Department of Health and Human Services

DEPARTMENTAL APPEALS BOARD

Civil Remedies Division

Christopher Keegan,
(OI File No. 4-08-40761-9),

Petitioner,

v.

The Inspector General.

Docket No. C-14-452

Decision No. CR3242

Date: May 27, 2014

DECISION

Petitioner, Christopher Keegan, owned a pharmaceutical company, National Respiratory Services, that was headquartered in the State of Kentucky. He was convicted of introducing misbranded drugs into interstate commerce. Based on his conviction, the Inspector General (I.G.) has excluded him for ten years from participating in the Medicare, Medicaid, and all federal health care programs, as authorized by section 1128(a)(1) of the Social Security Act (Act). Petitioner now challenges the exclusion. For the reasons discussed below, I find that the I.G. properly excluded Petitioner and that the ten-year exclusion falls within a reasonable range.

I. Background

Petitioner Keegan was the owner and majority shareholder in National Respiratory Services, a pharmaceutical company. I.G. Ex. 3 at 2. He was charged in federal district court with one count of health care fraud and one count of introducing misbranded drugs into interstate commerce. I.G. Ex. 2. He pled guilty to a misdemeanor count of introducing misbranded drugs into interstate commerce, specifically, he caused "sub-potent, super-potent, and non-sterile" drugs, which were therefore "misbranded and

adulterated," to be sent to patients through interstate commerce, in violation of the Food, Drug & Cosmetics Act, 21 U.S.C. §§ 331(a), 333(a)(1), and 352(a). I.G. Ex. 3. The court entered judgment against him on July 23, 2013. I.G. Ex. 4.

In a letter dated November 29, 2013, the I.G. notified Petitioner that he was excluded from participation in Medicare, Medicaid, and all federal health care programs for a period of ten years, because he had been convicted of a criminal offense related to the delivery of an item or service under the Medicare or state health care program. The letter explained that section 1128(a)(1) of the Act authorizes the exclusion. I.G. Ex. 1. Petitioner requested review, and the matter is before me for resolution.

Neither party submits any witness testimony, and they agree that an in-person hearing is not necessary. I.G. Br. at 14; P. Br. at 6. Each party submitted an initial brief (I.G. Br.; P. Br.). The I.G. submitted five exhibits (I.G. Exs. 1-5) and Petitioner submitted two exhibits (P. Exs. 1-2). The I.G. submitted a reply brief (I.G. Reply). In the absence of any objection, I admit into evidence I.G. Exs. 1-5 and P. Exs. 1-2.

II. Issues

The issues before me are: 1) was Petitioner convicted of a criminal offense related to the delivery of an item or service under Medicare or a state health care program, within the meaning of section 1128(a)(1), thus providing a basis for excluding him from program participation; and 2) if so, is the length of the exclusion (ten years) reasonable.

III. Discussion

A. Petitioner must be excluded from program participation, because he was convicted of a criminal offense related to the delivery of an item or service under Medicare or a state health care program, within the meaning of section 1128(a)(1).[1]

Under section 1128(a)(1) of the Act, the Secretary of Health and Human Services (HHS) 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. *See also* 42 C.F.R. § 1001.101(a).

Petitioner concedes, as he must, that he was convicted of a criminal offense, but he argues that his offense was not related to the Medicare program. According to Petitioner,

[1] My findings of fact and conclusions of law are set forth, in italics and bold, in the discussion captions of this opinion.

the I.G. should consider the "language of the statute" under which he was convicted, not the underlying bases for his guilty plea. In Petitioner's view, introducing misbranded drugs into interstate commerce does not suggest an offense "directly related to the delivery of items or services" under Medicare. His offense should therefore not be subject to exclusion under section 1128(a)(1). P. Br. at 3-5.

But it is well-settled that, in determining whether a conviction is program-related within the meaning of section 1128(a)(1), I look beyond the language of the statute under which the individual was convicted and the precise wording of his plea. An offense is related to the delivery of an item or service under Medicare or a state health care program, if there is "a nexus or common-sense connection" between the conduct giving rise to the offense and the delivery of the item or service. *Lyle Kai, R.Ph.*, DAB No. 1979 at 5 (2005); *Berton Siegel, D.O.*, DAB No. 1467 at 5 (1994). The I.G. may rely on extrinsic evidence to explain the circumstances underlying a conviction. The regulations specifically provide that evidence of "crimes, wrongs, or acts other than those at issue in the instant case is admissible in order to show motive, opportunity, intent, knowledge, preparation, identity, lack of mistake, or existence of a scheme." 42 C.F.R. § 1005.17(g); *see Narendra M. Patel*, DAB No. 1736 (2000); *Tanya A. Chuoke, R.N.*, DAB No. 1721 (2000); *Bruce Lindberg, D.C.*, DAB No. 1280 (1991).

Petitioner's plea agreement leaves no doubt that his conviction was related to the Medicare program. He not only admitted that he (and others) introduced adulterated and misbranded drugs into interstate commerce, he also admitted that he "then submitted or caused to be submitted" to Medicare "false and fraudulent billings," claiming that the medications were non-compounded and FDA-approved, when they were not. CMS Ex. 3 at 2. His duplicity cost the Medicare program $2,030,343.11, and his company was ordered to pay that amount in restitution to the Centers for Medicare & Medicaid Services (CMS), the HHS division that administers the Medicare program. CMS Ex. 4 at 4-5.

Thus, Petitioner was convicted of a program-related crime and must be excluded for at least five years. I now consider whether the length of his exclusion, beyond five years, falls within a reasonable range.

B. Based on the aggravating factors present in this case, the ten-year exclusion falls within a reasonable range.

An exclusion 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 regulation may not be used to decide whether an exclusion of a particular length is reasonable.

Among the factors that may serve as bases for lengthening the period of exclusion are two relied on by the I.G. in determining the length of Petitioner's exclusion: 1) the acts resulting in the conviction, or similar acts, resulted in a financial loss to Medicare and state health care programs 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). 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)). Petitioner's actions resulted in program financial losses more than 400 times greater than the $5,000 threshold for aggravation. As noted above, Petitioner admitted that his criminal activity caused Medicare program losses of $2,030,343.11, which the court ordered be paid in restitution to CMS. I.G. Ex. 3 at 2, I.G. Ex. 4 at 4-5. Restitution has long been considered a reasonable measure of program losses. *Jason Hollady, M.D.*, DAB No. 1855 (2002). Because the financial losses were significantly in excess of the threshold amount for aggravation, the I.G. may justifiably increase significantly Petitioner's period of exclusion. *See Jeremy Robinson*, DAB No. 1905 at 9 (2004); *Donald A. Burstein, Ph.D.*, DAB No. 1865 at 12 (2003).

Duration of crime (42 C.F.R. § 1001.102(b)(2)). Petitioner was convicted of criminal acts that were committed over a period of more than two years, from July 2006 through August 2008. I.G. Ex. 2 at 2; *see* I.G. Ex. 4 at 2.

C. No mitigating factors justify decreasing the period of exclusion.

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 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 being imposed. 42 C.F.R. § 1001.102(c). Characterizing a 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).

Petitioner claims that he was suffering from a substance abuse problem during the period of criminal conduct, so could not be responsible for his company's actions. P. Br. at 5. But nothing in the record of criminal proceedings suggests that Petitioner's mental, physical, or emotional condition reduced his culpability. In its judgment, the court explicitly suspended any drug-testing condition "based on [its] determination that the

defendant pose[d] a low risk of future substance abuse," which shows that the court did not find that Petitioner had a significant history of substance abuse. CMS Ex. 4 at 3. Further, as part of his plea agreement, Petitioner "accepted responsibility" for his misconduct. CMS Ex. 3 at 4.

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)). In this case, Petitioner's crime demonstrates that he presents significant risks to the integrity of health care programs. He engaged in illegal conduct that cost the Medicare program a significant amount of money. His criminal conduct lasted more than a year. No mitigating factors offset the aggravating factors. I therefore find that the ten-year exclusions falls within a reasonable range.

IV. Conclusion

For these reasons, I conclude that the I.G. properly excluded Petitioner from participation in Medicare, Medicaid and all federal health care programs, and I sustain as reasonable the period of exclusion.

/s/
Carolyn Cozad Hughes
Administrative Law Judge