The seriousness of Petitioner's offenses is also established by the fact that he was sentenced to serve ten years special parole in addition to his incarceration. Finding 16; see 42 C.F.R. 1001.125(b)(5).

40. Petitioner did not prove a community need for his services as a neurological surgeon which establishes that the exclusion imposed against him is unreasonable. See Tr. at 227-229.

41. Even if Petitioner proved a community need for his services as a neurological surgeon, that would not establish that the exclusion imposed against him is unreasonable.

42. Petitioner did not prove that his early release from incarceration establishes that the exclusion imposed against him is unreasonable. See Tr. at 157-158.

43. Petitioner did not prove that his age establishes that the exclusion imposed against him is unreasonable. See Tr. at 227.

44. Petitioner did not prove that his current drug-free status or his acknowledgement of responsibility for his addiction establishes that the exclusion imposed against him is unreasonable. See Tr. at 120, 161-162, 236.

45. Petitioner did not prove that his involvement in drug education and rehabilitation programs establishes

that the exclusion imposed against him is unreasonable. See Tr. at 187-188, 208-209.

46. Petitioner did not establish that, in light of mitigating factors, the exclusion imposed against him is unreasonable. Findings 42-47.

47. The 15-year exclusion against Petitioner participating in Medicare or Medicaid is reasonable. Findings 40-46; Social Security Act, section 1128(b)(3); see 42 C.F.R. 1001.125(b)(1)-(7); 42 C.F.R. 1001.128.

ANALYSIS

The parties do not dispute that Petitioner was convicted of criminal offenses relating to the unlawful distribution, prescription, or dispensing of controlled substances. The I.G. has authority under section 1128(b)(3) of the Social Security Act to impose and direct an exclusion against Petitioner from participating in the Medicare and Medicaid programs. The only contested issue in this case is the reasonableness of the 15-year exclusion which the I.G. imposed and directed against Petitioner.

The I.G. contends that the lengthy exclusion imposed and directed against Petitioner is reasonable, when considered in the context of the evidence and the purpose of the exclusion law. The I.G. argues that Petitioner was convicted of very serious criminal offenses perpetrated over a period of several years. According to the I.G., Petitioner's conduct was not only unlawful, but it endangered the health and well-being of others, including the patients whom Petitioner treated. The I.G. argues that a lengthy exclusion is necessary to protect Medicare recipients and Medicaid beneficiaries from the possibility that Petitioner might again jeopardize their well-being by abusing controlled substances.

Petitioner acknowledges his unlawful conduct, but contends that there is little likelihood that it will recur. He asserts that there exists a need in his community for his special medical skills and that restoring his participant status will serve to meet that need. Petitioner argues that, because there is little likelihood that he will again engage in the conduct for which he was convicted, a lengthy exclusion is unnecessarily punitive.

The exclusion law was enacted by Congress to protect the integrity of the Medicare and Medicaid programs. Among other things, the law was designed to protect program recipients and beneficiaries from individuals who had demonstrated by their behavior that they posed a threat to the well-being and safety of recipients and beneficiaries.

There are two ways that exclusions imposed and directed pursuant to this law advance this remedial purpose. First, the law protects recipients and beneficiaries from untrustworthy providers until such time as these providers demonstrate that they can be trusted to treat program recipients and beneficiaries. Second, exclusions serve as examples to deter providers of items or services from engaging in conduct which threatens the well-being and safety of recipients and beneficiaries. See House Rep. No. 95-393, Part II, 95th Cong., 1st Sess., reprinted in 1977 U.S. Code Cong & Admin. News, 3072.

An exclusion imposed and directed pursuant to section 1128 will likely have an adverse financial impact on the person against whom the exclusion is imposed. However, the law places the well-being and safety of recipients and beneficiaries ahead of the pecuniary interests of providers. Thus, in determining the reasonableness of an exclusion, the primary consideration must be the degree to which the exclusion serves the law's remedial objectives. An exclusion is not punitive if it does reasonably serve these objectives, even if it has a severe adverse impact on the person against whom it is imposed.

In order to decide whether an exclusion is reasonable in a particular case, I must judge the exclusion in light of the evidence of the case and the intent of the exclusion law. 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 the legislative purpose.

The hearing is, by law, de novo. Social Security Act, section 205(b). Evidence which is relevant to the reasonableness of an exclusion will be admitted in a hearing on an exclusion even if that evidence was not available to the I.G. at the time the I.G. made his exclusion determination. I permitted the parties to this case to offer evidence as to the reasonableness of the exclusion which was not available to the I.G. at the time he made his exclusion determination. For example, I

admitted evidence from Petitioner pertaining to his efforts at rehabilitation while incarcerated in federal prison.

An exclusion will be held to be reasonable where, given the evidence of the case, it is shown to fairly comport with legislative intent. "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." (Emphasis added). 48 Fed. Reg. 3744 (Jan. 27, 1983). However, should I determine that an exclusion is unreasonable, 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 only to exclusions for "program-related" offenses (convictions for criminal offenses related to Medicare and Medicaid). However, they do express the Secretary's policy for evaluating cases where permissive exclusions may be appropriate. Thus, the regulations are instructive as broad guidelines for determining the appropriate length of exclusions in cases where the Secretary has authority to exclude individuals and entities. The regulations require the I.G. in determining exclusions to consider factors related to the seriousness and program impact of the offense and to balance those factors against any mitigating factors that may exist. 42 C.F.R. 1001.125(b)(1)-(7).

I conclude that the 15-year exclusion imposed against Petitioner is entirely consistent with the exclusion law's remedial purpose. My conclusion is grounded on the very serious crimes Petitioner committed and the jeopardy in which Petitioner's unlawful conduct placed his patients. I find that the danger of harm to patients is so great, should Petitioner resume his previous behavior, that a lengthy exclusion is justified to insure that program recipients and beneficiaries are protected from even a slight possibility that they will be exposed to such danger. I also conclude that a lengthy exclusion may have the additional benefit of deterring other providers of services from engaging in the conduct engaged in by Petitioner.

The evidence establishes a pattern of many criminal violations by Petitioner over a long period of time. See 42 C.F.R. 1001.125(b)(1). The seriousness of

Petitioner's violations is in some measure reflected in the sentence imposed on him. See 42 C.F.R. 1001.125(b)(5). The evidence also establishes that Petitioner's conduct jeopardized the safety of his patients. See 42 C.F.R. 1001.125(b)(2).

For years, Petitioner was addicted to Dilaudid, and he abused other medications. Findings 4-17. In order to support his addiction, Petitioner engaged in a scheme whereby he prescribed Dilaudid and other controlled substances to patients who were also addicted to these drugs. These patients then gave back to Petitioner a portion of the drugs they obtained from him. Finding 17.

Among the people whom Petitioner enlisted in his scheme were patients who had histories of substance abuse and treatment for drug addiction. Rather than treat these patients, Petitioner abetted and encouraged their addiction in order to supply his own needs. The persons whom Petitioner used as fronts for the purpose of obtaining drugs included a child, aged 15 years.

Moreover, Petitioner rendered treatment, including performing neurological surgery, while addicted to Dilaudid. He did so despite the potential side effects of this drug, which include drowsiness and impaired judgment. Finding 20.

The record establishes that on several occasions prior to being indicted, Petitioner was investigated for his pattern of prescribing large quantities of controlled substances and warned by investigating authorities that his conduct was questionable. These warnings failed to deter Petitioner. It was only after Petitioner was indicted and faced the possibility of incarceration that he sought treatment for his addiction. Even then, Petitioner failed to complete the programs he enrolled in. Findings 23-25.

The inescapable inference that this evidence creates is that Petitioner is an individual who is highly susceptible to the temptations posed by addictive drugs. He is a person who has engaged in destructive and self-destructive behavior in spite of his education and his knowledge of the medical risks and dangers posed by his conduct. Most disturbing, the record supports the conclusion that Petitioner is an individual who can consciously place gratification of his needs above the well-being of those he has sworn to treat and to protect.

Petitioner's argument that the exclusion is unreasonable is essentially premised on his contention that he has learned his lesson and that he is therefore not about to repeat his misconduct. He asserts that in light of his rehabilitation, the very long exclusion imposed against him is punitive.

The evidence does show that Petitioner has made some recent efforts to rehabilitate himself. For example, while incarcerated, Petitioner instructed fellow inmates on the dangers of drug addiction. Tr. at 187-188, 208-209. Petitioner has remained drug-free since his conviction. However, I conclude that the 15-year exclusion imposed against Petitioner is nonetheless reasonable. See 42 C.F.R. 1001.125(b)(4).

I do not accept Petitioner's argument that the exclusion is unreasonable in light of his efforts at rehabilitation. Petitioner has not established to my satisfaction that he will not relapse, if again exposed to the temptation presented by unlawful drugs. The evidence in this case documents a long history of substance abuse by Petitioner, and a stubborn refusal by him to do anything about his condition. The record also documents efforts by Petitioner to cover up the dimensions of his addiction and his involvement of his patients in his scheme to obtain drugs.[3] His rehabilitation, so far, has been accomplished in environments of confinement (including federal prison) where his access to unlawful substances has been restricted, and where he has been subjected to strict scrutiny. The opportunities for relapse will multiply if and when Petitioner returns to his former profession.

Furthermore, the potential dangers to Petitioner's future patients are enormous should Petitioner relapse. Given this, a substantial margin of safety must be built into any exclusion imposed against Petitioner. A 15-year exclusion does not appear to be unreasonable in view of the damage that Petitioner could cause to recipients and beneficiaries should he resume his past conduct.

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[3] The judge who sentenced Petitioner to incarceration found that Petitioner had perjured himself as a witness in his criminal trial and characterized elements of Petitioner's testimony as "blatant lies." I.G. Ex. 14/38-39.

Petitioner argues that the exclusion imposed against him is unreasonable in view of the asserted need for neurological surgeons in his community. Petitioner's evidence as to need consists largely of his uncorroborated assertion that a need exists. More important, even if a need for surgeons of Petitioner's specialty does exist, that need is for surgeons who are not addicted to controlled substances. In this case, the loss to recipients and beneficiaries of Petitioner's talents and skills is more than compensated for by the protection to the safety of recipients and beneficiaries which results from excluding Petitioner.

I am not persuaded by Petitioner's assertion that, in light of his age (46), a 15-year exclusion is unreasonable. As is noted supra, an exclusion will be upheld as reasonable, even where it has an adverse effect on the excluded party, if there is a legitimate need for the exclusion in order to protect the integrity of the Medicare and Medicaid programs.

Both parties compared this case to my decision in the case of Leonard N. Schwartz, R.Ph., v. The Inspector General, DAB Docket No. C-62 (1989). In Schwartz, I upheld an eight-year exclusion for a pharmacist convicted of two counts of knowingly and intentionally omitting material information from required records in dispensing controlled substances, a violation of 21 U.S.C. 843(a)(4)(A). I held in Schwartz (p. 13), that an eight-year exclusion is justified where an individual participated in numerous unlawful transactions of a controlled substance, after having succumbed to personal and psychological pressures, and where the individual's conduct endangered the health and safety of others.

Both parties argued the comparisons between this case and Schwartz. The I.G. stressed the many ways in which the circumstances here justify a lengthier exclusion than Schwartz; Petitioner relied principally on his assertion that he was driven by his addiction and did not profit from his wrongdoing, whereas the petitioner in Schwartz did profit.

I conclude that the comparison with Schwartz amply justifies the greater 15 year exclusion in this case. The petitioner in Schwartz was convicted on two counts of omitting required information in connection with the distribution of controlled substances; Petitioner here on 163 counts of illegally distributing controlled substances. The offenses in Schwartz were committed over

a period of 17 months; here, over a period of six to seven years. The petitioner in Schwartz was sentenced to 18 months prison; Petitioner here was sentenced to 3.5 years. Both endangered the lives of others by making controlled substances available in an unlawful manner; in addition Petitioner here risked the lives of patients on whom he performed operations while he was under the influence of controlled substances, ignored warnings by governmental agencies that he should discontinue the activities of which he was later convicted, and perjured himself when questioned by authorities about his activities.

Petitioner attempted to distinguish Schwartz by contending that the petitioner there profited from his illegal activities, whereas Petitioner was driven by his addiction and not profit. The I.G. argues that Petitioner did profit because had he not been able to obtain these substances in the illegal manner which he did (i.e., by having patients give him a share of their prescriptions), he would have had to pay for them himself, at considerable expense. I find that Petitioner did "profit" to the extent described by the I.G. Also, I conclude that even if Petitioner did not "profit" per se, the fact that he was driven by his addiction instead of a desire for profit makes him less, not more, trustworthy. Thus, even Petitioner's alleged distinction supports a lengthier exclusion.

The exclusion imposed in this case may have the ancillary benefit of deterring other individuals from engaging in the conduct Petitioner engaged in. It should send a message that individuals who engage in this kind of behavior can expect to incur substantial exclusions from participation in Medicare and Medicaid.

CONCLUSION

Based on the evidence in this case and the law, I conclude that the 15-year exclusion imposed against Petitioner from participating in the Medicare and Medicaid programs is reasonable. Therefore, I sustain the exclusion imposed against Petitioner, and I enter a decision in favor of the I.G.

/s/

Steven T. Kessel
Administrative Law Judge