Department of Health and Human Services DEPARTMENTAL APPEALS BOARD Appellate Division

Rita Patel Docket No. A-18-74 Decision No. 2884 August 3, 2018

FINAL DECISION ON REVIEW OF ADMINISTRATIVE LAW JUDGE DECISION

Rita Patel (Petitioner) appeals the April 30, 2018, Administrative Law Judge (ALJ) decision upholding the five-year exclusion from federal health care programs imposed by the Inspector General (IG) under section 1128(a)(4) of the Social Security Act (Act). Rita Patel, DAB CR5085 (2018) (ALJ Decision). The exclusion became effective October 19, 2017.

On appeal, Petitioner contends that the ALJ should have changed the effective date so that the exclusion would have taken effect beginning with the date of the underlying conviction or the date on which the IG had notice of the conviction. Notice of Appeal (NA) at 1.

We conclude that the ALJ did not err in holding that she did not have the authority to change the effective date of the exclusion from that prescribed by regulation. *See* ALJ Decision at 5. We have no such authority under the applicable law either. Therefore, we sustain the ALJ and uphold the exclusion as imposed.

Applicable Legal Authorities

Section 1128(a)(4) of the Act mandates the exclusion of any individual "under Federal or State law, of a criminal offense consisting of a felony relating to the unlawful manufacture, distribution, prescription, or dispensing of a controlled substance." *See also* 42 C.F.R. § 1001.101(d).

¹ The current version of the Act can be found at http://www.socialsecurity.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 http://uscode.house.gov/table3/1935_531.htm and https://www.ssa.gov/OP_Home/comp2/G-APP-H.html.

Section 1128(c)(3)(B) of the Act provides that the minimum period of exclusion generally shall not be less than 5 years. The period of exclusion may be extended based upon the application of aggravating factors listed in 42 C.F.R. § 1001.102(b). If the exclusion period is extended based on application of one or more aggravating factors, mitigating factors may then be applied to reduce the length of the exclusion period to no less than five years. 42 C.F.R. § 1001.102(c).

Section 1128(c)(1) states that an exclusion "shall be effective at such time and upon such reasonable notice to the public and to the individual or entity excluded as may be specified in regulations" within certain parameters not relevant here. The regulation on notice and effective date of exclusions provides as follows:

- (a) Except as provided in § 1001.2003,^[2] if the OIG determines that exclusion is warranted, it will send a written notice of this decision to the affected individual or entity.
- **(b)** The exclusion will be effective 20 days from the date of the notice.
- (c) The written notice will state -
 - (1) The basis for the exclusion;
 - (2) The length of the exclusion and, where applicable, the factors considered in setting the length;
 - (3) The effect of the exclusion;
 - (4) The earliest date on which the OIG will consider a request for reinstatement:
 - (5) The requirements and procedures for reinstatement; and
 - (6) The appeal rights available to the excluded individual or entity. . . .

42 C.F.R. § 1001.2002.

An excluded individual may request a hearing before an ALJ but only on the issues of whether the "basis for the imposition of the [exclusion] exists" and, except for mandatory exclusions set at the minimum required period, whether the "length of exclusion is unreasonable." 42 C.F.R. § 1001.2007(a)(1). An adverse ALJ decision may be appealed to the Board. 42 C.F.R. § 1005.21.

² Both parties agree that section 1001.2002 applied here. NA at 2; IG Br. at 3.

Case background³

Petitioner is a pharmacist in New Jersey who pled guilty to attempted criminal sale of a prescription for a controlled substance by a practitioner or pharmacist in violation of N.Y. Penal Law §§ 110 and 220.65. The ALJ summarized the basis of the criminal conviction as follows:

The grand jury detailed Petitioner's role in an extensive scheme to sell prescriptions "for oxycodone based upon perfunctory or nonexistent treatment" by Petitioner's co-conspirator. I.G. Ex. 2 at 1. Specifically, "it was ... part of the conspiracy for [Petitioner's co-conspirator] to direct patients to use [Petitioner] of the Shayona Pharmacy . . . to fill their prescriptions." I.G. Ex. 2 at 2. Petitioner "fill[ed] prescriptions for oxycodone issued by [her co-conspirator]," and she directed him "to issue oxycodone prescriptions to patients based upon their insurance coverage so as to maximize the profit of the conspiracy." *Id.* Further, she "instruct[ed] [her co-conspirator] how to prescribe oxycodone to avoid detection by law enforcement ... [and] charged [her co-conspirator's] patients more than their insurance copayment to fill their oxycodone prescriptions." *Id.*

ALJ Decision at 3. Before the ALJ, Petitioner admitted that she was convicted of a felony and that her plea was to "attempted criminal sale of a prescription drug," but suggested that no exclusion under section 1128(a)(4) should apply because certain facts "weighed against her guilt." *Id.* at 4 (quoting Petitioner Br. at 3). The ALJ rejected Petitioner's collateral attacks on her conviction and concluded that it clearly fell within the scope of section 1128(a)(4). *Id.* (citing *Shaikh M. Hasan, M.D.*, DAB No. 2648, at 4-5 (2015)). The ALJ further concluded that evidence proffered to try to show Petitioner's professional achievements or personal character was irrelevant, because the exclusion was mandatory regardless of any equitable consideration and because the exclusion period was set at the lowest time permitted by law so no mitigating factors could be considered. *Id.* at 4-5 (citing *Donna Rogers*, DAB No. 2381, at 6 (2011); and *Stefan Murza, D.C.*, DAB No. 2848, at 4 (2018)).

The ALJ concluded that neither party had proffered any testimony relevant to any issue properly before her and therefore that an in-person hearing would serve no purpose. ALJ Decision at 2. The ALJ decided the case on the written record before her. This appeal ensued.

³ The background discussion is drawn from the ALJ Decision and the record below and is not intended as new factual findings. None of the facts discussed is disputed by either party.

Standard of review

On disputed issues of law, the Board's standard of review is whether the ALJ's decision is erroneous. 42 C.F.R. § 1005.21(h). On disputed issues of fact, the Board's standard of review is whether the ALJ's decision is supported by substantial evidence on the whole record. *Id*.

Analysis

Petitioner presents a single issue on appeal – whether the effective date of the exclusion is proper. NA at 1. She posits several bases on which she proposes we alter the effective date to begin the exclusion earlier, and therefore end it sooner. We explain below why her proposed bases are untenable.

1. Petitioner identifies no authority to make an exclusion begin retroactively, as she proposes.

Petitioner argues that section 1128(a)(3) of the Act "does not prohibit a retroactive application of the exclusionary period." *Id.* at 2. This statement is accurate but irrelevant. Section 1128(a)(3) does not contain a prohibition on "retroactive application." The relevant provision, section 1128(c)(1), calls for an exclusion to become effective at the time to be set by regulation, subject to reasonable notice to the public and provider to be excluded. The regulations set the effective date of an exclusion as 20 days from the date of the written notice of the IG's exclusion determination. 42 C.F.R. § 1001.2002(b). The timing of the effective date in Petitioner's case is governed by that regulation.

Petitioner relies on an Eleventh Circuit decision which held that, since exclusions are remedial rather than punitive in nature, "the exclusionary periods provided by the statute . . . are not precluded from retroactive application by a governmental agency." NA at 2 (quoting *Patel v. Thompson*, 319 F.3d 1317, 1319 (11th Cir. 2003) (in turn citing *Manocchio v. Kusserow*, 961 F.2d 1539, 1543 (11th Cir. 1992))). In *Patel*, the court found no error in applying an aggravating factor to extend the length of the exclusionary period even though that aggravating factor was added to the regulations after the date of the appellant's offense. As the court explained, the remedial purpose of an exclusion is "to protect current and future federal medical program recipients from 'abusers of these programs." 319 F.3d. at 1320 (quoting 961 F.2d at 1542).

These authorities provide no support for Petitioner's argument. The IG may apply exclusion regulations retroactively where doing so fosters the remedial goal of the statute to protect the program and does not raise concerns of the kind presented in a punitive context. It does not follow that the IG is somehow compelled to set the

effective date of an exclusion retroactively to a date prior to issuance of written notice of exclusion. Such a requirement would certainly not serve the purpose of providing more protection to current and future recipients from abusers.

2. Petitioner's theory of "constructive notice" does not justify an earlier effective date.

Petitioner contends that "constructive notice of Petitioner's inability to process prescriptions for Federal healthcare programs" was provided to the public (and Petitioner) on November 2, 2016, when she pled guilty. NA at 2. Relying on the requirement that the IG provide "reasonable notice" to the public and the provider before a determination to exclude goes into effect, Petitioner seems to theorize that Petitioner and the public could have constructively assumed an exclusion to be effective once Petitioner was convicted of a felony that would authorize exclusion. This interpretation ignores the fact that the statute empowers the IG to determine by regulation what constitutes reasonable notice, and that the IG has done so. Section 1128(c)(1) of the Act; 42 C.F.R. § 1001.2002.

The regulations make clear that the required notice is not merely constructive notice of the potential for an exclusion but explicit written notice of the determination to exclude. Thus, the IG "will send a written notice of this decision to the affected individual or entity." 42 C.F.R. § 1001.2002(a). That written notice will contain six specific elements, including a statement of appeal rights. *Id.* § 1001.2002(c). And it is from the date of that notice that the 20 days are calculated until the exclusion takes effect. *Id.* § 1001.2002(b).

Petitioner suggests that, because subsection (b) only refers to "the notice," whereas subsections (a) and (c) refer to "written notice," we should conclude that "the notice requirements referred to in subsection (b) are different from the written notice requirements set forth in subsections (a) and (c)." NA at 2-3. The conclusion proposed by Petitioner is untenable. The statement that the "exclusion will be effective 20 days from the date of the notice" would be without meaning if "the notice" did not take as its antecedent the written notice described in the immediately preceding subsection. The logical reason to specify "written" in subsection (c) is that the list of 6 items to be conveyed to the affected party is in that subsection. Absent the explicit requirement that all 6 items be stated in the written notice, a question might arise whether some of the information could permissibly be conveyed separately from the required notice itself. Finally, Petitioner's approach would violate the principle of in pari materia which favors construing regulatory language with the

same purpose in a consistent, complementary manner. *See, e.g., Victor Valley Comm. Hosp./Clinical Laboratory and Dr. Tomasz Pawlowski, M.D.*, DAB No. 2340, at 9 (2010), and cases cited therein. In the case of section 1001.2002, the purpose is to provide clear notice of the imposition of an exclusion and the resulting appeal rights to the excluded party prior to the exclusion taking effect. In light of that common purpose, subsection (b) can only be read to refer to the IG's written notice of the exclusion required by subsection (a).

The Board has previously addressed the question of regulatory notice in the context of when the period to appeal begins. Section 1001.2007(b) provides that the excluded party has 60 days from receipt of notice described in section 1001.2002 in which to file an appeal. The Board rejected the IG's argument that a petitioner appealed untimely because communications with the IG (which petitioner admitted receiving) other than formal notice (which petitioner denied receiving) should have provided constructive notice of the exclusion. *Mark K. Mileski*, DAB No. 1945 (2004), *aff'd*, *Mileski v. Leavitt*, Civ. No. 04-00403 RAS-DDB, 2005 WL 1346885 (E.D. Tex. Jun. 6, 2005). As the Board explained, nothing in the language of the regulation "suggests that constructive notice is sufficient," and the significance of the "actual receipt of the notice of exclusion rather than mere knowledge of the fact that a petitioner has been excluded" is that the official written notice "is logically required in order for the right to a hearing to be meaningful since the notice provides an explanation of a petitioner's appeal rights." *Id.* at 6.

While Petitioner here attempts to use the concept of "constructive notice" in an effort to move back the starting date of the exclusion (whereas in *Mileski* the IG sought to use it as a basis to find an appeal untimely), we apply the same understanding of the regulatory requirement for actual written notice to deny both efforts. The written notice of exclusion issued by the IG is the regulatory determinant of the effective date of the exclusion (i.e., 20 days later) and its receipt triggers the appeal period (i.e., the following 60 days).

3. The effective date of Petitioner's exclusion cannot be changed based on how long after her conviction the IG imposed the exclusion.

Petitioner also proposes an alternative basis for altering the effective date of the exclusion based on the failure of the IG to take action against Petitioner until almost a year after her conviction, even though she asserts that she timely advised the IG of her conviction in November 2016. NA at 2 (citing Petitioner Ex. A (September 29, 2017)

IG exclusion notice)). Petitioner alleges that denying her request "would effectively extend the exclusionary period by an additional year, simply because of processing delays on the part of the Government" resulting in "a prejudicial effect on Petitioner's ability to earn a living...." *Id*.

This assertion amounts to an attempt to apply an equitable doctrine (laches) to benefit Petitioner, but the Board has long held that it does not have the power to decline to apply a regulation based on equity alone because the Board is bound by all applicable laws and regulations. Kenneth Schrager, DAB No. 2366, at 6 (2011). Specifically, the Board has concluded that, in exclusion matters, the applicable statute and regulations do not give an ALJ, and by extension the Board, any authority to adjust the beginning date of an exclusion. Shaikh M. Hasan, M.D., DAB No. 2648, at 8 (2015) (citing, inter alia, Kailash C. Singhvi, M.D., DAB No. 2138 (2007), aff'd, Singhvi v. Inspector General, Dept. of Health & Human Servs., No. CV-08-0659 (SJF) (E.D.N.Y. Sept. 21, 2009); Thomas Edward Musial, DAB No. 1991, at 4 (2005); Douglas Schram, R.PH., DAB No. 1372, at 11 (1992) ("Neither the ALJ nor this Board may change the beginning date of Petitioner's exclusion.")). Moreover, the Board has previously made clear that, although the regulations do require reasonable notice, neither the statute nor the regulations guarantee prompt notice or prompt action on exclusions. Samuel W. Chang, M.D., DAB No. 1198, at 13-14 (1990); see also Seide v. Shalala, 31 F. Supp. 2d 466, 469 (E.D. Pa. 1998) ("Neither the Social Security Act nor its implementing regulations set any deadline within which the Inspector General must act.").

We conclude that Petitioner's exclusion properly became effective on October 19, 2017, in accordance with the regulations. We find no error in the ALJ's determination upholding that date. ALJ Decision at 5.

4. Petitioner identifies no error in the ALJ Decision.

As noted, Petitioner makes no argument before us that any other legal conclusion in the ALJ Decision was erroneous. Petitioner proffers a "factual background" in which she reiterates claims she made to the ALJ that, despite her admitted guilty plea, some facts mitigated her guilt, that she otherwise had good character and did good work as a pharmacist, and that she and her family will suffer hardship as a result of her exclusion. NA at 3-4 (citing Petitioner Exs. B-F).

The ALJ addressed all of these contentions and concluded that none were relevant to the issues properly before her because they either amounted to collateral attacks on the underlying conviction or raised equitable arguments that the ALJ could not entertain. ALJ Decision at 3-5. Petitioner points to no error in the ALJ's conclusion in that regard.

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Conclusion

We uphold the ALJ decision in its entirety.

/s/
Christopher S. Randolph

/s/

Constance B. Tobias

/s/

Leslie A. Sussan
Presiding Board Member