Department of Health and Human Services

DEPARTMENTAL APPEALS BOARD

Civil Remedies Division

In the Case of:	)	
	)	
Robert S. Baker,	)	Date: January 10, 2008
	)	
Petitioner,	)	
	)	
- v. -	)	Dcoket No. C-07-652
	)	Decision No. CR1724
The Inspector General.	)	
	)	

DECISION

Robert S. Baker (Petitioner) appeals the decision of the Inspector General (I.G.), made pursuant to section 1128(a)(3) of the Social Security Act (Act), to exclude him from participation in Medicare, Medicaid, and all federal health care programs for a period of five years. For the reasons discussed below, I find that the I.G. is authorized to exclude Petitioner. The five-year exclusion is the mandatory minimum period as a matter of law.

I. Background

In a letter dated June 29, 2007, the I.G. notified Petitioner that he was excluded from program participation for five years because of his felony conviction in federal district court "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." I.G. Ex. 1.

Petitioner thereafter requested review, and the matter has been assigned to me for resolution. I held a prehearing conference on September 20, 2007, during which I directed the parties to advise me in writing whether an in-person hearing was necessary, and, if so, to explain why. Order and Schedule for Filing Briefs (September 24, 2007), at 2. The I.G. asserts that the matter may be decided based on written submissions and documentary evidence, without an in-person hearing. I.G. Brief (Br.) at 2. In his submission, Petitioner did not say that an in-person hearing was necessary, but said that he "desires to reserve the right to request an in-person hearing pending any further

submissions by the [I.G.] in response to Petitioner's brief." P. Br. at 2. However, following the I.G.'s reply to Petitioner's brief, Petitioner did not request an in-person hearing. Petitioner thus did not assert that an in-person hearing is necessary, nor set forth any reason as to why it would be.

The parties have submitted their briefs. Attached to the I.G.'s brief (I.G. Br.) are I.G. Exhibits (I.G. Exs.) 1-5. Petitioner submitted a brief in opposition (P. Br.), along with two exhibits, P. Exs. 1-2. The I.G. submitted a reply brief (I.G. Reply) with one additional exhibit, I.G. Ex. 6. Petitioner has not requested an additional opportunity to respond to the I.G.'s most recent submission, which is a copy of the Petitioner's Proffer for Plea Agreement, signed by Petitioner and his criminal attorneys, and filed with the federal district court.

Petitioner objects to the admission of I.G. Ex. 5, which is a copy of the second superceding indictment in his criminal case. Petitioner argues that the indictment alone does not establish that his conviction is connected with the delivery of a health care item or service. While I agree that the indictment is not dispositive of any of the issues, neither is it irrelevant or immaterial evidence that must be excluded. 42 C.F.R. § 1005.17. Indeed, contained within the indictment is the mail fraud charge to which Petitioner pleaded guilty – Count 11 – which makes the document directly relevant to the issue before me. I.G. Ex. 2, at 1; I.G. Ex. 5, at 24.

Petitioner also objects to the admission of I.G. Ex. 4, which is the Arizona Medical Board's announcement that Petitioner's medical license was surrendered, citing his January 30, 2006 criminal conviction. Again, I do not find this document irrelevant or immaterial. Considered along with Petitioner's own exhibit, P. Ex. 1, which is the Agreed Order of Surrender (of Petitioner's medical license), the two documents establish that Petitioner's license surrender is related to his criminal conviction, which provided the Medical Board legal grounds for license surrender.

I.G. Exs. 1-6 and P. Ex. 1-2 are therefore admitted into evidence.

II. Issue

The sole issue before me is whether the I.G. had a basis upon which to exclude Petitioner from participation in Medicare, Medicaid, and all federal health care programs. This depends on whether the offenses for which he was convicted were "in connection with the delivery of a health care item or service."

The length of the period of exclusion is not an issue because the I.G. imposed the statutory minimum.

III. Discussion

I make findings of fact and conclusions of law to support my decision in this case. I set forth each finding below, in italics, as a separate numbered or lettered heading.

A. Petitioner was convicted of a felony relating to fraud in connection with the delivery of a health care item, within the meaning of section 1128(a)(3) of the Act.

Petitioner was a physician licensed to practice medicine in the Commonwealth of Kentucky. He was one of multiple defendants charged with participating in a scheme to market and sell to health care providers a substance called Botulinum Toxin Type A ("Mimic Botox"). Those health care providers would then provide the toxin to their patients without telling them that Mimic Botox is not the FDA-approved Botox cosmetic, and, in fact, does not have FDA approval. I.G. Ex. 5, at 24. For his part in the scheme, Petitioner pled guilty to one count of mail fraud, admitting that he sent to a practicing physician (identified as H.D.) approximately $9,400 worth of Mimic Botox for use on patients without their knowledge that it had not been approved for use on humans. I.G. Ex. 3; I.G. Ex. 5, at 24-25; I.G. Ex. 6.

1. Where an individual has been convicted of a felony relating to fraud in connection with the delivery of a health care item or service, the statute does not require any connection between the fraud and a government or any other health care program.

The I.G. has not claimed that Petitioner's crime was connected to any particular health care program, but maintains that the statute does not require that connection. Although acknowledging that Departmental Appeals Board (Board) decisions hold otherwise, Petitioner argues that the Board has simply misread section 1128(a)(3). He maintains that, because his crime bore no relationship to any government-funded or operated health care program, he should not be excluded.

It is well-settled that the statute does not require a relationship between the fraud and any health care program. Section 1128(a)(3) of the Act authorizes the Secretary of Health and Human Services (Secretary) to exclude from participation in any federal health care program:

> [a]ny individual or entity that has been convicted for an offense . . . under Federal or State law, in connection with the delivery of a health care item or service or with respect to any act or omission in a health care program . . . operated by or financed in whole or in part by any Federal, State, or local government agency, of

> a criminal offense consisting of a felony relating to fraud, theft, embezzlement, breach of fiduciary responsibility, or other financial misconduct.

I find that the relevant statutory language – "operated by or financed in whole or in part by any Federal, State, or local government agency," modifies only the object that directly precedes it – "health care program." That language is independent of the preceding phrase – "in connection with the delivery of a health care item or service."

As the Board has ruled, section 1128(a)(3) is written in the disjunctive and covers two different categories of felonies relating to "fraud, theft, embezzlement, breach of fiduciary responsibility, or other financial misconduct."

> Thus, section 1128(a)(3) covers as a first category, any individual convicted of one of the listed felonies "in connection with the delivery of a health care item or service" (see 42 C.F.R. § 1001.101(c)(2)), and it covers, as a second category, any individual convicted of a listed felony with respect to any act or omission in the health care program operated by or financed in whole or in part by any Federal, State or local government. See 42 C.F.R. § 1001.101(c)(2).

Erik D. DeSimone, R.Ph., DAB No. 1932, at 4 (2004).

I am also bound by the regulations implementing this statutory provision. Those regulations leave no doubt that connection to a government program is not required to sustain exclusion under section 1128(a)(3).

> [T]he delivery of a health care item or service includes the provision of any item or service to an individual to meet his or her physical, mental, or emotional needs or well-being, *whether or not reimbursed under Medicare, Medicaid or any Federal health care program*.

42 C.F.R. § 1001.101(b) (emphasis added). Moreover, the regulations echo the statutory language and, by setting forth each category in a separate subparagraph, separated by the

conjunction "or," resolve any ambiguity as to whether or not the two phrases should be read in the disjunctive:

> The OIG will exclude any individual or entity that–
>
> * * * *
>
> (c) Has been convicted under Federal or State law, of a felony that occurred after August 21, 1996, relating to fraud, theft, embezzlement, breach of fiduciary responsibility, or other financial misconduct–
>
> (1) In connection with the delivery of a health care item or service, including the performance of management or administrative services relating to the delivery of such items or services, *or*
>
> (2) With respect to any act or omission in a health care program (other than Medicare and a State health care program) operated by, or financed in whole or in part, by any Federal, State or local government agency;

42 C.F.R. § 1001.101(c) (emphasis added). Thus, I need not find any connection to a government or other health care program in order to sustain an exclusion under section 1128(a)(3).

2. Petitioner's fraud was "in connection with" the delivery of a health care item.

Petitioner also argues that I should not look beyond the elements of mail fraud, 18 U.S.C. § 1341, which do not require the delivery or receipt of any item. According to Petitioner, a mail fraud conviction, standing alone, "supplies an insufficient record to support a relationship with the delivery of health care services or items." P. Br. at 11-12.

It is well-settled that the statute does not require a direct connection between the offense and the delivery of a health care item or service, but requires a "common sense analysis" of whether the offense had a connection with the delivery of a health care item or service. *DeSimone* at 4. Services that are purely managerial or administrative may be considered "in connection with" the delivery of a healthcare item or service. 42 C.F.R. § 1001.101(c)(1).

In this case, I need not look beyond the language of Petitioner's felony conviction in order to find that his crime was related to the delivery of a health care item or service. Count 11 of the indictment, to which Petitioner pled guilty, includes three paragraphs, ¶¶ 103, 104, and 105. I.G. Ex. 5, at 24. Petitioner, however, limits his discussion of Count 11 to one portion of paragraph 105, which says that he (among others) "caused to be delivered" to H.D. in North Miami, Florida, two vials of Mimic Botox. I.G. Ex. 5, at 25. Petitioner then disingenuously asserts that "H.D. is not identified, thus the inference may not be made that H.D. is a patient, physician or health care provider." P. Br. at 14.

Paragraph 104 describes the overall scheme, of which Petitioner was a part:

> It was the object of the scheme and artifice for the defendants to enrich themselves unjustly by marketing and selling to health care providers for use in human patients TRI's Botulinum Toxin Type A that was not approved by the FDA for use in human beings, as a cheap facial wrinkle treatment alternative to Allergan's Botox® Cosmetic, without the administering health care providers advising their human patients that TRI's Mimic Botox was not Allergan's Botox® Cosmetic and was not approved by the FDA for use in human beings.

I.G. Ex. 5, at 24.

Paragraph 103 also incorporates into Count 11 paragraphs 1-41 of the indictment's general allegations, and paragraphs 47-49, 51-58, and 60-62 of Count 1 of the indictment. I.G. Ex. 5, at 24. Paragraph 54 states that Petitioner (and others) participated in workshops at which he promoted Mimic Botox for use in treating human facial wrinkles. I.G. Ex. 5, at 11-12. Paragraph 61 says that Petitioner (and others) "aided and abetted" health care providers to breach their fiduciary duties to their patients and defrauded the patients who believed that they were paying for and receiving FDA-approved treatment when, in truth, they were receiving potentially dangerous, non-FDA-approved Mimic Botox. I.G. Ex. 5, at 14. In pleading guilty to Count 11, Petitioner acknowledged the truth of each of these allegations against him.

Finally, with respect to the identity of H.D., in his Proffer for Guilty Plea, Petitioner acknowledged that, had the case proceeded to trial, the United States would prove beyond a reasonable doubt that H.D. is a practicing physician, which she "made known" to Petitioner at a workshop sponsored by Petitioner's co-defendants. She confessed to an FDA agent that Petitioner advised her that Mimic Toxin was safe for use on human beings, and that Petitioner "had reason to believe" that she would use the product on paying human patients without telling them that it was not FDA-approved. Invoices and

shipping records establish that H.D. subsequently purchased $9,400 worth of Mimic Toxin. I.G. Ex. 6, at 3-4.

The paragraphs incorporated into Count 11, to which Petitioner pled guilty, and the Proffer for Guilty Plea, signed by Petitioner and his criminal attorneys individually and together establish a direct relationship between Petitioner's mail fraud conviction and the delivery of a health care item or service.

B. The statute mandates a five-year mandatory minimum exclusion, and mitigating factors may not be considered to reduce that period of exclusion.

An exclusion under section 1128(a)(1) of the Act must be for a minimum mandatory period of five years. As set forth in section 1128(c)(3)(B) of the Act:

> Subject to subparagraph (G), in the case of an exclusion under subsection (a), the minimum period of exclusion shall be not less than five years . . . .

When the I.G. imposes an exclusion for the mandatory five-year period, the reasonableness of the length of the exclusion is not an issue. 42 C.F.R. § 1001.2007(a)(2).

IV. Conclusion

For these reasons, I conclude that the I.G. properly excluded Petitioner from participation in Medicare, Medicaid, and all other federal health care programs, and I sustain the five-year exclusion.

/s/
Carolyn Cozad Hughes
Administrative Law Judge