Department of Health and Human Services

DEPARTMENTAL APPEALS BOARD

Civil Remedies Division

Erick Antoine Falconer, M.D.,
(OI File No.: H-14-41347-9),

Petitioner,

v.

The Inspector General.

Docket No. C-14-1940

Decision No. CR3698

Date: March 10, 2015

DECISION

Petitioner, Erick Antoine Falconer, M.D., appeals the determination of the Inspector General (IG) for the U.S. Department of Health and Human Services to exclude him from participating in Medicare, Medicaid, and all federal health care programs pursuant to section 1128(a)(3) of the Social Security Act (Act) (42 U.S.C. § 1320a-7(a)(3)) for the minimum statutory period of five years. For the reasons discussed below, I conclude that the IG has a basis for excluding Petitioner from program participation and that the five-year exclusion is mandated by law.

I. Background and Procedural History

By letter dated August 29, 2014, the IG notified Petitioner that he was being excluded from Medicare, Medicaid, and all federal health care programs for a minimum period of five years pursuant to section 1128(a)(3) of the Act (42 U.S.C. § 1320a-7(a)(3)). The IG advised Petitioner that the exclusion was based on his felony conviction in the United States District Court for the Eastern District of Missouri of a criminal offense related to

fraud, theft, embezzlement, breach of fiduciary responsibility, or other financial misconduct in connection with the delivery of a health care item or service. IG Ex. 1 at 1.

Petitioner timely filed his request for hearing before an administrative law judge (ALJ) and this case was assigned to me for hearing and decision. A prehearing telephone conference was held with the parties on November 19, 2014, the substance of which I summarized in my Order and Schedule for Filing Briefs and Documentary Evidence issued November 24, 2014 (Order). *See* 42 C.F.R. § 1005.6. During the prehearing conference, I explained to Petitioner that he was entitled to representation by counsel, but that I could not appoint counsel for him. I also told Petitioner that if he should choose later to be represented by counsel, he need only have his attorney submit a Notice of Appearance to my office as soon as possible. Petitioner proceeded to represent himself.

Pursuant to my Order, the IG filed his brief (IG Br.) together with seven exhibits (IG Exs. 1-7). Petitioner submitted his brief (P. Br.) together with sixteen exhibits (P. Exs. 1-16). The IG submitted a reply brief (IG Reply). Absent objection, I admit IG Exs. 1-7 and P. Exs. 1-16.[1]

Both parties indicated that a hearing was not necessary in this case and that they did not have any testimony to offer at a hearing. IG Br. at 11-12; P. Br. at 12. Therefore, I decide this case on the written record. *See* Order ¶ 4.

II. Discussion

A. Issues

The only issue before me is whether the IG was authorized to exclude Petitioner from participating in Medicare, Medicaid, and all federal health care programs for five years pursuant to section 1128(a)(3) of the Act. 42 C.F.R. § 1001.2007(a)(1)-(2).

B. Findings of Fact and Conclusions of Law

The IG is excluding Petitioner based on section 1128(a)(3) of the Act (42 U.S.C. § 1320a-7(a)(3)). The four essential elements necessary in this case to support the IG's exclusion are: (1) the individual to be excluded must have been convicted of a felony

[1] On January 1, 2015, Petitioner filed a motion seeking a one-hour extension to supplement his exhibits due to technical difficulties uploading the exhibits to the Departmental Appeals Board's electronic filing system. Petitioner electronically filed his exhibits and then uploaded amended versions of the exhibits. The IG did not object to Petitioner's motion. I grant the motion and admit the amended versions of Petitioner's exhibits into the record.

offense; (2) the felony offense must have been based on conduct relating to fraud, theft, embezzlement, breach of fiduciary responsibility, or other financial misconduct; (3) the felony offense must have been for conduct in connection with the delivery of a health care item or service; and (4) the felonious conduct must have occurred after August 21, 1996. Act § 1128(a)(3); 42 C.F.R. § 1001.101(c).

My findings of fact and conclusions of law (FFCL) are set forth below in bold and italics as headings in this section, followed by an analysis for each FFCL.

1. ***Petitioner pled guilty to one count of Making a False Statement in violation of 18 U.S.C. § 1001(a)(2) and agreed to forfeit $20,000 in proceeds from his illegal activity.***

The following facts are undisputed. During the relevant period at issue here, Petitioner was licensed to practice medicine in the state of Missouri as a physician and as a surgeon. IG Ex. 2. Petitioner operated several medical offices at various locations in St. Louis County, Missouri. IG Ex. 3 at 3; IG Ex. 4 at 1. Petitioner's medical practice, the Youthful Body, Inc., provided cosmetic treatments to patients that included injections of the prescription drug OnabotulinumtoxinA that is marketed in the United States as Botox® Cosmetic. IG Ex. 3 at 3; IG Ex. 4 at 2. From August 2009 to February 2013, Petitioner's medical practice purchased 50 separate prescription drugs from a wholesale online drug distributor identified in court documents as Company A. IG Ex. 3 at 3; IG Ex. 4 at 5. Petitioner bought "Botox (Turkish)" from Company A for $354.99 per vial, which was less than the $525 per vial being charged by U.S.-licensed wholesale distributors selling the Food and Drug Administration (FDA)-approved version of Botox® Cosmetic. IG Ex. 4 at 4-5. Petitioner paid for the prescription drugs that his practice bought from Company A with his medical practice's checking account and also his personal credit card. IG Ex. 3 at 3; IG Ex. 4 at 5. Petitioner "ultimately provided these drugs to his patients without informing them of the source of the drugs, and the Youthful Body received over $70,000 in proceeds from administering these illegal drugs to patients." IG Ex. 3 at 3.

The FDA was concerned that the product sold by Company A could be unsafe, ineffective, and could cause harm to patients. P. Ex. 11. The FDA believed that the prescription drugs sold by Company A and labeled as "Botox®" did not undergo FDA-review and did not meet the legal requirement for sale in the United States. P. Ex. 11. The FDA's Office of Criminal Investigations initiated a review into Company A's sales. FDA agents were investigating the purchases Petitioner made from Company A, and, on February 12, 2013, Petitioner was interviewed by these agents. During that interview, Petitioner represented to the FDA agents that his medical practice had made just three purchases of Botox® from Company A, and that these purchases were made over a three-month time period in 2012. IG Ex. 3 at 3-4; IG Ex. 4 at 6. Following the interview, the FDA agents found out that Petitioner had falsely represented the number of orders his

medical practice had placed and received for Botox® from Company A. Instead of the three orders in 2012 as reported by Petitioner, his medical practice had placed 50 separate orders for Botox® from Company A over a three-year period between August 2009 and February 2013. IG Ex. 3 at 3; IG Ex. 4 at 5; IG Ex. 6 at 16, 19-20. After obtaining samples of the Botox® product Company A was selling to Petitioner, the FDA determined that the drugs were adulterated, misbranded, and counterfeit. IG Ex.5 at 2, 3; IG Ex. 4 at 5.

On November 6, 2013, an Information was filed in the Eastern District of Missouri charging Petitioner with one count of Making a False Statement in violation of 18 U.S.C. § 1001(a)(2). IG Ex. 4. That same day, Petitioner entered into a plea agreement with the Office of the United States Attorney and also pled guilty in the U.S. District Court for the Eastern District of Missouri to the charge. IG Ex. 3 at 1-4; IG Ex. 6 at 3; IG Ex. 7 at 1. The District Court accepted Petitioner's guilty plea and convicted Petitioner of one count of Making a False Statement in violation of 18 U.S.C. § 1001(a)(2). IG Ex. 6 at 21; IG Ex. 7 at 1. Petitioner was sentenced to five months of imprisonment, one year of supervised release, and payment of a $100 assessment. IG Ex. 6 at 21; IG Ex. 7 at 1-5. Additionally, Petitioner agreed to forfeit $20,000 representing the proceeds of his illegal activity. IG Ex. 3 at 8.

2. The IG had a legitimate basis to exclude Petitioner from Medicare, Medicaid, and all other federal health care programs under Section 1128(a)(3) of the Act.

a. Petitioner was convicted of a felony offense.

To support an exclusion under section 1128(a)(3) of the Act, the individual must have been "convicted of a felony offense." An individual is "convicted" of a criminal offense "when a judgment of conviction has been entered against the individual . . . by a Federal . . . court"; "when there has been a finding of guilt against the individual . . . by a Federal . . . court"; or "when a plea of guilty . . . by the individual . . . has been accepted by a Federal . . . court. Act § 1128(i); *see also* 42 C.F.R. § 1001.2. The record is clear, and Petitioner agrees, that he was convicted of a felony under federal law that occurred after August 21, 1996. P. Br. at 1. Petitioner entered a guilty plea to one count of Making a False Statement in violation of 18 U.S.C. § 1001(a)(2). IG Ex. 3; IG Ex. 6 at 3; IG Ex 7 at 1. The charge to which Petitioner pled guilty to is a Class D felony, which provides for imprisonment of up to five years, a fine of up to $250,000, or both, and up to one year of supervised release. IG Ex. 3 at 4; IG Ex. 6 at 14;18 U.S.C. §§ 1001(a), 3559(a)(4). The plea was accepted by the District Court. IG Ex. 6 at 21; *see also* IG Ex. 7 at 1. Further, the District Court then entered a Judgment in a Criminal Case in which Petitioner was "adjudged guilty" of the 18 U.S.C. § 1001(a)(2) violation and sentenced to imprisonment. IG Ex. 7. Therefore, I find that Petitioner's offense meets the definition for a conviction under section 1128(i) of the Act.

b. Petitioner's felony conduct related to fraud or financial misconduct.

Petitioner pled guilty to, and was convicted of, making a false statement, a criminal offense that is in violation of 18 U.S.C. § 1001(a)(2). It is illegal under 18 U.S.C. § 1001 to knowingly and willfully make "any materially false, fictitious, or fraudulent statement or presentation" in "any matter within the jurisdiction of the executive, legislative, or judicial branch of the Government." 18 U.S.C. § 1001(a)(2).

During his November 6, 2013 plea hearing, Petitioner admitted to the stipulated facts in the negotiated plea agreement. IG Ex. 6 at 20 (stating to the District Court that the facts in the plea agreement are true); *see also* IG Ex. 3 at 2-4; P. Ex. 1 at 2-4. Petitioner noted further that the stipulated facts in the plea agreement accurately described what he did. *Id.* During his plea colloquy, Petitioner admitted that on February 13, 2013, he "gave a false statement to FDA investigators when they made a visit to [his] medical office." IG Ex. 6 at 16. He further admitted that the false statement he made to the FDA agents was: "the number of orders that had been placed by my business, medical practice . . . [for] Botox® cosmetics." IG Ex. 6 at 17. He admitted that he knew the FDA agents were investigating the purchases his practice made of Botox® from Company A. He further admitted that he told the FDA agents that in 2012 his medical practice made three purchases in a three-month period from Company A and that at the time he made the statement to the FDA agents he knew "[t]hat [it] was not a true statement," and he acknowledged that he intentionally told the FDA agents a lie as to the number of orders he had placed with Company A. IG Ex. 6 at 18-20. Further, Petitioner bought "Botox (Turkish)" from Company A for $354.99 per vial, which was less than the $525 per vial being charged by U.S.-licensed wholesale distributors selling the FDA-approved version of Botox® cosmetic. IG Ex. 4 at 4-5. Petitioner also admitted that in using the Botox®, he "received over $70,000 in proceeds from administering these illegal drugs to patients." IG Ex. 3 at 3; P. Ex. 1 at 3.

With this background, it is significant that Petitioner agreed to forfeit $20,000, which he stipulated were the proceeds of his illegal activities: "The defendant specifically admits that the funds supporting this cashier's check constitute the proceeds of defendant's illegal activities and that he has no rightful interest in those funds." IG Ex. 3 at 8; P. Ex. 1 at 8; *see also* IG Ex. 6 at 12. The admission of facts about the scheme in the guilty plea and the agreement that Petitioner forfeit the illegal proceeds from his conduct show that Petitioner's crime is related to the money he illegally obtained as part of his criminal scheme. Specifically, Petitioner purchased the Botox® at a significantly reduced price and generated $70,000 in proceeds from administering the Botox®, $20,000 of which he considered proceeds of illegal activities.

In order for a conviction to qualify as one mandating exclusion under section 1128(a)(3), it must be "a felony relating to fraud . . . or other financial misconduct." The terms

"related to" and "relating to" simply mean that there must be a nexus or common sense connection. *See James Randall Benham*, DAB No. 2042 (2006) (internal citations omitted); *see also Friedman v. Sebelius*, 686 F.3d 813, 820 (D.C. Cir. 2012) (describing the phrase "related to" in another part of section 1320a-7 as "deliberately expansive words," "the ordinary meaning of [which] is a broad one," and one that is not subject to "crabbed and formalistic interpretation") (internal quotes omitted). In the present case, Petitioner derived $20,000 in illegal proceeds from purchasing cheaper non-FDA approved Botox® and providing that to patients without their knowledge. IG Ex. 3 at 3. Because the forfeiture is part of the plea agreement in Petitioner's criminal case, there is a sufficient nexus between the criminal offense for which he was convicted and fraud or other financial misconduct.

c. Petitioner's felonious conduct was in connection with the delivery of a health care item or service.

In order for Petitioner to be excluded under section 1128(a)(3), the felony offense that was the basis of Petitioner's conviction must have been for conduct in connection with the delivery of a health care item or service. Petitioner maintains that his conviction for making a false statement to FDA agents is not in connection with the delivery of a health care item or service. P. Br. at 2-8. However, to be "in connection with" the delivery of a health care item or service, there only needs to be a nexus or common sense connection to the delivery of a health care item or service. *Charice D. Curtis*, DAB No. 2430, at 5 (2011).

In his plea agreement, Petitioner admitted that he used the Botox® he obtained from Company A in medical procedures with patients at his medical practice. He admitted that patients were injected with the Botox®. IG Ex. 3 at 3-4; P. Ex. 1 at 3-4. Petitioner also admitted that in using the Botox®, he "received over $70,000 in proceeds from administering these illegal drugs to patients." IG Ex. 3 at 3; P. Ex. 1 at 3. Further, the Information also confirms that Petitioner provided the adulterated, misbranded, and counterfeit drugs he obtained from Company A to his patients. IG Ex. 4 at 5.

Petitioner argues that the FDA agents were not at his medical practice for the purpose of "investigat[ing] conduct in connection with the delivery of a health care item or services." P. Br. at 8. However, the evidence shows otherwise. The plea agreement clearly shows that FDA agents specifically asked Petitioner about his administration of the illegal drugs to patients. IG Ex. 3 at 2; P. Ex. 1 at 2. The evidence also shows that the FDA agents were investigating Petitioner's receipt of adulterated, misbranded, or counterfeit drugs – the same drugs Petitioner admitted were purchased by his medical practice and injected into his patients as part of the services provided by his practice. IG Ex. 3 at 4; IG Ex. 4 at 7. When Petitioner lied about the number of Botox® orders he had made from Company A during the three-month period in 2012, the FDA agents were obviously investigating health care crimes related to the purchase of adulterated,

misbranded, and counterfeit drugs from an unlicensed online pharmacy vendor and the potential health risks these illegal drugs could pose for patients being treated with Botox®. I.G. Ex. 5 at 2; P. Ex. 3 at 1-2; P. Ex. 11 at 2. The facts listed in the plea agreement and in the Information outline the entire scheme for which Petitioner was being investigated and not just the facts related to his false statement.

d. The underlying conduct of Petitioner's felony conviction occurred after August 21, 1996.

Under section 1128(a)(3), Petitioner's felony offense "must have occurred after August 21, 1996." The record shows that the conduct on which Petitioner's conviction was based occurred in February 2013, well after 1996. IG Ex. 3 at 3; IG Ex. 4 at 6; IG Ex. 6 at 16; IG Ex. 7 at 1. Petitioner agrees. P. Br. at 1.

For the reasons outlined above, I find that Petitioner's conviction meets the four elements of a mandatory exclusion under section 1128(a)(3) of the Act and, therefore, the IG was authorized to impose a mandatory exclusion.

3. *Petitioner's five-year exclusion is mandated by law.*

An exclusion that is imposed pursuant to section 1128(a)(3) of the Act must be for a minimum period of five years. Act § 1128(c)(3)(B); 42 C.F.R. § 1001.102(a). Based on my findings, I concluded that the IG was authorized to exclude Petitioner under section 1128(a)(3); therefore, the minimum mandatory period of exclusion is for five years. Act § 1128(c)(3)(B); 42 C.F.R. § 1001.2007(a)(2).

Petitioner discusses several mitigating factors that I cannot consider here because the IG imposed the minimum five-year mandatory exclusionary period. These include Petitioner's characterization of the facts emphasizing that: there was an absence of fraud or financial harm to any federal or state health care program; there was no harm to patients; his misconduct was an isolated incident; his involvement in the misconduct was as a Chief Executive Officer of a company that does not participate in any federal or state health care program; the misconduct neither involved patients nor occurred during his practice of medicine; he cooperated with the investigation; he paid $20,000 to the federal government as a result of the offense, showing that he was responsible and willing to conform to the laws and regulations; there is minimal risk that he will repeat the offense; and his medical specialty of emergency physician is unrelated to the offense. P. Br. at 17-18. I am, however, only authorized to consider aggravating and mitigating factors where the IG has imposed more than the minimum mandatory period of exclusion. 42 C.F.R. § 1001.102(c). Here, the IG did not rely on any aggravating factors to expand the period of exclusion; consequently, I am precluded from considering any of the factors Petitioner claims are mitigating.

Further, Petitioner disputes that he should be excluded under section 1128(a)(3) of the Act and argues that his conviction of making a false statement in violation of 18 U.S.C. § 1001(a)(2) falls into a category of a permissive exclusion under section 1128(b)(2) of the Act, which deals with a conviction relating to obstruction of an investigation. P. Br. at 2-4, 17-19. However, I cannot review whether the IG ought to have excluded Petitioner based on a different ground than the IG selected. I can only apply the facts to determine if a section 1128(a)(3) exclusion is warranted. The preamble to the final rule establishing the exclusion regulations indicates that a criminal offense may invoke both a mandatory exclusion and permissive exclusion (i.e., they are not necessarily exclusive), and if it does, then the IG will proceed under the mandatory exclusion. 55 Fed. Reg. 12,205, 12,207 (Apr. 2, 1990).

Petitioner asserts that the Assistant United States Attorney stated that he thought that the IG would treat Petitioner's conviction as a permissive exclusion and not a mandatory one. P. Ex. 2. However, Petitioner's plea agreement does not mention this matter specifically and, as the plea agreement indicates, it only binds the U.S. Attorney's Office. IG Ex. 3 at 1; P. Ex. 1 at 1; *see also* IG Ex. 6 at 7, 10 (Petitioner telling the District Court that he had not been promised anything beyond the plea agreement to induce his waiver of rights and his guilty plea).

Petitioner also sets forth arguments which amount to collateral attacks on the accuracy of the charge underlying his conviction. Petitioner denies any culpability for the crime and maintains that his guilty plea was a result of both prosecutorial misconduct and fabricated evidence. P. Br. at 13-14, 16. Petitioner denies that he even knew that the Botox® that he purchased from Company A was adulterated, misbranded, or counterfeit. According to Petitioner, he did not know that the information he provided to the FDA agents was false. He also argues that the statement he did provide was not material to the FDA's investigation. P. Br. at 13-14, 16. I cannot consider these argument as the regulations explicitly preclude any collateral attack on Petitioner's conviction. 42 C.F.R. § 1001.2007(d). Further, as noted above, the court records in this case are clear as to the facts to which Petitioner pled guilty and the conduct of which he was convicted.

Finally, Petitioner asserts that he is seeking withdrawal of his guilty plea and has filed a motion to vacate or set aside his judgment with the District Court. P. Br. at 12-13. Under the Act, an individual has been "convicted" of a criminal offense if a judgment of conviction has been entered, "regardless of whether there is an appeal pending . . . ." Act § 1128(i)(1). Moreover, the applicable regulations consider a conviction to be no longer valid for purposes of an exclusion only if it is "reversed or vacated on appeal." 42 C.F.R. § 1001.3005(a)(1). Consequently, unless and until the District Court takes the action sought by Petitioner, Petitioner's motion to vacate or set aside his judgment has no bearing on this decision. If Petitioner later receives relief from the court, Petitioner may seek reinstatement from the IG. 42 C.F.R. § 1001.3005.

III. Conclusion

For the foregoing reasons, the IG has a basis to exclude Petitioner from participating in Medicare, Medicaid, and all federal health care programs. The five-year exclusion is for the statutory minimum period. Act § 1128(a)(3), (c)(3)(B). Therefore, I affirm the IG's exclusion of Petitioner for five years.

/s/
Scott Anderson
Administrative Law Judge