Department of Health and Human Services

DEPARTMENTAL APPEALS BOARD

Civil Remedies Division

Francisco Cintron Acevedo
(O.I. File No. 2-11-4-0532-9),

Petitioner,

v.

The Inspector General,
Department of Health and Human Services.

Docket No. C-15-3477

Decision No. CR4521

Date: February 4, 2016

DECISION

Petitioner, Francisco Cintron Acevedo, is excluded from participation 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)), effective May 20, 2015. Petitioner's exclusion for the minimum period of five years is required by section 1128(c)(3)(B) of the Act (42 U.S.C. § 1320a-7(c)(3)(B)).[1]

I. Background

The Inspector General (I.G.) notified Petitioner by letter dated April 30, 2015, that he was being excluded from participation in Medicare, Medicaid, and all federal health care programs for five years. The I.G. cited section 1128(a)(3) of the Act as the basis for Petitioner's exclusion and stated that the exclusion was based on his conviction in the United States District Court for the District of Puerto Rico (District Court) of a criminal

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[1] Pursuant to 42 C.F.R. § 1001.3001, Petitioner may apply for reinstatement only after the period of exclusion expires. Reinstatement is not automatic upon completion of the period of exclusion.

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.

Petitioner filed a request for hearing (RFH) dated June 30, 2015. The case was assigned to me on August 12, 2015, for hearing and decision. A prehearing telephone conference was convened on September 3, 2015. The substance of the conference is memorialized in my Order to Show Cause, Prehearing Conference Order, and Schedule for Filing Briefs and Documentary Evidence dated September 9, 2015 (Prehearing Order).

The I.G. filed a motion for summary judgment and supporting brief (I.G. Br.) on October 6, 2015, with I.G. exhibits (Exs.) 1 through 3. Petitioner did not object to my consideration of I.G. Exs. 1 through 3 and they are admitted as evidence. The I.G. failed to file a copy of the April 30, 2015 notice of exclusion as an I.G. exhibit as required by my Prehearing Order ¶ 7. The I.G. is required by 42 C.F.R. § 1001.2003(a)[2] to give an individual or entity to be excluded proper notice. Whether or not Petitioner has a right to hearing, whether or not I have jurisdiction, and whether or not the I.G. may proceed with the exclusion action are all dependent upon whether Petitioner was properly notified by the I.G. The I.G. has the burden under 42 C.F.R. § 1005.15(c) and paragraph 7 of my Prehearing Order to establish that proper notice was given. In this case, Petitioner has raised no issue related to the sufficiency of the April 30, 2015 notice. Petitioner filed two pages of the April 30, 2015 notice with his request for hearing and as an exhibit. Therefore, I conclude that there is no issue to be resolved regarding the sufficiency of the notice Petitioner received, and there is no prejudice due to the I.G.'s failure to comply with my Prehearing Order by not filing the notice of exclusion as evidence. Counsel for the I.G. is admonished, however, to ensure careful compliance with my Prehearing Order in the future.

Petitioner filed two documents in response to the I.G. motion for summary judgment, one titled "Petitioner's Opposition to Motion for Summary Judgment" (P. Opp.) and the other titled "Opposition to Motion for Summary Judgment" (P. Br.)[3] on November 20, 2015. Petitioner also filed three exhibits marked "EXIBIT I," "EXHIBIT II," and "EXHIBIT III" (DAB E-File Item # 13c). Petitioner failed to mark and number the pages of the exhibits as required by Civil Remedies Division Procedures (CRDP) § 14. Rather than reject the documents, I treat them as being marked as follows:

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[2] References are to the 2014 revision of the Code of Federal Regulations (C.F.R.), unless otherwise stated.

[3] Departmental Appeals Board Electronic Filing System (DAB E-File) Items # 13 and 13a, respectively.

P. Ex. 1: "EXIBIT I," a five-page document containing the judgment the District Court entered against Petitioner, which is also I.G. Ex. 1.

P. Ex. 2: "EXHIBIT II," two pages of the April 30, 2015 notice letter the I.G. sent to Petitioner providing him notice of the proposed exclusion.

P. Ex. 3: "EXHIBIT III," the last page of the I.G.'s notice letter informing Petitioner of the limitations an exclusion imposes on him.

The I.G. has not objected to my consideration of P. Exs. 1 through 3 and they are admitted as evidence. On December 7, 2015, the I.G. filed a reply brief.

II. Discussion

A. Applicable Law

Section 1128(f) of the Act (42 U.S.C. § 1320a-7(f)) establishes Petitioner's rights to a hearing by an administrative law judge (ALJ) and judicial review of the final action of the Secretary of Health and Human Services (the Secretary).

Pursuant to section 1128(a)(3) of the Act, the Secretary must exclude from participation in any federal health care program:

> Any individual or entity that has been convicted for an offense which occurred after . . . [August 21, 1996], 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 (other than those specifically described in [section 1128(a)(1)]) 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.

The Secretary has promulgated regulations implementing these provisions of the Act. 42 C.F.R. § 1001.101(c).

Pursuant to section 1128(i) of the Act, an individual is convicted of a criminal offense when: (1) a judgment of conviction has been entered by a federal, state, or local court whether or not an appeal is pending or the record has been expunged; (2) there is a finding of guilt in a court; (3) a plea of guilty or no contest is accepted by a court; or (4) the individual has entered into any arrangement or program where judgment of conviction has been withheld. 42 U.S.C. § 1320a-7(i)(1)-(4); 42 C.F.R. § 1001.2.

Section 1128(c)(3)(B) of the Act provides that an exclusion imposed under section 1128(a) of the Act will be for a period of not less than five years. 42 C.F.R. § 1001.102(a). The Secretary has published regulations that establish aggravating factors the I.G. may consider to extend the period of exclusion beyond the minimum five-year period, as well as mitigating factors that may be considered only if the I.G. proposes to impose an exclusion greater than five years. 42 C.F.R. § 1001.102(b), (c).

The standard of proof is a preponderance of the evidence, and there may be no collateral attack of the conviction that provides the basis of the exclusion. 42 C.F.R. § 1001.2007(c), (d). Petitioner bears the burden of proof and the burden of persuasion on any affirmative defenses or mitigating factors, and the I.G. bears the burden on all other issues. 42 C.F.R. § 1005.15(b), (c).

B. Issues

The Secretary has by regulation limited my scope of review to two issues:

> Whether the I.G. has a basis for excluding Petitioner from participation in Medicare, Medicaid, and all federal health care programs; and
>
> Whether the length of the proposed period of exclusion is unreasonable.

42 C.F.R. § 1001.2007(a)(1).

If, as in this case, the I.G. imposes the minimum authorized five-year period of exclusion under section 1128(a) of the Act, there is no issue as to whether the period of exclusion is unreasonable. 42 C.F.R. § 1001.2007(a)(2).

C. Findings of Fact, Conclusions of Law, and Analysis

My conclusions of law are set forth in bold followed by the pertinent findings of fact and analysis.

1. Petitioner's request for hearing was timely and I have jurisdiction.

2. Summary judgment is appropriate in this case.

The I.G. informed Petitioner by letter dated April 30, 2015, that the I.G. was excluding Petitioner effective 20 days from the date of the letter. P. Ex. 2 at 1. Petitioner requested a hearing by letter dated June 30, 2015. The Civil Remedies Division received Petitioner's request for hearing on July 7, 2015, via U.S. Mail. The I.G. has not offered evidence that he personally served Petitioner with the notice of exclusion. In the absence

of evidence of personal service, Petitioner is presumed to have received the notice of exclusion on May 5, 2015, and Petitioner states that he did in fact receive the notice of exclusion on May 5, 2015. 42 C.F.R. § 1005.2(c); RFH at 1. Petitioner had 60 days from the date he received the notice of exclusion to request a hearing, or Saturday, July 4, 2015, a federal holiday. 42 C.F.R. § 1005.2(c). Therefore, Petitioner had until the next business day, July 6, 2015, to file his request for hearing. CRDP § 11. Because Petitioner filed his request for hearing via regular U.S. Mail and the Civil Remedies Division received it on July 7, 2015, I infer that Petitioner filed his hearing request timely, consistent with the date Petitioner's counsel certified he filed it. RFH at 4. I conclude, that Petitioner's request for hearing was timely, and I have jurisdiction pursuant to section 1128(f) of the Act and 42 C.F.R. pt. 1005.

Pursuant to section 1128(f) of the Act, a person subject to exclusion has a right to reasonable notice and an opportunity for a hearing. The Secretary has provided by regulation that a sanctioned party has the right to hearing before an ALJ. Pursuant to 42 C.F.R. § 1005.15(a), Petitioner is entitled to a "hearing on the record." Both the sanctioned party and the I.G. have a right to participate in the hearing. 42 C.F.R. §§ 1005.2-.3. Either or both parties may choose to waive appearance at an oral hearing and to submit only documentary evidence and written argument for my consideration. 42 C.F.R. § 1005.6(b)(5).

Petitioner did not appear during the prehearing conference and did not waive the right to appear at an oral hearing. In his opposition to the motion for summary judgment, Petitioner stated that he "opposes the [I.G.'s] Motion for Summary Judgment and moves for a remedy as a matter of law, on the record, since there are no issues of fact to be decided." P. Opp. at 1. I interpret Petitioner's statement to be a concession that there are no genuine disputes of material fact that require an oral hearing and that only issues of law are presented for decision. However, Petitioner has not unambiguously waived an oral hearing in writing. Therefore, I evaluate whether summary judgment is appropriate in this case.

Summary judgment is appropriate, and no hearing is required, where either: there are no genuine disputes of material fact and the only questions that must be decided involve application of law to the undisputed facts; or, the moving party prevails as a matter of law even if all disputed facts are resolved in favor of the party against whom the motion is made. A party opposing summary judgment must allege facts which, if true, would refute the facts relied upon by the moving party. Deciding a case on summary judgment differs from deciding a case on the merits after a hearing. An ALJ does not assess credibility or weigh conflicting evidence when deciding a case on summary judgment. *Bartley Healthcare Nursing & Rehab.*, DAB No. 2539 at 3-4 (2013); *Senior Rehab. & Skilled Nursing Ctr.*, DAB No. 2300 at 3 (2010); *Holy Cross Village at Notre Dame, Inc.*, DAB No. 2291 at 5 (2009); *see* Fed. R. Civ. Pro. 56.

Petitioner does not dispute that: he was convicted within the meaning of section 1128(i) of the Act; he pled guilty to and was convicted of felony misbranding and adulterating prescription medications with intent to mislead and defraud; his criminal offense was related to fraud; and the offense for which he was convicted occurred after August 21, 1996. RFH at 2; P. Br. at 1-2. Petitioner argues that his exclusion violates the District Court's judgment; is vague and overbroad; and constitutes double jeopardy. The issues that Petitioner raises are issues that must be resolved against him as a matter of law. I conclude that summary judgment is appropriate as there are no genuine disputes as to any material facts related to the elements for an exclusion pursuant to section 1128(a)(3) of the Act. The I.G. prevails as a matter of law on the issue of whether there is a basis for exclusion based on the facts conceded by Petitioner. The five-year period of exclusion is not unreasonable as a matter of law because the period is the minimum authorized by Congress for exclusion pursuant to section 1128(a) of the Act. Petitioner's defenses are unavailing as matters of law.

3. Petitioner's exclusion is required by section 1128(a)(3) of the Act.

a. Facts

On February 26, 2014, a 14-count indictment was filed against Petitioner and three other individuals in the District Court. Petitioner was charged with six counts of health care fraud in violation of 18 U.S.C. §§ 2 and 1347; one count of conspiracy to commit health care fraud in violation of 18 U.S.C. §§ 1347 and 1349; and five counts of misbranding prescription medications with intent to mislead and defraud in violation of 21 U.S.C. §§ 331(k); 333(a)(2); 351(a)(2)(A)-(B); and 352(a), (b), and (o). I.G. Ex. 2 at 8, 13, 16-17; I.G. Ex. 3 at 8.

Petitioner entered into a plea agreement with the United States Attorney on July 11, 2014. The agreement provided that Petitioner would plead guilty to Count Ten of the indictment, which alleged misbranding and adulterating prescription medications with intent to mislead and defraud. I.G. Ex. 3 at 1. Petitioner stipulated as part of his plea agreement that on or about April 11, 2011, he and others aiding and abetting each other:

> cause[d] drugs known as Levalbuterol and Budenoside (sic) to become misbranded and adulterated by among other:
>
> (1) Bearing labeling that was false and misleading in any particular in violation of 21 U.S.C. §352(a);
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> (2) Failing to bear a label containing the name and place of business of the manufacturer, packer, and distributor in violation of Title 21 U.S.C. §352(b);

> (3) Being manufactured, prepared, propagated, compounded, and processed in an establishment not duly registered with FDA in violation of Title 21 U.S.C. §352(o));
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> (4) Being prepared, packed, and held under insanitary conditions whereby they may have been contaminated with filth and may have been rendered injurious to health in violation of 21 U.S.C. §351(a)(2)(A);
>
> (5) Employing methods used in, and facilities and controls used for, their manufacture, packing, storage, and installation that did not conform with the current good manufacturing practices established by Title 21 U.S.C. §35l(a)(2)(B);
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> All in violation of Title 21, United States Code, Sections 331(k), 333(a)(2), 351(a)(2)(A) and (B), 352(a), (b), 352(o) and Title 18, United States Code, Section 2.

I.G. Ex. 3 at 8.

On November 21, 2014, Petitioner entered a guilty plea in the District Court to Count Ten of the indictment. The District Court accepted Petitioner's guilty plea to misbranding and adulterating prescription medications with intent to mislead and defraud in violation of 21 U.S.C. §§ 331(k), 333(a)(2), 351(a)(2)(A) and (B), and 352(a),(b) and (o). The District Court entered a judgment of conviction against Petitioner and sentenced him to three years of probation, including six months of home detention, a $100 assessment, and a forfeiture of $134,871.41. I.G. Ex. 1.

b. Analysis

The I.G. cites section 1128(a)(3) of the Act as the basis for Petitioner's mandatory exclusion. The statute provides:

> (a) MANDATORY EXCLUSION.—The Secretary **shall** exclude the following individuals and entities from participation in any Federal health care program (as defined in section 1128B(f)):
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> (3) Felony Conviction Relating to Health Care Fraud. — Any individual or entity that has been convicted for an offense which occurred after the date of the enactment of the Health Insurance Portability and Accountability Act of 1996, 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 (other than those specifically described in paragraph (1)) 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.

Act § 1128(a)(3) (emphasis added). The statute requires that the Secretary exclude from participation any individual or entity: (1) who was convicted for an offense under federal or state law; (2) whose offense occurred after August 21, 1996 (the date of enactment of the Health Insurance Portability and Accountability Act of 1996); (3) whose offense was committed in connection with the delivery of a health care item or service; (4) whose crime was a felony offense; and (5) whose offense was related to fraud, theft, embezzlement, breach of fiduciary responsibility, or other financial misconduct.

All the elements for exclusion under section 1128(a)(3) of the Act are satisfied in this case. Petitioner does not dispute that he was convicted of a criminal offense within the meaning of section 1128(i) of the Act (42 U.S.C. § 1320a-7(i)). RFH; P. Br. at 1-2. Petitioner's guilty plea was accepted and he was found guilty based on his plea. The District Court issued a judgment of conviction and sentenced Petitioner for the offense for which he was convicted. I conclude that Petitioner was convicted of a criminal offense within the meaning of section 1128(i) of the Act.

The statute requires that Petitioner be excluded if he was convicted of a felony criminal offense that occurred after August 21, 1996, 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. Act § 1128(a)(3). Petitioner does not dispute that he pled guilty to and was convicted of a felony criminal offense under federal law. I.G. Exs. 1 at 1; 3 at 1. Petitioner does not contest that his offense occurred after August 21, 1996. I.G. Ex. 1 at 1. Petitioner does not contest that his offense related to fraud. Count Ten, to which Petitioner pled guilty, alleges specifically that Petitioner had the "intent to mislead and defraud." I.G. Exs. 2 at 16; 3 at 1. Finally, Petitioner does not dispute that his felony offense was committed in connection with the delivery of a health care item or service. Count Ten specifically alleged that the misbranded or adulterated prescription of Budesonide was dispensed to a Medicare Beneficiary with the initials A.L. I.G. Ex. 2 at 16. The nexus between Petitioner's offense and the delivery of a health care item or service is plain.

Petitioner argues that the exclusion runs contrary to the District Court's order that as part of his probation Petitioner remain employed. P. Br. at 4-5. As part of the "Standard Conditions of Supervision," the District Court ordered Petitioner to "support his or her dependents and meet other family responsibilities" and "work regularly at a lawful

occupation, unless excused by the probation officer for schooling, training, or other acceptable reasons." I.G. Ex. 1 at 2 ¶¶ 4-5. Petitioner argues that because of the broad nature of the exclusion, Petitioner's ability to support his family by working at a pharmacy will be impeded should the exclusion remain in place without any modification. P. Br. at 4-5. Petitioner's argument is without merit. The fact that Petitioner cannot participate in any capacity in the Medicare program, Medicaid program, and all state health care programs as defined in Section 1128B(f) of the Act, in no way prevents him from supporting his family by engaging in other lawful occupations. P. Ex. 2 at 1. The District Court did not specify that Petitioner support his family as a pharmacist or by otherwise working at a pharmacy. While excluded, Petitioner is free to obtain any employment whatsoever, as long as it does not violate the terms of his exclusion by causing him to participate in the Medicare program, Medicaid program, or any state health care programs as defined in Section 1128B(f) of the Act. Therefore, the exclusion does not conflict with the District Court judgment.

Petitioner argues that the exclusion is vague and overbroad, and thereby violates his due process rights because it does not notify him of the conduct it prohibits. P. Br. at 5-8. He asserts that "the Office of the Inspector General's interpretation and enforcement of the law must be consistent with the Court's judgment, and rational and consistent with the statute." P. Br. at 7. Petitioner's argument verges on frivolity. The April 30, 2015 notice of exclusion (P. Ex. 2) and its attachment (P. Ex. 3) are detailed and absolutely clear in describing the exclusion, its basis, and its scope.[4] Petitioner and his counsel cannot credibly claim ignorance or confusion about the fact that he has been excluded, why he has been excluded, or the scope and effect of the exclusion. The I.G. action and notice is based on and consistent with the clear direction of Congress. Section 1128(a) of the Act requires that the Secretary exclude an individual convicted of an offense within the scope of section 1128(a)(3), except when the limited circumstances exist that give the Secretary discretion to grant a waiver under section 1128(c)(3)(B) – circumstances which do not exist in this case. Congress mandates exclusion for a minimum of five years. Act § 1128(c)(3)(B). Congress also mandates that exclusion be from any federal health care program as defined in section 1128B(f) of the Act. Section 1128B(f) defines federal health care program as:

> (1) any plan or program that provides health benefits, whether directly, through insurance, or otherwise, which is funded directly, in whole or in part, by the United States Government

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[4] To the extent Petitioner has further questions about the scope of his exclusion, the I.G. has provided additional guidance in its *UPDATED Special Advisory Bulletin on the Effect of Exclusion from Participation in Federal Health Care Programs*, available at: http://oig.hhs.gov/exclusions/files/sab-05092013.pdf.

> (other than the health insurance program under chapter 89 of title 5 United States Code); or
>
> (2) any State health care program, as defined in section 1128(h).

Act § 1128B(f). Section 1128(h) of the Act includes any state plan or program that is approved or receives federal funds under title V, XIX, XX, or XXI of the Act.

Furthermore, I have no authority to find the provisions of the Act or regulations unconstitutionally vague or overbroad. *Susan Malady, R.N.*, DAB No. 1816 (2002); 42 C.F.R. § 1005.4(c)(1). While I must interpret the Act and the Secretary's regulations in a manner consistent with Constitutional principles, Petitioner does not ask me to interpret the term "exclusion" and the scope of exclusion specified by Congress, but rather, asks that I invalidate the exclusion itself or somehow compel the Inspector General to interpret the term in a certain manner. Petitioner does not request relief that I am empowered to grant.

Finally, Petitioner argues that his exclusion constitutes double jeopardy because the exclusion is a second punishment from the government that "rises upon the federal court judgment" and "carries with it" criminal sanctions. P. Br. at 8-10. Petitioner is in error. Exclusion under section 1128 of the Act is not a criminal penalty. It is well-settled that I.G. exclusions pursuant to section 1128 of the Act are civil sanctions designed to protect the beneficiaries of health care programs and are remedial in nature.[5] I.G. exclusions thus do not trigger double jeopardy, since they are primarily remedial and not punitive. *Manocchio v. Kusserow*, 961 F.2d 1539, 1542-43 (11th Cir. 1992); *Greene v. Sullivan*, 731 F.Supp. 838 (E.D. Tenn. 1990); *cf. Patel v. Thompson*, 319 F.3d 1317 (11th Cir. 2003), *cert. denied*, 539 U.S. 959 (2003) (finding exclusions present no ex post facto problem because they are remedial, not punitive).

Accordingly, I conclude that the elements of section 1128(a)(3) of the Act are satisfied, including the required nexus between Petitioner's criminal offense and the delivery of a

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[5] Congress enacted the exclusion provisions to serve two purposes: the protection of federal funds and program beneficiaries from untrustworthy individuals; and the deterrence of health care fraud. S. REP. NO. 109, 100th Cong., 1st Sess. 1-2 (1987), *reprinted in* 1987 U.S.C.C.A.N. 682, 686 (noting "clear and strong deterrent"); *Joann Fletcher Cash*, DAB No. 1725, at 18 (2000) (discussing trustworthiness and deterrence). When Congress added section 1128(a)(3) in 1996, it again focused upon the deterrent effect of exclusions: "greater deterrence was needed to protect the Medicare program from providers who have been convicted of health care fraud felonies . . . ." H.R. REP. 496(1), 104th Cong., 2nd Sess. (1996), *reprinted in 1996* U.S.C.C.A.N. 1865, 1886.

health care item or service. Therefore, I conclude that there is a basis for Petitioner's exclusion pursuant to section 1128(a)(3) of the Act and that his exclusion is required.

4. Five years is the minimum authorized period of exclusion pursuant to section 1128(a)(3) of the Act.

5. Petitioner's exclusion for five years is not unreasonable as a matter of law.

I have concluded that there is a basis to exclude Petitioner pursuant to section 1128(a)(3) of the Act. Therefore, Petitioner must be excluded for a minimum period of five years pursuant to section 1128(c)(3)(B) of the Act.

Exclusion is effective 20 days from the date of the I.G.'s notice of exclusion to the affected individual or entity. 42 C.F.R. § 1001.2002(b).

III. Conclusion

For the foregoing reasons, Petitioner is excluded from participation in Medicare, Medicaid, and all federal health care programs for the minimum statutory period of five years, effective May 20, 2015.

/s/
Keith W. Sickendick
Administrative Law Judge