Department of Health and Human Services

DEPARTMENTAL APPEALS BOARD

Civil Remedies Division

Vinod Chandrashekhar Patwardhan, M.D.,
(OI File No.: L-08-40719-9),

Petitioner

v.

The Inspector General.

Docket No. C-11-615

Decision No. CR2471

Date: December 8, 2011

DECISION

Petitioner, Vinod Chandrashekhar Patwardhan, M.D., is a California physician, specializing in internal medicine and oncology, who organized a scheme to smuggle unapproved chemotherapy drugs into the United States from India and Honduras and to administer those drugs to patients. He was eventually caught and convicted on felony counts of conspiracy, introducing misbranded drugs into interstate commerce, smuggling goods into the United States, and knowingly and intentionally aiding, abetting and causing the fraudulent importation of drugs purchased in Honduras. Based on his convictions, the Inspector General (I.G.) excluded him from participation in Medicare, Medicaid, and all federal health care programs for a period of 23 years. However, responding to a request from a state healthcare program, the I.G. partially waived his exclusion, allowing him to bill the programs for the oncology services he provides in a medically-underserved area.

Petitioner appeals the exclusion.

The parties agree that, based on his convictions, Petitioner Patwardhan is subject to

a minimum five-year exclusion under sections 1128(a)(1) and 1128(a)(3) of the Social Security Act (Act). They dispute the length of his exclusion beyond five years.

For the reasons set forth below, I find that, based on the narrow and unique circumstances of this case, a 23-year exclusion does not fall within a reasonable range and reduce the period of exclusion to 12 years.

I. Background

By letter dated June 30, 2011, the I.G. notified Petitioner that he was partially excluded from participation in Medicare, Medicaid, and all federal health care programs for a period of 23 years, because he had been convicted of felony criminal offenses related to: 1) the delivery of an item or service under the Medicare or state health care program; and 2) fraud, theft, embezzlement, breach of fiduciary responsibility, or other financial misconduct in connection with the delivery of a health care item of service. The letter explained that sections 1128(a)(1) and 1128(a)(3) of the Act authorize the exclusion. I.G. Ex. 1.

The letter also explained that the I.G. partially waived the exclusion in response to a November 19, 2010 letter from David Maxwell-Jolly, Director of the California Department of Health Care Services. Director Maxwell-Jolly asked the I.G. to waive Petitioner's exclusion pursuant to 42 C.F.R. § 1001.1801(b), because the physician was the sole source of oncology services in his community. The I.G. therefore granted a limited waiver for "services [Petitioner provides] under the Medicare, Medicaid, and all federal health care programs . . . in Upland, California for oncological items and services" for as long as the state agency determines that a need exists. I.G. Ex. 1 at 1-2; P. Ex. 8.

Petitioner concedes that he was convicted and is subject to exclusion under sections 1128(a)(1) and 1128(a)(3) of the Act. P. Brief (Br.) at 1, 2.

Each party submitted a written argument (I.G. Br.; P. Br.). The I.G. also submitted five exhibits (I.G. Exs. 1-5) and a reply brief (I.G. Reply). Petitioner submitted ten exhibits (P. Exs. 1-10).

In the absence of an objection, I admit into evidence I.G. Exs. 1-5.

The I.G. objects to P. Exs. 1 and 4-10, arguing that they are irrelevant. P. Ex. 1 is a written declaration from Noam Drazin, M.D., a physician specializing in oncology and hematology, in which he opines that patient responses to the illegally-imported drugs "were not atypical" and that the standard of care Petitioner provided his patients was "not worse than the standard of care for oncologists in the area." P. Ex. 1. P. Exs. 4-7 include hundreds of letters from grateful patients, their families, and health care providers

describing Petitioner's practice and attesting to his professional abilities, charitable works and many kindnesses. P. Ex. 8 is the letter from Director Maxwell-Jolly requesting a waiver. P. Exs. 9 and 10 are letters from California state senators attesting to the importance of Petitioner's clinic to the medically-underserved community in which it is located.

I find none of these exhibits irrelevant. Because they relate to the waiver, P. Exs. 8-10 explain the current scope of Petitioner's exclusion.[1] Moreover, these and the other challenged documents also provide evidence of Petitioner's motive and intent, which, by regulation, makes them relevant and admissible. 42 C.F.R. § 1005.17(g) (making admissible "acts other than those at issue in the instant case. . . in order to show motive, opportunity, intent, knowledge, preparation, identity, lack of mistake, or existence of a scheme. . . ."); *Emem Dominic Ukpong*, DAB No. 2220 (2008); *Narendra M. Patel*, M.D., DAB No. 1736 (2000), *aff'd sub nom, Patel v. Thompson*, No. 00-00222-CV-HLM-4 (N.D.G. 2002), *aff'd*, 319 F. 3d 1317 (11th Cir. 2003)(holding that extrinsic evidence is admissible to fill in the circumstances surrounding the events that formed the basis for the offense of which Petitioner was convicted). I therefore admit into evidence P. Exs. 1-10.

I directed the parties to indicate in their briefs whether an in-person hearing would be necessary and, if so, to "describe the testimony it wishes to present, the names of the witnesses it would call, and a summary of each witnesses' proposed testimony." I specifically directed the parties to explain why the testimony would be relevant. Order and Schedule for Filing Briefs and Documentary Evidence, Attachment 1 (Informal Brief of Petitioner ¶ IV) and Attachment 2 (Informal Brief of I.G. ¶ III) (Aug. 15, 2011). The I.G. indicates that an in-person hearing is not necessary. Petitioner, on the other hand, contends that an in-person hearing is necessary and lists himself, Dr. Drazin, and some unidentified patients as potential witnesses. He says that he and his patients would describe his practice, his ignorance of the law, the low level of his culpability, and the impact of his exclusion on the population he serves. Dr. Drazin's testimony would repeat the statements included in his written declaration: in his opinion, Petitioner did not endanger patients when he gave them the illegally-imported drugs. P. Ex. 1.

Evidence of Petitioner's purported ignorance is not admissible here. Knowledge was an element of his crimes, and he may not collaterally attack in this forum the underlying conviction. 42 C.F.R. § 1001.2007(d); *Joann Fletcher Cash*, DAB No. 1725 (2000).

The remaining evidence that Petitioner proposes to submit through these witnesses is already in the record. As discussed below, for example, the sentencing judge laid out, in

[1] I recognize that I have no authority to review the I.G.'s decision to grant or deny a waiver. It does not follow, however, that the scope of Petitioner's current program participation is irrelevant to the issues before me.

considerable detail, Petitioner's practice and level of culpability. *See, e.g.*, P. Ex. 2 at 18-24. In her decision, which was adopted by the Medical Board of California, State Administrative Law Judge Mary Agnes Matyszewski set forth in detail the testimony of Petitioner and his other witnesses and incorporates that testimony into her findings. P. Ex. 3. The I.G. has not challenged any portion of that decision. I therefore conclude that an in-person hearing would serve no purpose but would repeat testimony and evidence that is already in the record.

II. Issue

Because the parties agree that the I.G. has a basis upon which to exclude Petitioner from program participation, the sole issue before me is whether the length of the exclusion (23 years) is reasonable. 42 C.F.R. § 1001.2007.

III. Discussion

> ***Based on the criminal convictions (including Petitioner's underlying motive and intent) and three aggravating factors, a 23-year exclusion is excessive; rather, a 12-year exclusion falls within a reasonable range.***[2]

Section 1128(a)(1) of the Act mandates that the Secretary of Health and Human Services exclude an individual who has been convicted under federal or state law of a criminal offense related to the delivery of an item or service under Medicare or a state health care program. 42 C.F.R. § 1001.101(a).

Section 1128(a)(3) says that an individual or entity convicted of felony fraud, theft, embezzlement, breach of fiduciary responsibility, or other financial misconduct in connection with the delivery of a health care item or service must also be excluded from participation in federal health care programs. 42 C.F.R. § 1001.101(c).

An exclusion under either section 1128(a)(1) or 1128(a)(3) must be for a minimum period of five years. Act § 1128(c)(3)(B); 42 C.F.R. §§ 1001.102(a), 1001.2007(a)(2). Federal regulations set forth criteria for lengthening exclusions beyond the five-year minimum. 42 C.F.R. § 1001.102(b). Evidence that does not pertain to one of the aggravating or mitigating factors listed in the regulation may not be used to decide whether an exclusion of a particular length is reasonable.

The conviction. Petitioner is a physician specializing in internal medicine and oncology who maintains a medical practice in California. On September 21, 2009, he was

[2] I make this one finding of fact/conclusion of law.

convicted in the U.S. District Court for the Central District of California of one count of conspiracy (18 U.S.C. § 371); two counts of introducing misbranded drugs into interstate commerce (21 U.S.C. §§ 331(a), 333(a)(2), 352(c), 352(f)(1)); two counts of smuggling goods into the United States, namely drugs purchased in India (18 U.S.C. § 545); and one count of knowingly and intentionally aiding, abetting, counseling, commanding, inducing, procuring, and causing the fraudulent and knowing importation and bringing into the United States drugs purchased in Honduras (18 U.S.C. §§ 2 (a),(b), 545). I.G. Ex. 2.[3]

The court sentenced him to nine months in-home detention followed by five years probation. It ordered him to pay a $10,000 fine, a $600 assessment and $1,313,634.10 in restitution to the Department of Health and Human Services, MediCal/MediCaid Services. I.G. Ex. 2.

Circumstances surrounding the events that formed the basis for the offenses of which Petitioner was convicted. Petitioner is a native of India with a medical degree from Nagpur University Medical College in Nagpur, India. P. Ex. 3 at 4. He eventually found his way to the United States and, since 1975, has conducted a private medical practice in California. P. Ex. 3 at 4. Sentencing Judge Virginia A. Phillips characterized Petitioner's history as "a lifetime of service to his profession and the provision of medical care without regard to his patient's ability to pay for it." P. Ex. 2 at 18, 33; *accord* P. Ex. 3 at 12. He treated patients "without much regard for reimbursement." However, beginning in 1997, changes in reimbursement policies put his practice in financial difficulty. P. Ex. 2 at 16.

When visiting family in India, Petitioner volunteered to treat patients, usually without charge. P. Ex. 2 at 20. Because the medications were so much cheaper there, he began purchasing them at an Indian pharmacy and taking them back to the United States, where he administered them to his patients, many of whom were indigent and could not afford to pay. P. Ex. 2 at 16; P. Ex. 3 at 10. These were the same drugs he used in treating patients in India. P. Ex. 2 at 16. Petitioner subsequently expanded that practice to other countries and involved some of his employees.

Judge Phillips found it "impossible" to view his crime as one that was motivated by greed. P. Ex. 2 at 18. She also found him "extraordinarily unlikely to commit another

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[3] The Court's judgment indicates that Petitioner entered a guilty plea, and the I.G. asserts that Petitioner pled guilty. I.G. Ex. 2; I.G. Br. at 3. However, during the sentencing proceedings, the participants repeatedly alluded to a trial. *See*, *e.g.*, P. Ex. 2 at 27-28 (in which counsel states "at trial evidence came out. . . ."); P. Ex. 2 at 29-30 (referring to trial testimony); P. Ex. 2 at 79 (in which government counsel states that "the jury found beyond a reasonable doubt. . . ."); P. Ex. 2 at 80 (referring to the "closing argument"); P. Ex. 2 at 82 (the court referring to the "trial of this case").

crime." P. Ex. 2 at 23. Similarly, State ALJ Matyszewski concluded that "no evidence suggests that [Petitioner's] actions were motivated by anything other than an attempt to provide oncology medications to poor and indigent patients . . . ." P. Ex. 3 at 17. Thus, Petitioner or others acting at his direction traveled to foreign countries (India, Honduras, the Philippines and Panama), where they bought drugs. They concealed the drugs, and brought them back to the United States without declaring them to customs officials. P. Ex. 2 at 15. Without telling his patients the source of the drugs, he administered them and, where feasible, billed health care programs as if the drugs were FDA-approved medicines.

Aggravating factors. Among the factors that may serve as bases for lengthening the period of exclusion are three that the I.G. relies on in this case: 1) the acts resulting in the conviction, or similar acts, caused a government program or another entity financial losses of $5,000 or more; 2) the acts that resulted in the conviction, or similar acts, were committed over a period of one year or more; and 3) the sentence imposed by the court included incarceration. 42 C.F.R. § 1001.102(b). The presence of an aggravating factor or factors, not offset by any mitigating factor or factors, justifies lengthening the mandatory period of exclusion.

Petitioner agrees that this case presents three aggravating factors. P. Br. at 2. First, the sentencing court ordered him to pay $1,313,634.10 in restitution to the Medicaid program. I.G. Ex.1 at 2. Restitution has long been considered a reasonable measure of program losses. *See Jason Hollady, M.D.*, DAB No. 1855 (2002). Second, the acts that formed the basis of his conviction occurred over a period of approximately three years, from 2005 until about July 30, 2008. I.G. Ex. 3 at 6, 14, 15. Third, even though the trial judge imposed a comparatively light jail sentence – 9 months in a home detention program without electronic monitoring – this qualifies as incarceration, within the meaning of the regulations. 42 C.F.R. § 1001.2(d)(defining incarceration as "imprisonment or any type of confinement with or without supervised release, including, but not limited to, community confinement, house arrest and home detention").

No mitigating factors. The regulations consider mitigating just three factors: 1) a petitioner was convicted of three or fewer misdemeanor offenses and the resulting financial loss to the program was less than $1,500; 2) the record in the criminal proceedings demonstrates that a petitioner had a mental, physical, or emotional condition that reduced his culpability; and 3) a petitioner's cooperation with federal or state officials resulted in others being convicted or excluded, or additional cases being investigated, or a civil money penalty being imposed. 42 C.F.R. § 1001.102(c). Characterizing mitigating factors as "in the nature of an affirmative defense," the Board has ruled that Petitioner has the burden of proving any mitigating factor by a preponderance of the evidence. *Barry D. Garfinkel*, M.D., DAB No. 1572 at 8 (1996).

Petitioner suggests that his "interminable humanitarian nature and altruism" falls within the meaning of a "mental, emotional or physical condition" that reduces his culpability. P. Br. at 5. I reject this argument. Altruism is a positive quality, not a mental or emotional "condition" within the meaning of the regulation.

I nevertheless recognize that Petitioner is not typical of the convicted felons excluded from program participation. That he was motivated by misguided altruism is well-established by the record before me. Both the criminal trial judge and the state licensing judge agreed that he poses no risk to his patients and virtually no risk to program integrity. Nevertheless, I cannot disregard the significant aggravating factors in this case. Because of those factors, I must reject his plea to reduce the exclusion to the statutory minimum.

On the other hand, I agree with Judges Phillips and Matyszewski: Petitioner poses less of a risk to program integrity than many of those subject to a minimum period of exclusion. Given the totality of circumstances in this case, I find a 23-year exclusion unreasonably harsh and reduce that period to 12 years, which I consider within a reasonable range.

IV. Conclusion

For these reasons, I conclude that the I.G. properly excluded Petitioner from participation in Medicare, Medicaid and all federal health care programs. Considering the unique circumstances of this case, I find a 23-year exclusion unreasonable and reduce his period of exclusion to 12 years.

/s/
Carolyn Cozad Hughes
Administrative Law Judge