Department of Health and Human Services
DEPARTMENTAL APPEALS BOARD
Appellate Division

Mohamed Basel Aswad, M.D.
Docket No. A-16-120
Decision No. 2741
October 18, 2016

FINAL DECISION ON REVIEW OF ADMINISTRATIVE LAW JUDGE DECISION

Mohamed Basel Aswad, M.D. (Petitioner) appeals a decision by an Administrative Law Judge (ALJ) upholding on the written record his exclusion by the Inspector General (I.G.) from participation in all federal health care programs for a period of 13 years. *Mohamed Basel Aswad, M.D.*, DAB No. CR4637 (2016) (ALJ Decision). The ALJ concluded that the I.G. was required to exclude Petitioner for at least five years pursuant to section 1128(a)(1) of the Social Security Act (Act).[1] The ALJ further concluded that a 13-year exclusion was not unreasonable based on the two aggravating factors on which the I.G. relied.

On appeal, Petitioner does not dispute that the I.G. was required to exclude him for five years, nor does Petitioner dispute the existence of the two aggravating factors. However, Petitioner challenges the ALJ's conclusion that a 13-year exclusion is not unreasonable, asserting that "the ALJ wholly failed to consider unique facts and circumstances surrounding his case." Notice of appeal (NA) at 2.

For the reasons set out below, we conclude that the 13-year period of exclusion is within a reasonable range based on the two aggravating factors and the absence of mitigating factors. Accordingly, we affirm the ALJ's decision to uphold the exclusion imposed by the I.G.

Legal Background

Section 1128(a)(1) of the Act states that the Secretary of the Department of Health and Human Services "shall exclude" from participation in federal health care programs "[a]ny individual or entity that has been convicted, under Federal or State law, of a criminal

[1] The current version of the Social Security Act can be found at www.ssa.gov/OP_Home/ssact/ssact-toc.htm. Each section of the Act on that website contains a reference to the corresponding United States Code chapter and section. Also, a cross-reference table for the Act and the United States Code can be found at 42 U.S.C.A. Ch. 7, Disp. Table.

offense related to the delivery of an item or service under title XVIII [Medicare] or under any State health care program." When an exclusion is imposed under section 1128(a)(1), section 1128(c)(3)(B) requires that the "minimum period of exclusion . . . be not less than five years[.]"[2] Section 1128(c)(3)(B) further provides:

> [U]pon the request of the administrator of a Federal health care program . . . who determines that the exclusion would impose a hardship on beneficiaries . . . of that program, the Secretary may, after consulting with the [I.G.], waive the exclusion . . . with respect to that program in the case of an individual or entity that is the sole community physician or sole source of essential specialized services in a community. The Secretary's decision whether to waive the exclusion shall not be reviewable.

See also 42 C.F.R. § 1001.1801 (the I.G. "has the authority to grant or deny a request from a State health care program that an exclusion from that program be waived with respect to an individual or entity . . . if the individual or entity is the sole community physician or the sole source of essential specialized services in a community").

The mandatory five-year minimum period of an exclusion under section 1128(a)(1) may be extended based on the application of the aggravating factors in 42 C.F.R. § 1001.102(b). The two aggravating factors found by the I.G. in this case are: "[t]he acts resulting in the conviction, or similar acts, . . . caused, or were intended to cause, a financial loss to a Government program or to one or more entities of $5,000 or more" and "[t]he 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)(1), (b)(2). If an exclusion period is extended based on the application of one or more aggravating factors, the I.G. may then apply any mitigating factors specified in section 1001.102(c)(1)-(3) to reduce the length of the exclusion period to no less than the mandatory minimum five years. *Id.* § 1001.102(c).

An excluded individual may request a hearing before an ALJ, but only on the issues of whether the I.G. had a basis for the exclusion and whether the length of an exclusion longer than the mandatory minimum period is unreasonable. *Id*. §§ 1001.2007(a), 1005.2(a). Any party dissatisfied with the ALJ's decision may appeal the decision to the Board. *Id*. § 1005.21.

[2] Paragraph (G) of section 1128(c)(3) requires an exclusion of more than five years in circumstances not present here.

Case Background[3]

On August 4, 2015, Petitioner pled guilty to violating 31 U.S.C. §§ 331(c) and 333(a)(1), which make it a crime for an individual to receive in interstate commerce any drug that is adulterated or misbranded and to deliver or offer delivery of such products for pay or otherwise. Specifically, Petitioner pled guilty to ordering and administering to his patients 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. The drug Petitioner ordered and administered was known as Bevacizumab, sold under the "trade name" (generic name) Altuzan. ALJ Decision at 2-3. Bevacizumab that is sold under the generic name Avastin is approved by the FDA. P. Ex. 1 at 5, 10. As part of Petitioner's plea, he agreed to pay restitution of $1,277,589 to the Medicare program. ALJ Decision at 3.[4]

By letter dated December 31, 2015, the I.G. notified Petitioner that, pursuant to section 1128(a)(1) of the Act, he was being excluded from Medicare, Medicaid, and all federal health care programs for a minimum period of 13 years based on the aggravating factors in 42 C.F.R. § 1001.101(b)(1) and (b)(2). I.G. Ex. 4, at 1-2. With respect to the aggravating factor in section 1001.101(b)(1), the I.G. stated that the "court ordered you to pay approximately $1,298,500 in restitution." *Id.* at 2. With respect to the aggravating factor in section 1001.101(b)(2), the I.G. stated that the "acts occurred from about July 2010 to about March 2012." *Id.*

By letter dated February 18, 2016, the I.G. notified Petitioner that it was granting the request of the New Mexico Human Services Department "for the waiver of your 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 prescriptions or referred services are provided, under the Medicare, Medicaid and all Federal health care programs." I.G. Ex. 7, at 1. The letter stated that "[t]his action does not otherwise change your current exclusion; it remains in effect . . . ." *Id.*

[3] The factual information in this section is drawn from the ALJ Decision and the record and is presented to provide a context for the discussion of the issues raised on appeal. Nothing in this section is intended to replace, modify, or supplement the ALJ's findings of fact.

[4] The full amount of restitution Petitioner was required to pay was $1,298,543, including $1,277,589 to the Centers for Medicare and Medicaid Services, and $20,954 to United Healthcare Military & Veterans. I.G. Ex. 10 (Amended Plea Agreement) at 7.

Shortly before he was notified of the limited waiver, Petitioner requested a hearing before the ALJ. I.G. Ex. 5. The parties filed briefs and exhibits, and the ALJ accepted into evidence all of their exhibits (I.G. Exs. 1-11 and P. Exs. 1-3). ALJ Decision at 1. Petitioner also filed a request for the production of documents, to which the I.G. objected, after which Petitioner filed a motion to compel, which the I.G. opposed. Request for Production of Documents, dated 4/20/16; Inspector General Discovery Response dated 5/19/16; Motion to Compel Production of Documents dated 5/27/16; Inspector General's Response to Petitioner's Motion to Compel Production of Documents dated 6/3/16. As relevant here, Petitioner sought "[a]ll documents related to the I.G.'s decision to Exclude or not to Exclude, and length of any such Exclusion, of individuals convicted of the misdemeanor offenses related to (a) the introduction or delivery for introduction into interstate commerce of any . . . drug . . . that is adulterated or misbranded and/or (b) the receipt, in interstate commerce, of any . . . drug. . . that is adulterated or misbranded, and the delivery or proffered delivery thereof for pay or otherwise, in violation of 21 §§ U.S.C. 331(a), 331(c)." Motion to Compel Production of Documents at 2. The ALJ denied Petitioner's motion to compel on the ground that it sought "privileged materials that include the I.G.'s internal deliberations and communications that involve counsel" and on the further ground that "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." ALJ Decision at 2.

As noted above, the ALJ concluded that the I.G. was required to exclude Petitioner for a minimum of five years based on his conviction and that a 13-year exclusion was not unreasonable. The ALJ explained this conclusion as follows:

> 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. [footnote omitted] 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.

Id. at 4.

The ALJ then turned to Petitioner's arguments on appeal, which challenged only the reasonableness of the 13-year period of exclusion. According to the ALJ, Petitioner's assertion "that his purchase of misbranded drugs was 'clearly inadvertent'" was "an attempt by Petitioner to relitigate the facts that resulted in his conviction." *Id*. The ALJ found this assertion "unavailing," stating "I have no authority to consider arguments by Petitioner that are collateral attacks on the basis for his conviction." *Id*., citing 42 C.F.R. § 1001.2007(d). The ALJ also found unavailing Petitioner's argument that the "restitution that he was ordered to pay [was] only a 'technical overpayment' that did not constitute a true measure of the harm caused by Petitioner," finding "this argument also to be an inappropriate effort by Petitioner to relitigate the facts that resulted in his conviction." *Id*. The ALJ stated that Petitioner acted—

> 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.

Id. at 5.

The ALJ further found that Petitioner's arguments "that the government has acknowledged 'the extraordinary unlikelihood that Petitioner will ever commit a crime again'" and that "there is a clear community need for his services" inappropriately relied on the I.G.'s waiver determination, stating that "I have no authority to consider whether the I.G. should have granted a broader waiver or whether granting any waiver was appropriate." *Id*.

Finally, the ALJ stated that Petitioner's argument that the I.G.'s exclusion "is unreasonable when compared with exclusions that the I.G. imposed in other cases under similar circumstances . . . is irrelevant to my review in this matter." *Id*. The ALJ continued: "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*." *Id*. (italics in original).

Standard of Review

Our standard of review of an exclusion imposed by the I.G. is established by regulation. We review a disputed issue of fact as to "whether the initial decision is supported by substantial evidence on the whole record." 42 C.F.R. § 1005.21(h). We review a disputed issue of law as to "whether the initial decision is erroneous." *Id*.

Analysis

As noted above, under 42 C.F.R. § 1001.2007(a)(1), where, as here, a petitioner challenges the length of an exclusion, the issue before the ALJ is whether the length of the exclusion "is unreasonable." The preamble to the final regulations explains that the regulations vest "broad discretion" in the I.G. to determine the length of exclusion. 57 Fed. Reg. 3298, 3315 (1992). The preamble further states: "So long as the amount of the time chosen by the [I.G.] is within a reasonable range, based on demonstrated criteria, the ALJ has no authority to change it[.]" *Id*. We explain below why we conclude that the 13-year exclusion upheld by the ALJ was within a reasonable range and not unreasonable.

1. *The ALJ did not err in finding the 13-year period of exclusion not unreasonable based on the aggravating factors in 42 C.F.R. § 1001.102(b)(1) and (b)(2).*

Petitioner argues that, although the amount of restitution he paid establishes the existence of the aggravating factor in section 1001.102(b)(1), the ALJ erred in concluding that the 13-year exclusion is not unreasonable based on that factor. As noted above, the ALJ reasoned that the "large restitution amount," $1,298,543, proves that Petitioner provided misbranded drugs "on a massive scale," which establishes "a cavalier disregard on his part" for the laws designed to protect patients from misbranded drugs, which in turn shows that Petitioner "abused the trust that his patients placed in him," in light of which the 13-year exclusion was "not unreasonable." ALJ Decision at 4. Petitioner disputes that the large restitution amount reflects his provision of the misbranded drug on a massive scale, asserting that "Bevacizumab is a costly chemotherapy drug" the price of which can reach nearly $100,000 per treatment. NA at 5. Petitioner also asserts that the large restitution amount "is not reflective of [his] inappropriate use of Bevacizumab" since "at no time has anyone alleged that the misbranded drugs in question were administered or used by [Petitioner] in a medically inappropriate manner." *Id*., citing P. Ex. 1, at 21-22 (state licensing board statement that "[t]here is absolutely no evidence that any of [Petitioner's] patients were harmed by the administration of the non-FDA approved medications").

We conclude that the large amount of restitution Petitioner paid pursuant to his plea agreement is a sufficient basis for extending his period of exclusion from the mandatory minimum of five years to 13 years. Under section 1001.102(b)(1), a "financial loss" to a government program of $5,000 or more caused by the acts resulting in the conviction constitutes an aggravating factor. The Board has held that the amount of restitution ordered by a court is "a reasonable valuation of financial losses of the program." *Laura Leyva*, DAB No. 2704, at 9 (2016) and Board decisions cited therein. The Board has further held that "it is entirely reasonable to consider a program loss amount substantially larger than the $5,000 threshold . . . an 'exceptional aggravating factor' to be accorded

significant weight." *Id*. Nothing in the Board decisions – or in the language of the regulation itself – suggests that how the amount of restitution is calculated might detract from the weight to be accorded to this aggravating factor. Thus, regardless of whether the ALJ correctly characterized restitution in the amount of $1,298,543 as proving that Petitioner provided misbranded drugs "on a massive scale," the ALJ reasonably concluded that this amount reflects a high degree of untrustworthiness warranting an extension of the five-year period of exclusion to 13 years.

Moreover, contrary to what Petitioner suggests, the alleged absence of any harm to Petitioner's patients from his use of misbranded drugs is not a basis for according less weight to the aggravating factor under section 1001.102(b)(1). The regulations establish as a separate aggravating factor that "[t]he acts that resulted in the conviction, or similar acts, had a significant adverse physical, mental or financial impact on one or more program beneficiaries or other individuals[.]" 42 C.F.R. § 1001.102(b)(3). Even assuming that there was no such adverse impact here,[5] the absence of that aggravating factor does not detract from the significance of the aggravating factor in section 1001.102(b)(1).

Accordingly, we conclude that the ALJ did not err in finding the 13-year period of exclusion not unreasonable based on the aggravating factor in section 1001.102(b)(1). The presence of a second aggravating factor under section 1001.102(b)(2), which is clearly shown by the record and not disputed by Petitioner, further supports the imposition of an exclusion period of this length.

2. *Petitioner's alleged lack of intent in purchasing and distributing misbranded drugs does not show that the 13-year period of exclusion is unreasonable.*

Petitioner reprises his argument below that "he was unaware he was purchasing misbranded drugs in the first instance." NA at 4; *see also* NA at 2 (Petitioner "inadvertently purchased non-[FDA] approved chemotherapy drugs"). According to Petitioner, the sales representative of the company from which he ordered the drugs, Non-RX, represented that it "was a large, United States based pharmaceutical company"; "the circumstances pursuant to which [Petitioner] . . . not only ordered, but received, the chemotherapy medications from Non-RX were not different from that of [Petitioner's] other interactions with other FDA approved manufacturers"; "the price paid by

[5] We note, however, that the New Mexico Medical Board notice suspending Petitioner's license states that "[m]isbranded non-FDA-approved drugs carry the significant, unreasonable risk that the safety and efficacy of the drugs will be inferior to FDA-approved drugs." I.G. Ex. 8, at 33.

[Petitioner] for Bevacizumab was consistent with market prices"; "potential warning signs" that the "Bevacizumab chemotherapy medication received by" Petitioner was a misbranded drug "were not obvious"; and Petitioner was not among the "approximately 160 health care providers located across the United States" who ordered this drug and received letters from the FDA "warning them of the FDA's suspicions that the Bevacizumab they ordered [was] counterfeit and not approved by the FDA." NA at 3-4. Petitioner also "emphasizes that the misbranding offense to which he pled guilty is a *strict liability*, misdemeanor offense," and that "[h]is guilty plea is thus not an admission of intent or even negligence." NA at 4 (italics in original). Petitioner takes the position that the ALJ erred in characterizing his argument that he lacked intent as an attempt to relitigate the criminal case. NA at 9. Instead, Petitioner maintains, he "sought to present the unique facts and circumstances underlying his strict liability misdemeanor misbranding offense, to establish the unreasonable nature of his exclusion *period*, not the exclusion itself." NA at 9-10 (italics in original).

Even assuming Petitioner raised lack of intent to try to establish that the length of the exclusion was unreasonable (rather than to try to relitigate his criminal case), he failed to establish that.[6] Under the applicable regulations, the mandatory minimum five-year exclusion period imposed under section 1128(a) may be extended based on the application of any of the aggravating factors specified in the regulations. 42 C.F.R. § 1001.102(b). If an exclusion period is extended based on the application of one or more of the aggravating factors, only the mitigating factors specified in the regulations may be considered and applied to reduce the length of the exclusion period to no less than the mandatory minimum five years. 42 C.F.R. § 1001.102(c). Petitioner's alleged lack

[6] Although we do not reach the issue of whether Petitioner lacked intent, his concessions that the medication he received "was labeled 'Altuzan' in lieu of the Bevacizumab brand name, 'Avastin,'" and that he "did not review [the] package inserts" show that at the very least, he did not exercise care to ensure that the drugs were FDA-approved before he administered them to his patients. NA at 3-4.

of intent to order and administer misbranded drugs on its face is not one of the mitigating factors specified in the regulation; accordingly, it cannot be considered in determining whether Petitioner's exclusion for more than the mandatory minimum five years is unreasonable.[7]

Petitioner points out that the Board has previously stated that an ALJ must "'determine whether [a period of exclusion] falls within a reasonable range given the aggravating and mitigating factors *and the circumstances underlying them*."' NA at 10, quoting *Joseph M. Rukse, Jr., R.Ph.*, DAB No. 1851, at 10-11 (2002) (emphasis added by Petitioner). However, the Board did not mean or hold that the circumstances underlying an aggravating or mitigating factor could either eliminate one of the aggravating factors specified in the regulations or add a new mitigating factor to those specified in the regulations. Circumstances underlying the extant aggravating factors may factor into the ALJ's assessment of the weight to be accorded the factors, but they may not replace the factors themselves as the basis for the ALJ's determination. Furthermore, as stated earlier, Petitioner's alleged lack of intent to order and administer misbranded drugs does not qualify as a mitigating factor under the regulations, and Petitioner has not even explained how his alleged lack of intent may be relevant to any of the mitigating factors applied by the I.G.

3. Comparisons with other cases where petitioners were excluded based on a conviction of a misbranding offense do not establish that a 13-year period of exclusion is unreasonable in Petitioner's case.

Petitioner argues that comparisons with the length of the exclusions at issue in Board and ALJ decisions show that his exclusion is unreasonable because "the I.G., in the face of *intentional* and significantly more egregious conduct, has imposed shorter exclusion

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[7] Section 1001.102(c) states:

. . . . Only the following factors may be considered mitigating—

(1) The individual or entity was convicted of 3 or fewer misdemeanor offenses, and the entire amount of financial loss (both actual loss and intended loss) to Medicare or any other Federal, State or local governmental health care program due to the acts that resulted in the conviction, and similar acts, is less than $1,500;

(2) The record in the criminal proceedings, including sentencing documents, demonstrates that the court determined that the individual had a mental, emotional or physical condition before or during the commission of the offense that reduced the individual's culpability; or

(3) The individual's or entity's cooperation with Federal or State officials resulted in—

(i) Others being convicted or excluded from Medicare, Medicaid and all other Federal health care programs,

(ii) Additional cases being investigated or reports being issued by the appropriate law enforcement agency identifying program vulnerabilities or weaknesses, or

(iii) The imposition against anyone of a civil money penalty or assessment under part 1003 of this chapter.

periods." NA at 6 (emphasis in original). The ALJ stated that a similar argument raised by Petitioner below "is irrelevant to my review in this matter." ALJ Decision at 5. The ALJ continued:

> 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 fact 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.").

Id. (emphasis added).

Although the Board has not held that case comparisons are irrelevant, it has held that they are of limited value and not dispositive. In *Goldman*, the Board summarized its treatment of this issue as follows:

> The Board has made it clear that the assessment of aggravating factors (and mitigating factors, if any), is first and foremost case-specific. Every case involves a complex interaction of diverse circumstances and regulatory factors with varying weights. For this very reason case comparisons, while sometimes informative for the ALJ's or the Board's decision-making in a given case, are of limited value and ultimately are not dispositive on the question of reasonableness of an exclusion period in a given case. *See, e.g., [Sushil Aniruddh] Sheth, M.D.*, DAB No. 2491, at 6 [(2012)].

DAB No. 2635, at 11.

Thus, the ALJ was correct to focus on the specific facts of this case: that the acts resulting in Petitioner's conviction caused a financial loss to federal programs more than 300 times the $5,000 required for an aggravating factor under section 1001.102(b)(1); that the acts that resulted in the conviction occurred over a period almost twice as long as the one year required for an aggravating factor under section 1001.102(b)(2); and that there were no mitigating factors as defined in section 1001.102(c)(1)-(3).

Moreover, the decisions Petitioner cites are not even informative. Petitioner lists several decisions involving petitioners who were excluded for the same or a shorter period than he was based on their conviction of criminal offenses he says were more egregious than his offense on the ground that those petitioners acted with intent. NA at 6-7. However, as discussed above, lack of intent to commit an offense is not a mitigating factor under the applicable regulations. Thus, even assuming the petitioners in the cited cases acted

intentionally and further assuming Petitioner did not, it does not follow that Petitioner was treated unfairly in being excluded for a period greater than or equal to the length of their exclusions. In addition, six of the seven cases cited involve exclusions ranging from 10 to 13 years and, thus, support a conclusion that an exclusion period of 13 years is within a reasonable range given circumstances that Petitioner claims are analogous to the circumstances in his case except for the element of intent.[8]

4. The limited waiver of Petitioner's exclusion based on the community need for his services is not a basis for finding that the 13-year period of exclusion is unreasonable.

Petitioner argues that the "overarching issue in determining whether the length of an exclusion is reasonable is whether it is consistent with the statutory purpose of protecting health care programs and their beneficiaries," and that his 13-year exclusion is unreasonable because it does not serve to protect federal health care programs or their beneficiaries.[9] NA at 7, quoting *Sheth*, DAB No. 2491, at 11. Petitioner relies primarily on the I.G.'s limited waiver of Petitioner's exclusion for the provision of oncology and oncology-related services in his community, which he says is evidence that the I.G. believed him to be trustworthy. *Id*. at 8. Petitioner asserts that his "trustworthiness is further evidenced by his longstanding community support . . . as evidenced by voluminous letters of support provided by [Petitioner's] patients and professional colleagues" and by statements made by the Licensing Board in recommending reinstatement of his license and by the State agency in recommending the waiver to the I.G. *Id*. at 9, citing I.G. Ex. 2, at 40-58, and quoting P. Ex. 6, at 1-2 and P. Ex. 1, at 23.

Contrary to what Petitioner appears to suggest, the Board's decision in *Sheth* does not hold that general "trustworthiness" is an independent basis, i.e., independent from the specified aggravating and mitigating factors, for determining whether the period of an exclusion is unreasonable. The statement in *Sheth* on which Petitioner relies refers back to language in that decision stating:

[8] Petitioner asserts that "disparate treatment of [Petitioner], as compared to that of similarly situated individuals," is also shown by the fact that of the approximately 160 health care providers who ordered Bevacizumab that was not FDA-approved, he was the only one who did not receive a warning letter from the FDA and was one of only seven who were "prosecuted by the government." NA at 7. This is a collateral attack on his conviction on procedural grounds, which may not be raised in an appeal of an exclusion. *See* 42 C.F.R. § 1001.2007(d).

[9] Petitioner referred to the ALJ's finding as a "finding that his exclusion period was reasonable." NA at 1. However, the ALJ, consistent with the language and standard codified in section 1001.2007(a)(1), actually found that the period was "not unreasonable." ALJ Decision at 6. We use the terminology correctly employed by the ALJ.

> The duration of a mandatory exclusion beyond the statutory five-year minimum is determined by evaluating the aggravating factors and mitigating factors set forth at 42 C.F.R. §§ 1001.102(b) and (c). . . . The evaluation does not rest on the specific number of aggravating or mitigating factors or any rigid formula for weighing those factors, but rather on a case-specific determination of the weight to be accorded each factor based on a qualitative assessment of the circumstances surrounding the factors in that case. . . . The protective purpose of the exclusion statutes is an overarching consideration when assessing the factors: "It is well-established that section 1128 exclusions are remedial in nature, rather than punitive, and are intended to protect federally-funded health care programs from untrustworthy individuals." *Donald A. Burstein, Ph.D.*, DAB No. 1865, at 12 (2003), *citing Patel v. Thompson,* 319 F.3d 1317 (11th Cir. 2003), *cert. denied,* 123 S.Ct. 2652 (2005); *Mannocchio v. Kusserow,* 961 F.2d 1539, 1543 (11th Cir. 1992).

Sheth at 5. *Sheth* further states that "[t]he aggravating and mitigating factors . . . were designed to evaluate" the "threat that Petitioner poses to the Medicare program and its beneficiaries." *Sheth* at 16, citing *Jeremy Robinson*, DAB No. 1905 (2004) and *Joann Fletcher Cash*, DAB No. 1725 (2000). Accordingly, as the Board stated in *Robinson*, the "aggravating and mitigating factors reflect the degree or level of the provider's untrustworthiness." *Robinson* at 11 (citing *Cash* at 18).

In addition, the Board has held that "none of the enumerated mitigating factors permit the consideration of Petitioner's qualifications, or skill or ability as a physician, or his standing in the medical community, or his reputation among the patients he served, to reduce the exclusion period." *Eugene Goldman, M.D.* at 10; *see also Laura Leyva* at 9 ("the regulations do not provide for consideration of character as a mitigating factor"); *Baldwin Ihenacho*, DAB No. 2667, at 8 (2015) ("character references are irrelevant because the regulations do not provide for consideration of character as a mitigating factor"). Thus, the ALJ did not err in not considering the "letters of support" from Petitioner's patients and professional colleagues and other statements Petitioner claims show he is trustworthy.

Moreover, Petitioner's reliance on the limited waiver granted by the I.G. pursuant to section 1128(c)(3)(B) of the Act to allow him to provide oncology services in his community is misplaced. The waiver, as the I.G. made plain in the letter granting it, simply allowed Petitioner a limited ability to provide oncology services because of the need for those services in his community and "does not otherwise change" his exclusion. I.G. Ex. 7, at 1. Thus, as the ALJ correctly found, the community need for Petitioner's oncology services is not a mitigating factor that may be applied to reduce a period of exclusion. ALJ Decision at 5; *see also Vinod Chandrashekhar Patwardhan, M.D.*, DAB No. 2454, at 8 (2012) (holding that the granting of a limited waiver under 42 C.F.R.

§ 1001.1801 is irrelevant because it is not a mitigating factor under the regulations).
The ALJ did not err in denying Petitioner's motion to compel.

Petitioner argues that the ALJ erred in denying his motion to compel discovery of documents related to the I.G.'s decision to exclude or not exclude other individuals convicted of crimes similar to the crime of which Petitioner was convicted and the length of any such exclusions. NA at 10-11. Under the applicable regulations, an ALJ may deny a motion to compel if the ALJ finds that the discovery sought: "(i) Is irrelevant, (ii) Is unduly costly or burdensome, (iii) Will unduly delay the proceeding, or (iv) Seeks privileged information." 42 C.F.R. § 1005.7(e)(2). In denying Petitioner's motion, the ALJ stated in part: "[H]ow 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." ALJ Decision at 2.

Documents related to the I.G.'s decision not to exclude other individuals are clearly irrelevant since the I.G. was mandated to exclude Petitioner based on his conviction and Petitioner does not even argue that he should not have been excluded. In addition, documents related to the I.G.'s decision to exclude individuals convicted of the same or similar crimes as he was and the length of their exclusions would have little, if any, relevance. As previously discussed, the Board has held that comparisons with the exclusions imposed in other cases decided by an ALJ or the Board are of limited value and not dispositive, and the same would be true of exclusions that were not appealed. Furthermore, we conclude that requiring the I.G. to produce documents related to the types of exclusions Petitioner identified would be unduly burdensome. The I.G. asserted that it would be required to manually search voluminous records in order to locate the information requested. Inspector General's Response to Petitioner's Motion to Compel Production of Documents at 5-6. The ALJ did not err in declining to impose such a burden on the I.G. for documents that would at most be of limited value and, in the end, not dispositive. For these reasons, we find no error in the ALJ's denial of Petitioner's motion pursuant to section 1005.7(e)(2)(ii). We therefore need not consider Petitioner's additional argument that the ALJ erred in denying his motion on the ground that the materials sought are privileged. ALJ Decision at 2; NA at 11.

Conclusion

For the foregoing reason, we affirm the ALJ's decision upholding the 13-year exclusion imposed by the I.G.

/s/
Constance B. Tobias

/s/
Susan S. Yim

/s/
Sheila Ann Hegy
Presiding Board Member