Department of Health and Human Services

DEPARTMENTAL APPEALS BOARD

Civil Remedies Division

Eduardo Miranda, M.D.,
(OI File No. H-14-4-3117-9),

Petitioner,

v.

The Inspector General.

Docket No. C-15-3603

Decision No. CR4639

Date: June 21, 2016

DECISION

Petitioner, Eduardo Miranda, is a physician who practices in the State of Texas. The parties agree that he was convicted of introducing misbranded drugs into interstate commerce and, pursuant to section 1128(a)(1) of the Social Security Act (Act), must be excluded from participating in federal health care programs for a minimum period of five years. The Inspector General (IG) wishes to exclude him for thirteen years. Petitioner challenges the length of that exclusion, arguing that thirteen years is excessive and unreasonable.

For the reasons set forth below, I find that a thirteen-year exclusion is reasonable.

Background

In a letter dated May 29, 2015, the IG advised Petitioner Miranda that he was excluded from participating in Medicare, Medicaid, and all federal health care programs for a minimum period of thirteen years because he had been convicted of a criminal offense related to the delivery of an item or service under Medicare or a state health care

program. The letter explained that section 1128(a)(1) of the Act authorizes the exclusion. I.G. Ex. 1. Petitioner timely requested review.

The IG has submitted his brief (IG Br.) and four exhibits (IG Exs. 1-4). Petitioner submitted a brief (P. Br.), along with twenty exhibits. (P. Exs. 1-20). The IG filed a reply brief (IG Reply). In the absence of any objection, I admit into evidence IG Exs. 1-4 and P. Exs. 1-20.

The parties agree that an in-person hearing is not necessary in order to decide this case. IG Br. at 9; P. Br. at 10. The parties also agree that Petitioner Miranda was convicted of a crime related to the delivery of an item or service under Medicare or a state health care program and must be excluded from program participation for at least five years. IG Br. at 1; P. Br. at 1, 2-3; *see* Order and Schedule for Filing Briefs and Documentary Evidence at 2 (December 2, 2015); Act §§ 1128(a)(1), (c)(3)(B). Because the parties agree that the IG has a basis upon which to exclude Petitioner from program participation, the sole issue before me is whether the length of the exclusion is reasonable. 42 C.F.R. § 1001.2007.

Discussion

Based on the aggravating factors and the absence of any mitigating factors, a thirteen-year exclusion is reasonable.[1]

Here, Petitioner Miranda practiced as an oncologist, providing medical services to cancer patients. P. Ex. 1 at 1. He ordered, prescribed, and administered oncology drugs that were not Food and Drug Administration (FDA)-approved; they came from a foreign source. Petitioner Miranda then billed Medicare, Medicaid, and a private insurance program (Blue Cross/Blue Shield) for the drugs. He billed approximately $3.4 million, and the various programs reimbursed him more than $1 million. IG Ex. 3 at 1-2; P. Ex. 1 at 1-2; *see* IG Ex. 2 at 4; IG Ex. 4 at 9.

Petitioner pled guilty in federal district court to one misdemeanor count of introducing misbranded drugs into interstate commerce, in violation of 21 U.S.C. §§ 331(a), 352(f), and 18 U.S.C. § 2. IG Ex. 2 at 1. The court entered judgment against him on November 25, 2014, sentenced him to five years probation, and ordered him to pay the health care programs $1,004,438.50 in restitution. IG Ex. 2 at 1, 2, 4.[2]

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

[2] The court assessed the program losses as follows: Blue Cross Blue Shield of Texas lost $403,966.99; the Medicaid program lost $361,959.31; and the Medicare program lost $238,512.20. IG Ex. 2 at 4.

Under section 1128(a)(1) of the Act, the Secretary of Health and Human Services must 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). An exclusion brought under section 1128(a)(1) 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 regulations may not be used to decide whether an exclusion of a particular length is reasonable.

Among the factors that may serve as a basis for lengthening the period of exclusion are the two that the IG 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; and 2) the acts that resulted in the conviction, or similar acts, were committed over a period of one year or more. 42 C.F.R. § 1001.102(b)(1) and (2). The presence of an aggravating factor or factors, not offset by any mitigating factor or factors, justifies lengthening the mandatory period of exclusion.

Program financial loss (42 C.F.R. § 1001.102(b)(1)): The sentencing court found that Petitioner's crime caused $1,004,438.50 in program losses and ordered him to pay that amount in restitution to Medicare, Medicaid, and Blue Cross/Blue Shield. IG Ex. 2 at 4. At a minimum, then, Petitioner's crimes cost these insurers significant financial losses – 200 times greater than the $5,000 threshold for aggravation – and the IG may justifiably increase significantly Petitioner's period of exclusion. *See Jeremy Robinson*, DAB No. 1905 (2004); *Donald A. Burstein, Ph.D.*, DAB No. 1865 (2003).

Petitioner concedes that he paid the restitution but claims that he did so "pursuant to his plea agreement" and "in his continued spirit of cooperation . . . ." P. Br. at 4. Why Petitioner pled guilty and agreed to pay restitution is irrelevant. Moreover, although restitution has long been considered a reasonable measure of program losses because one could infer the loss based on the amount of restitution paid, where, as here, the court's judgment explicitly determined the program losses, I need not rely on the restitution amount to infer the amount of the loss. That amount has been firmly established by the court, and I will not disturb the court's finding. *See* 42 C.F.R. § 1001.2007(d) (precluding a collateral attack on the court's judgment "where the facts were adjudicated and a final decision was made"); *see also Juan de Leon, Jr.*, DAB No. 2533 at 5 (2013); *Jason Hollady, M.D.*, DAB No. 1855 (2002) (finding the amount of restitution ordered a reasonable measure of program losses).

Petitioner also asserts that the restitution he paid to the private insurer (Blue Cross/Blue Shield) is of no significance because it does not represent a financial loss to a government program. P. Br. at 4 n.2. The regulation that defines aggravating factors does not limit

itself to financial losses to government programs. It considers aggravating losses of $5,000 or more "to a [g]overnment program or *to one or more entities*." 42 C.F.R. §1001.102(b)(1) (emphasis added). Losses to a private insurer fall within this broad definition. *See, e.g., Jeremy Robinson*, DAB No. 1905 at 8 (determining that a $205,000 loss to private insurance companies supported a fifteen-year exclusion).

Length of criminal conduct (42 C.F.R. § 1001.102(b)(2)). In his guilty plea, Petitioner conceded that his criminal activity began "[o]n or about October 1, 2007" and continued "through January 28, 2009." IG Ex. 3 at 5; P. Ex. 1 at 5; *see* IG Ex. 4 at 6. Thus, the acts that resulted in Petitioner's conviction and similar acts were committed over a period that exceeded the one year necessary to constitute an aggravating factor. *See Jeremy Robinson*, DAB No. 1905 at 12, *citing Donald A. Burstein, Ph.D.*, DAB No. 1865 at 12 (finding that wrongful acts committed over "slightly more" than a year justified increasing the period of exclusion).

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 the court determined 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 (CMP) being imposed. 42 C.F.R. § 1001.102(c). Characterizing the mitigating factor as "in the nature of an affirmative defense," the Departmental Appeals Board has ruled that a 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).

Obviously, because Petitioner's crime resulted in financial losses far in excess of $1,500, the first factor does not apply here. Nor does Petitioner claim any mental, physical, or emotional condition that reduced his culpability.

Petitioner suggests that the third mitigating factor applies because he "immediately" cooperated with the FDA and with federal prosecutors, answering their questions "without hesitation" and sparing them from investigating further or going to trial. P. Br. at 10. Petitioner is entitled to no special consideration simply because he cooperated with authorities in his own case. The regulation requires that his cooperation result in *others* being convicted or excluded, *additional cases* being investigated, or a CMP being imposed. Petitioner must show that he provided information that resulted in the investigation of a *new* target. *Marcia C. Smith*, DAB No. 2046 at 9-11 (2006).

Petitioner also attempts to minimize the significance of his crime. He points out that he was convicted under a strict liability statute and claims that he did not realize that he was ordering drugs from a foreign distributor. He argues that his actions posed no threat to

his patients because the foreign drugs were exactly the same as medications distributed by suppliers in the United States, except that they lacked FDA-required language ("Rx only"); did not include National Drug Code numbers found on FDA-approved versions; and included package inserts in languages other than English. How he can be so sure that a non-FDA-approved drug is exactly the same as an FDA-approved drug is a mystery. Moreover, he concedes that these drugs bore indicia of illegitimacy – lacking FDA-required language and National Drug Code numbers, and with package inserts written in a foreign language – which undermines his claims of ignorance. But even accepting that he was not aware of the drugs' origins does not mean that he is not a threat to federal health care programs. His actions were either deliberate or negligent, and a negligent physician can do much harm.

Petitioner also points out that the IG granted a limited waiver of his exclusion so that he could continue to provide oncology services in a medically-underserved area. P. Br. at 11. The waiver provision, 42 C.F.R. § 1001.1801(b), authorizes the IG to grant or deny a state health care program's request that exclusion be waived "if the individual . . . is the sole community physician or the sole source of essential specialized services in a community." The IG's waiver under section 1001.1801 does not establish that an individual is trustworthy or a low risk to federal healthcare programs and is not a relevant factor in determining whether an exclusion period is reasonable. *See Vinod Chandrashekhar Patwardhan, M.D.*, DAB No. 2454 at 8 (2012).

Petitioner also cites the decision of the Texas Medical Board to buttress his argument that he poses no threat to federal healthcare programs. P. Ex. 2. On November 7, 2014, the medical board imposed a remedial plan requiring Petitioner to participate in remedial education, take and pass the board's medical jurisprudence examination, and pay $500 per year to cover the board's costs in administering the plan. The medical board's actions are not a mitigating factor. To the contrary, "any other adverse action" by a federal, state, or local government agency or board is an *aggravating* factor, if based on the same set of circumstances that serve as the basis for imposing the exclusion. 42 C.F.R. § 1001.102(b)(9) (emphasis added). That the IG opted not to invoke this factor does not render it mitigating.

Finally, Petitioner offers letters and other evidence attesting to his good character and service to the community. Under the regulations, these do not create mitigating factors.

Thus, no mitigating factor offsets the aggravating factors present in this case.

Conclusion

So long as the period of exclusion is within a reasonable range, based on demonstrated criteria, I have no authority to change it. *Joann Fletcher Cash*, DAB No. 1725 at 7 (2000), *citing* 57 Fed. Reg. 3298, 3321 (1992). The record in this case establishes that

Petitioner committed a crime over a long period of time that caused significant financial losses to healthcare programs. Based on these aggravating factors, and, in the absence of any mitigating factors, I find that the thirteen-year exclusion falls within a reasonable range.

/s/
Carolyn Cozad Hughes
Administrative Law Judge