Department of Health and Human Services

DEPARTMENTAL APPEALS BOARD

Civil Remedies Division

Mohamed Basel Aswad, M.D.,
(OI File No. H-15-42738-9),

Petitioner,

v.

The Inspector General.

Docket No. C-16-304

Decision No. CR4637

Date: June 21, 2016

DECISION

I sustain the determination of the Inspector General (I.G.) to exclude Petitioner, Mohamed Basel Aswad, M.D., from participating in Medicare, State Medicaid programs, and all federally funded health care programs for a period of at least 13 years.

I. Background

Petitioner requested a hearing in order to challenge the I.G.'s exclusion determination. The I.G. filed a brief in support of his determination plus 11 exhibits that are identified as I.G. Ex. 1 – I.G. Ex. 11. The I.G. also filed a reply brief. Petitioner filed a brief (P. Br.) in opposition to the exclusion plus three exhibits. He identified two exhibits as P. Ex. 1 and P. Ex. 2. A third exhibit consists of Petitioner's written direct testimony made under affirmation. I identify this exhibit as P. Ex. 3.

I receive into evidence I.G. Ex. 1 – I.G. Ex. 11 and P. Ex. 1 – P. Ex. 3. The I.G. did not request to cross-examine Petitioner so I find no need to convene an in-person hearing. I decide this case based on the written record.

Petitioner filed discovery requests that were opposed by the I.G. In summary, he requested the production of documents consisting of all documents related to the I.G.'s decision to:

1. exclude Petitioner;
2. establish the length of Petitioner's exclusion; and
3. exclude or not exclude other individuals convicted of crimes similar to the crime of which Petitioner was convicted.

The I.G. objected to these requests on several grounds and I sustain the I.G.'s objections. Specifically, I find Petitioner's requests to be objectionable because: (1) the I.G. supplied relevant and non-privileged documents as part of his pre-hearing exchange; (2) the documents requested by Petitioner plainly include documents that are either attorney work product or deliberative in nature; and (3) the request calls for the production of irrelevant material. The discovery requirements at 42 C.F.R. § 1005.7 extend only to the inspection of non-privileged documents. In calling for all documents "related to" the I.G.'s decision making, Petitioner plainly seeks privileged materials that include the I.G.'s internal deliberations and communications that involve counsel. Moreover, and as I discuss in greater detail below, how the I.G. may have evaluated other cases involving crimes similar to that of which Petitioner was convicted is irrelevant to deciding this case. Consequently, discovery of documents that relate to such evaluations would not lead to the production of relevant evidence.

II. Issues, Findings of Fact and Conclusions of Law

A. Issues

The issues are whether Petitioner was convicted of a crime that mandates exclusion pursuant to section 1128(a)(1) of the Social Security Act (Act) and whether an exclusion period of 13 years is unreasonable.

B. Findings of Fact and Conclusions of Law

I find the following facts to be undisputed. On August 4, 2015, Petitioner pled guilty to violating 21 U.S.C. §§ 331(c) and 333(a)(1). I.G. Ex. 10. These sections make it a crime for an individual to receive in interstate commerce any food, drug, device, tobacco product or cosmetic that is adulterated or misbranded and to deliver or offer delivery of such products for pay or otherwise.

Petitioner specifically pled guilty to ordering a drug known as Bevacizumab, under the trade name Altuzan, introducing that drug into interstate commerce and transferring or selling the drug to a third party. I.G. Ex. 10. Altuzan is a chemotherapy drug that has not been listed by the Food and Drug Administration (FDA) as a drug manufactured for

commercial distribution in the United States. As part of Petitioner's plea he agreed to pay restitution of $1,277,589 to the Medicare program. *Id.* Petitioner was sentenced to pay a money judgment of $750,000 in addition to the restitution. I.G. Ex. 11 at 4.

In sum, Petitioner was convicted of receiving and then distributing a chemotherapy drug that was not approved by the FDA to be distributed to his patients. The restitution amount that Petitioner agreed to pay establishes that he obtained reimbursement from Medicare and State Medicaid programs in very substantial amounts for administering unapproved chemotherapy drugs.

Section 1128(a)(1) of the Act mandates the exclusion of any individual convicted of a criminal offense related to the delivery of an item or service under Medicare or a State Medicaid program. The facts that I find in this case plainly prove that Petitioner was convicted of such a crime. Indeed, they show that Petitioner's obtaining and redistribution of unapproved drugs was intimately related to Medicare and Medicaid items or services because Petitioner claimed reimbursement – in very substantial amounts – from these programs for his unlawful distribution of drugs. That is all the nexus that is required to prove that Petitioner was convicted of a section 1128(a)(1) offense.

The Act mandates the exclusion for at least five years of any individual who is convicted of a section 1128(a)(1) offense. Act, § 1128(c)(3)(B). The I.G. has discretion to exclude an individual for a longer period than five years if there is evidence that relates to aggravating factors that is not offset by evidence relating to mitigating factors. 42 C.F.R. § 1001.102(b), (c). These factors function very much like rules of evidence. The presence of evidence that falls within an aggravating or mitigating factor does not dictate that an exclusion of a particular length is reasonable. Such evidence is, however, admissible to be weighed in order to decide whether an exclusion of a particular length is reasonable. Ultimately, the question becomes one of trustworthiness. What does evidence pertaining to a particular aggravating or mitigating factor or factors say about an individual's trustworthiness to provide care to program beneficiaries and recipients of program funds?

The I.G. asserts, and I find, evidence that relates to two aggravating factors. First, the I.G. proved that Petitioner's crimes caused federally funded health care programs to sustain losses in excess of $5,000. 42 C.F.R. § 1001.102(b)(1). Petitioner was sentenced to pay restitution to Medicare and to State Medicaid programs in excess of $1.2 million. Court-ordered restitution is a measure of the financial impact of one's crimes. *Juan de Leon, Jr.*, DAB No. 2533 at 5 (2013). Second, Petitioner's crimes were committed over a period of more than a year. 42 C.F.R. § 1001.102(b)(2). Petitioner was charged with, and pled guilty to, distributing unauthorized drugs over a period that extended from July 2010 to April 2012, a period of slightly less than two years. P. Br. at 3; I.G. Ex. 9 at 4; I.G. Ex. 10 at 2.

Petitioner has neither alleged nor proved that there is evidence that falls under any of the mitigating factors set forth at 42 C.F.R. § 1001.102(c).

The I.G. excluded Petitioner for a period of 13 years and contends that evidence relating to the two aggravating factors that I have identified proves that the length of the exclusion is not unreasonable.[1] The evidence that the I.G. principally relies on is the amount of restitution that Petitioner was ordered to pay. I agree with the I.G. that this restitution of more than $1.2 million is a very substantial sum. I infer from this large restitution amount that Petitioner did much more than provide an unauthorized drug to a patient or patients. The amount of restitution proves that Petitioner provided such drugs on a massive scale, establishing indifference on his part to the requirement that he not introduce unapproved drugs into interstate commerce. Whether that was something that Petitioner did willfully or through criminal negligence, it establishes a cavalier disregard on his part for legal requirements pertaining to the distribution of such drugs. It is not unreasonable to conclude that Petitioner abused the trust that his patients placed in him as their physician to provide treatments and care that were bounded by the requirements of law. I find the exclusion period to be not unreasonable in light of that abuse of trust.

Petitioner makes several arguments in opposition to the exclusion determination. I have considered all of them and find them to be unavailing. First, Petitioner asserts that his purchase of misbranded drugs was "clearly inadvertent." In support of this assertion Petitioner contends that he was in effect duped into acquiring drugs that were unapproved for use. P. Br. at 3-4. I am not persuaded by this argument. It is an attempt by Petitioner to relitigate the facts that resulted in his conviction. In effect, Petitioner asserts that he is not really guilty of the crime to which he entered his guilty plea. I have no authority to consider arguments by Petitioner that are collateral attacks on the basis for his conviction. 42 C.F.R. § 1001.2007(d).

Next, Petitioner contends that his use of misbranded drugs for patient care was medically appropriate and did not result in patient harm. He characterizes the restitution that he was ordered to pay as being only a "technical overpayment" that did not constitute a true measure of the harm caused by Petitioner. P. Br. at 4-5. I find this argument also to be an inappropriate effort by Petitioner to relitigate the facts that resulted in his conviction.

[1] In this case the I.G. modified the exclusion by granting a partial waiver. On February 18, 2016, the I.G. granted a request by the State of New Mexico to waive the exclusion "with respect to the provision of oncology and oncology-related services within Luna County, New Mexico, and with respect to any resultant prescriptions or referrals for services, regardless of the location in which such prescription or referred services are provided, under the Medicare, Medicaid and all Federal health care programs." I.G. Ex. 7. I have no authority to review the I.G.'s determination to grant this partial waiver nor may I consider whether the waiver should be expanded to include other items or services provided by Petitioner. 42 C.F.R. § 1001.1801(f).

But, more than that, it is belied by Petitioner's acknowledgement of guilt. Petitioner characterizes his offense as being at most a technical violation of law. In fact, what Petitioner did in this case was to administer to patients drugs that bore inadequate directions, did not indicate they were for prescription only, and came from a foreign facility not registered with the FDA to manufacture such drugs for the United States. He committed these acts in obvious disregard of the requirement that he, as a physician, be certain that what he administered had governmental approval. The amount of restitution that he was ordered to pay proves that he did so on a massive scale. Petitioner's disregard of legal requirements had the potential for causing great harm to patients even if there is no proof that any individual patients suffered actual harm.

Petitioner also argues that the government has acknowledged "the extraordinary unlikelihood that Petitioner will ever commit a crime again." P. Br. at 5. As principal support for this argument Petitioner relies on the I.G.'s approval of a limited waiver for Petitioner to provide oncology and oncology-related services. *See* n.1, *supra*. As I have discussed, I have no authority to consider whether the I.G. should have granted a broader waiver or whether granting any waiver was appropriate. Moreover, the fact that the I.G. determined to exclude Petitioner for 13 years establishes that the government has not conceded the "extraordinary unlikelihood" Petitioner will commit a crime again. Regardless of whether Petitioner will offend again, the issue is his trustworthiness to participate in Medicare and federal health care programs, not his likelihood of recidivism. Indeed, the length of the exclusion in this case is more than ample proof that the government, in the guise of the I.G., takes a jaundiced view of Petitioner's overall trustworthiness.

Petitioner also argues that there is a clear community need for his services. P. Br. at 5-6. That argument is irrelevant because it does not relate to any of the regulatory aggravating or mitigating factors. Moreover, it again addresses the scope of the I.G.'s waiver determination.

Finally, Petitioner argues that the I.G.'s exclusion determination is arbitrary and that it is unreasonable when compared with exclusions that the I.G. imposed in other cases under similar circumstances. P. Br. at 7-8. This argument is irrelevant to my review in this matter. My role is not to compare and contrast the I.G.'s action in this case with those that the I.G. took in other cases. Rather, I must decide whether the exclusion is unreasonable based on the facts of *this case*. *Eugene Goldman, M.D., a/k/a Yevgeniy Goldman, M.D.*, DAB No. 2635 at 11 (2015) (observing that "the assessment of

aggravating factors . . . is first and foremost case-specific" and "the reasonableness question ultimately turns on an analysis of the circumstances of each case."). For the reasons that I have discussed, I find that this exclusion is not unreasonable.

/s/
Steven T. Kessel
Administrative Law Judge