Department of Health and Human Services

DEPARTMENTAL APPEALS BOARD

Civil Remedies Division

Leo Parrino,

Petitioner,

v.

The Inspector General.

Docket No. C-14-582

Decision No. CR3287

Date: July 9, 2014

DECISION

The Inspector General (I.G.) of the U.S. Department of Health and Human Services (HHS) notified Petitioner, Leo Parrino, that he was being excluded from participation in Medicare, Medicaid, and all other federal health care programs for a minimum period of five years under 42 U.S.C. § 1320a-7(a)(1). Petitioner requested a hearing before an administrative law judge to dispute the exclusion. For the reasons stated below, I conclude that the I.G. has a basis for excluding Petitioner from program participation and that the five-year exclusion is mandated by law.

I. Background

By letter dated December 31, 2013, the I.G. 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 1320a-7(a)(1). The I.G. advised Petitioner that the exclusion was based on his conviction in the United States District Court, Western District of Kentucky (District Court), of a criminal offense related to the delivery of an item or service under the Medicare or a state health care program, including the performance of management or administrative services relating to the delivery of items or services, under any such program. I.G. Exhibit (Ex.) 1.

Petitioner timely filed a request for hearing (RFH) and this case was assigned to me for hearing and decision. On February 19, 2014, I convened a prehearing conference by telephone, the substance of which is summarized in my Order and Schedule for Filing Briefs and Documentary Evidence (Order), dated February 21, 2014. *See* 42 C.F.R. § 1005.6. Pursuant to the Order, the I.G. filed a brief (I.G. Br.) and four exhibits (I.G. Exs. 1-4). Petitioner filed a response brief (P. Br.). The I.G. filed a reply brief.

II. Decision on the Record

Petitioner did not object to the I.G.'s proposed exhibits. Therefore, I admit I.G. Exs. 1-4 into the record. Because both parties indicated that a hearing is not necessary in this case (I.G. Br. at 7; P. Br. at 4-5), I decide this case on the basis of the written record.

III. Issue

The sole issue before me is whether the I.G. has a basis for excluding Petitioner from participating in Medicare, Medicaid, and all other federal health care programs for five years pursuant to 42 U.S.C. § 1320a-7(a)(1). *See* 42 C.F.R. § 1001.2007(a)(1)-(2).

IV. Findings of Fact, Conclusions of Law, and Analysis[1]

HHS must exclude an individual from participation in Medicare, Medicaid and all other federally-funded health care programs if the individual was 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 U.S.C. § 1320a-7(a)(1). Therefore, the essential elements necessary to support an exclusion based on 42 U.S.C. § 1320a-7(a)(1) are: (1) the individual to be excluded must have been convicted of a criminal offense; and (2) the criminal offense must have been related to the delivery of an item or service under Title XVIII of the Social Security Act (Medicare) or any state health care program. A state health care program includes Medicaid. 42 U.S.C. § 1320a-7(h)(1); 42 C.F.R. § 1001.2 (definition of *State health care program*).

A. Petitioner pled guilty in a federal court to a misdemeanor count of introducing misbranded inhalation drugs into interstate commerce, the court accepted the plea, and the court sentenced Petitioner to probation and ordered Petitioner to pay restitution of $14,098.24 to the Centers for Medicare & Medicaid Services.

Petitioner is a pharmacist. Under the terms of a plea agreement dated September 8, 2011, he agreed to plead guilty to a misdemeanor count of introducing misbranded drugs into

[1] My findings of fact and conclusions of law are set forth in italics and bold font.

interstate commerce, in violation of 21 U.S.C. §§ 331(a), 333(a)(1), and 352(a). *See* I.G. Exs. 2, at 1; 4, at 1-2.[2] As part of the plea agreement, Petitioner agreed to the following factual basis for the plea:

> Leo Parrino was employed as a pharmacist at National Respiratory Services ("NRS") between April 2002 through October 31, 2006. Thereafter he served as a consulting pharmacist at NRS for the state of Michigan for several months. It was his responsibility to prepare medication for patients and ensure that the appropriate medications were sent out to patients. During the course of his employment and thereafter as a consultant, Parrino assisted in causing compounded medications to be sent out to patients which were sub-potent and misbranded. Once these medication requests were filled, that information was supplied to others who used it for billing purposes. This is a strict liability statute.

I.G. Ex. 2, at 2.

The District Court accepted Petitioner's plea and entered judgment against him on May 15, 2013. I.G. Exs. 3, at 1-8; 4. The judgment described the nature of Petitioner's violation of 21 U.S.C. §§ 331(a), 333(a)(1) and 352(a), as follows:

> Aided and abetted by others, introduced and delivered for introduction into interstate commerce, and caused to be introduced and delivered for introduction into interstate commerce, inhalation drugs that were misbranded, in that, the defendant introduced compounded inhalation drugs into interstate commerce that bore false and misleading labeling representing them to be of greater strength and potency than they actually had[.]

I.G. Ex. 4, at 2. The District Court sentenced Petitioner to one year of probation, a $25 assessment, and payment of $14,098.24 in restitution to the Centers for Medicare & Medicaid Services. I.G. Exs. 3, at 6-7; 4.

[2] The plea agreement reached between Petitioner and the United States indicates that there was a misdemeanor Information filed with the District Court. Neither party submitted the Information as evidence in this case.

B. Petitioner's conviction requires exclusion under 42 U.S.C. § 1320a-7(a)(1) because his criminal conduct related to the delivery of an item or service under Medicare.

1. Petitioner was convicted of a criminal offense for the purposes of 42 U.S.C. § 1320a-7(a)(1).

In order for Petitioner to be excluded, he must be "convicted of a criminal offense." 42 U.S.C. § 1320a-7(a)(1). An individual is considered "convicted" when a judgment of conviction has been entered by a federal, state, or local court or a plea of guilty or no contest has been accepted in a federal, state, or local court. 42 U.S.C. § 1320a-7(i)(1), (3). In the present matter, the District Court issued a judgment of conviction and sentenced Petitioner pursuant to that conviction. I.G. Ex. 4. Moreover, Petitioner pled guilty and that plea was accepted by the District Court. I.G. Exs. 2-4. Based on these facts and Petitioner's admission that he was convicted (P. Br. at 1), I conclude that Petitioner was convicted of a criminal offense for purposes of exclusion under 42 U.S.C. § 1320a-7(a)(1).

2. Petitioner's conviction requires exclusion under section 42 U.S.C. § 1320a-7(a)(1) because his criminal conduct related to the delivery of an item or service under Medicare.

In order for Petitioner to be excluded under 42 U.S.C. § 1320a-7(a)(1), Petitioner's criminal conviction must be related to the delivery of an item or service under Medicare or a state health care program. Although the term "related to" is not defined in the statute, it is well established "that an offense is 'related to' the delivery of an item or service under a covered program if there is a . . . nexus between the offense and the delivery of an item or service under the program." *James Randall Benham*, DAB No. 2042 (2006) (internal citations omitted);[3] *cf. 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 determining whether an offense is related to the delivery of an item or service under Medicare or a state health care program, it is not the label of the statute that controls. *See Lyle Kai, R.Ph.*, DAB No. 1979 (2005) *quoting Berton Siegel, D.O.*, DAB No. 1467, at 7 (1994); *see also Dewayne Franzen*, DAB No. 1165 (1990). Therefore, to determine whether Petitioner's offense is related to the delivery of an item or service under Medicare, it is necessary to examine the underlying conviction documents.

[3] Administrative decisions cited in this decision are accessible on the internet at: http://www.hhs.gov/dab/decisions/index.html.

Petitioner was convicted of introducing misbranded inhalation drugs into interstate commerce. Neither the language of the statutory sections under which Petitioner was convicted specifically states that his crime had any relationship to the Medicare program. However, a review of the record reveals that there is a sufficient connection between Petitioner's criminal conduct and the Medicare program.

As Petitioner admits, "the overarching case of which [Petitioner] was a small part, was one against his employer, National Respiratory Services, and their owners and managers for fraud against the Medicare and Medicaid programs of the United States Government." RFH at 3. This is consistent with the plea agreement in which Petitioner stated that he understood "that the United States will inform the court that it should order payment of restitution in an amount of $15,727.17, jointly and severally with the co-defendants, payable to the Centers for Medicare and Medicaid Services." I.G. Ex. 2, at 3. The District Court later ordered Petitioner to pay restitution to the "Centers for Medicare and Medicaid Services." I.G. Ex. 4, at 4.

Significantly, the District Court reviewed the case in order to ensure that there was sufficient evidence that Petitioner should pay restitution, stating at the sentencing hearing: "I'm going to order that [Petitioner] pay restitution in the amount that was agreed to as the corrected amount of $14,098.24 . . . . the proof on that seems clear enough to the Court to come down with a particular number." I.G. Ex. 3, at 6. It is worth noting that the District Court declined to order restitution for a co-defendant because "I think the proof was more difficult for the U.S. as to [the co-defendant]." I.G. Ex. 3, at 8.

In exclusion cases, restitution has long been considered a reasonable measure of program loss. *See Craig Richard Wilder*, DAB No. 2416, at 9 (2011); *Jason Hollady, M.D.*, DAB No. 1855 (2002). If an individual has been convicted of a criminal offense, then proof that any sentence based on that conviction included the payment of restitution to a protected program or the agency in charge of that program provides significant proof that there is a connection between the conviction and the delivery of an item or service under the program. *Blessing Okuji*, DAB CR2343, at 6 (2011); *Alexander Nepomuceno Jamias*, DAB CR1480 (2006). The District Court ordered Petitioner to pay restitution to the Centers for Medicare & Medicaid Services, which administers the Medicare program. In the absence of evidence to the contrary, this order of restitution proves that a nexus exists between Petitioner's criminal conviction and the delivery of items or services under the Medicare program.

C. Petitioner's other arguments are unavailing.

Petitioner argues that the I.G.'s decision to exclude him under 42 U.S.C. § 1320a-7(a)(1) is "unlawful, arbitrary, and capricious." P. Br. at 1. Petitioner alleges that, unlike the owners and managers of the company who were more culpable, he was just an employee with no intent to commit any crimes. He contends that the I.G. is depriving him of

"valuable property rights, his pharmacy license, without due process of law" and that the I.G.'s construction of the statutory scheme regarding exclusions also violates notions of fundamental fairness and equal application of the laws. RFH at 4; P. Br. at 2. Petitioner further argues that if his exclusion is warranted, the I.G. should have applied the permissive exclusion provisions under 42 U.S.C. § 1320a-7(b) rather than the mandatory exclusion provision of 42 U.S.C. § 1320a-7(a)(1). RFH at 2-5. In Petitioner's view, it is unfair that the I.G. must exclude him based on his misbranding offense for which no *mens rea* was required when, under the permissive exclusion provisions of 42 U.S.C. § 1320a-7(b), the I.G. may exclude an individual who has been convicted of one of the enumerated offenses (e.g., fraud, theft, embezzlement), all of which "require some culpable mental state." P. Br. at 2-3. Petitioner contends that if the mandatory exclusion applies to his offense, then all the offenses under the permissive exclusion provisions would be subsumed into 42 U.S.C. § 1320a-7(a)(1), rendering 42 U.S.C. § 1320a-7(b) null or at least redundant. Petitioner also cites several U.S. Supreme Court cases in support of his argument that the constitutionality of strict liability offenses comes in question when they are associated with substantial penalties. P. Br. at 2-3.

Petitioner's arguments are without merit. Although 42 U.S.C. § 1320a-7(a)(1) broadly includes any criminal convictions (i.e., felony or misdemeanor), it is narrow in that those convictions must be related to the Medicare and Medicaid (i.e., state health care programs) programs. Most of the permissive exclusions do not have the requirement that they be related to the Medicare or Medicaid programs. Despite this, it is still possible that a single conviction may cause the convicted individual to be subject to exclusion under both a mandatory and permissive exclusion. In such a case, the I.G. is required to impose a mandatory exclusion pursuant to 42 U.S.C. § 1320a-7(a)(1). *Gregory J. Salko, M.D.*, DAB No. 2437, at 4 (2012), *citing Timothy Wayne Hensley*, DAB No. 2044, at 15 (2006) (and cases cited therein); *Craig Richard Wilder*, DAB No. 2416, at 7; *Lorna Fay Gardner*, DAB No. 1733, at 6 (2000).

Further, Petitioner argues that exclusion should not be permitted when the excluded individual was convicted of a strict liability offense because such offenses lack criminal intent or knowledge. However, nowhere in the statutory language of 42 U.S.C. § 1320a-7(a)(1) is there any mention of intent. Therefore, criminal intent does not need to be an element in the offense for which the excluded individual was convicted. *DeWayne Franzen*, DAB No. 1165 (1990) ("Section 1128(a)(1) [42 U.S.C. § 1320a-7(a)(1)] does not require that the individual must intend to commit a criminal offense, or indeed fraud, for an exclusion to be proper."); *see also Lyle Kai, R.Ph.*, DAB No. 1979 (2005), *aff'd, Kai v. Leavitt*, Civ. No. 05-00514 BMK (D. Haw. 2006) (upholding the I.G.'s mandatory exclusion of a pharmacist pursuant to 42 U.S.C. § 1320a-7(a)(1) because a criminal conviction could be program-related even if the excluded individual did not personally engage in the scheme or was not aware of the underlying Medicaid billing fraud scheme involving mislabeled pharmaceuticals.); *see also Friedman*, 686 F.3d at 813, 822-824 (D.C. Cir. 2012) (rejecting an argument, made in a permissive exclusion

case, that exclusion cannot be predicated on the conviction of a criminal offense that did not include *mens rea*).

Moreover, to the extent that Petitioner suggests in his brief that he was not really guilty of the criminal offenses to which he pled guilty, I consider such an argument to constitute an impermissible collateral attack upon his conviction. I may not review the basis of a conviction, or consider a collateral attack on that conviction on procedural or substantive grounds. 42 C.F.R. § 1001.2007(d); *Joann Fletcher Cash*, DAB No. 1725 (2000); *Lyle Kai, R.Ph.*, DAB No. 1979, at 8 (2005), *aff'd, Kai v. Leavitt*, Civ. No. 05-00514 BMK (D. Haw. 2006).

With respect to Petitioner's argument that his exclusion violates his due process rights, I do not have jurisdiction to consider that argument. However, I note that Petitioner made the argument in order to preserve his right to raise this argument in federal court, which has jurisdiction to review constitutional issues.

D. Petitioner must be excluded for the statutory minimum of five years under 42 U.S.C. § 1320a-7(c)(3)(B).

Petitioner concedes that if I conclude that the I.G. had a basis for excluding him under 42 U.S.C. § 1320a-7(a)(1), then the five-year exclusion period is mandated because it is the statutory minimum period. P. Br. at 1. Petitioner is correct. Because I made such a conclusion, Petitioner must be excluded for a minimum period of five years. 42 U.S.C. § 1320a-7(c)(3)(B); 42 C.F.R. § 1001.102(a).

V. Conclusion

For the foregoing reasons, I affirm the I.G.'s determination to exclude Petitioner from participating in Medicare, Medicaid, and all federal health care programs for the statutory five-year minimum period pursuant to 42 U.S.C. § 1320a-7(a)(1), (c)(3)(B).

/s/
Scott Anderson
Administrative Law Judge