

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Departmental Appeals Board

Civil Remedies Division

In the Case of:)	
)	DATE: February 12, 1990
Ralph W. Wilkinson and)	
Lamar's Pharmacy,)	
)	
Petitioners,)	Docket No. C-77
)	
- v. -)	DECISION CR 67
)	
The Inspector General.)	
)	

DECISION OF ADMINISTRATIVE LAW JUDGE

By letter dated September 30, 1988, the Inspector General (the I.G.) notified Petitioners Ralph W. Wilkinson (Petitioner) and Lamar's Pharmacy that they were being excluded from participation in Medicare and any State Health care program for five years.¹ Both Petitioners were advised that they were being excluded because they had been convicted of a criminal offense related to the unlawful manufacture, distribution, prescription, or dispensing of a controlled substance. Petitioners were advised further that their exclusions were authorized by section 1128(b)(3) of the Social Security Act.

Petitioners timely requested a hearing, and the case was assigned to me for a hearing and a decision. Prior to the hearing, the I.G. moved for summary disposition on all issues. This motion was contested by Petitioners. On September 11, 1989, I issued a Ruling which granted in part and denied in part the I.G.'s motion. I ruled that, based on undisputed material facts, Petitioner had been convicted of a criminal offense related to the unlawful

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.

manufacture, distribution, prescription or dispensing of a controlled substance within the meaning of section 1128(b)(3) of the Social Security Act. I concluded that the I.G. had authority to exclude Petitioner from participating in Medicare and to direct his exclusion from participating in Medicaid. I ruled that the record did not contain facts which enabled me to rule as to the I.G.'s authority to exclude Lamar's Pharmacy. I also ruled that both Petitioners were entitled to a hearing as to the reasonableness of the length of the five year exclusions which the I.G. had imposed and directed against them.

I conducted a hearing in the case in Atlanta, Georgia on November 3, 1989. Prior to the hearing, counsel for Petitioners advised me that Lamar's Pharmacy wished to withdraw its request for a hearing. I therefore dismissed Lamar's Pharmacy's hearing request.

I have considered the evidence introduced by both parties at the November 3 hearing. Based on the evidence and on applicable law, I conclude that the five year 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.

ISSUES

The issues in this case are whether:

1. Petitioner was convicted of a criminal offense within the meaning of section 1128(b)(3) of the Social Security Act; and
2. the exclusion imposed and directed against Petitioner by the I.G. is reasonable.

FINDINGS OF FACT AND CONCLUSIONS OF LAW

1. Petitioner is a pharmacist. Tr. at 40.²
2. On November 10, 1987, Petitioner was indicted in federal court on two counts of unlawfully distributing controlled substances in violation of 21 U.S.C. 841(a)(1), and on two counts of omitting or failing to maintain prescriptions for controlled substances in violation of 21 U.S.C. 843(a)(4)(A). I.G. Ex. 1.
3. On February 9, 1988, Petitioner pleaded guilty to, and was convicted of, one count of violating 21 U.S.C. 843(a)(4)(A). I.G. Ex. 2.
4. Petitioner was convicted of failing to maintain prescriptions for Diazepam 10 mg tablets. I.G. Ex. 2.
5. Diazepam is a controlled substance sold under the trade name of Valium. Tr. at 44.
6. Petitioner was sentenced to 18 months in prison and was ordered to pay a fine of \$2,500.00. I.G. Ex. 2.
7. Petitioner unlawfully dispensed Valium without valid prescriptions for a sixteen month period. Tr. at 49.
8. Petitioner unlawfully dispensed Valium to regular customers of his pharmacy who had prescriptions for Valium which were no longer valid. Tr. at 47, 50.
9. Petitioner failed to keep required records as to the sale of approximately 25,000 tablets of Valium. Tr. at 47.
10. Petitioner unlawfully dispensed at least 1200 Valium tablets to customers of his pharmacy. Tr. at 44-45.
11. Petitioner's customers compensated him for his unlawful sales of Valium. Tr. at 49-50.

² The parties' exhibits and the transcript of the hearing will be cited as follows:

I.G.'s Exhibit	I.G. Ex.
Petitioner's Exhibit	P. Ex.
Transcript	Tr. at

12. Petitioner's unlawful sales of Valium endangered the health of his customers. Tr. at 47.

13. Petitioner was convicted of a criminal offense relating to the unlawful manufacture, distribution, prescription, or dispensing of a controlled substance. Findings 2-12.

14. The criminal offense of which Petitioner was convicted is a criminal offense as described in section 1128(b)(3) of the Social Security Act. Social Security Act, section 1128(b)(3).

15. 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).

16. 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).

17. On September 30, 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. 5.

18. Petitioner was notified that he was being excluded for five years pursuant to section 1128(b)(3) of the Social Security Act. I.G. Ex. 5.

19. 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).

20. 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 provide items or services to program

beneficiaries and recipients. Social Security Act, section 1128.

21. 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.

22. Petitioner was convicted of a serious criminal offense, resulting in his incarceration. Findings 3-6; See 42 C.F.R. 1001.125(b)(1).

23. Petitioner perpetrated the conduct, which resulted in his conviction, over a 16 month period, a lengthy period of time. Finding 7; See 42 C.F.R. 1001.125(b)(6).

24. Petitioner's actions endangered the health and safety of his customers. Finding 12; See 42 C.F.R. 1001.125(b)(2).

25. Petitioner did not establish that, in light of mitigating factors, the exclusion imposed against him is unreasonable.

26. The five year exclusion against Petitioner participating in Medicare or Medicaid is reasonable. Findings 20-25; Social Security Act, section 1128(b)(3); See 42 C.F.R. 1001.125(b)(1)-(7); 42 C.F.R. 1001.128.

ANALYSIS

Petitioner was convicted of failing to maintain records of sales of the controlled substance Diazepam (Valium), in violation of 21 U.S.C. 843(a)(4)(A). I previously ruled that this conviction comprised a conviction of a criminal offense relating to the unlawful manufacture, distribution, prescription or dispensing of a controlled substance. I ruled that the I.G. was authorized 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. I hereby incorporate that Ruling in this Decision.

What remains to be decided is the reasonableness of the exclusion which the I.G. imposed and directed against Petitioner. The I.G. contends that a five year exclusion was justified by the facts of this case.

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 could not be entrusted with 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 they can be trusted to serve program recipients and beneficiaries. Second, exclusions function 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 in 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 consisting of letters from members of his family and from business associates and members of his community attesting to his character and trustworthiness. See P.Ex. 1-18.

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).

An exclusion determination 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).

I conclude that the five year exclusion imposed against Petitioner is not extreme or excessive. Given the seriousness of the crime of which Petitioner was convicted, and his admissions as to the conduct he engaged in, the I.G. was justified in concluding that Petitioner was not trustworthy to deal with program recipients and beneficiaries and should not be trusted to deal with such individuals for a substantial period of time. Furthermore, the exclusion imposed and directed by the I.G. may have the additional benefit of deterring other providers of services from engaging in the conduct engaged in by Petitioner.

The evidence establishes protracted and serious criminal misconduct by Petitioner. By his own admission, he misused his position as a pharmacist to sell many units of Valium to individuals who did not have valid

prescriptions for that drug. His admitted misconduct extended over a period of many months. 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 health and safety of Petitioner's customers. See 42 C.F.R. 1001.125(b)(2).

Petitioner testified that he was aware that his misconduct was wrong. He asserted that he had learned his lesson and would not repeat the offense. His assurances were in some measure supported by the testimonials he offered from members of his family and his community. I do not question Petitioner's sincerity or his intentions. I also recognize that a lengthy exclusion is likely to have a severe impact on Petitioner's career plans and personal finances. However, given the seriousness of Petitioner's criminal misconduct, the I.G. is justified in determining that, for a time, a barrier must be erected between Petitioner and program recipients and beneficiaries in order to assure that these individuals are protected from future misconduct.

The five year exclusion imposed and directed by the I.G. serves that purpose. Petitioner's misconduct is so serious that even a slight potential for repetition justifies imposition of an exclusion. The record of this case shows that Petitioner displayed extremely poor judgment in his dealings with members of the public. He engaged in conduct that he knew was illegal, and he profited by that conduct. Moreover, he betrayed a position of trust that he held as a licensed pharmacist. Despite Petitioner's assurances, I cannot say with confidence, based on the record of this case, that Petitioner will not repeat his misconduct if given the opportunity.

The exclusion imposed in this case may have the ancillary benefit of deterring other individuals from engaging in the conduct in which Petitioner engaged. 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 five 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